

Securities Prospectus

dated 29 January 2018

for the public offering in Germany and Luxembourg

of

6,000,000 no-par registered shares

- each with a notional participation in the registered share capital of EUR 1,00 per no-par share and  
with dividend rights from 1 January 2017 on -

of

Biofrontera Aktiengesellschaft

Leverkusen

International Securities Identification Number (ISIN): DE0006046113

German Securities Identification Number (WKN): 604611

Stock Ticker Symbol: B8F

The issuer is a small / medium enterprise (SME) in the meaning of art. 2 paragraph 1 lit. (f) of the Prospectus Directive. The disclosures made in this prospectus are in accordance with the requirements applicable under art. 26b of the Prospectus Regulation.

The New Shares and subscription rights are not and will not be registered in accordance with the provisions of the U.S. Securities Act 1933 as amended from time to time („*Securities Act*“) nor with the securities authorities of the states of the USA. They may not be offered or sold in the USA nor directly nor indirectly delivered there, except based on an exemption from the requirements of the Securities Act and the securities regulations of the individual US states and other applicable US regulations. In particular, this subscription offer is not a public offer nor a request for an offer to purchase the New Shares in the USA and may therefore not be disseminated there.

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## 1. Summary

Summaries are composed of disclosure requirements, which are referred to as “elements”. These elements are numbered in sections A through E (A.1 through E.7).

This summary contains all elements, which are required to be included into a summary for this type of securities and issuer. Since certain elements are not required for this type of securities and issuer, gaps may exist in the numbering sequence of the elements.

Even though an element, due to the type of security and issuer, may be required to be included in this summary, it is possible that no relevant information regarding this element exists. In this case, a short description of the summary with the term “Not Applicable” is inserted.

### 1.1 Section A – Introduction and Warnings

|     |                       |   |
|-----|-----------------------|---|
| A.1 | Warnings              | <p>This summary should be read as introduction to the prospectus;</p> <p>Any decision to invest in the securities should be based on consideration of the prospectus as a whole by the investor;</p> <p>Where a claim relating to the information contained in the prospectus is brought before a court, the plaintiff investor might, under the national legislation of the Member States, have to bear the costs of translating the prospectus before the legal proceedings are initiated.</p> <p>Biofrontera AG with registered seat in Leverkusen, and business address Hemmelrather Weg 201, 51377 Leverkusen (also the “<i>Issuer</i>” and together with its subsidiaries “<i>Biofrontera Group</i>”) assumes the responsibility for the contents of this summary, including any translation thereof, pursuant to sec. 5 para. 2b no. 4 of the German Securities Prospectus Law (Wertpapierprospektgesetz, WpPG). The persons who have assumed responsibility for this summary and any translations thereof, or from whom its issuance originates, can be held liable, but only insofar as the summary is misleading, inaccurate or inconsistent when read together with other parts of the prospectus or does not provide, when read together with the other parts of the prospectus, all necessary key information.</p> |
| A.2 | Consent to the use of | Not applicable. The issuer did not grant consent for the use of the   |

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| the prospectus by financial intermediaries | prospectus for subsequent resale or final placement of securities by financial intermediaries. |
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## 1.2 Section B – Issuer

|     |   |   |
|-----|---|---|
| B.1 | Legal and commercial name of the issuer.  | The legal and commercial name of the issuer is „Biofrontera Aktiengesellschaft“.  |
| B.2 | Domicile and legal form of the issuer, legislation under which the issuer operates and its country of incorporation.  | The domicile of the issuer is Leverkusen. The issuer is a public stock corporation (Aktiengesellschaft, AG) operating under German law, which was incorporated in Germany and registered at the lower court of Cologne under HRB 49717.   |
| B.3 | Description of and key factors relating to the nature of the issuer’s current operations and its principal activities and principal markets in which the issuer competes. | <p>Biofrontera Group is an international biopharmaceutical enterprise 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 Group’s approved products focus on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer (also “<b>AK</b>”), in Europe and the United States, as well as the treatment of basal cell carcinoma (also “<b>BCC</b>”) in the EU. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots. Because of their location and appearance, actinic keratoses are often cosmetically unappealing.</p> <p>Biofrontera Group’s principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy (also “<b>PDT</b>” and as PDT with Ameluz® “<b>Ameluz® PDT</b>”). Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized</p> |

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|      |  | <p>European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. A major advantage of treating actinic keratosis and basal cell carcinoma with photodynamic therapy (as opposed to other common treatments such as surgery and cryotherapy) is that it is a non-invasive alternative that can have better cosmetic results, <i>i.e.</i>, removal of tumors without leaving clearly visible scarring.</p> <p>In addition, Biofrontera Group has developed its own PDT lamp, BF-RhodoLED®, for use in combination with Ameluz®. The BF-RhodoLED® lamp was approved as a medical device in the EU in November 2012 and is approved for sale in all EU countries, although the use of the BF-RhodoLED® lamp is not required to be used in combination with Ameluz® in the EU or Switzerland.</p> <p>In May 2016, Biofrontera Group received approval from the U.S. Food and Drug Administration (“<b>FDA</b>”), for US marketing of Ameluz® in combination with photodynamic therapy using the BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Group launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the US in October 2016.</p> <p>Biofrontera Group currently sells Ameluz® in 12 countries in Europe and in the U.S., and commenced sales of Ameluz® in Israel in the second half of 2017.</p> <p>Biofrontera Group’s principal markets are Germany, the United States and, to a lesser degree, other European countries.</p> |
| B.4a | Most significant recent trends affecting the issuer and the industries in which it operates. | <p>In January 2017, the European approval of Ameluz® was extended to treatment of basal cell carcinoma. The Issuer expects this to improve the market standing of Ameluz®.</p> <p>In January 2017, the Issuer placed a convertible bond in an amount of EUR 5 million. Furthermore, the Issuer entered into a facility loan agreement with the European Investment Bank in May 2017, under</p>   |

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|     |  | <p>which the Issuer has the right to draw down EUR 10 million immediately and further EUR 10 million pending fulfillment of certain milestones. An amount of EUR 10 million was drawn down in July 2017. The Issuer expects that these financing measures provide more liquidity and allow for more investments.</p> <p>Marketing activities by competitors have made the so-called daylight therapy more popular. With daylight therapy, a patient does not need to be treated with a lamp, but the agent in the PDT drug is activated by daylight. This may reduce discomfort to the patient and effort to the treating doctor. The competitor drug Luxerm®, which is identical to Metvix® but only approved for treatment in daylight therapy, has sold more units in July 2017 than all other PDT drugs together.</p> <p>In May 2017, Biofrontera filed for extension of the European approval of Ameluz® to daylight therapy in order to improve competitiveness.</p> |
| B.5 | Description of the group and the issuer's position within the group.   | <p>Biofrontera Group consists of the Issuer (Biofrontera Aktiengesellschaft) as ultimate parent company and five wholly owned direct subsidiaries, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, each with seat in Leverkusen, and Biofrontera Inc., with seat in Wilmington, Delaware, USA.</p>  |
| B.6 | Persons who, directly or indirectly, have a (notifiable) interest in the issuer's capital and voting rights. | <p>Insofar as known to the issuer, the following persons directly or indirectly have an interest in the issuer's capital or voting rights which is notifiable under German law:</p> <p><b><u>Direct Interest:</u></b></p> <p>Deutsche Balaton AG, Heidelberg, Germany: 8.28%</p> <p>Maruho Deutschland GmbH, Düsseldorf, Germany: 21.58 %</p> <p>FEHO Vermögensverwaltungsgesellschaft mbH, Frankfurt, Germany: 3.14 %</p> <p><b><u>Indirect Interest:</u></b></p> <p>Maruho Co., Ltd., Osaka, Japan: 21.58 %</p> <p>Universal Investment Gesellschaft mbH, Frankfurt, Germany: 3.14 %</p> <p>Wilhelm K. T. Zours: 11.21 %</p>   |

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| Different voting rights of major shareholders, if any.   | Not applicable. The Issuer's major shareholders do not have different voting rights.                             |
| To the extent known to the issuer, whether the issuer is directly or indirectly owned or controlled. | Not applicable; to the extent known to the Issuer, the Issuer is not directly or indirectly owned or controlled. |

B.7 Selected historical key financial information:

| <b><i>Profit and loss related financial information</i></b>                 |   |  |   |   |
|---|---|--|---|---|
|   | Fiscal year ending 31 December 2015                               | Half year ending 30 June 2016                                      | Fiscal year ending 31 December 2016                               | Half year ending 30 June 2017                                   |
| Source of the financial information : (all numbers given in thousand Euros) | audited consolidated financial statements as per 31 December 2015 | Unaudited consolidated financial statements as per 30 June 2017(1) | audited consolidated financial statements as per 31 December 2016 | Unaudited consolidated financial statements as per 30 June 2017 |
| Sales revenue   | 4,138   | 1,709  | 6,130   | 5,006.4   |
| Cost of sales (2)   | -1,236  | -764   | -1,652  | -635.4  |
| Gross Profit  | 2,902   | 945  | 4,478   | 4,371.1   |
| Research and development costs  | -6,204  | -1,852   | -4,640  | -2,185.4  |
| General administrative costs  | -2,759  | -1,372   | -2,853  | -1,695.5  |
| Sales costs (2)   | -4,170  | -2,832   | -8,763  | -8,275.3  |
| Net loss before taxes   | -11,203   | -3,472   | -10,579   | -8,736.6  |
| Loss after taxes  | -11,203   | -3,472   | -10,579   | -8,736.6  |

(1) Taken from prior year comparison

(2) Note: While "cost of sales" refers to general costs of revenue, "sales costs" refers to distribution costs.

***Balance sheet related financial information***

|  | 31 December<br>2015   | 31 December<br>2016   | 30 June 2017  |
|--|---|---|---|
| Source of the financial information :<br>(all numbers given in thousand Euros) | audited consolidated financial statements as per 31 December 2015 | audited consolidated financial statements as per 31 December 2016 | Unaudited consolidated financial statements as per 30 June 2017 |
| Long term liabilities (end of period)  | 11,230  | 3,597   | 2,654.0   |
| Current liabilities (end of period)  | 1,911   | 2,426   | 4,161.3   |
| Equity (end of period)   | -4,809  | 15,842  | 10,388.9  |
| Cash & cash equivalents (end of period)  | 3,959   | 15,126  | 11,451.5  |
| Sum of assets  | 9,498   | 23,879  | 19,347.9  |
| Employees (end of period)<br>(3)   | 58  | 94  | 124   |

(3) Unaudited; source: management report for the respective period.

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|---|--|
| Significant changes to the issuer's financial condition and operating results | <p>During the period covered by the historical financial information, the expansion to the United states has caused a significant change with respect to operating results during the period covered by the historical key financial information, showing an increase both in revenues (approx. EUR 5 million for the first half of 2017 compared to approx. EUR 1.7 million for the first half of 2016) and in sales costs, which have increased from EUR 2.8 to EUR 8.3 million for the period. This development has proportionally continued after the date of the last historical key financial information.</p> <p>Since Biofrontera Group is currently not generating profits, Biofrontera Group's working capital and equity are significantly lower than on 30 June 2017, i.e. the end of the last financial period for which audited financial information or interim financial information have been published.</p> <p>No further significant change in the Issuer's or Biofrontera Group's financial or trading position has occurred since 30 June 2017, i.e. the end of the last financial period for which audited financial information or interim financial information have been published.</p> |
|---|--|

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| B.8  | Selected key pro forma financial information.                               | Not applicable. The Issuer and Biofrontera Group were not required to prepare pro forma financial information.  |
| B.9  | Profit forecast or estimate.  | The Issuer has published a profit forecast in its 2016 financial report, as updated in November 2017, pursuant to which it expects an annual turnover (referred to as sales revenues in the table above) of approx. EUR 12 million and a net result (referred to as loss after taxes in the table above) of EUR -18 million in 2017.  |
| B.10 | Qualifications in the audit report on the historical financial information. | <p>Not applicable. The audited historical financial information were not subject to qualifications in the audit reports.</p> <p>However, the auditors' opinion regarding the report for the fiscal year 2016 contained the following note:</p> <p><i>“Without modifying our opinion, we would like to point out the statements made in the combined management report. As mentioned in the section “Risk, opportunity and forecast report” under “Liquidity risk”, during the financial year 2017 additional capital measures will be needed until the break-even is reached, for the planned investments into marketing in the USA and to meet obligations from the issued option bond. On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realized, this could constitute a threat to the company’s continued existence.”</i></p> <p>The auditors' opinion regarding the report for the fiscal year 2015 contained the following note:</p> <p><i>“Without qualifying this opinion we refer to the explanations in the combined management report. In particular, the Management Board clarifies under section “Opportunities and risks relating to future business performance”, “Liquidity risk” that further capital measures are necessary until the break even is reached. Particularly to obtain approval in the USA, the planned investments into marketing in the US and to meet obligations from the issued option bond further capital measures during the fiscal year 2016 will be necessary. On the basis of its previous, invariably successful experience with capital measures, the</i></p> |



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|      |  | <p><i>Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realized, this could constitute a threat to the company's continued existence."</i></p>  |
| B.11 | <p>Insufficient working capital for the Issuer's present requirements.</p> | <p>The Issuer is of the opinion that the working capital of Biofrontera Group is currently not sufficient to meet the obligations due in the next twelve months.</p> <p>The current working capital will, in the Issuer's current estimation, be sufficient to cover due obligations until approx. May 2018.</p> <p>For the coming twelve months, the Issuer will require under the current estimate, approx. EUR 10 million more in order to cover the payment obligations due in the next twelve months. This includes, in particular, the ongoing operative business of Biofrontera Group, including the marketing activities in Europe and the United States and maintaining and extending the European and US approval.</p> <p>The Issuer plans to rectify a part of this shortfall with the capital increase described in this prospectus. At the date of this prospectus, the Issuer's management is optimistic that sufficient placement in the US and Europe will be possible. However, no binding purchase / subscription orders have yet been made. A success of the capital measure described in this prospectus is therefore not guaranteed.</p> <p>Cost-cutting measures might be possible, but not to the extent necessary to ensure the ability to cover all payment obligations that become due in the next twelve months on their own. Furthermore, such cost-cutting measures would cause material constraints to Biofrontera Group's business and future prospects. The Issuer expects that cost-cutting measures could reduce expenses by approx. EUR 100 thousand per month. The Issuer only considers to implement such cost-cutting measures as a supplemental means if proceeds from the capital measure described in this prospectus are insufficient as such, but will suffice together with cost-cutting measures. On their own, cost-cutting measures will not be sufficient to provide for sufficient working capital to meet the obligations due in the next twelve months.</p> <p>Furthermore, if the Issuer is not in a position to generate sufficient proceeds from this capital increase, the Issuer may initiate further</p> |

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|  |  | <p>financing measures. In particular, the Issuer has in the past placed convertible and option bonds, which may also be used as a financing instrument in the future.</p> <p>A failure of financing measures would result in the inability of the Issuer to meet its obligations and therefore an insolvency in the short term. Potential investors should therefore be aware that the Issuer is dependent on raising additional capital to avoid an insolvency during the next twelve months, and that the success of raising such capital is outside of the Issuer's influence.</p> |
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### 1.3 Section C – Securities

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| C.1 | Type and the class of the securities being offered, security identification number. | Subject of the offering are 6,000,000 new, no-par registered shares, representing a total notional participation in the registered share capital of the Issuer of EUR 6,000,000, with the German Securities Identification Number (WKN) 604611 and the International Securities Identification Number (ISIN) DE0006046113 („ <i>New Shares</i> “). The subscription rights have the German Securities Identification Number (WKN) A2G8YC and the International Securities Identification Number (ISIN) DE000A2G8YC5. |
| C.2 | Currency of the securities issue.   | EUR.   |
| C.3 | Issued shares.  | Currently, the Issuer has 38,416,828 shares issued. All shares are fully paid up. The issued shares, as well as the New Shares, do not have a par value.   |
| C.4 | Rights attached to the securities.  | <p>The New Shares shall carry dividend rights from 1 January 2017 on.</p> <p>Each New Share grants one vote in the Issuer's general shareholder meeting. The New Shares furthermore generally entitle to receive further shares from capital measures, and to participate in liquidation proceeds after a dissolution of the Issuer. The rights attached to the New Shares are pari passu to the rights attached to the existing shares.</p>   |

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| C.5 | Restrictions on the free transferability of the securities.   | Not applicable. The New Shares are freely transferable.   |
| C.6 | Application for admission to trading on a regulated market; regulated markets where the securities are or are to be traded. | The Issuer intends to have the shares admitted prospectus-free to the regulated market of the Frankfurt Stock Exchange and the regulated market of the Düsseldorf Stock Exchange. The application is intended to be filed on 27 February 2018; the Issuer expects the admission of the New Shares on 7 March 2018 and an inclusion of the New Shares in the existing quotation of the Issuer's shares on 12 March 2018. An admission for trading to other regulated markets is not intended. <u>An admission to the regulated markets referred to above is not guaranteed.</u> It should be noted that the Issuer intends to apply for admission of certificates representing its shares, including the New Shares, to the NASDAQ, a US stock exchange. |
| C.7 | Dividend policy.  | The Issuer has not made any dividend payments to date. Considering the substantial loss carry-forward, no dividend payments are expected in the near future.  |

#### 1.4 Section D – Risks

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| D.1 | Key information on the key risks that are specific to the Issuer or its industry. | <p>Biofrontera Group has a history of operating losses and anticipate that it will continue to incur operating losses in the future and that it may never sustain profitability.</p> <p>Biofrontera Group's existing and any future indebtedness could adversely affect its ability to operate its business.</p> <p>Certain of Biofrontera Group's important patents will expire in 2019, which may result in the entry into the market of generic versions of Ameluz®. If this happens, Biofrontera Group may need to reduce the price of Ameluz® significantly and may lose significant market share.</p> <p>Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for products or product candidates, which could make it difficult for Biofrontera Group to sell products.</p> |
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|  | <p>Healthcare legislative changes may have a material adverse effect on business and results of operations.</p> <p>Competing products and technologies based on traditional treatment methods may make Biofrontera Group’s products or potential products noncompetitive or obsolete.</p> <p>Biofrontera Group faces significant competition from other pharmaceutical and medical device companies and operating results will suffer if Biofrontera Group fails to compete effectively. Biofrontera Group also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.</p> <p>Biofrontera Group depends on a single unaffiliated contract manufacturer to manufacture Ameluz®. If Biofrontera Group fails to maintain the relationship with this manufacturer or if that manufacturer is unable to continue to produce Ameluz® for Biofrontera Group, Biofrontera Group’s business could be materially harmed.</p> <p>Biofrontera Group may fail to manufacture Ameluz® or BF-RhodoLED® or other marketed products and product candidates in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice (“cGMP”), or other applicable manufacturing regulations.</p> <p>Biofrontera Group is subject to healthcare laws, regulation and enforcement. Failure to comply with those laws could have a material adverse effect on results of operations and financial condition.</p> <p>A recall of Biofrontera Group’s drug or medical device products, or the discovery of serious safety issues with drugs or medical device products, could have a significant negative impact.</p> <p>Biofrontera Group’s medical device product, the BF-RhodoLED® lamp, is subject to extensive governmental regulation.</p> <p>If product liability lawsuits are brought against Biofrontera Group, it may incur substantial liabilities and may be required to limit commercialization of products.</p> <p>Clinical drug development is expensive and involves uncertain outcomes, and results of earlier studies and trials may not be predictive</p> |
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|     |   | <p>of future trial results. If one or more future Phase III clinical trials for Ameluz® were unsuccessful, or significantly delayed, Biofrontera Group could be required to abandon development, may suffer reputational harm and Biofrontera Group’s business will be materially harmed.</p> <p>Biofrontera Group relies on third parties to conduct clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Biofrontera Group may not be able to obtain regulatory approval for or commercialize product candidates.</p> <p>If Biofrontera Group’s efforts to protect the proprietary nature of the intellectual property related to Biofrontera Group’s technologies are not adequate, Biofrontera Group may not be able to compete effectively in its market.</p> <p>Third party claims of intellectual property infringement may prevent or delay Biofrontera Group’s product discovery and development efforts.</p> <p>Biofrontera Group may be involved in lawsuits to defend or enforce patents, which could be expensive, time-consuming and unsuccessful.</p> <p>Biofrontera Group may be subject to claims that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.</p> <p>Biofrontera Group’s trade secrets are difficult to protect.</p> |
| D.3 | Key information on the key risks that are specific to the securities. | <p>An investment in shares always bears the risk of a total loss of the invested capital.</p> <p>If the capital increase set out in this prospectus is not executed, buyers of subscription rights may lose the investment made into the subscription rights. In particular, the commercial register might refuse entering the capital increase into the commercial register due to the litigation against the appointment of supervisory board members.</p> <p>An investment in the New Shares is not an appropriate investment for every investor.</p> <p>The stock price and the trade volume of the New Shares may be subject to high volatility.</p> <p>A large-scale disposal of shares would have detrimental effects on the</p>   |

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|  | <p>stock price of the New Shares.</p> <p>Shareholder with large shareholding may exercise or achieve a controlling influence on the general shareholder meeting of the Issuer.</p> <p>A future exercise of option rights and potential further capital rounds may cause a dilution of the investors' shareholding.</p> <p>Currency exchange risks exists for investors with foreign currencies.</p> <p>Short sales of shares of the Issuer may cause losses to investors.</p> <p>The New Shares may not be tradable temporarily or permanently. In particular, a down-listing or delisting of the New Shares might affect the liquidity and the stock market price of the New Shares.</p> |
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### 1.5 Section E – Offer

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| E.1  | Total net proceeds, estimate of the total expenses of the issue/offer, including estimated expenses charged to the investor. | Under the assumption that all New Shares are placed at a subscription price of EUR 3.50 to EUR 4.50, the issuer expects gross proceeds from this offer in an amount of approximately EUR 21 million to EUR 27 million and net proceeds of EUR 20 million to EUR 26 million. Total financing costs of this issue are expected to be up to approx. EUR 1 million. Financing costs will not be charged to the investor, neither by the issuer nor by any agent.  |
| E.2a | Reasons for the offer, use of proceeds, estimated net amount of the proceeds.  | <p>Under the assumption that all New Shares are placed at a subscription price of EUR 3.50 to EUR 4.50, the issuer expects net proceeds from this offer in an amount of EUR 20 to EUR 26 million.</p> <p>The proceeds will be used as follows: An amount of EUR 5 million will be used for R&amp;D purposes, in particular to extend the indications which Ameluz® may be used for. An amount of EUR 5 million will be used to improve US marketing and sales. The remaining amount, expected to be between EUR 10 million and EUR 16 million, will be used to cover the working capital of the Issuer.</p> <p>Furthermore, New Shares shall be used as an underlying</p> |

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|     |   | <p>for the creation of American Depositary Shares in the context of a so-called sponsored Level-III-program. Under the US Offer, ADSs will be offered to subscribers in the US, and a listing on the NASDAQ stock exchange will be applied for. The New Shares used for this purpose are intended to be admitted for trading at the Frankfurt Stock Exchange.</p>   |
| E.3 | Description of the terms and conditions of the offer. | <p>The offer is first addressed to the shareholders of the Issuer, and, respectively, holders of subscription rights, to which the subscription offer is communicated via Lang &amp; Schwarz Broker GmbH with seat in Düsseldorf, Breite Str. 34, 40213 Düsseldorf (also „<i>Lang &amp; Schwarz Broker GmbH</i>“). As far as not all New Shares are subscribed to in the execution of the statutory subscription right, the New Shares which have not been subscribed to (including those New Shares to which the statutory subscription right has been excluded to avoid fractions) will be offered insofar as legally possible at the Subscription Price to third parties until 23 February 2018.</p> <p>Pursuant to section 7 paragraph 3a of the articles of association, the management board is authorized to increase the registered capital of the Issuer until 23 May 2022 with the approval of the supervisory board by up to EUR 6,000,000 by way of issuing, on one or several occasions, up to 6,000,000 no-par registered shares against contribution in cash and/or kind (“<i>Authorized Capital</i>”). Based on said authorization, the management board of the Issuer has resolved on 29 January 2018 with approval of the supervisory board of the same day to increase the registered capital of the Issuer from currently EUR 38,416,828 by up to EUR 6,000,000 from Authorized Capital to up to EUR 44,416,828 by issuing up to 6,000,000 new no-par registered shares representing a notional amount of registered capital of EUR 1.00 each.</p> <p>The exact definition of the amount of the capital increase as well as the respective amendment of the articles of</p> |

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|  |  | <p>association will be effected after the end of the offer.</p> <p><b>Subscription Rights</b></p> <p>The statutory subscription right of the shareholders is granted by admitting Lang &amp; Schwarz Broker GmbH to subscribe and take over up to 6,000,000 New Shares at an issue price of EUR 1.00 per New Share, together with the obligation to offer the New Shares to the shareholders for subscription (“<b>Subscription Offer</b>”) in a quota of 13:2 against payment of a subscription price (“<b>Subscription Price</b>”). The subscription right to 89,719 excess shares is excluded.</p> <p>The Subscription Price is expected to be determined on 9 February 2018, taking into account offers received from institutional investors in a bookbuilding process. The Subscription Price will be published presumably on 9 February 2018 as an ad hoc release and on the same day in the German Federal Gazette and on the Issuers homepage under <a href="http://www.biofrontera.com">www.biofrontera.com</a>. The Subscription Price will not exceed EUR 4.50 (“<b>Maximum Subscription Price</b>”).</p> <p>The shareholders are requested to execute their subscription right to the New Shares, in order to avoid exclusion, within the period from 30 January 2018 to 12 February 2018 („<b>Subscription Period</b>“) at Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen (“<b>Bankhaus Gebr. Martin Aktiengesellschaft</b>“), acting as settlement agent for Lang &amp; Schwarz Broker GmbH, during the usual business hours.</p> <p>In order to execute their subscription rights, the Issuer request shareholders or the holders of subscription rights, respectively, to instruct the bank managing their securities account accordingly. For 13 old shares of the Issuer, 2 New Shares may be subscribed to at the Subscription Price. For any fractions resulting from the subscription quota of 13:2 for the respective number of old shares held</p> |
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|  |  | <p>in each case, no New Shares may be subscribed to, only a subscription of 2 New Shares or a multiple thereof is possible. The amount of shares held at the end of 29 January 2018 shall be relevant for calculating the number of subscription rights allocated to each shareholder. At this time, the subscription rights (ISIN DE000A2G8YC5) are separated from the shares to the extent of the existing subscription rights and booked to the shareholders' securities accounts by their respective banks.</p> <p>The subscription rights are tradable, but the Issuer will neither organize a trade on the stock market, nor a private trade. Subscription rights not executed are forfeit and will be booked out as invalid at the end of the subscription period.</p> <p>From 26 January 2018 on, the old shares will be traded as "ex subscription rights".</p> <p>Shareholders executing subscription rights shall pay the Subscription Price upon execution of the subscription right, but no later than the end of the Subscription Period on 12 February 2018. The subscription rights shall be proof that the shareholder is entitled to subscribe to New Shares.</p> <p>The receipt of the subscription request and the Subscription Price at the agent referred to above is relevant for keeping the deadline. Shareholders / holders of subscription rights are charged the usual bank fee for the subscription.</p> <p>The banks managing the securities accounts are requested to communicate the subscription rights collectively in one registration no later than and including 12 February 2018 at Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen, telefax +49 (0)7161 969317, and to transfer the Subscription Price per New Share also no later than the end of the Subscription Period on the following account of Lang &amp; Schwarz Broker GmbH at Bankhaus</p> |
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|     |   | <p>Gebr. Martin Aktiengesellschaft:</p> <p>Bank: Bankhaus Gebr. Martin Aktiengesellschaft</p> <p>Account no. 9673</p> <p>IBAN: DE88 610 300 00 000 000 9673</p> <p>BIC: MARBDE6G</p> <p>Reference: „W/Biofrontera“</p> <p><b>Placement of New Shares not subscribed to under the statutory subscription right</b></p> <p>As far as not all New Shares are subscribed to in the execution of the statutory subscription right, the New Shares which have not been subscribed to (including those New Shares the statutory subscription right has been excluded to avoid fractions) will be offered insofar as legally possible at the Subscription Price to third parties until 23 February 2018.</p>  |
| E.4 | Any interest that is material to the issue/offer, including conflicting interests | <p>Lang &amp; Schwarz Broker GmbH will receive a variable remuneration for its services depending on the issue amount. Due to the nature of the compensation the issuer does not expect any conflicts of interest.</p> <p>Members of the management and supervisory boards hold shares of the Issuer as well as option rights to the acquisition of shares of the Issuer. They have an own interest regarding the development of the stock market price of the Issuer’s shares. In the opinion of the Issuer, this does not constitute a conflict of interest, since the private interest of the members of the management and supervisory boards are not contrary to the company’s interests.</p> <p>The Issuer is not aware of any further interests, conflicts of interest or potential conflicts of interest of natural or legal persons which might be relevant for the Offer.</p> |
| E.5 | Name of the person or entity  | The New Shares will not be sold by existing shareholders; New Shares will solely be generated by the Issuer and   |

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|     | <p>offering to sell the security.</p> <p>Lock-up provisions.</p>   | <p>offer via Lang &amp; Schwarz Broker GmbH as issuing bank.</p> <p>Not applicable. There are no lock-up provisions related to the New Shares.</p>  |
| E.6 | <p>The amount and percentage of immediate dilution resulting from the offer.</p> <p>In the case of a subscription offer to existing equity holders, the amount and percentage of immediate dilution if they do not subscribe to the new offer.</p> | <p>Before the consummation of the capital increase the net asset value (“NAV”) of the Biofrontera Group amounted to approximately EUR 10,388.9 thousand or to approximately EUR 0.27 per share (calculated on the basis of the number of 38,416,828 issued shares of the Issuer as of the date of this prospectus). The NAV of the Biofrontera Group is calculated on the basis of the unaudited consolidated interim financial statements ended 30 June 2017 by deducting the amount of the long-term liabilities (EUR 2,654.0 thousand) and the current liabilities (EUR 6,305.0 thousand) as of 30 June 2017 from the amount of total assets as of 30 June 2017 (EUR 19,347.9 thousand, referred to as “sum of assets” in the financial statement).</p> <p>Under the assumption that all New Shares are placed at a subscription price of EUR 4.00 (being the arithmetic mean of the range of 3.50 and 4.50), the issuer expects gross proceeds from this offer in an amount of EUR 24 million, and net proceeds of EUR 23 million.</p> <p>Assuming the capital increase against cash contributions is consummated in full at a subscription price of EUR 4.00, the net proceeds amount to approximately EUR 23 million, the NAV of the Biofrontera Group as 30 June 2017 would have amounted to approximately EUR 33,388,900.00 or to approximately EUR 0.75 per share (calculated on the basis of the number of 44,416,828 issued shares of the Issuer after the consummation of the share capital increase against cash contributions).</p> <p>Based on a subscription price of EUR 4.00, this would result in an increase of the NAV of Biofrontera Group as of 30 June 2017 by approximately EUR 0.48 per share to EUR 0.75 per share for existing shareholders. This would</p> |

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|     |  | <p>amount to an increase by approximately 178 %. There would be an immediate dilution of EUR 3.25 per share or approximately 81.25 % for the purchasers of the New Shares since the subscription price of EUR 4.00 per share would be above the calculated NAV per share of approximately EUR 0.75.</p> <p>Insofar as shareholders do not exercise their subscription rights, and the New Shares from the capital increase which is described in this prospectus (6,000,000 shares) are subscribed in full, the participation of such shareholders will be reduced by approx. 15.6 %. The dilution will be lower if not all New Shares are subscribed to.</p> |
| E.7 | Estimated expenses charged to the investor by the issuer or the offeror. | Not applicable. Neither the issuer nor any other potential offeror will charge any costs to subscribers of the New Shares. Subscribers' depot holding banks may charge a customary securities provision for the acquisition of the New Shares.  |

## 2. German Translation of the Summary of the Prospectus – Zusammenfassung des Prospekts

Zusammenfassungen bestehen aus Offenlegungserfordernissen, die als „Elemente“ bezeichnet werden. Diese Elemente sind in die Abschnitte A bis E (A.1 bis E.7) eingeteilt.

Diese Zusammenfassung enthält alle Elemente, die in eine Zusammenfassung für diese Art von Wertpapieren und Emittenten aufzunehmen sind. Da einige Elemente nicht angeführt werden müssen, können Lücken in der Zahlenreihenfolge der Elemente bestehen.

Auch wenn ein Element, bedingt durch Art des Wertpapiers und des Emittenten, in die Zusammenfassung aufzunehmen ist, kann es sein, dass keine relevante Information betreffend dieses Elements besteht. In diesem Fall wird eine kurze Beschreibung des Elements mit dem Hinweis „entfällt“ aufgenommen.

### 2.1 Abschnitt A – Einleitung und Warnhinweise

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| A.1 | Warnhinweise | <p>Die Zusammenfassung sollte als Einführung zum Prospekt verstanden werden.</p> <p>Der Anleger sollte sich bei jeder Entscheidung zur Anlage in die hier beschriebenen Wertpapiere auf die Prüfung des gesamten Prospekts stützen.</p> <p>Für den Fall, dass vor einem Gericht Ansprüche auf Grund der in dem Prospekt enthaltenen Informationen geltend gemacht werden sollen, könnte der als Kläger auftretende Anleger in Anwendung der einzelstaatlichen Rechtsvorschriften der Staaten des Europäischen Wirtschaftsraums die Kosten für die Übersetzung des Prospekts vor Prozessbeginn zu tragen haben.</p> <p>Die Biofrontera Aktiengesellschaft mit Sitz in Leverkusen, Hemmelrather Weg 201, 51377 Leverkusen, (auch „<i>Emittentin</i>“ und zusammen mit ihren Tochtergesellschaften „<i>Biofrontera Gruppe</i>“) übernimmt gemäß § 5 Abs. 2b Nr. 4 Wertpapierprospektgesetz (WpPG) die Verantwortung für den Inhalt dieser Zusammenfassung einschließlich etwaiger Übersetzungen hiervon. Diejenigen Personen, die die Verantwortung für die Zusammenfassung einschließlich</p> |
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|     |   | etwaiger Übersetzungen hiervon übernommen haben oder von denen der Erlass ausgeht, können haftbar gemacht werden, jedoch nur für den Fall, dass die Zusammenfassung irreführend, unrichtig oder widersprüchlich ist, wenn sie zusammen mit den anderen Teilen des Prospekts gelesen wird, oder sie, wenn sie zusammen mit den anderen Teilen des Prospekts gelesen wird, nicht alle erforderlichen Schlüsselinformationen vermittelt. |
| A.2 | Verwendung des Prospekts durch Finanzintermediäre | Entfällt. Eine Zustimmung zur Verwendung des Prospekts für eine spätere Weiterveräußerung oder endgültige Platzierung von Wertpapieren durch Finanzintermediäre ist nicht erteilt worden.   |

## 2.2 Abschnitt B – Emittent

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| B.1 | Juristische und kommerzielle Bezeichnung der Emittentin   | Die juristische und kommerzielle Bezeichnung der Emittentin lautet „Biofrontera Aktiengesellschaft“.   |
| B.2 | Sitz und Rechtsform, geltendes Recht, Land der Gründung   | Sitz der Emittentin ist Leverkusen. Die Emittentin ist eine Aktiengesellschaft nach deutschem Recht, die in Deutschland gegründet wurde und im Handelsregister des Amtsgerichts Köln unter HRB 49717 eingetragen ist.  |
| B.3 | Art der derzeitigen Geschäftstätigkeit und Haupttätigkeiten der Emittentin samt der hierfür wesentlichen Faktoren und Hauptmärkte | Die Biofrontera-Gruppe ist ein internationales biopharmazeutisches Unternehmen, das auf die Entwicklung und Kommerzialisierung einer Plattform pharmazeutischer Produkte für die Behandlung dermatologischer Erkrankungen spezialisiert ist, die im wesentlichen durch die Aussetzung der Haut an Sonneneinstrahlung verursacht werden. Die zugelassenen Produkte der Biofrontera Gruppe fokussieren sich auf die Behandlung der Aktinischen Keratose, bei der es sich um Hautläsionen handelt, die manchmal zu Hautkrebs führen können (auch „ <b>AK</b> “), in Europa und den USA, sowie der Behandlung von Basalzellkarzinom („ <b>BCC</b> “) in Europa. Aktinische Keratose entsteht typischerweise in Hautpartien, die der Sonne ausgesetzt sind, |

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|  |  | <p>wie Gesicht, kahle Kopfhaut, Arme oder Handrücken, und zeigt sich oft als hervorgehoben, schuppig und rau, und erscheint auf der Haut als hyperpigmentierter Fleck. Wegen des Orts des Auftretens und des Erscheinungsbild werden aktinische Keratosen oft als kosmetisch unattraktiv wahrgenommen.</p> <p>Das wichtigste Produkt der Biofrontera-Gruppe ist Ameluz®, ein verschreibungspflichtiges Medikament, das für die Verwendung in der photodynamischen Therapie zugelassen ist („PDT“ bzw. in Verbindung mit Ameluz „Ameluz® PDT“). Die Ameluz® PDT hat 2011 eine zentrale europäische Zulassung von der Europäischen Kommission erhalten, für die Behandlung von leichten bis mittelschweren aktinischen Keratosen auf Gesicht und Kopfhaut. Seit der erstmaligen zentralen europäischen Zulassung der Ameluz® PDT hat die Europäische Kommission Erweiterungen der Zulassung der Ameluz® PDT gewährt für (i) die Behandlung von Feldkanzerisierung, d.h. großflächiger Hautbereiche auf Gesicht und Kopf mit mehreren aktinischen Keratosen und (ii) die Behandlung oberflächlicher und/oder nodulärer Basalzellkarzinome, bei denen eine operative Entfernung aufgrund möglicher Morbidität oder wegen des unvorteilhaften kosmetischen Ergebnisses ausscheidet. Ein wesentlicher Vorteil der Behandlung von aktinischer Keratose und Basalzellkarzinom mit photodynamischer Therapie (im Gegensatz zu anderen verbreiteten Behandlungsarten wie operativer Entfernung und Cryotherapie), ist, dass es sich um eine nicht-invasive Alternative handelt, die bessere kosmetische Ergebnisse haben kann, d.h. die Entfernung von Tumoren ohne Hinterlassung klar sichtbarer Narben.</p> <p>Zusätzlich hat die Biofrontera-Gruppe ihre eigene PDT-Lampe entwickelt, BF-RhodoLED®, zur Verwendung mit Ameluz®. Die BF-RhodoLED®-Lampe wurde als Medizingerät in der EU im November 2012 zugelassen und ist zum Vertrieb in allen EU-Mitgliedsstaaten zugelassen, obwohl die Verwendung der BF-RhodoLED®-Lampe nicht zwingend in Kombination mit Ameluz® in der EU oder der Schweiz erfolgen muss.</p> <p>Im Mai 2016 hat die Biofrontera-Gruppe die Zulassung von der US-Food and Drug Administration („FDA“) für den US-Vertrieb von Ameluz® in Kombination mit photodynamischer Therapie unter</p> |
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|      |  | <p>Verwendung der BF-RhodoLED®-Lampe für läsions- und feldbezogene Behandlung von aktinischen Keratosen milder bis mittlerer Schwere auf Gesicht und Kopfhaut erhalten. Die Biofrontera-Gruppe hat den Vertrieb von Ameluz® und BF-RhodoLED® für die Behandlung der aktinischen Keratose in den USA im Oktober 2016 aufgenommen.</p> <p>Die Biofrontera-Gruppe vertreibt derzeit Ameluz® in 12 Ländern in Europa und in den USA, und hat den Vertrieb in Israel in der zweiten Hälfte 2017 aufgenommen.</p> <p>Die wichtigsten Märkte der Biofrontera-Gruppe sind Deutschland, die USA und, in geringerem Umfang, andere europäische Länder.</p>  |
| B.4a | <p>Wichtigste jüngste Trends, die sich auf die Emittentin und die Branchen, in denen sie tätig ist, auswirken.</p> | <p>Im Januar 2017 wurde die europäische Zulassung von Ameluz® auf die Behandlung von Basalzellkarzinomen ausgedehnt. Die Emittentin erwartet, dass dies die Marktaussichten von Ameluz® verbessern wird.</p> <p>Im Januar 2017 konnte die Emittentin eine Wandelschuldverschreibung im Volumen von EUR 5 Millionen platzieren. Ebenfalls schloss die Emittentin im Mai 2017 einen Darlehensvertrag mit der Europäischen Investitionsbank ab, wonach der Emittentin das Recht zusteht, EUR 10 Millionen sogleich und weitere EUR 10 Millionen vorbehaltlich der Erreichung bestimmter Meilensteine abzurufen. Ein Betrag von EUR 10 Millionen wurde im Juli 2017 abgerufen. Die Emittentin erwartet, dass diese Finanzierungen die Liquidität erhöhen und mehr Investitionen erlauben.</p> <p>Marketingmaßnahmen von Wettbewerbern haben die sogenannte Tageslicht-Therapie populärer gemacht. Im Rahmen der Tageslicht-Therapie muss ein Patient nicht mit einer Lampe behandelt werden, sondern der Wirkstoff im PDT-Medikament wird durch Tageslicht aktiviert. Dies kann die empfundenen Schmerzen beim Patienten und den Aufwand des behandelnden Arztes reduzieren. Vom Wettbewerbsmedikament Luxerm®, das identisch mit dem Wettbewerbsmedikament Metvix® ist, allerdings nur für die Tageslicht-Therapie zugelassen, wurden im Juli 2017 mehr Einheiten verkauft als von allen anderen PDT-Medikamenten zusammen.</p> <p>Im Mai 2017 hat die Biofrontera-Gruppe beantragt, die Zulassung von</p> |



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|     |   | Ameluz® auf die Tageslicht-Therapie zu erweitern, um die Wettbewerbsfähigkeit zu verbessern.   |
| B.5 | Gruppenstruktur   | Die Biofrontera Gruppe besteht aus der Emittentin (Biofrontera Aktiengesellschaft) als Muttergesellschaft und fünf 100%igen unmittelbaren Tochtergesellschaften, der Biofrontera Bioscience GmbH, der Biofrontera Pharma GmbH, der Biofrontera Development GmbH, und der Biofrontera Neuroscience GmbH, jeweils mit Sitz in Leverkusen, und der Biofrontera Inc. mit Sitz in Wilmington, Delaware, USA.  |
| B.6 | Meldepflichtige direkte oder indirekte Beteiligungen am Eigenkapital der Emittentin<br><br>Unterschiedliche Stimmrechte der Hauptanteilseigner<br><br>Angabe, ob, soweit der Emittentin bekannt, an ihr unmittelbare oder mittelbare Beteiligungen oder Beherrschungsverh | <p>Soweit der Emittentin bekannt, halten die nachfolgenden Personen direkt oder indirekt eine Beteiligung am Eigenkapital der Emittentin oder den entsprechenden Stimmrechten, die nach deutschem Recht zu melden sind.</p> <p><b><u>Direkte Beteiligungen:</u></b></p> <p>Deutsche Balaton AG, Heidelberg, Germany: 8.28%</p> <p>Maruho Deutschland GmbH, Düsseldorf, Germany: 21.58 %</p> <p>FEHO Vermögensverwaltungsgesellschaft mbH, Frankfurt, Germany: 3.14 %</p> <p><b><u>Indirekte Beteiligungen:</u></b></p> <p>Maruho Co., Ltd., Osaka, Japan: 21.58 %</p> <p>Universal Investment Gesellschaft mbH, Frankfurt, Germany: 3.14 %</p> <p>Wilhelm K. T. Zours: 11.21 %</p> <p>Entfällt. Die Hauptaktionäre der Emittentin haben keine unterschiedlichen Stimmrechte.</p> <p>Entfällt, da nach Kenntnis der Emittentin keine unmittelbaren oder mittelbaren Beteiligungen, die eine Beherrschung ermöglichen, oder sonstige Beherrschungsverhältnisse bestehen.</p> |

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| ältnisse bestehen,<br>wer diese<br>Beteiligungen hält<br>bzw. diese<br>Beherrschung<br>ausübt und welcher<br>Art die<br>Beherrschung ist. |
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B.7 Ausgewählte wesentliche historische Finanzinformationen

**Information betreffend Gewinn- und Verlustrechnung**

|  | Geschäftsjahr<br>endend zum 31.<br>Dezember 2015                | Halbjahr endend<br>zum 30. Juni<br>2016                             | Geschäftsjahr<br>endend zum<br>31. Dezember<br>2016                   | Halbjahr<br>endend zum<br>30. Juni 2017                             |
|--|---|---|---|---|
| Quelle der Finanzinformationen:<br>(all Angaben in TEUR) | Geprüfter IFRS-<br>Konzernabschluss<br>zum 31.<br>Dezember 2015 | Ungeprüfter<br>Halbjahresfinanz-<br>bericht zum 30.<br>Juni 2017(1) | Geprüfter<br>IFRS-<br>Konzernabschluss<br>zum 31.<br>Dezember<br>2016 | Ungeprüfter<br>Halbjahresfin-<br>anzbericht<br>zum 30. Juni<br>2017 |
| Umsatzerlöse   | 4.138   | 1.709   | 6.130   | 5.006,4   |
| Umsatzkosten (2)   | -1.236  | -764  | -1.652  | -635,4  |
| Bruttoergebnis vom Umsatz                                | 2.902   | 945   | 4.478   | 4.371,1   |
| Forschungs- und<br>Entwicklungskosten                    | -6.204  | -1.852  | -4.640  | -2.185,4  |
| Allgemeine Verwaltungskosten                             | -2.759  | -1.372  | -2.853  | -1.695,5  |
| Vertriebskosten (2)                                      | -4.170  | -2.832  | -8.763  | -8.275,3  |
| Nettoergebnis vor Steuern                                | -11.203   | -3.472  | -10.579   | -8.736,6  |
| Ergebnis nach Steuern                                    | -11.203   | -3.472  | -10.579   | -8.736,6  |

(1) Entnommen aus Vorjahresspalte

(2) Hinweis: während „Umsatzkosten“ die allgemeinen Kosten der Umsatzerzielung bezeichnen, bezieht sich „Vertriebskosten“ auf die ausschließlichen Kosten der Distribution

**Informationen betreffend Bilanz**

|  | 31. Dezember 2015   | 31. Dezember 2016   | 30. Juni 2017  |
|--|---|---|--|
| Quelle der Finanzinformationen:<br>(all Angaben in TEUR) | Geprüfter IFRS-<br>Konzernabschluss<br>zum 31. Dezember<br>2015 | Geprüfter IFRS-<br>Konzernabschluss<br>zum 31. Dezember<br>2016 | Ungeprüfter<br>Halbjahresfinanz-<br>bericht zum 30.<br>Juni 2017 |
| Langfristige Verbindlichkeiten<br>(zum Periodenende)     | 11.230  | 3.597   | 2.654,0  |

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| Kurzfristige Verbindlichkeiten (zum Periodenende) | 1.911  | 2.426  | 4.161,3  |
| Eigenkapital (zum Periodenende)                   | -4.809 | 15.842 | 10.388,9 |
| Liquide Mittel (zum Periodenende)                 | 3.959  | 15.126 | 11.451,5 |
| Summe Aktiva                                      | 9.498  | 23.879 | 19.347,9 |
| Angestellte (zum Periodenende) (3)                | 58     | 94     | 124      |

(3) ungeprüft; Quelle: jeweiliger Lagebericht

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|     | Erhebliche Änderungen in Finanzlage oder Betriebsergebnis | <p>Betreffend das Betriebsergebnis hat während der von den historischen Finanzinformationen abgedeckten Periode die Expansion in die USA zu einer erheblichen Erhöhung sowohl der Umsatzerlöse (ca. EUR 5 Millionen im ersten Halbjahr 2017 gegenüber ca. EUR 1,7 Millionen im ersten Halbjahr 2016) als auch der Vertriebskosten, die sich von ca. EUR 2,8 Millionen auf ca. EUR 8,3 Millionen erhöht haben, geführt. Diese Entwicklung hat sich proportional nach dem Datum der letzten historischen Finanzinformationen fortgesetzt.</p> <p>Da die Biofrontera-Gruppe derzeit keine Gewinne erzielt, ist das Betriebskapital und das Eigenkapital der Biofrontera-Gruppe derzeit deutlich niedriger als zum 30. Juni 2017, d.h. dem Ende der letzten Finanzperiode für die geprüfte Finanzinformationen oder Zwischenfinanzinformationen veröffentlicht wurden.</p> <p>Keine weiteren wesentlichen Änderungen in der Finanzlage oder dem Betriebsergebnis der Emittentin oder der Biofrontera-Gruppe sind seit dem 30. Juni 2017 eingetreten, d.h. dem Ende der letzten Finanzperiode für die geprüfte Finanzinformationen oder Zwischenfinanzinformationen veröffentlicht wurden.</p> |
| B.8 | Ausgewählte wesentliche Pro-forma-Finanzinformationen     | Entfällt. Die Emittentin hat keine pro-forma-Finanzinformationen erstellt.  |
| B.9 | Gewinnprognosen oder Schätzungen                          | Die Emittentin hat im Jahresabschluss für das Geschäftsjahr 2016 eine Prognose abgegeben, die sie im November 2017 aktualisiert hat, nach der sie im Geschäftsjahr 2017 Umsätze (in der obigen Tabelle als  |

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|      |   | Umsatzerlöse bezeichnet) von ca. EUR 12 Mio. und ein Nettoerträge (in der obigen Tabelle als Ergebnis nach Steuern bezeichnet) von EUR –18 Mio. erwartet.  |
| B.10 | Etwaige Beschränkungen im Bestätigungsvermerk | <p>Entfällt. Die in diesem Prospekt enthaltenen geprüften historischen Finanzinformationen wurden mit uneingeschränktem Bestätigungsvermerk versehen.</p> <p>Der Bestätigungsvermerk zum Konzernabschluss für das Geschäftsjahr 2016 enthielt allerdings folgenden Hinweis:</p> <p><i>Ohne diese Beurteilung einzuschränken, weisen wir auf die Ausführungen im Konzernlagebericht hin. Dort ist insbesondere in dem Abschnitt „Chancen und Risiken der zukünftigen Geschäftsentwicklung“ unter „Liquiditätsrisiko“ ausgeführt, dass bis zum Erreichen des Break-Even, für die geplanten Investitionen in den Ausbau der Eigenvermarktung in den USA und zur Erfüllung der Verpflichtungen aus der begebenen Wandelanleihe im Laufe des Geschäftsjahres 2017 weitere Kapitalmaßnahmen nötig werden. Der Vorstand geht auf der Grundlage der bisherigen, stets erfolgreichen Erfahrungen mit Kapitalmaßnahmen davon aus, dass die für den Geschäftsverlauf erforderliche Liquidität auch weiterhin gewährleistet werden kann. Sollten sich diese validen Einschätzungen wider Erwarten nicht realisieren, so würde hieraus eine Bestandsgefährdung erwachsen.“</i> Der Bestätigungsvermerk zum Konzernabschluss für das Geschäftsjahr 2015 enthielt folgenden Hinweis:</p> <p><i>„Ohne diese Beurteilung einzuschränken, weisen wir auf die Ausführungen im zusammengefassten Lage- und Konzernlagebericht hin. Dort ist insbesondere in dem Abschnitt „Chancen und Risiken der zukünftigen Geschäftsentwicklung“ unter „Liquiditätsrisiko“ ausgeführt, dass bis zum Erreichen des Break Even und insbesondere durch die USA-Zulassung, die geplanten Investitionen in die Eigenvermarktung in den USA und zur Erfüllung der Verpflichtungen aus der begebenen Wandelanleihe im Laufe des Geschäftsjahres 2016 weitere Kapitalmaßnahmen nötig werden. Der Vorstand geht auf der Grundlage der bisherigen, stets erfolgreichen Erfahrungen mit Kapitalmaßnahmen davon aus, dass die für den Geschäftsverlauf erforderliche Liquidität weiterhin gewährleistet werden kann. Sollten</i></p> |

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|      |                                      | <i>sich diese validen Einschätzungen wider Erwarten nicht realisieren, so würde hieraus eine Bestandsgefährdung erwachsen.“</i>   |
| B.11 | Nicht ausreichendes Geschäftskapital | <p>Die Emittentin ist der Auffassung, dass die Biofrontera Gruppe aus heutiger Sicht nicht ausreichend Geschäftskapital hat, um in den nächsten zwölf Monaten ihren fälligen Zahlungsverpflichtungen nachzukommen. Das derzeitige Geschäftskapital wird nach derzeitiger Einschätzung der Emittentin etwa ausreichen, den fälligen Zahlungsverpflichtungen bis Mai 2018 nachzukommen. Für die kommenden zwölf Monate werden nach der derzeitigen Einschätzung etwa EUR 10 Millionen zusätzliche Mittel benötigt werden, um den dann jeweils fälligen Zahlungsverpflichtungen nachzukommen. Dies beinhaltet vor allem den laufenden operativen Betrieb der Biofrontera Gruppe, einschließlich der Vermarktungsaktivitäten in Europa und den USA sowie dem Erhalt bzw. der Erweiterung der europäischen und US-Zulassung.</p> <p>Die Emittentin beabsichtigt, das fehlende Geschäftskapital mit der in diesem Prospekt dargestellten Kapitalmaßnahme einzuwerben. Zum Datum dieses Prospekts ist der Vorstand der Emittentin optimistisch, dass eine hinreichende Platzierung in Europa und den USA möglich ist. Es wurden bislang allerdings noch keine bindenden Kauf- oder Bezugsvereinbarungen geschlossen. Ein Erfolg der in diesem Prospekt beschriebenen Kapitalmaßnahme ist daher nicht gewährleistet.</p> <p>Einsparungsmaßnahmen wären möglich, allerdings nicht in einem Umfang, der für sich sicherstellt, in den nächsten zwölf Monaten den fälligen Zahlungsverpflichtungen nachzukommen. Zudem würden solche Einsparungen eine wesentliche Einschränkung des Geschäftsbetriebs und der Zukunftsaussichten bewirken. Die Emittentin schätzt, mit Einsparungsmaßnahmen die monatlichen Kosten um ca. TEUR 100 reduzieren zu können. Die Emittentin wird solche Einsparungsmaßnahmen nur als ergänzendes Mittel einsetzen, wenn die Erträge aus der Kapitalmaßnahme unzureichend sind, aber zusammen mit Einsparungsmaßnahmen den Fortbestand der Emittentin sichern können. Für sich allein werden Einsparungsmaßnahmen nicht hinreichend sein, um hinreichendes Geschäftskapital zur Deckung der in den kommenden zwölf Monaten</p> |

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|  |  | <p>fälligen Verbindlichkeiten zu erlangen.</p> <p>Wenn die Emittentin nicht in der Lage ist, aus dieser Kapitalmaßnahme hinreichende Erlöse zu generieren, könnte die Emittentin auch weitere Kapitalmaßnahmen einleiten. Insbesondere hat die Emittentin in der Vergangenheit Wandel- und Optionsanleihen platziert, die auch in der Zukunft als Finanzierungsinstrument verwendet werden könnten.</p> <p>Folge des Scheiterns von Finanzierungsmaßnahmen wäre demnach eine Zahlungsunfähigkeit und mithin die Insolvenz der Emittentin in absehbarer Zeit. Potentielle Anleger sollten daher gewärtig sein, dass die Emittentin von der Beschaffung zusätzlichen Kapitals abhängig ist, um eine Insolvenz in den nächsten zwölf Monaten zu verhindern, und dass der Erfolg der Maßnahmen zur Kapitalbeschaffung nicht im Einfluss der Emittentin steht.</p> |
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### 2.3 Abschnitt C – Wertpapiere

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| C.1 | Art und Gattung der Wertpapiere, Wertpapierkennung | Gegenstand des Angebots sind insgesamt 6.000.000 auf den Namen lautende Stammaktien der Emittentin ohne Nennbetrag mit einem rechnerischen Anteil am Grundkapital der Emittentin von EUR 6.000.000 mit der WKN 604611 und der ISIN DE0006046113 (nachfolgend „ <i>Neue Aktien</i> “). Die Bezugsrechte haben die WKN A2G8YC und die ISIN DE000A2G8YC5.  |
| C.2 | Emissionswährung                                   | EUR.  |
| C.3 | Ausgegebene Aktien                                 | Zurzeit sind 38.416.828 Aktien der Emittentin ausgegeben. Sämtliche Aktien sind voll eingezahlt. Die ausgegebenen Aktien, ebenso wie die Neuen Aktien, haben keinen Nennwert.   |
| C.4 | Mit den Wertpapieren verbundene Rechte             | Die Neuen Aktien gewähren einen Anspruch auf Beteiligung am Gewinn der Emittentin ab dem 1. Januar 2017.<br><br>Jede Neue Aktie gewährt eine Stimme in der Hauptversammlung der Emittentin. Die Aktien berechtigen ferner grundsätzlich zum Bezug weiterer Aktien aus Kapitalmaßnahmen sowie zur Beteiligung an Liquidationserträgen bei Beendigung der Gesellschaft. Die Ausstattung der Neuen Aktien entspricht der |

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|     |   | Ausstattung der bestehenden Aktien.  |
| C.5 | Beschränkungen der Übertragbarkeit                                      | Entfällt. Die angebotenen Neuen Aktien der Emittentin sind uneingeschränkt übertragbar.  |
| C.6 | Erfolgte bzw. beabsichtigte Anträge auf Zulassung zu geregelten Märkten | Die Emittentin beabsichtigt, die Neuen Aktien am regulierten Markt der Frankfurter Wertpapierbörse und am regulierten Markt der Börse Düsseldorf prospektfrei zuzulassen. Der Antrag wird voraussichtlich am 27. Februar 2018 gestellt werden. Die Emittentin erwartet die Zulassung der Neuen Aktien am 7. März 2018 und deren Einbeziehung in den Handel der bestehenden Aktien der Emittentin am 12. März 2018. Eine Zulassung zum Handel an weiteren geregelten Märkten ist nicht beabsichtigt. Es wird darauf hingewiesen, dass eine Zulassung zu den genannten regulierten Märkten nicht mit Sicherheit gewährleistet ist. Es sollte berücksichtigt werden, dass die Emittentin beabsichtigt, eine Einbeziehung von Zertifikaten, die Aktien der Emittentin einschließlich der Neuen Aktien vertreten, in den Handel an der US-Börse NASDAQ zu beantragen. |
| C.7 | Dividendenpolitik   | Die Emittentin hat bislang keine Dividenden gezahlt. Eine Zahlung von Dividenden ist angesichts der wesentlichen Verlustvorträge in der nächsten Zeit auch nicht zu erwarten.  |

#### **2.4 Abschnitt D – Risikofaktoren**

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| D.1 | Zentrale Angaben zu den zentralen Risiken, die der Emittentin oder ihrer Branche eigen sind. | <p>Die Biofrontera-Gruppe hat in der Vergangenheit bislang nur Verluste erzielt, und geht davon aus, dass sie in absehbarer Zeit Verluste erzielen wird, und möglicherweise nie profitabel wird.</p> <p>Die bestehende und künftige Verschuldung der Biofrontera-Gruppe könnte ihre Fähigkeit zur Führung ihrer Geschäfte nachteilig beeinflussen.</p> <p>Bestimmte wichtige Patente der Biofrontera-Gruppe werden in 2019 auslaufen, was einen Markteintritt von Generikaversionen von Ameluz® verursachen kann. In diesem Fall könnte die Biofrontera-Gruppe gezwungen sein, die Preise für Ameluz® zu reduzieren, und könnte einen wesentlichen Marktanteil verlieren.</p> |
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|  |  | <p>Die Übernahme und Erstattung von Versicherungskosten für Medikamente kann in bestimmten Marktsegmenten für Produkte oder Produktkandidaten nicht verfügbar sein, was den Vertrieb durch die Biofrontera-Gruppe erschweren kann.</p> <p>Änderungen in der Rechtslage betreffend das Gesundheitswesen können nachteilige Auswirkungen auf das Geschäft und die Erträge der Biofrontera-Gruppe haben.</p> <p>Im Wettbewerb stehende Produkte und Technologien, die auf traditionellen Behandlungsmethoden gestützt sind, können die Produkte oder potentiellen Produkte der Biofrontera-Gruppe wettbewerbsuntauglich oder obsolet machen.</p> <p>Die Biofrontera-Gruppe sieht sich signifikanten Wettbewerb von anderen Unternehmen aus dem Bereich Pharmazeutika und Medizingeräte ausgesetzt, und Erträge werden sich nachteilig entwickeln, wenn die Biofrontera-Gruppe nicht effektiv im Wettbewerb steht. Die Biofrontera-Gruppe steht auch im Wettbewerb mit bestehenden Behandlungsmethoden, wie einfache Curettage und Kryotherapie, die keine Medikamente beinhalten, aber signifikante Akzeptanz im Markt erlangt haben.</p> <p>Die Biofrontera-Gruppe hängt für die Herstellung von Ameluz® von einem einzelnen unabhängigen Vertragshersteller ab. Wenn es der Biofrontera-Gruppe nicht gelingt, die Vertragsbeziehung mit diesem Hersteller aufrechtzuerhalten, oder wenn dieser Hersteller nicht in der Lage ist, Ameluz® für die Biofrontera-Gruppe zu produzieren, könnte dies die Biofrontera-Gruppe nachhaltig schädigen.</p> <p>Der Biofrontera-Gruppe könnte es nicht gelingen, Ameluz® oder BF-RhodoLED® oder andere vertriebene Produkte und Produktkandidaten in hinreichender Menge und akzeptabler Qualität und Kosten zu produzieren, oder die Anforderungen der „derzeitigen guten Herstellungspraxis“ (current good manufacturing practice “cGMP”) oder andere anwendbare Herstellungsregularien einzuhalten.</p> <p>Die Biofrontera-Gruppe unterliegt Gesetzen, Regularien und Verwaltungsakten im Bereich Gesundheitswesen. Hält sie diese nicht ein, kann dies wesentlich nachteilige Auswirkungen auf Erträge und</p> |
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|  |  | <p>Finanzlage haben.</p> <p>Ein Rückruf von Medikamenten oder Medizingeräten der Biofrontera-Gruppe, oder die Entdeckung wesentlicher Sicherheitsprobleme mit Medikamenten oder Medizingeräten könnte wesentlich nachteilige Auswirkungen haben.</p> <p>Das Medizingerät der Biofrontera-Gruppe, die BF-RhodoLED®-Lampe, unterliegt extensiver Regulierung.</p> <p>Wenn Produkthaftungsklagen gegen die Biofrontera-Gruppe anhängig gemacht werden, kann sich diese wesentlichen Verbindlichkeiten ausgesetzt sehen, und muss gegebenenfalls die Vermarktung ihrer Produkte begrenzen.</p> <p>Die Entwicklung von Medikamenten ist kostspielig und beinhaltet ungewisse Ergebnisse, und Resultate früherer Studien und Versuche sind möglicherweise kein sicheres Zeichen für die Ergebnisse künftiger Versuche. Wenn eine oder mehrere künftige Phase-III-Versuche für Ameluz® erfolglos oder verzögert verläuft, könnte die Biofrontera-Gruppe die Entwicklung aufgeben müssen, Reputationsverluste erleiden, und ihr Geschäft wäre Schädigungen ausgesetzt.</p> <p>Für die Durchführung klinischer Versuche bedient sich die Biofrontera-Gruppe Dritter. Wenn diese Dritten ihre vertraglichen Verpflichtungen nicht erfolgreich ausführen oder erwartete Fristen einhalten, könnte die Biofrontera-Gruppe nicht in der Lage sein, regulatorische Genehmigungen zu erhalten oder Produktkandidaten zu vertreiben.</p> <p>Wenn die Bemühungen der Biofrontera-Gruppe, ihre gewerblichen Schutzrechte zu schützen nicht hinreichend sind, könnte die Biofrontera-Gruppe Wettbewerbsnachteile erleiden.</p> <p>Behauptungen Dritter betreffend die Verletzung von gewerblichen Schutzrechten können die Forschungs- und Entwicklungsbemühungen der Biofrontera-Gruppe verhindern oder verzögern.</p> <p>Die Biofrontera-Gruppe könnte in Rechtsstreitigkeiten zur Verteidigung oder Durchsetzung von Patenten gezogen werden, die sich als teuer, zeitlich aufwendig, und erfolglos erweisen können.</p> |
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|     |   | <p>Die Biofrontera-Gruppe könnte sich Behauptungen ausgesetzt sehen, dass Angestellte, Berater oder unabhängige Vertragspartner vertrauliche Informationen Dritter unzulässigerweise verwendet oder offengelegt haben.</p> <p>Die Geschäftsgeheimnisse der Biofrontera-Gruppe sind schwierig zu schützen.</p>  |
| D.3 | Zentrale Angaben zu den zentralen Risiken, die den Wertpapieren eigen sind. | <p>Eine Investition in Aktien birgt stets das Risiko eines Verlusts des eingesetzten Kapitals.</p> <p>Wird die in diesem Prospekt beschriebene Kapitalerhöhung nicht durchgeführt, so können Erwerber von Bezugsrechten einen Verlust in Höhe der für die Bezugsrechte getätigten Aufwendungen erleiden. Insbesondere könnte das Handelsregister eine Eintragung der Kapitalerhöhung vor dem Hintergrund der Anfechtungsklage gegen die Wahl der Aufsichtsratsmitglieder verweigern.</p> <p>Eine Anlage in die Neuen Aktien ist nicht für jeden Anleger zweckmäßig.</p> <p>Der Kurs und das Handelsvolumen der Aktien der Biofrontera Aktiengesellschaft können starken Schwankungen unterliegen.</p> <p>Die Veräußerung von Aktien in großem Umfang kann negative Auswirkungen auf den Börsenkurs der Emittentin haben.</p> <p>Aktionäre mit größeren Aktienbeständen könnten über die Hauptversammlung einen beherrschenden Einfluss auf die Emittentin ausüben bzw. erlangen.</p> <p>Durch die künftige Ausübung von Optionsrechten und mögliche Kapitalerhöhungen besteht das Risiko der Verwässerung.</p> <p>Es bestehen Währungsrisiken für Anleger in Fremdwährungen.</p> <p>Leerverkäufe von Aktien der Emittentin können Verluste des Investors verursachen.</p> <p>Es könnte zeitweilig oder dauerhaft keine Handelbarkeit der Neuen Aktien bestehen. Insbesondere könnte ein Downlisting oder Delisting die Liquidität und den Kurs der Neuen Aktien nachteilig beeinflussen.</p> |

## 2.5 Abschnitt E – Angebot

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| E.1  | Gesamterlöse und geschätzte Gesamtkosten der Emission/des Angebots, einschließlich der geschätzten Kosten, die dem Anleger vom Emittenten oder Anbieter in Rechnung gestellt werden | Die Emittentin erwartet unter der Annahme, dass sämtliche Neue Aktien bei einem Bezugspreis je Neuer Aktie von EUR 3,50 bis EUR 4,50 platziert werden, einen Brutto-Gesamterlös von EUR 21 Mio. bis EUR 27 Mio. und einen Netto-Gesamterlös der Emission von etwa EUR 20 Mio. bis EUR 26 Mio. Die Gesamtkosten der Emission werden voraussichtlich bis zu etwa EUR 1 Mio. betragen. Kosten des Angebots werden dem Anleger weder von der Emittentin noch von einem Anbieter in Rechnung gestellt.  |
| E.2a | Gründe für das Angebot, Zweckbestimmung der Erlöse, geschätzte Netto-Erlöse.  | <p>Die Emittentin erwartet unter der Annahme, dass sämtliche Neue Aktien bei einem Bezugspreis je Neuer Aktie von EUR 3,50 bis EUR 4,50 platziert werden, einen Netto-Gesamterlös der Emission von EUR 20 Mio. bis EUR 26 Mio.</p> <p>Die Emissionserlöse werden wie folgt verwendet werden: Ein Betrag von EUR 5 Mio. wird für Zwecke von Forschung und Entwicklung eingesetzt werden, insbesondere zur Erweiterung der Indikationen, für die Ameluz® verwendet werden darf. Ein Betrag von EUR 5 Mio. wird zur Förderung der Vermarktung in den USA verwendet. Der verbleibende Betrag, der in Höhe zwischen EUR 10 Mio. und EUR 16 Mio. erwartet wird, soll der allgemeinen Finanzierung der Gesellschaft dienen.</p> <p>Des Weiteren sollen Neue Aktien der Schaffung von American Depositary Shares im Zusammenhang mit einem sogenannten „sponsored Level-III program“ zugrundeliegen. Unter dem US-Angebot sollen ADSs an Zeichner in den USA angeboten werden, und ein Listing an der NASDAQ soll beantragt werden. Die Neuen Aktien, die für diesen Zweck verwendet werden, sollen auch an der Frankfurter Wertpapierbörse zum Handel</p> |

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|     |                                       | zugelassen werden.   |
| E.3 | Beschreibung der Angebotskonditionen. | <p>Die Neuen Aktien werden zunächst den Aktionären der Emittentin bzw. Inhabern von Bezugsrechten durch die die Lang &amp; Schwarz Broker GmbH mit Sitz in Düsseldorf, Breite Str. 34, 40213 Düsseldorf (nachfolgend „<i>Lang &amp; Schwarz Broker GmbH</i>“), zum Bezug angeboten. Für den Fall, dass nicht alle Neuen Aktien im Rahmen des Bezugsangebots bezogen werden, werden die nicht bezogenen Neuen Aktien (einschließlich solcher, auf die das Bezugsrecht zur Herstellung eines glatten Bezugsverhältnisses ausgeschlossen wurde), soweit rechtlich zulässig, bis zum 23. Februar 2018 Dritten zum Bezugspreis zum Erwerb angeboten.</p> <p>Gemäß § 7 Abs. 3a der Satzung ist der Vorstand ermächtigt, das Grundkapital der Gesellschaft bis zum 23. Mai 2022 mit Zustimmung des Aufsichtsrats um bis zu EUR 6.000.000 durch ein- oder mehrmalige Ausgabe von bis zu 6.000.000 auf den Namen lautenden Stückaktien gegen Bar- und/oder Sacheinlagen zu erhöhen (Genehmigtes Kapital). Auf Grundlage dieser Ermächtigung hat der Vorstand der Gesellschaft am 29. Januar 2018 mit Zustimmung des Aufsichtsrats vom gleichen Tage beschlossen, das Grundkapital der Gesellschaft in Höhe von derzeit EUR 38.416.828 um bis zu EUR 6.000.000 aus Genehmigtem Kapital auf bis zu EUR 44.416.828 durch Ausgabe von bis zu 6.000.000 neuen, auf den Namen lautenden Stückaktien mit einem auf die einzelne Stückaktie entfallenden anteiligen Betrag des Grundkapitals in Höhe von EUR 1,00 („<i>Neue Aktien</i>“) zu erhöhen.</p> <p>Die genaue Festlegung des Umfangs der Kapitalerhöhung erfolgt ebenso wie die entsprechende Änderung der Satzung nach Ablauf des Angebots.</p> <p><b>Bezugsrechtsangebot</b></p> |

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|  | <p>Den Aktionären wird das gesetzliche Bezugsrecht in der Weise gewährt, dass die Lang &amp; Schwarz Broker GmbH zur Zeichnung und Übernahme der bis zu 6.000.000 Neuen Aktien zum Ausgabebetrag von EUR 1,00 je Neuer Aktie zugelassen wird, verbunden mit der Verpflichtung, die Neuen Aktien den Aktionären im Verhältnis 13:2 gegen Zahlung eines Bezugspreises („<b>Bezugspreis</b>“) zum Bezug anzubieten („<b>Bezugsangebot</b>“). Auf eine Spitze von 89.719 Neuen Aktien ist das Bezugsrecht ausgeschlossen.</p> <p>Der Bezugspreis wird voraussichtlich am 9. Februar 2018 festgelegt, unter Berücksichtigung von Angeboten, die von institutionellen Investoren in einem Verfahren zur Interessenbekundung (sog. Bookbuilding-Verfahren) erhalten wurden. Der Bezugspreis wird voraussichtlich am 9. Februar 2018 durch ad-hoc-Mitteilung bekanntgegeben sowie am selben Tag im Bundesanzeiger und auf der Internetseite der Emittentin unter <a href="http://www.biofrontera.com">www.biofrontera.com</a> veröffentlicht. Der Bezugspreis wird EUR 4,50 nicht überschreiten („<b>Maximaler Bezugspreis</b>“).</p> <p>Die Aktionäre werden aufgefordert, ihr Bezugsrecht auf die Neuen Aktien zur Vermeidung des Ausschlusses in der Zeit vom 30. Januar 2018 bis einschließlich 12. Februar 2018 („<b>Bezugsfrist</b>“) bei der für die Lang &amp; Schwarz Broker GmbH als Abwicklungsstelle tätig werdenden Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen („<b>Bankhaus Gebr. Martin Aktiengesellschaft</b>“), während der üblichen Geschäftszeiten auszuüben.</p> <p>Zur Ausübung des Bezugsrechts bitten wir unsere Aktionäre bzw. Inhaber von Bezugsrechten, ihrer Depotbank eine entsprechende Weisung zu erteilen. Für 13 alte Stückaktien der Gesellschaft können 2 Neue Aktien zum Bezugspreis bezogen werden. Für sich aus dem individuellen Aktienbestand aufgrund des</p> |
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|  | <p>Bezugsverhältnisses 13:2 rechnerisch ergebende Bruchteile Neuer Aktien können keine Neuen Aktien bezogen werden, sondern es ist nur der Bezug von je 2 Neuen Aktie oder einem Vielfachen davon möglich. Maßgeblich für die Berechnung der Anzahl der den Aktionären jeweils zustehenden Bezugsrechte ist deren jeweiliger Bestand an Aktien der Gesellschaft mit Ablauf des 29. Januar 2018. Zu diesem Zeitpunkt werden die Bezugsrechte (ISIN DE000A2G8YC5) von den Aktienbeständen im Umfang des bestehenden Bezugsrechts abgetrennt und den Aktionären von ihren Depotbanken eingebucht.</p> <p>Die Bezugsrechte können gehandelt werden, die Emittentin wird allerdings weder einen börslichen noch einen privaten Handel organisieren. Nicht ausgeübte Bezugsrechte verfallen und werden nach Ablauf der Bezugsfrist wertlos ausgebucht.</p> <p>Vom 26. Januar 2018 an werden die alten Aktien „ex-Bezugsrecht“ notiert.</p> <p>Aktionäre, die Bezugsrechte ausüben, haben den Bezugspreis bei Ausübung des Bezugsrechts, spätestens jedoch zum Ende der Bezugsfrist am 12. Februar 2018, zu entrichten. Als Bezugsrechtsnachweis für die Neuen Aktien gelten die Bezugsrechte.</p> <p>Entscheidend für die Einhaltung der Frist ist der Eingang der Bezugsanmeldung sowie des Bezugspreises bei der genannten Stelle. Für den Bezug wird Aktionären bzw. Inhabern von Bezugsrechten die übliche Bankprovision berechnet.</p> <p>Die Depotbanken werden gebeten, die Bezugsanmeldungen in einer Anmeldung bis spätestens 12. Februar 2018 (einschließlich) bei der Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen, Telefax +49 (0)7161 969317, aufzugeben und den Bezugspreis je Neuer Aktie ebenfalls bis</p> |
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|     |  | <p>spätestens zum Ende der Bezugsfrist auf folgendes Konto der Lang &amp; Schwarz Broker GmbH bei der Bankhaus Gebr. Martin Aktiengesellschaft zu zahlen:</p> <p>Bank: Bankhaus Gebr. Martin Aktiengesellschaft</p> <p>Konto-Nr.: 9673</p> <p>IBAN: DE88 610 300 00 000 000 9673</p> <p>BIC: MARBDE6G</p> <p>Verwendungszweck „W/Biofrontera“</p> <p><b>Verwertung nicht im Rahmen des Bezugsrechts bezogener Neuer Aktien</b></p> <p>Für den Fall, dass nicht alle Neuen Aktien im Rahmen des Bezugsangebots bezogen werden, werden die nicht bezogenen Neuen Aktien, soweit rechtlich zulässig, bis zum 23. Februar 2018 Dritten zum Bezugspreis zum Erwerb angeboten.</p>   |
| E.4 | Wesentliche Interessen einschließlich Interessenkonflikten | <p>Die Lang &amp; Schwarz Broker GmbH erhält für ihre Tätigkeiten im Rahmen des Angebots eine variable Vergütung in Abhängigkeit vom Emissionsvolumen. Interessenkonflikte bestehen auf Grund der Gewährung der festen Vergütung nach Einschätzung der Gesellschaft nicht.</p> <p>Mitglieder des Vorstands und des Aufsichtsrats halten Aktien an der Emittentin sowie Optionsrechte auf den Erwerb von Aktien der Emittentin. Sie haben daher ein eigenes Interesse an der Entwicklung des Kurses der Aktien der Emittentin. Nach Einschätzung der Emittentin liegt hierin kein Interessenkonflikt, da die privaten Interessen der Mitglieder von Vorstand und Aufsichtsrat den Interessen der Emittentin nicht widersprechen.</p> <p>Weitere Interessen, Interessenkonflikte oder mögliche Interessenkonflikte von Seiten natürlicher und juristischer Personen sind für die Emittentin nicht erkennbar.</p> |

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| E.5 | <p>Anbieter der Wertpapiere.</p> <p>Lock-up Vereinbarungen.</p>  | <p>Die Neuen Aktien stammen aus einer Kapitalerhöhung, werden also von der Emittentin über die Lang &amp; Schwarz Broker GmbH als Emissionsbank angeboten.</p> <p>Entfällt. Es bestehen keine Lock-up-Vereinbarungen betreffend die Neuen Aktien.</p>  |
| E.6 | <p>Angebotsbetrag und Prozentsatz der aus dem Angebot resultierenden unmittelbaren Verwässerung.</p> <p>Im Falle eines Zeichnungsangebots an die existierenden Anteilseigner Betrag und Prozentsatz der unmittelbaren Verwässerung für den Fall, dass sie das neue Angebot nicht zeichnen.</p> | <p>Vor der Durchführung der Kapitalerhöhung beträgt der Nettobuchwert der Biofrontera Gruppe ca. TEUR 10.388,9 oder ca. EUR 0,27 je Aktie (berechnet auf der Grundlage von 38.416.828 ausgegebenen Aktien der Emittentin zum Datum dieses Prospekts). Der Nettobuchwert der Biofrontera-Gruppe wird auf Grundlage des geprüften Halbjahresabschlusses auf den 30. Juni 2017 berechnet, indem von der Bilanzsumme 30. Juni 2017 (TEUR 19.347,9, im Abschluss als „Summe Aktiva“ bezeichnet) die gesamten kurzfristigen (TEUR 6.305,0) und langfristigen Verbindlichkeiten (TEUR 2.654,0) zum 30. Juni 2017 in Abzug gebracht werden.</p> <p>Die Emittentin erwartet unter der Annahme, dass sämtliche Neue Aktien bei dem Bezugspreis je Neuer Aktie von EUR 4.00 platziert werden, einen Brutto-Gesamterlös der Emission von EUR 24 Mio. und einen Netto-Emissionerlös von EUR 23 Mio.</p> <p>Unter der Annahme der vollständigen Durchführung der Kapitalerhöhung gegen Bareinlagen zu einem Bezugspreis in Höhe von EUR 4,00 je Aktie und einem Nettoerlös von ca. EUR 23 Mio. würde sich der Nettobuchwert der Biofrontera Gruppe mit Stand vom 30. Juni 2017 auf ca. EUR 33.388.900 oder ca. EUR 0,75 je Aktie belaufen (berechnet auf der Grundlage von 44.416.828 ausgegebenen Aktien der Emittentin nach Durchführung der Barkapitalerhöhung).</p> <p>Ausgehend von einem Bezugspreis von EUR 4,00 je Aktie würde dies zu einer Erhöhung des Nettobuchwerts</p> |



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|     |   | <p>der Biofrontera-Gruppe zum 30. Juni 2017 um EUR 0,48 je Aktie auf EUR 0,75 je Aktie für die Altaktionäre führen. Dies entspräche einer Steigerung um ca. 178 %. Für den Erwerber Neuer Aktien ergäbe sich eine unmittelbare Verwässerung von EUR 3,25 je Aktie oder ca. 81,25 %, da der angenommene Bezugspreis von EUR 4,00 je Aktie über dem errechneten neuen Nettobuchwert je Aktie von EUR 0,75 liegen würde.</p> <p>Soweit Aktionäre von ihrem Bezugsrecht keinen Gebrauch machen und keine Neuen Aktien zeichnen, wird deren prozentualer Anteil am stimmberechtigten Kapital der Emittentin bei vollständiger Platzierung sämtlicher Aktien (6.000.000 Stück) aus der Kapitalerhöhung, die Gegenstand dieses Prospekts ist, um ca. 15,6 % verwässert. Werden nicht sämtliche Neuen Aktien platziert, wird die Verwässerung dementsprechend geringer ausfallen.</p> |
| E.7 | Schätzung der Ausgaben, die dem Anleger von der Emittentin oder Anbieter in Rechnung gestellt werden. | Entfällt. Weder die Emittentin noch ein etwaiger Anbieter stellen den Zeichnern der Neuen Aktien Kosten in Rechnung. Die depotführenden Banken der Zeichner können ggf. eine marktübliche Effektenprovision für den Erwerb der Neuen Aktien berechnen.  |

### 3. Risk Factors

Before taking the decision whether to acquire shares of Biofrontera Aktiengesellschaft with registered seat in Leverkusen, business address Hemmelrather Weg 201, 51377 Leverkusen (also “**Issuer**” and together with its subsidiaries “**Biofrontera Group**”), in particular the 6,000,000 registered no-par shares of the Issuer with a notional participation in the registered share capital of EUR 1.00 per no-par share, WKN 604611, ISIN DE0006046113 subject to this prospectus (also “**New Shares**”), Investors should carefully read and consider the following risks and the other information contained in this prospectus.

**The following risks, alone or together with additional risks and uncertainties not currently known to the Issuer, or which the Issuer might currently deem immaterial, could materially adversely affect the business, financial condition and results of operations of the Issuer and Biofrontera**

**Group. If any of these risks were to materialize, the operations of the Issuer and Biofrontera group may be materially impaired, and the business, financial position and results of operation of the Issuer and Biofrontera Group may be materially adversely affected. In such cases, the trading price of the New Shares could materially decline. Investors could lose all or part of their investment (total loss risk). The order in which the following risks are presented does not indicate the likelihood of their occurrence, nor the scope of any potential impairment these risks may cause to the business, financial position and results of operation of the Issuer or Biofrontera Group. The risks mentioned may materialize individually or cumulatively.**

This prospectus contains forward-looking statements that are subject to future events, risks and uncertainties. The actual results of the Issuer and Biofrontera Group could differ materially from those anticipated in these forward-looking statements as a result of many factors, including, but not limited to, the risks the Issuer and Biofrontera Group face as described below and elsewhere in this prospectus.

### **3.1 Risk factors specific to the Issuer and its industry**

#### **3.1.1 Financial risks**

- 3.1.1.1 Biofrontera Group has a history of operating losses and anticipate that it will continue to incur operating losses in the future and that it may never sustain profitability.

Biofrontera Group has incurred losses in each year since inception. The net loss for the fiscal years ended December 31, 2015 and December 31, 2016 was EUR 11.2 million and EUR 10.6 million, respectively. As of June 30, 2017, Biofrontera Group had an accumulated deficit of EUR 129.1 million.

Biofrontera Group's ability to become profitable depends on the ability to further commercialize the principal product Ameluz®. Even if Biofrontera Group is successful in increasing product sales, Biofrontera Group may never achieve or sustain profitability. Biofrontera Group anticipates substantially increasing sales and marketing expense as Biofrontera Group attempts to exploit the recent regulatory approvals Biofrontera Group has received to market Ameluz® in the U.S. for the photodynamic therapy treatment of actinic keratoses of mild-to-moderate severity on the face and scalp and in the EU for the treatment of field cancerization and basal cell carcinoma. There can be no assurance that sales and marketing efforts will generate sufficient sales to allow Biofrontera Group to become profitable. Moreover, of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, the Issuer is unable to predict the extent of any future losses or when Biofrontera Group will become profitable, if ever.

3.1.1.2 If Biofrontera Group fails to obtain additional financing, it may be unable to complete the development and commercialization of products and product candidates.

Biofrontera Group's operations have consumed substantial amounts of cash since inception. The Issuer expects to continue to spend substantial amounts to pursue additional indications for which products and product candidates may be commercialized, and to continue the clinical development of product candidates, including further Phase III clinical trials. Biofrontera Group also requires significant additional funds in order to commercialize Ameluz® in the U.S.

Biofrontera Group believes that existing cash and cash equivalents will be sufficient to fund operations for the next 12 months at least. However, changing circumstances may cause Biofrontera Group to consume capital significantly faster than currently anticipated, and Biofrontera Group may need to spend more money than currently expected because of circumstances beyond the control of the Issuer.

The Issuer cannot be certain that additional funding will be available on acceptable terms, or at all. If the Issuer is unable to raise additional capital in sufficient amounts and on acceptable terms, Biofrontera Group may have to significantly delay, scale back or discontinue the commercialization of products or development of product candidates. Biofrontera Group also could be required to license rights to products and product candidates to third parties on unfavorable terms. In addition, any equity financing would likely result in dilution to existing holders of shares and ADSs, and any debt financing would likely involve significant cash payment obligations and include restrictive covenants that may restrict Biofrontera Group's ability to operate its business.

3.1.1.3 Biofrontera Group's existing and any future indebtedness could adversely affect its ability to operate its business.

In May 2017, Biofrontera Group entered into a finance contract with the European Investment Bank ("**EIB**"), under which EIB agreed to provide Biofrontera Group with loans of up to EUR 20 million in the aggregate. The finance contract with EIB ("**EIB Credit Facility**"), is unsecured, is guaranteed by certain subsidiaries, and is available to be drawn in tranches during a two year period. Future tranches require the achievement of certain milestones. Each tranche must be repaid five years after drawdown. The EIB Credit Facility contains undertakings by Biofrontera Group regarding the use of proceeds and limitations on debt, liens, mergers, acquisitions, asset sales, dividends and other restrictive covenants. As of the date of this prospectus, Biofrontera Group has borrowed EUR 10 million under the EIB Credit Facility. On July 6, 2022, Biofrontera Group will be required to repay this EUR 10 million principal amount, plus EUR 3 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in market capitalization between disbursement and maturity of the loan. Under the EIB Credit Facility, Biofrontera Group is not permitted to incur additional third-party debt in excess of EUR 1 million without the prior consent of

the EIB (subject to certain exceptions, such as for ordinary course deferred purchase arrangements and, subject to maximum amounts, various types of leases).

In addition, in December 2016 Biofrontera Group issued convertible bonds in the aggregate initial principal amount of EUR 5.0 million maturing on January 1, 2021 of which EUR4 .9 million has already been converted into shares. In January 2017, Biofrontera Group issued convertible bonds maturing on January 1, 2022 in the aggregate initial principal amount of EUR 5.0 million of which EUR 2.3 million has already been converted into shares.

Biofrontera Group may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under existing debt obligations, in particular the minimum EUR 13 million payment that must be made on July 6, 2022. Failure to make payments or comply with other covenants under existing debt could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender or lenders accelerate the amounts due, Biofrontera Group may not be able to make accelerated payments, and such lenders could file suit to collect the amounts due under such obligations or pursue other remedies. In addition, the covenants under existing debt obligations could limit the ability to obtain additional debt financing.

### **3.1.2 Regulatory Risks**

3.1.2.1 Certain of Biofrontera Group's important patents will expire in 2019, which may result in the entry into the market of generic versions of Ameluz®. If this happens, Biofrontera Group may need to reduce the price of Ameluz® significantly and may lose significant market share.

The patent family that protects aminolevulinic acid hydrochloride, an active ingredient in Ameluz®, against copying by competitors will expire on November 12, 2019. This patent family serves as a material, significant, and possibly the only barrier to entry into the market by generic versions of Ameluz®. Once this patent expires, Biofrontera Group will not be able to prevent generic versions of Ameluz® from entering the market and competing with Ameluz®. This may cause a significant price drop and, therefore, a significant drop in profits. Biofrontera Group may also lose significant market share for Ameluz.

3.1.2.2 Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for products or product candidates, which could make it difficult for Biofrontera Group to sell products.

Government authorities and third party payors, such as private health insurers and health maintenance organizations or, in some jurisdictions such as Germany, statutory health insurance, decide which

products they will cover and the amount of reimbursement. Reimbursement by a third party payor may depend upon a number of factors, including the government or third party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- reasonable and appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third party payor is a time-consuming and costly process that could require Biofrontera Group to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of products. Biofrontera Group may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or a particular reimbursement amount. If reimbursement of future products or extended indications for existing products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Biofrontera Group may be unable to achieve or sustain profitability.

The pricing of prescription pharmaceuticals is subject to governmental control in some of the countries in which Biofrontera Group has received and/or seek to receive approval to commercialize certain of products. Biofrontera Group is approved to market certain products in the EU and the U.S., and intends to seek approval to market product candidates in selected other jurisdictions. If Biofrontera Group obtains approval in one or more foreign jurisdictions for product candidates, Biofrontera Group will be subject to rules and regulations in those jurisdictions. In some countries, particularly those in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a product candidate. In addition, market acceptance and sales of product candidates will depend significantly on the availability of adequate coverage and reimbursement from government or other third party payors for product candidates and may be affected by existing and future health care reform measures. Without adequate levels of reimbursement by government health care programs and private health insurers, the market for products will be limited. While Biofrontera Group continues to support efforts to improve reimbursement levels to physicians and plan to work to improve coverage for its products, if such efforts are not successful, a broader adoption of products and sales of products could be negatively impacted.

In the US, for a drug to be eligible for reimbursement by Medicare, a pharmaceutical company generally must obtain a permanent "J-code" for the drug that can usually be applied for in January following the year of a drug's approval. The process for applying and obtaining a permanent "J-code"

typically takes at least one year. Until Biofrontera Group has obtained a permanent “J-code”, doctors making reimbursement claims must apply for reimbursement by use of a “miscellaneous” J-code, which creates additional administrative hurdles and delay for the doctors to get reimbursed, especially after launch, when payers are not yet familiar with claims for the new drug. Biofrontera Group applied for a “J-code” for Ameluz® in January 2017, and expects to receive a permanent “J-code” in January 2018. If Biofrontera Group does not timely receive the “J-code” for Ameluz®, doctors in the U.S. could be discouraged from using Ameluz®.

3.1.2.3 Healthcare legislative changes may have a material adverse effect on business and results of operations.

In the U.S. and certain other countries, there have been a number of legislative and regulatory changes to the health care system that could impact Biofrontera Group’s ability to sell products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the U.S., which has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the Affordable Care Act. There is no guarantee whether the Affordable Care Act will remain in effect or be repealed/replaced. There is significant uncertainty about the future of the Affordable Care Act in particular and healthcare laws generally in the United States. This expansion of the government’s role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. Biofrontera Group is unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact its profitability.

3.1.2.4 Clinical drug development is expensive and involves uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If one or more future Phase III clinical trials for Ameluz® were unsuccessful, or significantly delayed, Biofrontera Group could be required to abandon development, may suffer reputational harm and Biofrontera Group’s business will be materially harmed.

If the results of clinical trials for Biofrontera Group’s current products or product candidates or clinical trials for any future product candidates do not achieve their primary efficacy endpoints or raise unexpected safety issues, the prospects for approval of product candidates or the extension of indications for products will be materially adversely affected. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to

achieve similar results in later clinical trials, or have ultimately failed to obtain regulatory approval of their product candidates. Many products that initially showed promise in clinical trials or earlier stage testing have later been found to cause undesirable or unexpected adverse effects that have prevented their further development and regulatory approval. Biofrontera Group's ongoing trial for the extension of the US approval to treatment of basal cell carcinoma may not produce the results that Biofrontera Group expects or that are required to achieve FDA approval.

In addition, Biofrontera Group may experience numerous unforeseen events that could cause clinical trials to be delayed, suspended or terminated, or which could delay or prevent Biofrontera Group's ability to receive regulatory approval or commercialize its products.

3.1.2.5 Biofrontera Group will be subject to ongoing regulatory requirements in every market where its engages in business and may face future development, manufacturing and regulatory difficulties.

Ameluz® and any other drug products Biofrontera Group develops will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping, submission of safety and other post-market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and the requirements of other similar regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP requirements.

Accordingly, Biofrontera Group will be required to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Biofrontera Group will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar regulatory authorities and to comply with certain requirements concerning advertising and promotion for potential products.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated or unacceptable severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions, including requiring withdrawal of the product from the market.

3.1.2.6 Biofrontera Group relies on third parties to conduct clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, Biofrontera Group may not be able to obtain regulatory approval for or commercialize product candidates.

Biofrontera Group has engaged third party clinical research organizations (“CROs”) in connection with Phase III clinical trials for products and product candidates and will continue to engage such



CROs in the future. Biofrontera Group will rely heavily on these parties for proper execution of clinical trials, and will control only certain aspects of their activities. Nevertheless, Biofrontera Group is responsible for ensuring that each study is conducted in accordance with applicable protocol, legal and regulatory requirements, and scientific standards, and reliance on CROs does not relieve Biofrontera Group of its regulatory responsibilities. Biofrontera Group and its CROs will be required to comply with current Good Clinical Practices (“*cGCP*”) requirements, which are a collection of regulations for products and product candidates in clinical development in order to protect the health, safety and welfare of patients and assume the integrity of clinical data.

Regulatory authorities enforce cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If Biofrontera Group or any of these CROs fail to comply with applicable cGCP regulations or record-keeping requirements at any point during the clinical trial process, the clinical data generated in clinical trials may be deemed unreliable and the FDA or EMA or comparable foreign regulatory authorities may require Biofrontera Group to perform additional clinical trials before approving marketing applications or, in some instances, require Biofrontera Group to suspend operations.

3.1.2.7 Biofrontera Group is subject to healthcare laws, regulation and enforcement. Failure to comply with those laws could have a material adverse effect on results of operations and financial condition.

Biofrontera Group may be subject to additional healthcare regulation and enforcement by authorities in the U.S., the EU and other jurisdictions. Such laws include e.g. anti-kickback, false claims, privacy, security, financial disclosure laws, anti-trust, and fair trade regulation and advertising laws and regulations. If Biofrontera Group’s operations are found to be in violation of any of such laws or any other governmental regulations, Biofrontera Group may be subject to penalties, including, but not limited to, civil and criminal penalties, damages, fines, the exclusion from participation in healthcare programs and imprisonment.

3.1.2.8 A recall of Biofrontera Group’s drug or medical device products, or the discovery of serious safety issues with drugs or medical device products, could have a significant negative impact.

The FDA, the EMA and other relevant regulatory agencies have the authority to require or request the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product. A government-mandated or voluntary recall by Biofrontera Group could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of products would divert



managerial and financial resources and have an adverse effect on reputation, financial condition and operating results.

3.1.2.9 Biofrontera Group's medical device product, the BF-RhodoLED® lamp, is subject to extensive governmental regulation.

The medical device industry is regulated extensively by governmental authorities. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit the ability to carry on or expand operations or result in higher than anticipated costs or lower than anticipated sales. The governmental agencies regulate numerous elements of Biofrontera Group's business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;
- distribution;
- labeling, manufacturing and storage;
- pre-market clearance or approval;
- advertising and promotion;
- marketing, manufacturing, sales and distribution;
- relationships and communications with health care providers;
- adverse event reporting;
- market exclusivity;
- servicing and post-market surveillance; and
- recalls and field safety corrective actions.

3.1.2.10 Modifications to medical device products, such as the BF-RhodoLED® lamp in Europe, may require reclassifications, new CE marking processes or may require Biofrontera Group to cease marketing or recall the modified products until new CE marking is obtained.

A modification to medical devices such as BF-RhodoLED® lamp, which is approved for sale in Europe, could lead to a reclassification of the medical device and could result in further requirements (including additional clinical trials) to maintain the product's CE marking. If Biofrontera Group fails

to comply with such further requirements it may be required to cease marketing or to recall the modified product until Biofrontera Group obtains clearance or approval, and may be subject to significant regulatory fines or penalties.

### **3.1.3 Business Risks**

#### **3.1.3.1 To date, Biofrontera Group has engaged in only limited sales of products, primarily in Germany and Spain and, more recently, in the U.S.**

Biofrontera Group has engaged in only limited sales of products to date. In Germany, the majority of sales have been generated in the private dermatology offices sector. Historically, sales partners in European countries outside of Germany have experienced difficulty in selling Ameluz® because that process involves selling both drug combined with a procedure, an area in which sales partners generally have little experience. Biofrontera Group launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016 and expects sales growth there to be limited until Biofrontera Group receives a permanent “J-code,” which the Issuer expects to receive in January 2018. Biofrontera Group’s products may never gain significant acceptance in the marketplace and, therefore, may never generate substantial revenue or profits. Biofrontera Group must establish a larger market for products and build that market through marketing campaigns to increase awareness of, and confidence by doctors in, Biofrontera Group’s products. If Biofrontera Group is unable to expand the current customer base and obtain market acceptance of its products, operations could be disrupted and business may be materially adversely affected. Even if Biofrontera Group achieves profitability, Biofrontera Group may not be able to sustain or increase profitability.

#### **3.1.3.2 Competing products and technologies based on traditional treatment methods may make Biofrontera Group’s products or potential products noncompetitive or obsolete.**

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of actinic keratosis and basal cell carcinoma. Doctors may prefer to use familiar therapies, rather than trying Biofrontera Group’s products.

Additionally, reimbursement issues affect the economic competitiveness of Biofrontera Group’s products as compared to other therapies.

Biofrontera Group’s industry is subject to rapid, unpredictable and significant technological change and intense competition. Biofrontera Group’s competitors may succeed in developing, acquiring, or licensing on an exclusive basis products that are safer, more effective or more desirable than Biofrontera Group’s. Many competitors have substantially greater financial, technical and marketing resources than Biofrontera Group. In addition, several of these companies have significantly greater

experience than Biofrontera Group in developing products, conducting preclinical and clinical testing, obtaining regulatory approvals to market products for health care, and marketing healthcare products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

Biofrontera Group cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on its business. Increased competition could result in price reductions, lower levels of government or other third party reimbursements, failure to achieve market acceptance and loss of market share. Further, Biofrontera Group cannot give any assurance that developments by competitors or future competitors will not render technologies obsolete or less advantageous.

3.1.3.3 Biofrontera Group faces significant competition from other pharmaceutical and medical device companies and operating results will suffer if Biofrontera Group fails to compete effectively. Biofrontera Group also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

The pharmaceutical and medical device industry is characterized by intense competition and rapid innovation. Competitors may be able to develop other products that are able to achieve similar or better results for the treatment of actinic keratosis. Potential competitors include mostly established pharmaceutical companies, such as Sun Pharma and Galderma. Most competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Competitors may succeed in developing, acquiring or licensing products that are more effective or less costly than Biofrontera Group's products and product candidates. In addition, Biofrontera Group's products must compete with other therapies, such as simple curettage and, particularly in the U.S., cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

3.1.3.4 If Biofrontera Group is unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell products, it may be unable to generate revenues.

In order to commercialize its products, Biofrontera Group must further build marketing, sales and distribution capabilities, in particular in the U.S. The establishment, development and training of sales force and related compliance plans to market products are expensive and time consuming and can potentially delay the commercial success of products. In the event Biofrontera Group is not successful in developing marketing and sales infrastructure, Biofrontera Group may not be able to successfully commercialize products, which would limit Biofrontera Group's ability to generate product revenues.

3.1.3.5 Biofrontera Group depends on a single unaffiliated contract manufacturer to manufacture Ameluz®. If Biofrontera Group fails to maintain the relationship with this manufacturer or if that manufacturer is unable to continue to produce Ameluz® for Biofrontera Group, Biofrontera Group's business could be materially harmed.

Biofrontera Group depends on a single unaffiliated contract manufacturer located in Switzerland to manufacture Ameluz®. If Biofrontera Group fails to maintain the relationship with this manufacturer, Biofrontera Group may be unable to obtain an alternative manufacturer of Ameluz® that could deliver the quantity of the product at the quality and cost levels that Biofrontera Group requires. Even if an acceptable alternative manufacturer could be found, Biofrontera Group would expect long delays in transitioning the manufacturing from the existing manufacturer to a new manufacturer. Problems of this kind could cause Biofrontera Group to experience order cancellations and loss of market share. The failure of the manufacturer to supply Ameluz® that satisfies quality, quantity and cost requirements in a timely manner could impair Biofrontera Group's ability to deliver Ameluz® and could increase costs, particularly if Biofrontera Group is unable to obtain Ameluz® from alternative sources on a timely basis or on commercially reasonable terms. In addition, the manufacturer is regulated by the country of Switzerland and by the FDA and must comply with applicable laws and regulations.

3.1.3.6 Biofrontera Group may fail to manufacture Ameluz® or BF-RhodoLED® or other marketed products and product candidates in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or other applicable manufacturing regulations.

The manufacture of Biofrontera Group's products requires significant expertise and capital investment. Currently, all commercial supply for Ameluz® is manufactured by a single unaffiliated

contract manufacturer. Biofrontera Group would need to spend substantial time and expense to replace that manufacturer if it failed to deliver products in the quality and quantities we demand or failed to meet any regulatory or cGMP requirements. Biofrontera Group takes precautions to help safeguarding the manufacturing facilities, including acquiring insurance, and performing on site audits. However, vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy manufacturing equipment or Biofrontera Group's inventory of raw material or finished goods, cause substantial delays in operations, result in the loss of key information, and cause Biofrontera Group to incur additional expenses. Insurance may not cover losses in any particular case. In addition, regardless of the level of insurance coverage, damage to facilities may have a material adverse effect on business, financial condition and operating results.

Biofrontera Group must comply with numerous regulations, including regulations governing cGMP enforced by the US FDA through its facilities inspection program. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. For medical device products, Biofrontera Group is required to comply with the FDA's Quality System Regulation ("*QSR*"), which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of medical device products.

Biofrontera Group's contract facilities have been inspected by the FDA for cGMP compliance. If Biofrontera Group does not successfully maintain cGMP compliance for these facilities, commercialization of products could be prohibited or significantly delayed. Even after cGMP compliance has been achieved, the FDA or similar foreign regulatory authorities at any time may implement new standards, or change their interpretation and enforcement of existing standards for manufacture, packaging, testing of or other activities. For Biofrontera Group's commercialized medical device product, the FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time.

Any failure to comply with applicable cGMP, QSR and other regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval.

3.1.3.7 If Biofrontera Group faces allegations of noncompliance with the law and encounter sanctions, its reputation, revenues and liquidity may suffer, and products could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of the law could require Biofrontera Group to expend significant time and resources in response and could generate negative publicity. Any failure to

comply with ongoing regulatory requirements may significantly and adversely affect Biofrontera Group's ability to commercialize and generate revenues.

3.1.3.8 Products may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community.

Even after obtaining regulatory approval in Europe and the US for Biofrontera Group's products or extending their indications, products may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community. Market acceptance of any products and product candidates depends on a number of factors, including:

- the clinical indications for which they are approved, including any restrictions placed upon the product in connection with its approval, such as patient registry or labeling restriction;
- the product labeling, including warnings, precautions, side effects, and contraindications that regulatory authorities approve;
- the potential and perceived advantages of products over alternative products or therapies;
- relative convenience and ease of administration;
- the effectiveness and compliance of sales and marketing efforts;
- acceptance by major operators of hospitals, physicians and patients of the product candidate as a safe and effective treatment;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of regulatory authorities;
- the timing of market introduction of Biofrontera Group's product candidates as well as competitive products;
- the perceived advantages of Biofrontera Group's products over alternative treatments;
- the cost of treatment in relation to alternative products; and
- the availability of adequate reimbursement and pricing by third party payors and government authorities, including any conditions for reimbursement required by such third party payors and government authorities.

3.1.3.9 Biofrontera Group is highly dependent on key personnel, and if Biofrontera Group is not successful in attracting and retaining highly qualified personnel, Biofrontera Group may be unable to successfully implement its business strategy.

Biofrontera Group's ability to compete in the highly competitive pharmaceutical industry depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel with specialized scientific and technical skills. Biofrontera Group is highly dependent on its management,

scientific, medical and operations personnel, including Prof. Hermann Lübbert, Ph.D., chairman of the management board and chief executive officer; Thomas Schaffer, member of the management board and chief financial officer and Christoph Dünwald, member of the management board and chief commercial officer. Biofrontera Group does not maintain “key man” insurance for any officers. The loss of the services of any executive officers or other key employees and an inability to find suitable replacements could potentially harm Biofrontera Group’s business, prospects, financial condition or results of operations.

Despite Biofrontera Group’s efforts to retain valuable employees, members of the management, scientific and development teams may terminate their employment on short notice. Although Biofrontera Group has employment agreements with key employees, these employees could leave employment at any time, with certain notice periods. Biofrontera Group does not maintain “key man” insurance policies on the lives of these individuals or the lives of any of other employees.

Many of the other biotechnology and pharmaceutical companies that Biofrontera Group competes against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than Biofrontera Group does. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what Biofrontera Group can offer.

3.1.3.10 Biofrontera Group’s employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

Biofrontera Group is exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with regulations, provide accurate information, comply with manufacturing standards, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, inability to obtain product approval and serious harm to Biofrontera Group’s reputation.



3.1.3.11 Biofrontera Group's business and operations would suffer in the event of an IT system failure.

Despite the implementation of security measures, Biofrontera Group's internal computer systems and those of current and future CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While Biofrontera Group has not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in Biofrontera Group's operations, it could result in a material disruption of development programs and business operations.

3.1.3.12 If product liability lawsuits are brought against Biofrontera Group, it may incur substantial liabilities and may be required to limit commercialization of products.

Biofrontera Group faces an inherent risk of product liability as a result of the clinical testing of products and faces an even greater risk with the commercialization of products on a larger scale. Any product liability claims may include allegations of defects in manufacturing; defects in design; a failure to warn of dangers inherent in the product, negligence, strict liability; and a breach of warranties. Medical products and medical devices may, under certain circumstances, be subject to no-fault liability. If Biofrontera Group cannot successfully defend ourselves against product liability claims, it may incur substantial liabilities or be required to limit commercialization of products and product candidates. Even a successful defense would require significant financial and management resources

3.1.3.13 Biofrontera Group's international operations may pose currency risks, which may adversely affect operating results and net income.

Biofrontera Group's operating results may be affected by volatility in currency exchange rates and Biofrontera Group's ability to effectively manage currency transaction risks. In general, Biofrontera Group conducts its business, earns revenues and incurs costs in the local currency of the countries in which it operates. In 2016, 80% of Biofrontera Group's revenue was generated and approximately 71% of Biofrontera Group's costs were incurred in euros (52% and 46%, respectively, for the six months ended June 30, 2017). Although currency exchange rate fluctuations have not had an impact on Biofrontera Group's operations to date, as Biofrontera Group executes its strategy to expand in the U.S. and internationally, exposure to currency risks will increase. Biofrontera Group does not manage its foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies, the dollar and



the euro will affect revenues, cost of goods sold, and operating margins, and could result in exchange losses in any given reporting period.

### **3.1.4 Intellectual Property (IP) Risks**

3.1.4.1 If Biofrontera Group's efforts to protect the proprietary nature of the intellectual property related to Biofrontera Group's technologies are not adequate, Biofrontera Group may not be able to compete effectively in its market.

Biofrontera Group relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to technologies and products. Any disclosure to or misappropriation by third parties of confidential proprietary information could enable competitors to quickly duplicate or surpass Biofrontera Group's technological achievements, thus eroding the competitive position in the market.

In addition, the patent applications that Biofrontera Group owns or that it may license may fail to result in issued patents in the U.S., the EU or in other countries or jurisdictions. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents and patent applications may not adequately protect intellectual property or prevent others from designing around Biofrontera Group's claims. Further, if Biofrontera Group encounters delays in clinical trials, the period of time during which Biofrontera Group could market products under patent protection would be reduced.

In addition to the protection afforded by patents, Biofrontera Group seeks to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although Biofrontera Group requires all of its employees to assign their inventions to Biofrontera Group to the extent permitted by law, and requires all employees, consultants, advisors and any third parties who have access to Biofrontera Group's proprietary know-how, information or technology to enter into confidentiality agreements, Biofrontera Group cannot be certain that trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. or the EU. As a result, Biofrontera Group may encounter problems in protecting and defending intellectual property both in the U.S., in the EU and in other countries.

3.1.4.2 Third party claims of intellectual property infringement may prevent or delay Biofrontera Group's product discovery and development efforts.

Biofrontera Group's commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Biofrontera Group's products may give rise to claims of infringement of the patent rights of others.

Third parties may assert that Biofrontera Group is employing their proprietary technology without authorization. There may be third party patents of which Biofrontera Group is currently unaware with claims to materials, formulations, devices, methods of manufacture or methods for treatment related to the use or manufacture of Biofrontera Group's products. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that Biofrontera Group's product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of Biofrontera Group's technologies infringes upon such patents.

3.1.4.3 Biofrontera Group may be involved in lawsuits to defend or enforce patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe Biofrontera Group's patents. To counter infringement or unauthorized use, Biofrontera Group may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of Biofrontera Group's patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that Biofrontera Group's patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of Biofrontera Group's patents at risk of being invalidated, held unenforceable, or interpreted narrowly. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources. In the event of a successful claim or counterclaim of infringement against Biofrontera Group, it may have to pay substantial damages or redesign the infringing products, which may be impossible or require substantial time and monetary expenditure.

3.1.4.4 Biofrontera Group may be subject to claims that employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

Biofrontera Group has received confidential and proprietary information from third parties. In addition, Biofrontera Group employs individuals who were previously employed at other biotechnology or pharmaceutical companies. Biofrontera Group may be subject to claims that Biofrontera Group or its employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or the employees' former employers. Litigation may be necessary to defend against these claims. Even if Biofrontera Group is successful in defending against these claims, litigation could result in substantial cost and be a distraction to management and employees.

3.1.4.5 Biofrontera Group's trade secrets are difficult to protect.

Confidentiality agreements with employees and others may not adequately prevent disclosure of trade secrets and other proprietary information and may not adequately protect intellectual property.

Biofrontera Group's success depends upon the skills, knowledge and experience of scientific and technical personnel, consultants and advisors as well as partners, licensors and contractors. Because Biofrontera Group operates in a highly competitive technical field of drug development, Biofrontera Group relies in part on trade secrets to protect proprietary technology and processes. However, trade secrets are difficult to protect. Biofrontera Group enters into confidentiality agreements with corporate partners, employees, consultants, sponsored researchers and other advisors. These agreements typically require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party. Biofrontera Group's agreements also provide that any inventions made based solely upon Biofrontera Group technology are Biofrontera Group's exclusive property.

These confidentiality and assignment agreements may be breached and may not effectively assign intellectual property rights. Trade secrets also could be independently discovered by competitors, in which case, Biofrontera Group would not be able to prevent use of such trade secrets by competitors. The enforcement of a claim alleging that a party illegally obtained and was using trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. In addition, courts outside the U.S. or the EU may be less willing to protect trade secrets. There exists a risk that Biofrontera Group may not be able to detect when misappropriation of Biofrontera Group trade secrets has occurred or where a third party is using trade secrets without Biofrontera Group's knowledge.

## **3.2 Risks relating to the securities**

### **3.2.1 An investment in shares always bears the risk of a total loss of the invested capital.**

Any investment in shares as corporate equity capital bears the risk that, in case of an insolvency of the target company, the shareholder loses the entirety of the capital invested in the shares; i.e. the investor may, in the case of an insolvency of the Issuer, lose the entire capital invested in the New Shares. In the case of an insolvency, the claims of debt capital creditors are settled, and claims of equity capital creditors will be paid only after a full settlement. In the case of an insolvency of the Issuer, shareholders may receive none or a minor quota of the monies invested for the acquisition of the New Shares. An investment in the Issuer should only be considered by experienced investors, who consciously accept high risks up to the total loss of their capital.

### **3.2.2 If the capital increase set out in this prospectus is not executed, buyers of subscription rights may lose the investment made into the subscription rights.**

In particular, the commercial register might refuse entering the capital increase into the commercial register due to the litigation against the appointment of supervisory board members.

The offer under the capital increase described in this prospectus is subject to the condition that the execution of the capital increase is entered into the commercial register by no later than 31 May 2018. The agreements entered by accepting the subscription offer and other subscription agreements will not be executed and become void if the capital increase is not entered into the commercial register. Holders of subscription rights who acquired subscription rights against consideration will suffer a loss in the amount of the investment made for the acquisition of the subscription rights. As set out above, a shareholder has contested the appointment of three supervisory board members. If this lawsuit is successful, the approval of the supervisory board regarding this capital increase would be invalid. While entering the capital increase into the commercial register prevents retroactive invalidity of the capital increase, there is a risk that the lower court of Cologne might refuse entering the capital increase into the commercial register, in order to avoid an irreversible situation.

### **3.2.3 An investment in the New Shares is not an appropriate investment for every investor.**

Each investor must review whether an investment in the New Shares is an appropriate investment considering their personal circumstances, since each investment in shares is linked with substantial risks, up to and including total loss of the invested capital. In particular, any investor should have the required knowledge and experience to understand chances and risks of the investment in the New Shares and make an informed decision consider the investor's personal affairs, especially considering

the economic situation of the Issuer. Furthermore, each investor should have sufficient financial reserves to compensate for the risks associated with an investment in the New Shares. Considering the situation of the Issuer, an investment in the New Shares is only appropriate for investors who consciously accept high risks up to a total loss of the invested capital.

**3.2.4 The stock price and the trade volume of the New Shares may be subject to high volatility.**

The market for shares of the Issuer, including the New Shares, is limited, so that small volume trades may substantially affect the stock price. Furthermore, there is no guarantee that a disposal of the shares is possible at any time; in the worst case, a shareholder willing to sell New Shares may not be able to find a trading purchaser, so that a disposal of New Shares is not possible at all, only partially, at certain times or with loss realization. The stock price might be developing detrimentally, independently of the business of the Issuer and Biofrontera Group, as driven by a disadvantageous environment.

**3.2.5 A large-scale disposal of shares would have detrimental effects on the stock price of the New Shares.**

Should a shareholder of the Issuer offer a large number of the Issuer's shares for sale, or should a large number of the Issuer's shareholders attempt to dispose of their shareholding simultaneously, this would cause an oversupply of the Issuer's shares on the market, which may prevent shareholders from disposing of their New Shares, and/or negatively affect the stock price of the New Shares.

**3.2.6 Shareholder with large shareholding may exercise or achieve a controlling influence on the general shareholder meeting of the Issuer.**

Several shareholders with large individual shareholding are invested in the Issuer. The free float is comparatively low. There is a risk that shareholders with large individual shareholding may execute their influence on the Issuer, which may have detrimental effects on the other shareholders.

**3.2.7 A future exercise of option rights and potential further capital rounds may cause a dilution of the investors' shareholding.**

The Issuer has a substantial amount of outstanding option rights from the option bonds issued in 2009 and 2011. If the option rights are exercised, the shareholders may face a substantial dilution of their participation in the Issuer. A dilution may also result from future capital measures, in particular considering the uncertainty regarding when the Issuer and Biofrontera Group will be in a position to finance their business from ongoing revenues.

### **3.2.8 Currency exchange risks exists for investors with foreign currencies.**

The New Shares certify a (notional) amount in Euro currency. Dividend payments will also be made in Euro. If the Euro is a foreign currency for an investor, currency risks may exist.

### **3.2.9 Short sales of shares of the Issuer may cause losses to investors.**

Should an investor enter into short sales before the New Shares are booked into the securities account, the investor as seller bears the risk not to be able to fulfill the obligations under the short sale, since the Issuer may revoke or suspend the offer until the New Shares come into existence by execution of the capital measure. If the capital measure is not executed, the seller may face substantial costs for acquiring the share necessary to fulfill the obligations under the short sale.

### **3.2.10 The New Shares may not be tradable temporarily or permanently.**

In particular, a down-listing or delisting of the New Shares might affect the liquidity and the stock market price of the New Shares.

The Issuer intends to apply for the admission of the New Shares for trading in the regulated markets of the Frankfurt Stock Exchange and the Düsseldorf Stock Exchange, in order to ensure that the New Shares would be tradable upon delivery. Should the admission be delayed or fail, the New Shares would not be able to be sold on a stock exchange. While an over-the-counter trade outside of stock exchanges may be possible, such trades generally have substantially less liquidity, so that a sale may not be possible at all, at the intended time, or only under realization of losses.

The Issuer's shares are currently traded on the regulated markets of the Frankfurt Stock Exchange and Düsseldorf Stock Exchange. Under the current German legal situation, a down listing of shares from a regulated market to an OTC market or entirely delisting shares is possible without the approval of the general shareholder meeting, and without compensation to the shareholders. In the case of a down listing or delisting, the liquidity of the New Shares would be adversely affected, prices of the New Shares would decline and sales may not be possible at all, at the intended time, or only under realization of losses.

## **4. General Information**

### **4.1 Persons responsible**

The Issuer, Biofrontera Aktiengesellschaft with its seat in Leverkusen, Hemmelrather Weg 201, 51377 Leverkusen, registered with the commercial of the local court of Cologne under register number HRB 49717, assumes responsibility for the information given in this prospectus pursuant to sec. 5 para. 4 WpPG. The Issuer hereby declares that to their knowledge, the information in this prospectus

are correct and no material facts are omitted. They further declare that, having taken all reasonable care to ensure that such is the case, the information contained in this prospectus is, to the best of the Issuer's knowledge, in accordance with the facts and contains no omission likely to affect its import.

The Issuer further declares that the information contained in this prospectus is, to their best knowledge, correct and no material facts are omitted.

## **4.2 Financial Information**

Audited historical financial information covering the latest two financial years, i.e. the fiscal years ending 31 December 2016 and 31 December 2015, have been prepared according to IFRS pursuant to Regulation (EC) No 1606/2002, and such financial statements may be obtained at the Issuer (Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen), on the Issuer's website ([www.biofrontera.com](http://www.biofrontera.com)) and the German federal gazette ([www.bundesanzeiger.de](http://www.bundesanzeiger.de)).

The Issuer has published quarterly and half-yearly financial information since the date of its last audited financial statements (for the first quarter of the fiscal year 2017 ending 31 March 2017 and the first half of the fiscal year ending 30 June 2017), which may be obtained at the Issuer (Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen), on the Issuer's website ([www.biofrontera.com](http://www.biofrontera.com)) and the German federal gazette ([www.bundesanzeiger.de](http://www.bundesanzeiger.de)). The quarterly and half-yearly information have not been audited.

## **4.3 Auditing**

### **4.3.1 Identity of auditors**

For the period covering the historical financial information (i.e. the fiscal years 2016 and 2015), Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, Johannstr. 39, 40476 Düsseldorf, Germany („*WKGT*“) was appointed as auditor of the Issuer. WKGT is a member of the German Chamber of Public Auditors (Wirtschaftsprüferkammer) in Berlin.

No auditors have resigned, been removed or not been re-appointed during the period covered by the historical financial information.

### **4.3.2 Results of auditing**

The annual reports for the fiscal years ending 31 December 2016 and 31 December 2015 included in this prospectus have been audited. No audit reports on the historical financial information has been refused by the statutory auditors, nor do they contain qualifications or disclaimers.

However, the auditors' opinion regarding the report for the fiscal year 2016 contained the following note: *“Without modifying our opinion, we would like to point out the statements made in the combined management report. As mentioned in the section "Risk, opportunity and forecast report" under*



*"Liquidity risk", during the financial year 2017 additional capital measures will be needed until the break-even is reached, for the planned investments into marketing in the USA and to meet obligations from the issued option bond. On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realized, this could constitute a threat to the company's continued existence."*

The auditors' opinion regarding the report for the fiscal year 2015 contained the following note: *"Without qualifying this opinion we refer to the explanations in the combined management report. The Management Board clarifies under section "Opportunities and risks relating to future business performance", "Liquidity risk" that further capital measures are necessary until the Break Even and admission of Ameluz in the US is reached. Because of the Management boards successful experiences with corporate capital actions, the Management board acts on the assumption that the necessary liquidity for further business development is guaranteed for the forecasting horizon and beyond. In the case and against all expectations that these valid estimations could not be realized, this could lead to a fact endangering the going concern assumption."*

No further information in this document has been audited by the auditors.

#### **4.4 Sources for information in this prospectus**

The financial information referred to in this prospectus was obtained from the audited consolidated financial reports of the Issuer, as well as from the unaudited half-year consolidated financial reports of the Issuer, and the unaudited internal controlling of the Issuer.

The following third-party information in this prospectus has been accurately reproduced and, as far as the Issuer is aware and is able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

- Technavio report on Global Non-melanoma Skin Cancer Market 2014-2018, by Infiniti Research Limited, 8 Wimpole Street, W1G 9SP London, United Kingdom (not publicly available).
- Research information from Insight Health GmbH & Co. KG, Auf der Lind 10, 65529 Waldem, Germany (not publicly available).

#### **4.5 Documentation on display**

During the period of validity of this prospectus, the following documents (or copies thereof), may be inspected at the business address of the Issuer, Hemmelrather Weg 201, 51377 Leverkusen:

- the articles of association of the Issuer;



- the audited consolidated financial statements as per 31 December 2016;
- the audited consolidated financial statements as per 31 December 2015;
- the unaudited consolidated half-year report as per 30 June 2017;
- the unaudited consolidated quarterly report as per 31 March 2017.

This prospectus will be published and may be inspected on the Issuer's website (<http://www.biofrontera.com>), under Investors / Listing/Prospectus / German Listing, or under the direct link <http://biofrontera.com/en/investors/listingprospectus.html>.

## **5. Information regarding the offer and the securities**

### **5.1 Subject of the offer**

#### ***5.1.1 Offer of New Shares***

Subject to the offer ("**Offer**") are a total of 6,000,000 no-par value ordinary shares of the Issuer which are registered in the name of the holder each representing a notional interest in the registered capital of the Issuer of EUR 1.00, for a total of EUR 6,000,000, from the capital increase resolved on 29 January 2018 by the management board, with the approval of the supervisory board dated the same day, against capital contributions in cash, with dividend rights from 1 January 2017 and ISIN DE0006046113 ("**New Shares**"). The delivery of the New Shares under the ISIN DE0006046113 requires an admission of the New Shares for trading to the regulated markets on which the existing shares are currently admitted. The Issuer will apply for an prospectus-free admission under the exemption of art. 1 paragraph 5 lit. a) of the regulation (EU) 2017/1129. The currency of the New Shares is the Euro. All New Shares except for the 89,719 excess shares are offered for subscription; shares not subscribed to will be offered for sale.

##### **5.1.1.1 Legal basis of the New Shares**

The New Shares are created under German law, from authorized capital created by resolution passed on the Issuer's general shareholder meeting of 24 May 2016, exercised by resolution by the management board on 29 January 2018 and approval by the supervisory board on the same date.

##### **5.1.1.2 Rights attached to the New Shares**

Regarding the rights attached to the New Shares, please confer the description set out under sec. 6.4.3.

#### 5.1.1.3 Certification of the New Shares

The New Shares will be represented by one or more global share certificates (the “*Global Share Certificates*”), which will be deposited with Clearstream Banking Aktiengesellschaft, with registered seat in Frankfurt / Main, Germany, and business address Mergenthalerallee 61, 65760 Eschborn, Germany (“*Clearstream Banking AG*”).

#### 5.1.1.4 Restrictions on transferability

The New Shares are freely transferable.

#### 5.1.1.5 Takeover bids on shares, exclusion of shareholders

##### *5.1.1.5.1 Statutory rules regarding takeover bids and exclusion of shareholders*

Any entity acquiring the control over a target must make a compulsory takeover offer. Control means 30 % of the voting rights of a target. In this case, the bidder must publish the fact that it has acquired control within seven calendar days. This publication replaces the publication regarding the decision to make an offer. Within four weeks after the publication, the bidder must publish an offer document. The general provisions of the German Securities Acquisition and Takeover Act (WpÜG), including the obligation to offer an adequate consideration, apply to the further procedure. In special cases, the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht, “*BaFin*”) may relieve an entity which has acquired control from the obligation to make an offer.

Under sec. 327 pp. AktG, the general shareholder meeting of a stock corporation may, at the request of a shareholder holding 95 % or more of the registered capital of the company (main shareholder), to transfer the shares of the remaining shareholders (minority shareholders) to the main shareholder in consideration of an adequate cash compensation (squeeze out). The cash consideration due to the minority shareholders is dependent on the circumstances of the company at the time of the respective resolution of the general shareholder meeting, and calculated based on the fair enterprise value of the company. The lower limit of the cash compensation is the volume-weighted stock exchange price of the company’s shares in the last three months prior to the announcement of the squeeze out.

The shareholding requirements for a squeeze out are lowered if the squeeze out takes place in connection with the merger of a subsidiary into the parent company. According to sec. 62 para. 5 of the German Transformation Act (Umwandlungsgesetz), the general shareholder meeting of a transferring stock corporation may, within three months after the signing of the merger agreement, adopt a squeeze out resolution in accordance with sec. 327a of the German Stock Corporation Act if the acquiring company is a German stock corporation, partnership limited by shares (Kommanditgesellschaft auf Aktien) or European public company (Societas Europea) that holds at

least 90% of the registered share capital. After registration of the squeeze out with the commercial register, the merger can be implemented without a further resolution by the general shareholder meeting of the subsidiary.

Furthermore, the German Securities Acquisition and Takeover Act (Wertpapiererwerbs- und Übernahmegesetz) permits the squeeze out under the law on takeovers. Under these provisions, a bidder holding at least 95% of the voting registered share capital in a target company after a public takeover offer or mandatory offer can generally file a motion with the district court of Frankfurt am Main for the transfer of the other voting shares in exchange for adequate compensation by means of a court order within three months after expiration of the acceptance period. A resolution of the company's general shareholder meeting is not necessary. The type of compensation must correspond to the consideration in the takeover offer or the mandatory offer; cash compensation must always be offered as an alternative. The consideration offered in connection with the takeover or mandatory offer is deemed to be reasonable if the bidder has acquired shares equal to at least 90% of the registered share capital affected by the offer. In addition, shareholders have a sell-out right. During squeeze-out proceedings under the law on takeovers initiated upon the motion of the bidder, the provisions on a squeeze-out under stock corporation law do not apply, and they are only applicable after a final conclusion of the squeeze-out proceedings under takeover law.

Pursuant to the provisions in sec. 319 et seq. of the German Stock Corporation Act regarding the integration (Eingliederung), the general shareholder meeting of a stock corporation can resolve upon the integration into another company if the future principal company holds at least 95% of the shares in the company to be integrated. The existing shareholders in the integrated company have a right to adequate compensation which must as a general rule be granted in the form of own shares in the principal company. The amount of the compensation must be determined using the "merger value ratio" (Verschmelzungswertrelation) between the two companies, i.e., the exchange ratio which would be considered reasonable in the event of merging the two companies.

#### *5.1.1.5.2 Takeover bids on the shares of the Issuer*

No mandatory takeover bids exist, nor are squeeze out or sell out rules as set out above currently applicable to the Issuer. No public takeover bids by third parties in respect of the Issuer's equity occurred during the last financial year and the current financial year.

## **5.2 Reasons for the Offer, use of proceeds**

Under the assumption that all New Shares are placed at the subscription price of EUR 3.50 to EUR 4.50, the issuer expects net proceeds (including financing costs of approx. up to EUR 1 million) from this offer in an amount of approximately EUR 20 million to EUR 26 million.

The proceeds will be used as follows: An amount of EUR 5 million will be used for R&D purposes, in particular to extend the indications which Ameluz® may be used for. An amount of EUR 5 million will be used to improve US marketing and sales. The remaining amount, expected to be between EUR 10 million and EUR 16 million, will be used to cover the working capital of the Issuer.

Furthermore, New Shares shall be used as an underlying for the creation of American Depositary Shares (“ADS”) in the context of a so-called sponsored Level-III-program (“US Offer”). Under the US Offer, ADSs will be offered to subscribers in the US, and a listing on the NASDAQ stock exchange will be applied for. To this end, a prospectus will be published in the US. For the avoidance of doubt, no New Shares will be publicly offered in the US; rather, the New Shares required to create the ADSs will be granted to a custodian safekeeping the shares, while the ADSs will be created and offered together with an affiliate of the custodian. The New Shares used for this purpose are intended to be admitted for trading at the Frankfurt Stock Exchange.

### **5.3 Conditions and prerequisites of the Offer**

#### **5.3.1 Conditions of the Offer**

The following is the translation of the German language offer expected to be published on 29 January 2018 in the federal gazette (Bundesanzeiger). Insofar as the timing schedule deviates from the timing schedule set out in this prospectus, such deviations will be disclosed in the offer as well as in a supplement to this prospectus.

*“Biofrontera Aktiengesellschaft*

*Leverkusen*

*ISIN: DE0006046113*

*Notification*

*Regarding a subscription offer to the subscription of up to 6,000,000 new shares of Biofrontera Aktiengesellschaft from the capital increase resolved upon on 29 January 2018 from authorized capital*

*The following subscription offer of Biofrontera Aktiengesellschaft (“Company”) is exclusively addressed to the shareholders of the Company, and, respectively, holders of subscription rights, to which the following subscription offer is communicated via Lang & Schwarz Broker GmbH, Breite Straße 34, 40213 Düsseldorf, Deutschland („Lang & Schwarz Broker GmbH“).*

*Pursuant to section 7 paragraph 3a of the articles of association, the management board is authorized to increase the registered capital of the company until 23 May 2022 with the approval of the supervisory board by up to EUR 6,000,000 by way of issuing, on one or several occasions, up to 6,000,000 no-par registered shares against contribution in cash and/or kind (“Authorized Capital”).*

*Based on said authorization, the management board of the Company has resolved on 29 January 2018 with approval of the supervisory board of the same day to increase the registered capital of the Company from currently EUR 38,416,828 by up to EUR 6,000,000 from Authorized Capital to up to EUR 44,416,828 by issuing up to 6,000,000 new no-par registered shares representing a notional amount of registered capital of EUR 1.00 each („New Shares“).*

*The execution of the capital increase has not been registered with the commercial register yet. The exact definition of the amount of the capital increase as well as the respective amendment of the articles of association will be effected after the end of the subscription period.*

*The statutory subscription right of the shareholders is granted by admitting Lang & Schwarz Broker GmbH to subscribe and take over up to 6,000,000 New Shares at an issue price of EUR 1.00 per New Share, together with the obligation to offer the New Shares to the shareholders in a quota of 13:2 against payment of a subscription price per New Share (“Subscription Price”) for subscription (“Subscription Offer”). The subscription right to 89,719 excess shares is excluded.*

*The Subscription Price will be published presumably on 9 February 2018 as an ad hoc release and on the same day in the German Federal Gazette. The Subscription Price is expected to be determined on 9 February 2018, taking into account offers received from institutional investors in a bookbuilding process. The Subscription Price will not exceed EUR 4.50 (“Maximum Subscription Price”).*

*The shareholders are requested to execute their subscription right to the New Shares, in order to avoid exclusion, within the period from 30 January 2018 to 12 February 2018 („Subscription Period“) at Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen (“Bankhaus Gebr. Martin Aktiengesellschaft“), acting as settlement agent for Lang & Schwarz Broker GmbH, during the usual business hours.*

*In order to execute their subscription rights, we request our shareholders or the holders of subscription rights, respectively, to instruct the bank managing their securities account accordingly. For 13 old shares of the Company, 2 New Shares may be subscribed to at the Subscription Price. For any fractions resulting from the subscription quota of 13:2 for the respective number of old shares held in each case, no New Shares may be subscribed to, only a subscription of 2 New Shares or a multiple thereof is possible. The amount of shares held at the end of 29 January 2018 shall be relevant for calculating the number of subscription rights allocated to each shareholder. At this time, the subscription rights (ISIN DE000A2G8YC5) are separated from the shares to the extent of the existing subscription rights and booked to the shareholders’ securities accounts by their respective banks.*

*The subscription rights are tradable, but the Company will neither organize a trade on the stock market, nor a private trade. Subscription rights not executed are forfeit and will be booked out as invalid at the end of the subscription period.*

*From 26 January 2018 on, the old shares will be traded as “ex subscription rights”.*

*Shareholders executing subscription rights shall pay the Subscription Price upon execution of the subscription right, but no later than the end of the Subscription Period on 12 February 2018. The subscription rights shall be proof that the shareholder is entitled to subscribe to New Shares.*

*The receipt of the subscription request and the Subscription Price at the agent referred to above is relevant for keeping the deadline. Shareholders / holders of subscription rights are charged the usual bank fee for the subscription.*

*The banks managing the securities accounts are requested to communicate the subscription rights collectively in one single form letter no later than and including 12 February 2018 at Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen, Telefax +49 (0)7161 969317, and to transfer the Subscription Price per New Share also no later than the end of the Subscription Period on the following account of Lang & Schwarz Broker GmbH at Bankhaus Gebr. Martin Aktiengesellschaft:*

*Bank: Bankhaus Gebr. Martin Aktiengesellschaft*

*Account no. 9673*

*IBAN: DE88 610 300 00 000 000 9673*

*BIC: MARBDE6G*

*Reference: „W/Biofrontera“*

*We ask that the banks managing the securities accounts are provided an instruction using the form provided via the banks managing the securities accounts.*

**Placement of New Shares not subscribed to under the statutory subscription right**

*As far as not all New Shares are subscribed to in the execution of the statutory subscription right, the New Shares which have not been subscribed to (including those New Shares the statutory subscription right has been excluded to avoid fractions) will be offered insofar as legally possible at the Subscription Price to third parties until 23 February 2018. Furthermore, New Shares shall be used as an underlying for the creation of American Depositary Shares in the context of a so-called sponsored Level-III-program.*

**Important notes**

**Non-execution of capital increase**

*The subscription offer is under the condition that the capital increase is registered with the commercial register by no later than 31 May 2018. Any agreements resulting by accepting the subscription offer will not be executed if the condition is not met and become void.*

**Securitization / delivery**



*The New Shares will be securitized in a global deed and deposited with Clearstream Banking AG, Frankfurt am Main. No right to individual securitization exists. Any New Shares acquired will be booked to the securities accounts of the acquirer. In case of short sales before booking the New Shares into the securities accounts, only the seller bears the risk of being unable to fulfil the obligations incurred under the short sale by timely delivering New Shares.*

#### **Stock Trade of New Shares**

*The Company intends to effect the admission of the New Shares to the regulated market until 7 March 2018.*

#### **Stabilizing measures**

*No stabilizing measure will be made.*

#### **Risks**

*Any investment in shares bears substantial risks and should only be made under careful considerations of these risks. Considering the state of the Company, the New Shares are only appropriate for investors who consciously accept high risks. A total or partial loss of funds invested by shareholders / holders of subscription rights is not impossible.*

*Potential investors are advised to read the prospectus published by the Company regarding the offer, and the current reports, both available Company's homepage (<http://www.biofrontera.com/>) before executing their subscription rights or purchasing shares.*

#### **Limits on sale**

*The publication, transfer, dissemination or reproduction of the subscription offer or the conditions of the offer in a summary or other description may be limited abroad. Excluding a notification in the federal gazette and the transfer of the subscription offer as permitted by the Company, the subscription offer may not be published, transferred, disseminated or reproduced abroad by third parties, neither directly nor indirectly, insofar as this is prohibited by applicable foreign regulations or depends on official procedures or receipt of an approval. This applies also to a summary or any other description of the conditions contained in this subscription offer. The Company does not guarantee that the publication, transfer, dissemination or reproduction of the subscription offer complies with the legal provisions applicable in each case. Accepting this offer outside Germany may be subject to limitations. Persons intending to accept the offer outside Germany are requested to research the legal restrictions applicable outside Germany.*

*The New Shares and subscription rights are not and will not be registered in accordance with the provisions of the U.S. Securities Act 1933 as amended from time to time („Securities Act“) nor with the securities authorities of the states of the USA. They may not be offered or sold in the USA nor directly nor indirectly delivered there, except based on an exemption from the requirements of the*

*Securities Act and the securities regulations of the individual US states and other applicable US regulations. In particular, this subscription offer is not a public offer nor a request for an offer to purchase the New Shares in the USA and may therefore not be disseminated there.*

*Leverkusen, February 2018*

*Biofrontera Aktiengesellschaft*

*The Management Board”*

### **5.3.2 Price**

The New Shares are first offered to the Issuer’s shareholders, by way of admitting Lang & Schwarz Broker GmbH, with seat in Düsseldorf, Breite Str. 34, 40213 Düsseldorf (also „**Lang & Schwarz Broker GmbH**“) for subscribing and taking over the 6,000,000 New Shares at a issue price of EUR 1.00 per New Share, with the obligation to offer the New Shares to the shareholders in a relation of 2 New Shares per 13 existing shares for subscription against payment of a subscription price (“**Subscription Price**”).

The Subscription Price is expected to be determined on 9 February 2018, taking into account offers received from institutional investors in a bookbuilding process. The Subscription Price will be published presumably on 9 February 2018 as an ad hoc release and on the same day in the German Federal Gazette. The Subscription Price will not exceed EUR 4.50 (“**Maximum Subscription Price**”).

Neither the Issuer nor Lang & Schwarz Broker GmbH will require a payment of fees from the subscribers or purchasers.

### **5.3.3 Subscription period and procedure**

The shareholders may execute their subscription right to the New Shares, in order to avoid exclusion, within the period from 30 January 2018 to 12 February 2018 („**Subscription Period**“) at Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen (“**Bankhaus Gebr. Martin Aktiengesellschaft**“), acting as settlement agent for Lang & Schwarz Broker GmbH, during normal business hours.

In order to execute their subscription rights, the shareholders or the holders of subscription rights, respectively, are requested to instruct the bank managing their securities account accordingly. For 13 old shares of the Issuer, 2 New Shares may be subscribed to at the Subscription Price. For any fractions resulting from the subscription quota of 13:2 for the respective number of old shares held in each case, no New Shares may be subscribed to, only a subscription of 2 New Shares or a multiple thereof is possible. The subscription right to 89,719 excess shares is excluded. The amount of shares held at the end of 29 January 2018 shall be relevant for calculating the number of subscription rights allocated to each shareholder. At this time, the subscription rights (ISIN DE000A2G8YC5) are



separated from the shares to the extent of the existing subscription rights and booked to the shareholders' securities accounts by their respective banks.

The subscription rights are tradable, but the Company will neither organize a trade on the stock market, nor a private trade. Subscription rights not executed are forfeit and will be booked out as invalid at the end of the subscription period.

From 26 January 2018 on, the old shares will be traded as "ex subscription rights".

Shareholders executing subscription rights shall pay the Subscription Price upon execution of the subscription right, but no later than the end of the Subscription Period on 12 February 2018. The subscription rights shall be proof that the shareholder is entitled to subscribe to New Shares.

The receipt of the subscription request and the Subscription Price at the agent referred to above is relevant for keeping the deadline. Shareholders / holders of subscription rights are charged the usual bank fee for the subscription.

#### **5.3.4 Placement of New Shares not subscribed to under the statutory subscription right**

As far as not all New Shares are subscribed to in the execution of the statutory subscription right, the New Shares which have not been subscribed to (including those New Shares the statutory subscription right has been excluded to avoid fractions) will be offered insofar as legally possible at the Subscription Price to third parties until 23 February 2018.

#### **5.3.5 Revocation / suspension of the Offer**

##### **5.3.5.1 Revocation / suspension by the Issuer**

The subscription offer is subject to the condition that the execution of the capital increase is entered into the commercial register no later than 31 May 2018. The subscriptions created by accepting the subscription offer and in the private placement will not become effective in case of this dissolving condition. Furthermore, the Offer may be revoked or suspended by the Issuer until the date on which the execution of the capital increase is entered into the commercial register, thereby creating the New Shares. After entering the execution of capital increase into the commercial register, the Offer cannot be revoked or suspended.

##### **5.3.5.2 Revocation by the subscriber**

A subscriber may revoke an executed subscription right until the end of the subscription period. If payments were made to Lang & Schwarz Broker GmbH before revoking the subscription declaration, these payments will be reimbursed in full. However, the depositary bank of the investor revoking a declaration might charge fees to the investor.

### **5.3.6 Minimum / maximum amount of application**

A minimum number of 2 New Shares must be subscribed to or purchased. No further minimum or maximum limits to the amounts of New Shares or aggregate amount for subscription or purchase exists.

## **5.4 Allotment, delivery, exclusion of pre-purchase rights**

### **5.4.1 Allotment**

The subscribers or purchasers will not be explicitly notified of the number of New Shares allotted to them; the notice will be limited to booking the respective number of New Shares into their securities account. No trade before allotment will be established.

In case of an oversubscription, the New Shares will be allotted in the discretion of the Issuer, pursuant to the statutory provisions, considering the general obligation to treat shareholders equally.

### **5.4.2 Tranches**

In no case will New Shares be offered at a different price to different parties.

No tranches of New Shares will be established; no preferential treatment of investors or investor groups is intended.

### **5.4.3 Delivery**

The New Shares can only be delivered after entering the capital increase into the commercial register.

The registration will probably be effected until 1 March 2018. There is no guarantee that the execution of the capital increase will be effected until this date. The New Shares will be incorporated in a global deed after the capital increase is entered into the commercial register and deposited with Clearstream Banking AG. There is no right to securitization of the New Shares. The New Shares will be booked into the securities accounts of shareholders who have executed subscription rights or acquired the New Shares during the Private Placement.

The delivery of the New Shares is expected to be effected on 12 March 2018.

### **5.4.4 Pre-purchase rights, subscription rights trade, non-executed subscription rights**

With the exception of the general subscription right of all shareholders, no pre-purchase rights regarding the New Shares exist. There will be no application to list the subscription rights for trading on an exchange; therefore, no sale or purchase of subscription rights on an exchange will be possible. While the trade of subscription rights is generally possible under German law, the Issuer will not

facilitate the sale or purchase of subscription rights. Subscription rights not executed will become void without compensation.

## **5.5 Intentions of major shareholders**

One major shareholder of the Issuer has offered the Issuer to assist in the structure of the potential NASDAQ listing, and entered into a Share Loan Service Agreement (as defined and described in 9.11). In order to recover the shares lent under the Share Loan Service Agreement, the shareholder will subscribe to the highest number of shares available under its subscription rights, which amount to approximately 1,400,000 New Shares.

Beyond this, the Issuer is not aware of the extent to which major shareholders intent to participate in the capital increase, or whether any person intends to subscribe for more than 5 % of the Offer. The members of the Issuers management board currently have no fixed decision to participate in the capital increase.

## **5.6 Time Schedule**

### **5.6.1 Provisionary time schedule**

|  |                  |
|--|------------------|
| Approval of the prospectus by BaFin  | 29 January 2018  |
| Publication of the prospectus on the Issuer's website  | 29 January 2018  |
| Publication of the subscription offer  | 29 January 2018  |
| Begin of the Subscription Period   | 30 January 2018  |
| Booking shareholders' subscription rights pursuant to the shares held as of 29 January 2018, close of business | 30 January 2018  |
| Determination of Subscription Price  | 9 February 2018  |
| End of the Subscription Period   | 12 February 2018 |
| End of the Private Placement period  | 23 February 2018 |
| Ad-hoc release of the number of New Shares subscribed  | 23 February 2018 |
| Entering of the capital increase in the commercial register  | 1 March 2018     |
| Delivery of the global certificate to Clearstream Banking AG   | 2 March 2018     |

Filing of application for admission for trading of the New Shares in the regulated markets of Frankfurt Stock Exchange and Düsseldorf Stock Exchange 27 February 2018

Resolution regarding admission for trading of the New Shares in the regulated markets of Frankfurt Stock Exchange and Düsseldorf Stock Exchange 7 March 2018

Entering of the New Shares into existing trading 12 March 2018

Delivery of New Shares 12 March 2018

### **5.6.2 Expected issue date**

The expected issue date of the New Shares, i.e. the date on which the New Shares are expected to be booked into the accounts of the subscribers, is 12 March 2018.

### **5.7 Placing and underwriting**

The Offer is coordinated by Lang & Schwarz Broker GmbH. The function of Lang & Schwarz Broker GmbH is limited to taking over New Shares pursuant to the provision of sec. 186 German Stock Corporation Code, with the obligation to offer the New Shares to the shareholders for subscription and to place them in the context of the Private Placement. The final placing agreement between the Issuer and Lang & Schwarz Broker GmbH will be entered during the subscription period. The underwriting function of Lang & Schwarz Broker GmbH will be limited to these coordination efforts; no “hard underwriting” will take place, in the meaning that Lang & Schwarz Broker GmbH will acquire New Shares for distribution on their own risk. In particular, Lang & Schwarz Broker GmbH is under no obligation to take over New Shares not subscribed to by shareholders.

The Offer is solely conducted in the interest of the Issuer. Lang & Schwarz Broker GmbH will receive a variable remuneration based on the Issue amount, but no performance-based bonus fees.

Bankhaus Gebrüder Martin Aktiengesellschaft, Kirchstr. 35, 73033 Göppingen, Germany, will function as payment agent. Clearstream Banking AG, Frankfurt, Mergenthalerallee 61, 65760 Eschborn, will function as depositary agent.

### **5.8 Designated Sponsor**

Lang & Schwarz Broker GmbH acts as designated sponsor for the Issuer. The function of the designated sponsor are set out in a designated sponsor agreement. The function of the designated sponsor is to provide trading liquidity, insofar as possible, in order to increase the trading options of

the market participants. To this end, the designated sponsor files limited sale and purchase orders for shares of the Issuer in the electronic trading system XETRA of the Frankfurt stock exchange. The designated sponsor has to consider the provisions of the stock exchange; they must keep a minimum quotation period, a minimum volume and a minimum price range. They are expected to participate in the daily auctions and in particular in case of volatility interruptions to react and provide an appropriate quotation price.

### **5.9 Admission to trading**

Shares of the same class as the New Shares are already admitted to trading in the regulated markets of Frankfurt Stock Exchange and Düsseldorf Stock Exchange.

The Issuer intends to have the New Shares admitted to the regulated market of the Frankfurt Stock Exchange and the regulated market of the Düsseldorf Stock Exchange. The Issuer will apply for an prospectus-free admission under the exemption of art. 1 paragraph 5 lit. a) of the regulation (EU) 2017/1129. The application is intended to be filed on 27 February 2018; the Issuer expects the admission of the New Shares on 7 March 2018 and an inclusion of the New Shares in the existing quotation of the Issuer's shares on 12 March 2018. An admission of the New Shares for trading to other regulated markets is not intended. An admission of the New Shares to the regulated markets referred to above is not guaranteed.

It should be noted that the Issuer intends to apply for admission of certificates representing its shares, including the New Shares, to the NASDAQ, a US stock exchange ("*US Offer*"). The certificates to be listed at the NASDAQ are so-called ADSs or ADRs, as defined and described under 9.11.3.

### **5.10 Stabilization measures**

No stabilization measures will be taken.

### **5.11 Selling Shareholders, lock-up agreements**

The New Shares will not be sold by existing shareholders; New Shares will solely be generated by the Issuer.

For the avoidance of doubt, Lang & Schwarz Broker GmbH receives a remuneration and is not acting as distributor but solely as issuing bank organizing the shareholders' indirect subscription right in the meaning of sec. 186 para. 5 of the German Stock Corporation Act (Aktiengesetz, AktG), so that Lang & Schwarz Broker GmbH should not be considered a seller of the New Shares.

Furthermore, it should be noted that, for structural reasons, a major shareholder of the Issuer will lend a certain number of shares to a financial institution, which in turn will offer certificates based on the underlying shares.

No lock-up agreements regarding the New Shares exist.

## **5.12 Net Proceeds, expenses of the Offer**

Under the assumption that all New Shares are placed at a subscription price of EUR 3.50 to EUR 4.50, the issuer expects net proceeds from this offer in an amount of approximately EUR 20 million to EUR 26 million. Total financing costs of this issue are expected to be up to approx. EUR 1 million.

## **5.13 Dilution**

### ***5.13.1 Immediate dilution resulting from the Offer***

Before the consummation of the capital increase the net carrying amount (“NAV”) of the Biofrontera Group amounted to approximately EUR 10,388.9 thousand or to approximately EUR 0.27 per share (calculated on the basis of the number of 38,416,828 issued shares of the Issuer as of the date of this prospectus). The NAV of the Biofrontera Group is calculated on the basis of the unaudited consolidated interim financial statements ended 30 June 2017 by deducting the amount of the long-term liabilities (EUR 2,654.0 thousand) and the current liabilities (EUR 6,305.0 thousand) as of 30 June 2017 from the amount of total assets as of 30 June 2017 (EUR 19,347.9 thousand).

Under the assumption that all New Shares are placed at a subscription price of EUR 4.00 (being the arithmetic mean of the range of 3.50 and 4.50), the issuer expects gross proceeds from this offer in an amount of EUR 24 million, and net proceeds of EUR 23 million.

Assuming the capital increase against cash contributions is consummated in full at a subscription price of EUR 4.00, the net proceeds amount to approximately EUR 23 million, the NAV of the Biofrontera Group as 30 June 2017 would have amounted to approximately EUR 33.388.900,00 or to approximately EUR 0.75 per share (calculated on the basis of the number of 44,416,828 issued shares of the Issuer after the consummation of the share capital increase against cash contributions).

Based on a subscription price of EUR 4.00, this would result in an increase of the NAV of Biofrontera Group as of 30 June 2017 by approximately EUR 0.48 per share to EUR 0.75 per share for existing shareholders. This would amount to an increase by approximately 178 %. There would be an immediate dilution of EUR 3.25 per share or approximately 81.25 % for the purchasers of the New Shares since the subscription price of EUR 4.00 per share would be above the calculated NAV per share of approximately EUR 0.75.

### ***5.13.2 Dilution for shareholders not participating in the Offer***

Insofar as shareholders do not exercise their subscription rights, and the New Shares from the capital increase which is described in this prospectus (6,000,000 shares) are subscribed in full, the

participation of such shareholders will be reduced by approx. 15.6 %. The dilution will be lower if not all New Shares are subscribed to.

#### **5.14 Interests of persons involved in the Offer, conflicts of interest**

Lang & Schwarz Broker GmbH will receive a variable remuneration for its services depending on the issue amount. In the opinion of the Issuer, no conflicts of interest exist due to the structure of the remuneration.

Members of the management and supervisory boards hold shares of the Issuer as well as option rights to the acquisition of shares of the Issuer. In the opinion of the Issuer, this does not constitute a conflict of interest, since the private interest of the members of the management and supervisory boards are not contrary to the company's interests.

The Issuer is not aware of any further interests, conflicts of interest or potential conflicts of interest of natural or legal persons which might be relevant for the Offer.

## **6. Information about the Issuer**

### **6.1 General information**

The legal and commercial name of the Issuer is "Biofrontera Aktiengesellschaft". The Issuer is registered with the commercial register of the local court of Cologne under register number HRB 49717. The Issuer was incorporated in August 1997, with an indefinite length of life. The seat of the Issuer is Leverkusen, Germany. It operates under German law and is incorporated in Germany. The registered office of the Issuer is Hemmelrather Weg 201, 51377 Leverkusen, Germany, with telephone number +49 214 87632 66.

### **6.2 History of the Issuer**

The Issuer was established in Lörrach as "BioFrontera Laboratories GmbH" in August 1997 with the aim of providing services to the pharmaceutical industry. In September 1997, the Issuer was relocated to Leverkusen and renamed "BioFrontera Pharmaceuticals GmbH" and commenced its current operations. On 24 August 2000 the Issuer was converted into a stock corporation (Aktiengesellschaft, AG). On 27 November 2003 the Issuer was renamed to its current name "Biofrontera Aktiengesellschaft".

On 30 October 2006 the Issuer's entire share capital was listed on the Düsseldorf stock exchange. The Shares were subsequently listed on the General Standard of the Frankfurt Stock Exchange, and in the Prime Standard segment as well as the AIM segment of the London Stock Exchange. The AIM listing

has since been cancelled. Since the initial public offering, the Issuer has carried out several capital fund raises.

Up until 2010, the Issuer predominantly focused on research activities. On 2 September 2010, the Issuer submitted a centralized European marketing authorization application for BF-200 ALA, its first self-developed drug now known as Ameluz®. In December 2011, Ameluz® was approved for the treatment of mild and moderate actinic keratosis. In November 2012, Biofrontera's BF-RhodoLED® PDT lamp received pan-European approval for use as a medical device and has since been sold in parallel with Ameluz®. Biofrontera Group has distributed Ameluz® and BF-RhodoLED® since 2012.

In addition, a range of cosmetic products were introduced; the first product in this range, Belixos®, was launched in the autumn of 2009. A hair tonic, Belixos® LIQUID, was introduced in the spring of 2014 and a Belixos® gel skin care for rosacea and acne was launched at the beginning of December 2014. Belixos® Protect was the latest addition to the Belixos® series in July 2015.

In May 2016 Ameluz® in combination with BF-RhodoLED® received approval by the FDA to be marketed in the US for lesion- as well as field-directed treatment of mild to moderate actinic keratoses.

In January 2017, Ameluz® received an extension in approval to treat basal cell carcinoma by the European Commission in the EU.

In May 2017, Biofrontera Group entered into a facility loan agreement with the European Investment Bank (EIB) under which Biofrontera Group received the right to draw down a total of EUR 20 million, of which EUR 10 million could be drawn down immediately, and EUR 10 million after achieving certain milestones.

In June 2017, Biofrontera Group filed to extend the approval of Ameluz® to daylight therapy.

### **6.3 Group structure**

The Biofrontera Group consists of the Issuer, Biofrontera Aktiengesellschaft, as the parent company, and five wholly owned subsidiaries, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH each with a statutory seat in Leverkusen, Germany, and Biofrontera Inc., with a statutory seat in Wilmington, Delaware, USA.

The subsidiaries are in each case likely to have a significant effect on the assessment of the Issuer's own assets and liabilities, financial position or profits and losses.

#### **6.3.1 Biofrontera Aktiengesellschaft**

Biofrontera Aktiengesellschaft functions as operative and financial holding company of Biofrontera Group.



### **6.3.2 Biofrontera Bioscience GmbH**

Biofrontera Bioscience GmbH is responsible for research and product development in Biofrontera Group. Furthermore, Biofrontera Bioscience GmbH holds the intellectual property rights of Biofrontera Groups products, with the exception of the product candidates BF-1 and BF-Derm1.

### **6.3.3 Biofrontera Pharma GmbH**

Biofrontera Pharma GmbH is responsible for sales and distribution in Biofrontera Group, and represents Biofrontera Group vis-à-vis dermatologists and physicians. A cooperation agreement with Biofrontera Bioscience GmbH governs the use of intellectual property rights.

### **6.3.4 Biofrontera Development GmbH**

Biofrontera Development GmbH holds since late 2012 the rights to the product candidate BF-Derm1. The intention of outsourcing the product candidate was to facilitate and external financing or to monetize the rights to the product candidate by disposing of the company or shares of the company.

### **6.3.5 Biofrontera Neuroscience GmbH**

Biofrontera Neuroscience GmbH holds since late 2012 the rights to the product candidate BF-1. The intention of outsourcing the product candidate was to facilitate and external financing or to monetize the rights to the product candidate by disposing of the company or shares of the company.

### **6.3.6 Biofrontera Inc.**

Biofrontera Inc. with its registered seat in Wilmington, Delaware, USA, was incorporated in 2015 with the goal of managing the US operations of Biofrontera.

## **6.4 Articles of association**

### **6.4.1 Objectives and purpose of the Issuer**

Pursuant to § 3 of its articles of association, the objectives and purpose of the Issuer are the research, development and distribution of pharmaceuticals, as well as acting as a holding entity, i.e. the acquisition and administration of companies or participations in companies. The Issuer may undertake all actions which have the purpose of serving the purpose of the Issuer, whether directly or indirectly.

## **6.4.2 Provisions relating to management and supervisory bodies**

### **6.4.2.1 Management board**

The management board consists of one or more members. The supervisory board appoints management board members and determines their number. The term of office can be up to five years. Members of the management board can be removed by the supervisory board for cause. It may appoint a chairman of the management board and a deputy chairman of the management board. If the management board consists of one member, he or she represents the Issuer alone. If the management board consists of several members, one member of the management board may legally represent the issuer, if the supervisory board grants the authority to solely represent the Issuer to such member of the management board. Save for this case, the Issuer may be represented by two members of the management board acting together or by one member of the management board together with an authorised officer (Prokurist).

The supervisory board enacts the rules of procedure for the management board, including certain transactions of the Issuer which cannot be executed without the approval of the supervisory board. The remuneration of the members of the management board must be appropriate in light of their duties.

### **6.4.2.2 Supervisory board**

The supervisory board generally consists of six members; at the moment, only five members are appointed though. Supervisory board members are elected for a term ending with the adjournment of the fourth annual general shareholder meeting following the beginning of their term of office, provided that no shorter term of office is determined upon such election. The financial year in which the term of office begins is not counted. Re-election is permitted. Successors elected in place of members who retire or leave prior to the expiration of the term are elected for the remainder of the term of office of the retired member. When a supervisory board member is elected, a substitute member may simultaneously be appointed. This person then becomes a supervisory board member if the elected member resigns before the expiry of the term of office without a successor having been appointed.

The office of a substitute member of the supervisory board expires as soon as a successor to the supervisory board member who has stepped down is appointed, which must occur not later than the expiry of the term of office of the former supervisory board member.

The supervisory board members may resign by providing written notification to the chairman of the supervisory board or the management board with one month's notice. The option to resign from office with immediate effect if there is good cause to do so remains unaffected. A supervisory board member elected by shareholders may be dismissed by a resolution of a shareholders' meeting. However, due to a clerical error, the Issuer's articles contain two conflicting provisions regarding the majority requirements for the removal. While originally, § 13 provided for a three quarter majority, in a later

revision, § 22(2) was introduced to provide for a simple majority. However, the original provision was erroneously not deleted.

The supervisory board elects a chairman and a deputy chairman from among its members by simple majority. In the event of a tied vote, the decision is made by drawing lots. If the chairman or his/her deputy withdraws before the expiration of the term of office, the supervisory board elects a successor at its next meeting to replace the withdrawing member. The supervisory board holds two meetings per half calendar year. It holds additional meetings if required by law or if deemed appropriate for business reasons.

The chairman, or in his absence the deputy chairman, convenes supervisory board meetings in writing with a notice period of 14 days. In urgent cases, the invitation period may be appropriately shortened and convened orally or by telephone. The items on the agenda must be issued when convening the meeting. The supervisory board constitutes a quorum when three members participate in the voting in person or by written voting instructions. A member who abstains from the vote is also deemed to be participating in the resolution vote. Absent supervisory board members may therefore participate in the casting of votes by providing other supervisory board members with written voting instructions. Supervisory board resolutions require a majority of votes cast, unless otherwise provided by law. In the event of a supervisory board vote being tied, should a new vote on the same subject of the resolution also result in a tie, the chairman of the supervisory board shall have a casting vote (two votes in total). Supervisory board resolutions are generally passed by personally attended meetings. They may also be passed without convening a meeting, and the vote may also occur verbally, in writing, by telephone, by facsimile, electronically or by video conference, if the chairman so directs and if no more than three members of the supervisory board raise any immediate objections to this procedure.

The supervisory board must keep minutes concerning resolutions, which have to be signed by the chairman of the supervisory board. The minutes of the meeting must be forwarded to all supervisory board members without delay.

The supervisory board is authorised to decide on amendments to the articles that do not change their material content, but only affect their wording.

Each supervisory board member receives reimbursement for expenses and a fixed annual remuneration of EUR 15,000. If Biofrontera Group's income per share increases in the financial year for which the fixed remuneration is paid (remuneration year), and in the financial year preceding the remuneration year compared to the previous year by 25 % or more, respectively, each supervisory board member will receive a performance-based annual salary for the remuneration year (performance-based remuneration).

If Biofrontera Group's income per share increases by 50 % or more, the performance-based annual remuneration will amount to EUR 20,000. The chairman of the supervisory board receives twice, and his/her deputy one-and-a-half times, the corresponding remuneration. The Issuer reimburses supervisory board members for expenses incurred in the performance of their duties including any sales tax (value added tax) payable on their remuneration and on reimbursement of their expenses.

### **6.4.3 Rights attaching to shares**

#### **6.4.3.1 Voting rights**

Each share carries one vote. Resolutions are adopted by a simple majority of the votes cast unless a larger majority or other requirements are determined by law or the articles. A majority of 75 % of the capital represented in a general shareholder meeting is required in order to pass the resolutions concerning the following:

- capital decreases;
- creation of authorised or conditional capital;
- exclusion of subscription rights;
- de-mergers and spin-offs;
- transfer of the entire assets of the Issuer;
- conclusions, amendments and terminations of management agreements (e.g. agreements regarding control and transfer of profits and losses);
- change of the legal form of the Issuer; and
- dissolution of the Issuer.

The right to vote may be exercised by proxy. Exercising the right to vote by proxy requires the issuing of a power of attorney. The power of attorney may be granted in writing or by facsimile. The articles do not restrict any other forms regulated by law for the granting of a proxy, its revocation and proof of authorization to the Issuer.

#### **6.4.3.2 Dividend rights, profit entitlements and liquidation proceeds**

The dividend available for distribution in any financial year is approved at the Issuer's general shareholder meeting. The dividend rights attached to the New Shares begin on 1 January 2017. The amount attributable to each share is based on the division of the total amount approved for distribution at the Issuer's annual general shareholder meeting by the number of dividend-bearing shares at the time the dividend is approved. No special procedure exists for non-domestic shareholders to claim their dividends. Any claim to the payment of a dividend lapses three years after the year in which the relevant dividend is approved. Should a claim arising from payment of dividends lapse, the Issuer is entitled but not obliged to pay out the dividends to the shareholder whose claim has lapsed.

The Issuer may, except in the case of insolvency, be dissolved by a resolution of shareholders, which to be passed requires a majority of the votes cast and in addition a majority of at least three-quarters of the share capital represented. In this case, the remaining assets after the fulfillment of the Issuer's liability obligations would be distributed, according to the provisions of the German Stock Corporation Act, among the shareholders in proportion to their stake in the share capital, i.e. according to the number of shares held. Preference shares for the Issuer do not exist. If a surplus exists after any insolvency proceedings are completed, the surplus is distributed amongst the persons who could claim such surplus if the Issuer was subject to an orderly winding-up, i.e. the former shareholders of the Issuer.

#### 6.4.3.3 Change of the rights attached to the shares

The articles do not provide for special rules governing changing the rights attaching to shares. Therefore, the general rules set out in statutory law apply. Accordingly, the rights attaching to shares set out in the articles may be changed with a simple majority of votes and capital represented, with the exception of the decisions requiring a majority of 75 % of the capital represented as set out above. Furthermore, if rights are only held by specific classes of share, the shareholders of such class have to take a separate decision. Individual rights attaching to shares can only be removed with the consent of each respective shareholder.

#### 6.4.4 General shareholder meetings

The annual general shareholder meeting must be held within the first eight months after the end of the Issuer's financial year at its headquarters, in a German city with at least 100,000 inhabitants or at a German stock exchange.

The management board convenes the annual general shareholder meeting. The supervisory board may also do so in cases prescribed by law. The annual general shareholder meeting must be convened on no less than 30 days' notice prior to the final date for shareholder registration of attendance at the meeting.

Attendance at the annual general shareholder meeting and the exercising of voting rights is restricted to shareholders who, on the day of an annual general shareholder meeting, are entered in the Issuer's share register and who have registered to attend in text form no later than the seventh day prior to the meeting. The following persons may participate in the general shareholder meeting instead of the shareholders:

- statutory representatives of shareholders (e.g. a company's directors, parents of a minor);
- persons authorized by a shareholder to exercise the rights from shares owned by such shareholder in the shareholder's name;

- if one shareholder authorized several persons, the company may exclude supernumerary representatives;
- a representative whom shareholders can authorize to vote may also be provided by the company;
- persons authorized by a shareholder to exercise the rights from shares owned by such shareholder in their own name (Legitimationsaktionär).

Shareholders may only exercise their rights from the shares, including voting rights, by electronic communication if the company's articles explicitly provide for or authorize the management board to allow such electronic communication. The Company's articles of association do not provide for electronic communication.

#### **6.4.5 Prevention of changes of control**

No specific provisions to delay, defer or prevent a change in control of the Issuer exist.

#### **6.4.6 Changes in capital**

The Issuer's registered share capital may be increased by a resolution of shareholders, which to be passed requires a simple majority of votes.

In addition, shareholders can create authorised capital (meaning, shares available for issue). Creating authorised capital requires a decision of a majority of three quarters of the share capital represented at the time of the resolution. Thereafter, the management board is authorised to issue those authorised shares at a certain price within a period of not more than five years. The nominal value may not exceed half of the share capital available at the time of the resolution.

Furthermore, shareholders may create conditional capital for the purpose of; (i) granting conversion or subscription rights to holders of convertible bonds; (ii) preparing for the merger of several companies; (iii) granting subscription rights to employees and members of the Issuer's management or an affiliated company by way of an authorization resolution, where a decision by a majority of at least three quarters of the represented share capital is required.

The nominal value of the conditional capital for the purpose of issuing shares to managers and employees may not exceed 10 % of the share capital available at the time of the resolution.

#### **6.4.7 Disclosure of shareholding**

The Issuer's articles of association do not provide for rules regarding the disclosure of shareholding. However, the Issuer is subject to the mandatory provisions and notification requirements of the German Securities Trading Act (Wertpapierhandelsgesetz, WpHG).

The Securities Trading Act states that any person who reaches, exceeds or falls below 3%, 5%, 10%, 15%, 20%, 25%, 30%, 50% or 75% of the voting rights of an issuer, for which the Federal Republic of Germany is the country of origin and whose shares are admitted to trading on an organized market, either through acquisition, sale or by any other means, must immediately, in any event within four days of trading, inform both the respective issuer and BaFin on reaching, exceeding or falling below the thresholds referenced and of the resultant percentage of their voting rights stating their address and the relevant date the threshold was reached, exceeded, or otherwise in writing or by facsimile in German or English. Upon receipt of a notification of voting rights, the Issuer must immediately, at the latest within three trading days following receipt of the notification, publicly disclose this and transfer this information to the commercial register following the disclosure. Exceptions from the obligation to report/register exist for (i) trading activities of securities trading companies up to 5% of the voting shares, (ii) shares that are held solely for the purpose of settling and clearing or for safekeeping for a short period, and (iii) the purchase and sale as part of so called market making. Investors who reach or exceed a threshold of 10% or higher have to disclose their future intentions with the Issuer and their sources of funds for the relevant acquisitions of shares. In addition members of the management bodies (and related parties) must disclose all dealings in shares for related financial products to the Issuer and BaFin within five business days of the relevant 'deal'.

## **6.5 Corporate Governance**

Pursuant to sec. 161 German Stock Corporation Act (AktG), the management board and the supervisory board of the Issuer are obligated to declare each year that the recommendations of the Government Commission on the German Corporate Governance Code, published by the Federal Ministry of Justice in the official section of the electronic Federal Gazette, have been or are being complied with, or which recommendations were not and are not being adhered to and why this is the case.

As of the date of this prospectus, the Issuer complies with the recommendations of the German Corporate Governance Code in the version of 17 February 2017, with the following exceptions, and for the reasons set out below in each case:

### **6.5.1 *Deductibles in respect of the D&O insurance (figure 3.8 para. 3)***

There is a D&O insurance policy for the company that provides no deductible for supervisory board members. In the company's view, such a deductible is not needed in order to ensure the motivation and sense of responsibility of the supervisory board members. A deductible would, however, probably undermine the company's aspirations to attract eminent persons from Germany and abroad to serve on its supervisory board. The supervisory board has therefore been expressly exempted from the new

provisions regarding the deductible in the German Act regarding the Appropriateness of Management Board Remuneration (VorstAG) (§ 116 AktG).

#### **6.5.2 General limit of supervisory board membership term to be determined**

In the context of its diversity targets, the supervisory board shall determine a general limit for the membership term of the supervisory board. The determination of a general limit for the membership term does from today's perspective of the Issuer not seem appropriate. A period which determines a general limit for the term of office, cannot be determined in an abstract way in the opinion of the supervisory board. Instead, it will be considered in each case if the elapsed term of the supervisory board membership could preclude an orderly and independent rendering of services as supervisory board member.

#### **6.5.3 Structure of remuneration for the Supervisory Board (figure 5.4.6)**

The Issuer does not take membership in committees into consideration when remunerating the supervisory board members. Given the close coordination in the supervisory board which can have six members at most, a differentiation of the supervisory board remuneration according to committee membership is not presently required, especially as the members generally have around the same workloads resulting from membership of the various committees.

#### **6.5.4 Reporting (figure 7.1.2)**

Financial reports, half-yearly reports and interim reports are published within the statutory periods.

### **6.6 Administrative, Management, and supervisory bodies and senior management**

#### **6.6.1 Members of the management board**

The management board of the Issuer is currently comprised of Prof. Hermann Lübbert, Ph.D., as CEO, Thomas Schaffer, CFO, and Christoph Dünwald, CCO. The business address of the members of the management board is Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen, Germany.

**Prof. Hermann Lübbert, Ph.D.**, is chairman of the management board of the Issuer and a managing director of all German subsidiaries of the Issuer, as well as a member of the board of directors of Biofrontera Inc. He studied biology in his home town of Cologne and received his doctorate there in 1984. Following eight years in academic research at the University of Cologne and the California Institute of Technology, he gained experience in managing a global research organization during ten years at Sandoz and Novartis Pharma AG. Prof. Lübbert founded the Issuer in 1997 and has been managing the Issuer ever since. He qualified as a university lecturer at the Swiss Federal Institute of



Technology (ETH), Zurich, and in addition to his position in the Issuer and its subsidiaries, holds a professorship for animal physiology at the Ruhr-University Bochum.

**Thomas Schaffer** is a member of the management board of the issuer and a managing director of all German subsidiaries of the Issuer. He began his professional career with various positions in the finance and controlling division at Siemens Semiconductor. He held the position of vice president and CFO in the Security & Chipcard IC division of Siemens and the subsequently formed Infineon Technologies AG. Following this, he spent four years as managing director and CFO of Infineon Ventures GmbH and continued his career as vice president and CFO of the Specialty DRAM Division of Qimonda AG, where he also took over management of Qimonda Solar GmbH, Dresden. With positions as CFO at Heptagon Oy, Finland/Switzerland, and Ubidyne Inc., Delaware, USA, he expanded his extensive international experience. Since June 2013, Mr. Schaffer has held the position of CFO of the Issuer and is a managing director of all German subsidiaries of the Issuer.

**Christoph Dünwald** is a member of the management board of the Issuer. He brings 24 years of comprehensive sales and marketing expertise in the healthcare sector which he gained working for pharmaceutical businesses in Europe, Asia Pacific and the US. He began his professional career at Bayer, where he worked for 15 years in positions of increasing responsibility in marketing in both Spain and the US, as well as in strategic management positions in Germany and Asia Pacific. He then oversaw Bayer's Healthcare Diagnostics Division in Belgium and Luxembourg as a general manager. Following two years as international sales and marketing director for Corporacion Dermoestetica in Spain and the UK, he moved on to the US pharmaceutical company Allergan. At Allergan he initially worked as senior commercial director in London until he was assigned the responsibility for Allergan's medical division in Spain and Portugal.

#### **6.6.2 Members of the supervisory Board**

The Issuer's supervisory board is currently composed of five members. The business address of the members of the management board is Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen, Germany.

**Ulrich Granzer, Ph.D.** (chairman of the supervisory board): Dr. Granzer is managing director of Granzer Regulatory Consulting & Services and was formerly director of regulatory affairs at GlaxoSmithKline plc., BASF Pharma AG and Bayer AG. Dr. Granzer is a pharmacist and has been a member of the supervisory board of the Issuer since 2003.

**Jürgen Baumann** (deputy chairman of the supervisory board): As an economics graduate, Mr. Baumann was formerly a member of the management board of Schwarz Pharma AG responsible for European operations with eight national subsidiaries and four production sites. Mr. Baumann has been a member of the supervisory board of Biofrontera since 2007. Up until October 2012, Mr. Jürgen Baumann was a member of the Supervisory Board of Riemser AG, Greifswald.

**John Borer III, J.D.**, is the senior managing director and head of investment banking at the Benchmark Company, LLC. He was formerly the CEO and head of investment banking at Rodman & Renshaw, and has held senior positions at Pacific Business Credit and Barclays American Business Credit. He holds a Doctor of Law degree (J.D.) from Loyola Law School in Los Angeles.

**Hansjörg Plaggemars** is a member of the management board of Deutsche Balaton AG. He was formerly the managing director and CFO at CoCreate Software GmbH, KAMPA AG, Unister Holdings and Müller Holdings. Hansjörg Plaggemars is also a board member of Bolanta AG, Carus AG, Eurohaus Frankfurt AG, and Fidelitas Deutsche Industrie Holding AG, among others. He holds a degree in Business Administration from the University of Bamberg.

**Kevin Weber** is the CEO of Paraffin International Inc. He has extensive experience in marketing and global operations and strategy, and has held senior roles at Depomed, Hyperion Therapeutics, and Medicis Pharmaceuticals. Kevin Weber is also a board member of the American Academy of Pain Management Foundation and the American Chronic Pain Association. He holds a B.A. in Management and Marketing from Western Michigan University.

Until 31 October 2017, Mr. Mark Reeth was member of the supervisory board. Mr. Mark Reeth has resigned effective 31 October 2017. **Mark Reeth, J.D.**, is an independent consultant specializing in trends in the pharmaceutical industry. He has more than 25 years of experience in a variety of senior management, legal and compliance positions with US based healthcare companies ranging from HMOs, pharmaceutical and medical device companies, such as NYLCare, Merck-Medco Managed Care, Bracco Diagnostics, Medicis Pharmaceuticals and Salix Pharmaceuticals. He holds a Doctor of Law degree (J.D.) and Master of Economics from Duke University.

### **6.6.3 Board Practices**

#### **6.6.3.1 Expiration of appointments**

The appointments and service agreements, respectively, with the members of the management board and supervisory board expire as follows:

- The appointment and service agreement with the CEO Prof Hermann Lübbert will expire on 31 October 2020.
- The appointment and service agreement with the CFO Thomas Schaffer will expire on 30 November 2020.
- The appointment and service agreement with CCO Christoph Dünwald began on 16 November 2015 and will expire on 15 November 2017.

- The appointment of the members of the supervisory board will expire with the end of the general shareholder meeting resolving on the discharge of the members of the supervisory board for the fiscal year 2020.

#### 6.6.3.2 Committees

The Issuer has several committees in place. These committees are sub-groups of the supervisory board.

##### 6.6.3.2.1 *Audit Committee*

The audit committee focuses in particular on issues relating to accounting and risk management, the auditor's mandatory independence and the issuing of the audit mandate to the auditor, as well as the overseeing of the audit of the company's annual financial statement. In companies as defined in sec. 264d of the German Commercial Code (Handelsgesetzbuch, HGB), which includes the Issuer, the supervisory board's nomination for the election of the auditor must be based on the audit committee's recommendation. Furthermore, pursuant to sec. 100 of the German Stock Corporation Code, in companies as defined in sec. 264d of the German Commercial Code, at least one member of the supervisory board must have expertise in the fields of accounting or auditing and be a member of the audit committee. The audit committee comprises the following individuals: Jürgen Baumann, John Borer and Hansjörg Plaggemars. Mr. Plaggemars is the current chairperson and the financial expert in the meaning of sec. 100 of the German Stock Corporation Code.

##### 6.6.3.2.2 *Remuneration Committee*

The Issuer currently has no remuneration committee in place. Unlike in the past, the plenum of the supervisory board is now assigned responsibility for remuneration decisions, as a result of changes in the German Act regarding the Appropriateness of Management Board Remuneration (VorstAG). Certain preparatory work for decisions regarding remuneration is allocated to the personnel committee.

##### 6.6.3.2.3 *Personnel Committee*

The personnel committee prepares decisions for the supervisory board regarding the appointment and dismissal of management board members. The personnel committee comprises the following individuals: Jürgen Baumann, John Borer, Ulrich Granzer. Mr Baumann is the current chairperson.

##### 6.6.3.2.4 *Research & Development and Market Access Committee*

The research & development and market access committee deals with key issues related to product development and commercialization. After discussions within the research and development and

market access committee, it makes appropriate recommendations to the management board and the supervisory board. The research & development and market access committee comprises the following individuals: Ulrich Granzer and Kevin Weber. Mr. Granzer is the current chairperson.

#### *6.6.3.2.5 Nomination Committee*

In addition to the chairperson, the nomination committee includes two further supervisory board members, who are elected to the committee. The nomination committee currently comprises: Ulrich Granzer (Chairperson) and Hansjoerg Plaggemars.

The nomination committee proposes suitable candidates for the future staffing of the supervisory board for its nominations at the annual general shareholder meeting. In so doing, the nomination committee considers the balance and variation of knowledge, skills and experience of all the supervisory board members, and creates candidate profiles. In addition, the nomination committee makes recommendations to or informs the supervisory board of results from regular evaluations of the knowledge, skills and experience of individual board members and the supervisory board in its entirety. In the course of performing its duties, the nomination committee can draw on company resources deemed appropriate and also on external consultants within the necessary framework.

#### **6.6.4 Disclosures**

No family relationships exist between any of those persons referred to under 6.6.1 and 6.6.2 above.

No member of the management board or the supervisory board was convicted in relation to fraudulent offences in the previous five years.

No member of the management board or of the supervisory board were associated with bankruptcies, receiverships or liquidations when acting as member of the management board, the supervisory board, or as senior manager in the last five years.

No official public incrimination and/or sanctions were made against members of the management board or members of the supervisory board by statutory or regulatory authorities (including designated professional bodies); no member of the management board or of the supervisory board has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer.

A potential conflict of interest exists between the duties of the supervisory board member Mr. Plaggemars vis-à-vis the Issuer on one hand, and vis-à-vis his duties as member of the management board of Deutsche Balaton AG on the other hand, since the interests of Deutsche Balaton AG as major shareholder may not coincide with the interests of the Issuer. Regarding the members of the management board and the supervisory board, no further conflict or potential conflict between their duties to the Issuer and their private interests and other duties exist.

No agreements are entered into with members of the management or supervisory board that provide for benefits upon termination of employment.

### 6.6.5 Remuneration

#### 6.6.5.1 Management Board

The total remuneration paid to members of the management board in the 2016 financial year, and the total accumulated stock options issued to the management board, were as follows on 31 December 2016:

|                              |   |   |
|------------------------------|---|---|
| Professor<br>Hermann Lübbert | Non-<br>performance<br>based salary<br>component:<br>Performance<br>based salary<br>component:<br>Stock options | EUR 363,000<br><br>EUR 72,000<br><br>231,850 (fair value when granted: EUR 366,435.50), of<br>which granted in 2016: 80,000 |
| Thomas Schaffer              | Non-<br>performance<br>based salary<br>component:<br>Performance<br>based salary<br>component:<br>Stock options | EUR 213,000<br><br>EUR 63,000<br><br>85,000 (fair value when granted: EUR 157,150), of which<br>granted in 2016: 50,000     |
| Christoph<br>Dünwald         | Non-<br>performance<br>based salary<br>component:<br>Performance<br>based salary<br>component:<br>Stock options | EUR 236,000<br><br>EUR 6,000<br><br>50,000 (fair value when granted: EUR 124,500), of which<br>granted in 2016: 50,000      |

Company cars are also available to the directors for business and private use.

The existing employment contracts stipulate that - depending on the achievement of targets to be mutually agreed - an annual bonus is payable. In the event of targets being exceeded, the maximum amount of the annual bonus payable is capped. In the event of up to 70% of the agreed target value being reached, the bonus payments are reduced linearly. If less than 70% of the target value is reached, no bonus is payable. The calculation factors are set at the end of each financial year for the following financial year in a mutually agreed target agreement.

Severance pay in the case of premature termination of management board duties without good reason is capped at twice the specified annual salary, and amounts to no more than the total remuneration due to the exiting member of the board for the remaining period of his or her contract (severance cap).

In order to further increase the long-term incentive effect of variable remuneration, and thus to gear it even more effectively to sustainable business development, the management board members have pledged to match the stock options granted as part of the 2010 stock option plan by holding ordinary shares of the Issuer as private investors, thereby undertaking a personal commitment for a period of three years, starting one month after the date of issue of the options (restricted shares). Different levels of commitment are specified for the different management board members. If such restricted ordinary shares are sold prematurely, which is an occurrence which is to be reported to the chairperson of the supervisory board without delay, the Issuer can request a free-of-charge return transfer of an equivalent number of stock options within a month of receiving such notification, with the most recently granted options being those that must be returned first (last in, first out). A return transfer will not be required if the management board member can demonstrate that the sale of the restricted shares was necessary in order to meet urgent financial obligations. In 2010, the CEO was granted 35,000 options, and the other board member was granted 20,000 options. In 2011, the CEO was granted 30,000 options, and the other board member was granted 20,000 options on this basis. In 2012, a further 40,000 options were granted to the CEO, and an additional 25,000 options were granted to the other board member. In the 2013 financial year, the CEO was granted 30,000 options, and the other board member was granted 15,000 options. In the 2014 financial year, a further 16,850 options were granted to the CEO, and an additional 20,000 options were granted to the other board member. No further options were granted to the management board members in 2015. In the 2016 financial year, 80,000 options were granted to the CEO, and an additional 20,000 options were granted to the other board member, 50,000 options were granted to the CFO and 50,000 options were granted to the CCO.

#### 6.6.5.2 Supervisory board

Each member of the Supervisory Board receives a fixed annual fee of EUR 15,000. If the consolidated result per share in the financial year for which the fixed fee is paid (salary year), and in the salary year of the previous financial year, improves by 25% or more compared with each respective previous financial year, each member of the Supervisory Board will be awarded an annual performance-related fee of EUR 10,000 over and above the fixed fee component for the salary year (performance-related pay). If the consolidated result per share improves by 50% or more, the performance-related pay will increase to EUR 20,000. The basis for calculating whether or not the required improvement is achieved in the relevant successive financial years (period under consideration) is the consolidated result per share in the financial year 2006 and in subsequent years; for example, if the required improvement in terms of consolidated result per share is achieved in 2007 compared with 2006, and

subsequently in 2008 compared with 2007, the performance-related pay for the financial year 2008 will have been earned. This bonus has not been earned yet.

The chairperson receives twice, and his/her deputy receives one-and-a-half times of the fee.

The Issuer can take out an indemnity insurance policy, to the benefit of the members of the supervisory board, which covers statutory liability arising from the activities of the supervisory board.

The Issuer does not pay fees for attendance at supervisory board meetings.

The members of the supervisory board will be entitled to reimbursement of their reasonable, documented expenses (including, but not limited to, travel, board and lodging and telecommunication expenses).

Insofar as supervisory board members receive remuneration for services rendered beyond their function as a supervisory board member, these remunerations are not considered fees, since they do not cover the activities as supervisory board member.

#### **6.6.6 Shareholding of Board members**

##### **6.6.6.1 Supervisory Board**

The following table provides information with respect to ownership of the Issuer's ordinary bearer shares, options and convertible bonds for each member of the Supervisory Board as of the date of this prospectus:

| Name                | Shares        | % of total Shares | Exercise Price | Expiration Date | Option rights |
|---------------------|---------------|-------------------|----------------|-----------------|---------------|
| Jürgen Baumann      | 30,000        | 0.10 %            |                |                 |               |
| <b><u>Total</u></b> | <b>30,000</b> | <b>0.10 %</b>     |                |                 |               |

Other members of the supervisory board do not hold shares or options of the Issuer.

##### **6.6.6.2 Management Board**

The following table provides information with respect to ownership of ordinary bearer shares and options for each member of the Management Board as of the date of this prospectus:

| Name                         | Shares  | % of total Shares | Option rights  | Exercise Price | Expiration Date |
|------------------------------|---------|-------------------|----------------|----------------|-----------------|
| Prof. Hermann Lübbert, Ph.D. | 720,512 | 2.37 %            |                |                |                 |
|                              |         |                   | 35,000 options | 1.91           | 11/23/2016      |
|                              |         |                   | 30,000 options | 2.48           | 10/06/2017      |
|                              |         |                   | 40,000 options | 3.30           | 03/30/2018      |
|                              |         |                   | 30,000 options | 3.373          | 09/01/2019      |



|                   |         |        |                 |       |            |
|-------------------|---------|--------|-----------------|-------|------------|
|                   |         |        | 16,850 options  | 3.43  | 04/01/2020 |
|                   |         |        | 80,000 options  | 2.49  | 04/17/2023 |
| Thomas Schaffer   | 30,570  | 0.10 % |                 |       |            |
|                   |         |        | 15,000 options  | 3.373 | 09/01/2019 |
|                   |         |        | 20,000 options  | 3.43  | 04/01/2020 |
|                   |         |        | 50,000 options  | 2.49  | 04/17/2013 |
| Christoph Dünwald | 71,000  | 0.23%  |                 |       |            |
|                   |         |        | 50,000 options  | 2.49  | 04/17/2023 |
| <b>Total</b>      | 822,082 | 2.71 % | 366,850 options |       |            |

As of 30 June 2017, the members of the Management Board held an aggregate of 822,082 shares of Biofrontera Aktiengesellschaft, while the members of the Supervisory Board held an aggregate of 30,000 shares. The aggregate amount of shares owned by current Management Board and Supervisory Board members amounts to approximately 2.8 % of the Issuer's outstanding share capital.

#### **6.6.7 Employee stock option programme 2010**

At the annual general shareholder meeting on 2 July 2010, the Issuer had resolved on a stock option program. Based on this authorization, share options could be granted until 1 July 2015. The program had a total nominal value of EUR 839,500 and a term of six years from the issue date, i.e. until 24 November 2016. At the time of the prospectus, no further options can be issued or exercised under the program.

#### **6.6.8 Employee stock option programme 2015**

The general meeting of the Issuer of 28 August 2015 has authorized the management board, with the approval of the supervisory board, to implement a further stock option program ("**Stock Option Program 2015**"), and has dedicated a conditional capital in a nominal amount of EUR 1,814,984 to create option rights. Based on this authorization, share options could be granted until 27 August 2020. In accordance with this, the management board, or the supervisory board if the beneficiaries are management board members, are entitled to issue up to 1.814.984 share options, the exercising of which is linked to specific targets.

The program has a total nominal value of EUR 1.814.984 and a term of six years from the issue date, i.e. until 7 April 2022. To this end, conditional capital of EUR 1.814.984 was enacted as a result of the issuing of up to 1.814.984 registered shares without par value (no-par value shares) and with a stake in the share capital of EUR 1.00 per share pursuant to sec. 192(1)(3) German Stock Corporation Act. The conditional capital was registered on 18 September 2015 in the commercial register. Eligibility for the Stock Option Program 2015 may be granted to members of the management board and employees of the Issuer as well as to members of management bodies and employees of affiliates of the Issuer.

On April 18, 2016 a first tranche of 425,000 options at an exercise price of EUR 2.49 were issued under this program.



In accordance with the associated conditions, each subscription right that is granted entitles the beneficiary to acquire one new registered share without par value (no-par value share) in the company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange Xetra trading for the Issuer's shares on the ten trading days prior to the issuing of the share. However, the minimum exercise price amounts to the proportionate share of the company's share capital allocated to each individual no-par value share, pursuant to sec.(9)(1) of the German Stock Corporation Act.

The options granted may only be exercised after expiry of a retention period. The retention period is four years from the respective date of issue. A prerequisite for the whole or partial exercising of the options is that the following performance target is achieved:

Exercising the options from a tranche is possible if at the beginning of the respective exercise period, the price (Reference Price) of a share in Biofrontera Aktiengesellschaft exceeds the exercise price by at least 20%. The Reference Price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange Xetra trading for the Company's shares between the 15th and the 5th trading day (inclusive in each case) prior to the respective exercise window. Additionally, the reference price compared to the exercise price has developed as well or better as the „MSCI World Health Care Index TR“ or a comparable successor index in the time period from the last trading day before the issue date until the fifth trading day before the respective exercise period.

The minimum reference price is adjusted in the following cases in order to bring the stated performance target into line with changed circumstances:

In the event of a capital increase from company funds being carried out by issuing shares, the minimum reference price is reduced by the same proportion as new shares issued compared to existing shares. If the capital increase is carried out from company funds without the issuing of new shares (sec. 207(2)(2) German Stock Corporation Act), the minimum reference price remains unchanged.

In the event of a capital reduction taking place, no adjustment is made to the minimum reference price, provided that the total number of shares is not affected by the reduction of capital, or if the capital reduction is associated with a return of capital or an acquisition of own shares in return for payment. In the event of a capital reduction achieved by consolidation of shares without repayment of capital or in the event of an increase in the number of shares without a change in capital (share split), the minimum reference price is increased in proportion to the reduction of capital or to the share split.

There are no other cases in which adjustments are made to the minimum reference price.

The exercising of options is limited to the following time periods, i.e. only declarations of exercising of rights submitted to the company within an exercise window will be considered:

- within the ten banking days after the date of issue of an annual or half-yearly report,

- within the ten banking days after the date of the annual general meeting,
- within the ten banking days after the date of issue of a quarterly report or an interim report.

After expiry of the relevant retention period, the options can be exercised up until the expiry of six years from the date of issue.

The right to exercise the options expires no later than six years after the first day of issue, i.e. on 7 April 2022. Any options not exercised by that date are forfeited without compensation.

Any claim by the beneficiary to receive a cash settlement in the event of non-exercise of the options is invalid, notwithstanding the existence of the above exercise prerequisites. An option right may only be exercised if the holder has a current service or employment contract with the company or another company affiliated with the company or if the holder is a member of the management board or the management team of another company affiliated with the company.

#### **6.6.9 Accrual for pension obligations**

The Issuer does not provide pension benefits to members of its management board or supervisory board, and therefore has not set aside or accrued monies to provide pension, retirement or similar benefits.

### **6.7 Employees**

As of the date of this prospectus, 124 employees have been working for Biofrontera Group.

On 31 December 2016, 94 employees worked for Biofrontera Group (31 December 2015: 58). Of these, 20 were employed at Biofrontera Aktiengesellschaft (31 December 2015: 17), 9 at Biofrontera Bioscience GmbH (31 December 2015: 6) and 41 at Biofrontera Pharma GmbH (31 December 2015: 34). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. Biofrontera Inc. employed a total of 24 staff (31 December 2015: 1).

Biofrontera Group does not employ a significant number of temporary employees.

### **6.8 Major shareholders**

Insofar as known to the issuer, the following persons who, directly or indirectly, have an interest in the issuer's capital or voting rights which is notifiable under German law:

#### **Direct Interest:**

- Deutsche Balaton AG, Heidelberg, Germany: 8.28%
- Maruho Deutschland GmbH, Düsseldorf, Germany: 21.58 %
- FEHO Vermögensverwaltungsgesellschaft mbH, Frankfurt, Germany: 3.14 %

### **Indirect Interest:**

- Maruho Co., Ltd., Osaka, Japan: 21.58 %
- Universal Investment Gesellschaft mbH, Frankfurt, Germany: 3.14 %
- Wilhelm K. T. Zours: 11.21 %

The Issuer's major shareholders do not have different voting rights. To the extent known to the Issuer, the Issuer is not directly or indirectly owned or controlled. No specific measures are in place to prevent abuse of a potential control of the Issuer.

No arrangement is known to the Issuer that may at a subsequent date result in a change in control of the Issuer.

## **6.9 Share capital**

As of the date of this prospectus, the structure of the Issuer's share capital is as follows:

### **6.9.1 Registered capital**

The registered share capital amounts to EUR 38,416,828, divided into 38,416,828 no par-value ordinary registered shares with a notional value of EUR 1.00 per share. The shares are fully paid in. No shares are issued that are not fully paid in.

As of 31 December 2016 (i.e. as of the date of the last audited financial accounts of the Issuer), the registered share capital of the Issuer amounted to EUR 35,360,763, divided into 35,360,763 no par-value ordinary registered shares with a notional value of EUR 1.00 per share. As of 30 June 2017 (i.e. as of the date of the last unaudited financial accounts of the Issuer), the registered share capital of the Issuer amounted to EUR 38,416,428, divided into 38,416,428 no par-value ordinary registered shares with a notional value of EUR 1.00 per share.

No shares were paid for with assets other than cash within the period covered by the historical financial information.

No shares exist that are not representing capital.

### **6.9.2 History of registered capital**

#### **6.9.2.1 Until 31 December 2014**

Until 31 December 2013, the registered capital of the Issuer had developed as follows:

| Date   | Share capital in EUR             |
|--|----------------------------------|
| Upon Incorporation (as Biofrontera Pharmaceuticals GmbH), October 1997 | DEM 50,000.00<br>(EUR 25,564.60) |

| Date  | Share capital in EUR              |
|---|-----------------------------------|
| December 1998   | DEM 75,000.00<br>(EUR 38,346.90)  |
| July 2000   | DEM 120,500.00<br>(EUR 61,610.69) |
| November 2000 (legal form change into AG and change of capital denomination in EUR) | EUR 72,300.00                     |
| June 2001   | EUR 72,502.00                     |
| August 2001   | EUR 1,015,028.00                  |
| January 2003  | 1,159,324.00                      |
| August 2003   | 1,862,869.00                      |
| August 2005   | 2,381,987.00                      |
| October 2005  | 2,480,132.00                      |
| June 2006   | 2,540,132.00                      |
| October 2006  | 3,205,403.00                      |
| August 2008   | 3,316,514.00                      |
| January 2009  | 3,647,514.00                      |
| April 2009  | 3,736,528.00                      |
| May 2009  | 5,736,628.00                      |
| September 2009  | 5,834,961.00                      |
| September 2009  | 7,595,486.00                      |
| January 2010  | 8,395,486.00                      |
| June 2010   | 8,975,486.00                      |
| September 2010  | 9,975,486.00                      |
| March 2011  | 10,855,486.00                     |
| August 2011   | 11,240,486.00                     |
| February 2012   | 11,740,486.00                     |
| March 2012  | 16,143,168.00                     |
| April 2013  | 17,753,168                        |
| February 2014   | 22,191,460                        |
| March 2014  | 22,196,570                        |

#### 6.9.2.2 Since 1 January 2015

Since 1 January 2015, i.e. during the period covered by the historical financial information, the registered capital of the Issuer developed as follows:

- By execution of authorized capital, effective 1 June 2015, the registered capital was increased to EUR 23,573,842;

- By execution of authorized capital, effective 3 December 2015, the registered capital was increased to EUR 25,490,430;
- By execution of authorized capital, effective 26 February 2016, the registered capital was increased to EUR 27,847,814;
- By execution of authorized capital, effective 26 April 2016, the registered capital was increased to EUR 30,347,813;
- By execution of authorized capital, effective 21 November 2016, the registered capital was increased to EUR 35,360,763;
- By conversion of convertible bonds and exercise of options attaching to option bonds, effective 26 January 2017, the registered capital was increased from conditional capital to EUR 37,715,273;
- By exercise of options attaching to option bonds, effective 9 February 2017, the registered capital was increased from conditional capital to EUR 37,715,273;
- By conversion of convertible bonds, effective 29 June 2017, the registered capital was increased from conditional capital to EUR 38,416,428.
- By conversion of convertible bonds, effective 22 December 2017, the registered capital was increased from conditional capital to EUR 38,416,503.
- By conversion of convertible bonds, which has not been entered into the commercial register as of the date of this prospectus, the registered capital was increased from conditional capital to EUR 38,416,828.

### **6.9.3 Authorized capital**

#### **6.9.3.1 Authorized Capital I**

Pursuant to sec. 6(3a) of the articles, the management board of the Issuer is authorized to increase the share capital by up to EUR 6,000,000 by issuing new ordinary registered shares, with the approval of the supervisory board, until 23 May 2022 against contribution in cash or in kind once or several times by issuing new ordinary shares (authorized capital I). The management board is entitled, with the approval of the supervisory board, to determine the content of the share's rights as well as the terms of the share issue. The new shares are to be offered to the shareholders. The shareholders' subscription right may be granted indirectly pursuant to sec. 186(5) German Stock Corporation Code. The management board is entitled, with the approval of the supervisory board, to exclude subscription rights of shareholders in cases of fractional amounts.

#### **6.9.3.2 Authorized Capital II**

The general meeting of the Issuer had resolved, on 24 May 2017, to authorize the management board of the Issuer to increase the share capital by up to EUR 4,000,000 by issuing new ordinary registered

shares, with the approval of the supervisory board, until 23 May 2022 against contribution in cash or in kind once or several times by issuing new ordinary shares, and entitle the management board to exclude the shareholders' subscription rights (authorized capital II). This authorized capital II has been contested by a shareholder. The authorized capital II has not been entered into the commercial register – which is required to render it effective – pending the results of the legal proceedings.

#### **6.9.4 Shares held by the Issuer**

No shares are held by or on behalf of the Issuer or subsidiaries of the Issuer.

#### **6.9.5 Convertible bonds**

The Issuer has issued two convertible bonds. The key terms of these bonds are summarized below.

##### **6.9.5.1 Convertible bond 2021**

In December 2016, the Issuer has issued a subordinated convertible bond with a term until 31 December 2020, to be repaid on 1 January 2021 (“**Convertible Bond 2021**”). The Convertible Bond 2021 was issued in a total nominal amount of EUR 4,990,000 and is divided into 49,990 fractional bonds with a nominal value of EUR 100 each. The Convertible Bond bears interest of 6 % p.a. and will be repaid on maturity at 100 % of its nominal value.

The Issuer has the right to cancel and repay the bond if less than 15 % of the originally issued fractional bonds are outstanding, or at any time after 31 December 2017.

Each fractional bond grants its holder the right to convert the fractional bond during the exercise period into registered non-par shares of the issuer with a participation of EUR 1.00 in the registered capital. The conversion price amounts to EUR 3.00 per share until 31 December 2016, EUR 4.00 per share until 31 December 2017 and EUR 5.00 per share afterwards. The conversion price is adjusted in certain cases to protect from dilution.

The Issuer has the right to deliver shares in the respective amount instead of repayment of the Convertible Bond 2021. Furthermore, the Issuer may convert the fractional bonds under the Convertible Bond 2021 into shares at any time once the Issuer's five-day average stock market price has exceeded EUR 5.00 at any point of time.

As of the date of this prospectus, fractional debentures in a total nominal amount of EUR 83,000 are outstanding under the Convertible Bond 2021.

##### **6.9.5.2 Convertible bond 2022**

In January, the Issuer has issued a subordinated convertible bond with a term until 31 December 2021, to be repaid on 1 January 2022 (“**Convertible Bond 2022**”). The Convertible Bond 2022 was issued in

a total nominal amount of EUR 4,990,000 and is divided into 49,990 fractional bonds with a nominal value of EUR 100 each. The Convertible Bond bears interest of 6 % p.a. and will be repaid on maturity at 100 % of its nominal value.

The Issuer has the right to cancel and repay the bond if less than 15 % of the originally issued fractional bonds are outstanding.

Each fractional bond grants its holder the right to convert the fractional bond during the exercise period into registered non-par shares of the issuer with a participation of EUR 1.00 in the registered capital. The conversion price amounts to EUR 3.50 per share until 31 March 2017, EUR 4.00 per share until 31 December 2017 and EUR 5.00 per share afterwards. The conversion price is adjusted in certain cases to protect from dilution.

As of the date of this prospectus, fractional debentures in a total nominal amount of EUR 2,654,400 are outstanding under the Convertible Bond 2022.

#### 6.9.5.3 Repaid option bond 2009/2017

The Issuer had issued an option bond 2009/2017, which had a term until 31 December 2017. The option bond 2009/2017 was prematurely repaid in full in July/August 2017. The options granted together with the fractional bonds of the option bond 2009/2017 expired on 01. January 2018.

#### 6.9.5.4 Repaid option bond 2011/2016

The Issuer had issued an option bond 2011/2016, which had a term until 31 December 2016 and was repaid in full on maturity.

### 6.9.6 Conditional Capital

The Issuer has created several conditional capitals.

#### 6.9.6.1 Conditional Capital I

Pursuant to § 7(2) of the Issuer's articles, the registered capital is conditionally increased by up to EUR 4,137,201 by issuing up to 4,137,201 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each ("*Conditional Capital I*").

The Conditional Capital I serves (i) to secure granting of option rights and agreeing on option obligations pursuant to the terms of a respective bond, or (ii) to secure fulfillment of conversion rights and fulfillment of conversion obligations pursuant to the terms of a respective bond, each issued, agreed upon or guaranteed based on the authorization of the general meeting of August 28, 2015, by the Issuer or its affiliates. The conditional capital increase will be implemented only if and insofar as (i) financial instruments based on the authorization of the general meeting of August 28, 2015, are

issued, and (ii) the holders or creditors of financial instruments exercise their option or conversion rights, or fulfill an option or conversion obligation, as the case may be. The new shares issued on the basis of the previous sentence entitle their holders to dividends of company profits from the beginning of the fiscal year in which they are issued. The management board is authorized (subject to the approval of the supervisory board) to make further stipulations regarding the implementation of the conditional capital increase.

The Conditional Capital I originally amounted to EUR 4,831,596 and was reduced pursuant to the exercise of conversion rights.

#### 6.9.6.2 Conditional Capital II

Pursuant to § 7(5) of the Issuer's articles, the registered capital is conditionally increased by up to EUR 500,000 by issuing up to 500,000 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each ("**Conditional Capital II**"). The Conditional Capital II served to cover the option rights under the option bond 2009/2017 (see 6.9.5.3).

#### 6.9.6.3 Conditional Capital III

Pursuant to § 7(6) of the Issuer's articles, the registered capital is conditionally increased by up to EUR 542,400 by issuing up to 542,400 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each ("**Conditional Capital III**"). The Conditional Capital III serves to cover option rights under options granted pursuant to the authorization of the general meeting between 2 July 2010 and 1 July 2015 (Employee Stock Option Program 2010).

#### 6.9.6.4 Conditional Capital IV

Pursuant to § 7(8) of the Issuer's articles, the registered capital is conditionally increased by up to EUR 1,814,984 by issuing up to 1,814,984 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each ("**Conditional Capital IV**"). The Conditional Capital IV serves to cover option rights under options granted pursuant to the authorization of the general meeting between 28 August 2015 and 27 August 2020 (Employee Stock Option Program 2015).

#### **6.9.7 Acquisition rights**

All shareholders are entitled to acquire newly issued shares pro rata to their shareholding under statutory German law, insofar as the statutory subscription right is not excluded. No further individual acquisition rights exist.



### **6.9.8 Options to shares**

No option rights to shares other than the rights granted under the employee stock option programmes 2010 and 2015, the Convertible Bonds 2021 and 2022 and the options issued under the option bond 2009/2017 exist.

### **6.10 Litigation**

In July 2017, the Issuer was served a lawsuit by its shareholder Deutsche Balaton AG, contesting the discharge (Entlastung) of the members of the management board for the business year 2016 and the creation of the Authorized Capital II (with the option to exclude the shareholders' subscription rights).

Regarding the discharge of the management board, the claimant alleges that the management board had given unfair preferential treatment to a major shareholder, by entering into an agreement detrimental to the Issuer, and granting shares at a discounted price. Furthermore, the claimant alleges that an employment agreement with the spouse of one member of the management board was incorrectly not listed in the notes to the Issuer's annual report 2016. Finally, the claimant alleges that the management board contravened legal obligations by refraining to publish an insider information, i.e. the identity of the backstop investor of the capital increase in November 2016.

Regarding the creation of the authorized capital with the option to exclude the shareholders' subscription rights, the claimant alleges that such creation of authorized capital would be illegal, since the Issuer does not require additional equity financing rounds, and that the reasons given to exclude the shareholders' subscription rights are insufficient.

Regarding both contested resolutions, the claimant alleges that a major shareholder had been prevented from voting, since this shareholder had not fulfilled its disclosure obligations and therefore lost its voting rights in accordance with sec. 28(1)(1) of the German Stock Trading Code.

In the first hearing in October 2017, the court has indicated that it does not consider the lawsuit merited. The management board of the Issuer consider the risk associated with the lawsuit as low.

### **6.11 Related party transactions**

After the end of the last financial period for which audited financial information have been published, i.e. 31 December 2016, the Issuer has entered into the following material transactions with related parties.

Under a research cooperation partnership (a collaboration and partnership agreement) entered into in 2016 between the Issuer and Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera Group's proprietary nanoemulsion technology are to be researched. Biofrontera Group, as part of research services, will conduct the requisite work for the exploratory research of these product candidates. Maruho Co., Ltd is bearing the related costs. Under

this agreement, Maruho Co., Ltd has paid an amount of EUR 1.4 million since 31 December 2016 as of the date of this prospectus.

## 6.12 Dividend policy

The Issuer has to date not made dividend payments. Considering the substantial loss carry-forward, no dividend payments are expected in the near future.

## 7. Financial Information

### 7.1 Selected financial information

The following tables contain selected financial information of the Issuer:

| <b><i>Profit and loss related financial information</i></b>                    |   |   |   |  |
|--|---|---|---|--|
|  | Fiscal year<br>ending 31<br>December<br>2015  | Half year<br>ending 30<br>June 2016   | Fiscal year<br>ending 31<br>December<br>2016  | Half year<br>ending 30<br>June 2017  |
| Source of the financial information :<br>(all numbers given in thousand Euros) | audited<br>consolidated<br>financial<br>statements as<br>per 31<br>December<br>2015 | Unaudited<br>consolidated<br>financial<br>statements as<br>per 30 June<br>2017(1) | audited<br>consolidated<br>financial<br>statements as<br>per 31<br>December<br>2016 | Unaudited<br>consolidated<br>financial<br>statements<br>as per 30<br>June 2017 |
| Sales revenue  | 4,138   | 1,709   | 6,130   | 5,006.4  |
| Cost of sales (2)  | -1,236  | -764  | -1,652  | -635.4   |
| Gross Profit   | 2,902   | 945   | 4,478   | 4,371.1  |
| Research and development costs   | -6,204  | -1,852  | -4,640  | -2,185.4   |
| General administrative costs   | -2,759  | -1,372  | -2,853  | -1,695.5   |
| Sales costs (2)  | -4,170  | -2,832  | -8,763  | -8,275.3   |
| Net loss before taxes  | -11,203   | -3,472  | -10,579,  | -8,736.6   |
| Loss after taxes   | -11,203   | -3,472  | -10,579,  | -8,736.6   |

(1) Taken from prior year comparison,

(2) Note: While “cost of sales” refers to general costs of revenue, “sales costs” refers to distribution costs. The unaudited consolidated financial statement as per 30 June 2016 uses the term “marketing costs”.

| <b><u>Balance sheet related financial information</u></b>                      |   |   |   |
|--|---|---|---|
|  | 31 December 2015  | 31 December 2016  | 30 June 2017  |
| Source of the financial information :<br>(all numbers given in thousand Euros) | audited consolidated financial statements as per 31 December 2015 | audited consolidated financial statements as per 31 December 2016 | Unaudited consolidated financial statements as per 30 June 2017 |
| Long term liabilities (end of period)  | 11,230  | 3,597   | 2,654.0   |
| Current liabilities (end of period)  | 1,911   | 2,426   | 4,161.3   |
| Equity (end of period)   | -4,809  | 15,842  | 10,388.9  |
| Cash & cash equivalents (end of period)  | 3,959   | 15,126  | 11,451.5  |
| Sum of assets  | 9,498   | 23,879  | 19,347.9  |
| Employees (end of period) (3)  | 58  | 94  | 124   |

(3) Unaudited; source: management report for the respective period.

## **7.2 Capital Resources**

### **7.2.1 Cash flows**

The cash flows of the Issuer for the fiscal years 2016 and 2015 are as follows:

Annual cash flow:

|  | Period from 1 January 2016 – 31 December 2016                     | Period from 1 January 2015 – 31 December 2015                     |
|--|---|---|
| Source of financial information<br>(all numbers in Euro) | audited consolidated financial statements as per 31 December 2016 | audited consolidated financial statements as per 31 December 2015 |
| Profit/loss for the period                               | (10,579,204.16)   | (11,203,410.20)   |
| Financial result   | 1,204,087.05  | 1,159,325.74  |
| Depreciation   | 830,779.04  | 811,681.84  |
| (Gains)/losses from disposal of assets                   | 5,630.83  | 115.00  |
| Non-cash expenses and income                             | (412,109.68)  | (22,203.75)   |
| Trade receivables  | (729,507.66)  | (585,574.61)  |
| Other assets and income tax assets                       | (870,059.80)  | (11,314.11)   |
| Inventories  | (2,112,674.39)  | (140,126.97)  |
| Trade payables   | 1,049,728.55  | 75,987.99   |
| Provisions   | 786,762.28  | 149,945.42  |
| Other liabilities  | 86,944.18   | 48,255.77   |
| Net cash flow from operational activities                | (10,739,623.76)   | (9,717,317.88)  |
| Purchase of intangible and tangible assets               | (484,537.07)  | (180,303.54)  |
| Interest received  | 2,935.14  | 183,978.17  |

|   | Period from 1 January 2016 – 31 December 2016                     | Period from 1 January 2015 – 31 December 2015                     |
|---|---|---|
| Source of financial information<br>(all numbers in Euro)  | audited consolidated financial statements as per 31 December 2016 | audited consolidated financial statements as per 31 December 2015 |
| Revenue from sale of intangible and tangible assets   | 26,295.86   | 13,353.71   |
| Net cash flow from (into) investment activities   | (455,306.07)  | 17,028.34   |
| Proceeds from the issue of shares   | 24,196,561.40   | 6,313,472.92  |
| Proceeds from conversions of convertible bonds 2016/2021  | 4,830,144.41  | 0.00  |
| Proceeds from conversions of option bond 2011/2016  | 2,245,515.20  | 0.00  |
| Interest paid   | (841,603.24)  | (1,224,598.00)  |
| Increase/(decrease) in long-term financial debt   | (7,633,049.11)  | 455,647.62  |
| Increase/(decrease) in short-term financial debt  | (435,749.94)  | (394,424.00)  |
| Net cash flows from financing activities  | 22,361,818.72   | 5,150,098.54  |
|   |   |   |
| Net increase (decrease) in cash and cash equivalents  | 11,166,888.89   | (4,550,191.00)  |
| Cash and cash equivalents at the beginning of the period  | 3,959,207.16  | 8,509,398.16  |
| Cash and cash equivalents at the end of the period  | 15,126,096.05   | 3,959,207.16  |
| Composition of financial resources at the end of the period: Cash and cash balances and cheques | 15,126,096.05   | 3,959,207.16  |

#### Interim period cash flow:

|   | Period from 1 January 2017 – 30 June 2017                       | Period from 1 January 2016 – 30 June 2016                       |
|---|---|---|
| Source of financial information<br>(all numbers in thousand Euro) | Unaudited consolidated financial statements as per 30 June 2017 | Unaudited consolidated financial statements as per 30 June 2016 |
| Profit/loss for the period  | (8,736.6)   | (3,472.3)   |
| Financial result  | 325.4   | 592.8   |
| Depreciation  | 443.8   | 404.3   |
| (Gains)/losses from disposal of assets                            | 0.0   | 4.8   |
| Non-cash expenses and income                                      | 3,340.8   | 46.4  |
| Trade receivables   | 422.0   | 382.1   |
| Other assets and income tax assets                                | 372.4   | (338.6)   |
| Inventories   | (188.1)   | (142.3)   |
| Trade payables  | (1,644.6)   | (45.3)  |
| Long-term and short-term financial debt                           | (2,551.7)   | 0.0   |
| Provisions  | 66.1  | 83.1  |

|  | Period from 1 January 2017 –<br>30 June 2017                       | Period from 1 January 2016 –<br>30 June 2016                       |
|--|--|--|
| Source of financial information<br>(all numbers in thousand Euro)                                  | Unaudited consolidated financial<br>statements as per 30 June 2017 | Unaudited consolidated financial<br>statements as per 30 June 2016 |
| Other liabilities  | 63.4   | (25.7)   |
| Net cash flow from operational activities  | (8,087.0)  | (2,510.7)  |
| Purchase of intangible and tangible assets   | (203.7)  | (154.6)  |
| Interest received  | 1.8  | 1.7  |
| Revenue from sale of intangible and tangible<br>assets   | 9.7  | 9.7  |
| Net cash flow from (into) investment activities  | (192.2)  | (143.2)  |
| Proceeds from the issue of shares  | 0.0  | 9,303.2  |
| Proceeds from conversions of convertible bonds<br>2017/2022  | 4,999.0  | 0.0  |
| Interest paid  | (394.4)  | (435.8)  |
| Net cash flows from financing activities   | 4,604.6  | 8,867.4  |
| Net increase (decrease) in cash and cash<br>equivalents  | (3,674.6)  | 6,213.4  |
| Cash and cash equivalents at the beginning of the<br>period  | 15,126.1   | 3,959.2  |
| Cash and cash equivalents at the end of the<br>period  | 11,451.5   | 10,172.6   |
| Composition of financial resources at the end of<br>the period: Cash and cash balances and cheques | 11,451.5   | 10,172.6   |

#### 7.2.1.1 First half of fiscal year 2017

Net cash flow from operational activities reduced compared with the first half of the 2016 from EUR - 2,511 thousand to EUR -8,087 thousand as of 30 June 2017.

Net cash flow from (into) investment activities decreased slightly, by EUR 49 thousand, to EUR -192 thousand.

Cash flow from financing activities diminished by EUR 4,262 thousand year-on-year, from EUR 8,867 thousand to EUR 4,605 thousand. This change arises especially from cash inflows from issuing new shares with total issue proceeds of EUR 9.3 million in the prior-year period, compared with cash flows from issuing the 2017/2022 convertible bond of EUR 5.0 million during the first half of 2017.

#### 7.2.1.2 Fiscal year 2016

Net cash flow from operational activities reduced year-on-year from EUR -9,717 thousand to EUR - 10,740 thousand in 2016.

Net cash flow from (into) investment activities diminished by EUR 472 thousand to EUR -455 thousand, especially due to capital expenditure, which increased by EUR 304 thousand to EUR 485 thousand.

Net cash flow from financing activities improved by EUR 17,212 thousand year-on-year, from EUR 5,150 thousand to EUR 22,362 thousand. This change arises particularly from the proceeds of new share issues generating EUR 24.2 million of issue proceeds. In the prior-year period, two capital increases with issue proceeds totalling EUR 6.3 million were implemented.

Interest paid amounted to EUR 842 thousand (previous year: EUR 1,225 thousand). The change resulted from the two interest payments for Warrant Bond I made in the 2015 financial year: firstly, on 1 January 2015 for the 2014 financial year, and, secondly, on 31 December 2015 interest for the 2015 financial year. Interest received amounted to EUR 3 thousand (previous year: EUR 184 thousand), consisting of interest received for deposits. In the previous year, the interest received from Warrant Bond I held by the company itself already accrued to the company as of 30 December 2015.

#### 7.2.1.3 Fiscal year 2015

In 2015, due to high net losses, net cash flow from operational activities fell from EUR -7,928 thousand in 2014 to EUR -9,717 thousand.

In both 2015 and 2014, capital increases were implemented in order to provide further financing for the company. Equity proceeds were significantly higher in 2014 than in 2015. Therefore, net cash flow from financing activities decreased from EUR 13,425 thousand to EUR 5,150 thousand. The sharp increase in short-term financial debt is due to the closing maturity of the 2009/2017 bond.

#### 7.2.2 Restrictions on the use of equity capital resources

In the Convertible Bond 2022, the Issuer has undertaken not to exceed (i) a net financial indebtedness of EUR 25 million and (ii) a net indebtedness quota of 4.0. Net financial indebtedness is defined as the sum of long term and short term financial liabilities, less cash and cash equivalents. Net indebtedness quota is defined as net financial indebtedness divided by EBITDA. If the Issuer exceeds both the permitted net financial indebtedness and the permitted net indebtedness quota, the bondholders have the right to cancel the bond and request repayment.

The EIB Credit Facility described under 9.11.2 provides for certain covenants. In particular, the Issuer may generally not incur additional third-party debt of more than EUR 1 million without EIB consent. Furthermore, the Issuer has – inter alia – agreed to refrain from granting securities, loans and guarantees as well as from disposing of assets or subsidiaries or changing its business.

No further restrictions on the use of equity capital resources are in place.

### 7.3 Capitalization and indebtedness

The following table shows the Issuer's capital as of 30 November 2017. The figures are taken from the internal controlling of the Issuer.

| Capitalization according to IFRS                                     | As of 30 November 2017, in thousand EUR |
|--|---|
| Total current debt   | 2.600                                   |
| Guaranteed   | -                                       |
| Secured  | -                                       |
| Unguaranteed / unsecured   | 2.600                                   |
| Total non-current debt (excluding current portion of long-term debt) | 12.852                                  |
| Guaranteed   | -                                       |
| Secured  | -                                       |
| Unguaranteed / unsecured   | 12.852                                  |
| Shareholder's Equity   |   |
| a. Share capital   | 38.416                                  |
| b. Legal reserve   | 101.472                                 |
| c. Other Reserve (1)   | -135.759                                |
| Sum of Shareholder's Equity  | 4.129                                   |
| Total  | 19.581                                  |

(1) loss carry-forward and accumulated losses

The following table shows the Issuer's indebtedness as of 30 November 2017. The figures are taken from the internal controlling of the Issuer.

| Indebtedness according to IFRS                       | As of 30 November 2017, in thousand EUR |
|--|---|
| A. Cash  | 11.323                                  |
| B. Cash equivalent                                   | -                                       |
| C. Trading Securities                                | -                                       |
| <b>D. Liquidity (A.+B.+C)</b>                        | 11.323                                  |
| <b>E. Current Financial Receivable</b>               | 2.913                                   |
| F. Current Bank debt                                 | -                                       |
| G. Current portion of non-current debt               | 125                                     |
| H. Other current financial debt                      | 626                                     |
| <b>I Current Financial Debt (F+G+H)</b>              | 751                                     |
| <b>J. Net Current Financial Indebtedness (I-E-D)</b> | -13.485                                 |
| K. Non-current Bank loans                            | -                                       |
| L. Bonds Issued                                      | 2.607                                   |
| M. Other non-current loans                           | 10.245                                  |
| <b>N. Non current Financial Indebtedness (K+L+M)</b> | 12.852                                  |
| <b>O. Net Financial Indebtedness (J+N)</b>           | -633                                    |

There is no indirect or contingent indebtedness.

#### 7.4 Working capital statement

The Issuer is of the opinion that the working capital of Biofrontera Group is currently not sufficient to meet the obligations due in the next twelve months.

The current working capital will, in the Issuer's current estimation, be sufficient to cover due obligations until approx. May 2018.

For the coming twelve months, the Issuer will require under the current estimate, approx. EUR 10 million more in order to cover the payment obligations due in the next twelve months. This includes,

in particular, the ongoing operative business of Biofrontera Group, including the marketing activities in Europe and the United States and maintaining and extending the European and US approval.

The Issuer plans to rectify a part of this shortfall with the capital increase described in this prospectus. At the date of this prospectus, the Issuer's management is optimistic that sufficient placement in the US and Europe will be possible. However, no binding purchase / subscription orders have yet been made. A success of the capital measure described in this prospectus is therefore not guaranteed.

Cost-cutting measures might be possible, but not to the extent necessary to ensure the ability to cover all payment obligations that become due in the next twelve months on their own. Furthermore, such cost-cutting measures would cause material constraints to Biofrontera Group's business and future prospects. The Issuer expects that cost-cutting measures could reduce expenses by approx. EUR 100 thousand per month. The Issuer only considers to implement such cost-cutting measures as a supplemental means if proceeds from the capital measure described in this prospectus are insufficient as such, but will suffice together with cost-cutting measures. On their own, cost-cutting measures will not be sufficient to provide for sufficient working capital to meet the obligations due in the next twelve months.

Furthermore, if the Issuer is not in a position to generate sufficient proceeds from this capital increase, the Issuer may initiate further financing measures. In particular, the Issuer has in the past placed convertible and option bonds, which may also be used as a financing instrument in the future.

A failure of financing measures would result in the inability of the Issuer to meet its obligations and therefore an insolvency in the short term. Potential investors should therefore be aware that the Issuer is dependent on raising additional capital to avoid an insolvency during the next twelve months, and that the success of raising such capital is outside of the Issuer's influence.

## **8. Profit Forecast**

### **8.1 Forecast of consolidated net result for Biofrontera AG for the financial year 2016**

The forecast provided in this section includes the consolidated net result, which is mainly driven by revenue development, research and development costs, financial result and other income. A forecast is not a representation of facts and should not be interpreted as such by investors. It is an estimate by the management board and the Issuer relating to the development of the Issuer's net income. Potential investors should rely on these forecast only to a limited extent.

Forecasts are based on below mentioned assumptions made by the management board of the Issuer relating to factors that have an influence on these forecasts. Those assumptions however are also related to factors that cannot at all or only to a limited extent be influenced by the Issuer. Although the Issuer concludes that these assumptions are reasonable at the time these are published by the



management board of the Issuer, in retrospective they may still prove to have been incorrect or unjustified. Therefore actual net income may deviate substantially from these forecasts.

In April 2017 the following forecast report has been published in the Issuer's consolidated audited financial statement for the fiscal year ending 31 December 2016:

“(…) the company (i.e. the Issuer) will achieve a net result of EUR -14 to -17 million in 2017. The achievement of this result however depends heavily on progress in terms of sales revenue.”

The underlying assumptions had been reviewed in May 2017 and confirmed in the Issuer's consolidated unaudited financial statement for the quarter ending 31 March 2017:

“The Management Board is retaining in full its forecast for the 2017 financial year”.

The underlying assumptions had been reviewed in August 2017 and conditionally confirmed in the Issuer's consolidated unaudited financial statement for the half-year ending 30 June 2017:

“With the aforementioned conditions and forecasts, the company will achieve a net result in 2017 in the lower end of the outlook range. The achievement of this result depends significantly on sales revenue trends.”

The underlying assumptions had been reviewed in November 2017 as follows:

“From today's perspective, we expect an annual turnover of approx. EUR 12 million and a net result of EUR -18 million.” (Annual turnover refers to sales revenues in the table under 7.1 above, net result refers to the loss after taxes in the table under 7.1 above).

## **8.2 Notes to the forecast report**

### **8.2.1 Principles**

The forecast for the current financial year 2017 was prepared in accordance with IDW Accounting principles: preparation of forecasts and estimates in accordance with special requirements of prospectus decree (IDW RH HFS 2.003) of the Institute of Public Auditors in Germany (IDW Rechnungslegungshinweis: Erstellung von Gewinnprognosen und -schätzungen nach den besonderen Anforderungen der Prospektverordnung (IDW RH HFS 2.003) des Instituts der Wirtschaftsprüfer („IDW“)).

This forecast was prepared by the Issuer in accordance with International Financial Reporting Standards, as adopted by the European Union („IFRS“), the applied disclosures, recognition and measurement principles are described in detail in the consolidated financial statements of December 31, 2016.

The forecast report is based on the following assumptions made by the management board of the Issuer. These include assumptions as further outlined below.

## **8.2.2 Factors and assumptions**

### **8.2.2.1 Factors that cannot be influenced**

The forecasted consolidated net income of Biofrontera Group is influenced by a number of factors that cannot be influenced by the company. These factors including the Issuer's assumptions relating to the development of these factors are listed below.

#### *8.2.2.1.1 Factor unexpected events*

The Issuer assumes that no unexpected events will occur that would lead to substantial obstruction of Biofrontera Group's business, such as force majeure (fire, floods, hurricanes, storms, earthquakes or terrorist attacks), strikes, exceptional macroeconomic events or war.

#### *8.2.2.1.2 Factor legislative actions*

The Issuer assumes that no major changes of the existing legal or regulatory regulations will occur.

#### *8.2.2.1.3 Factor economic development of the pharmaceutical industry*

The Issuer assumes that no major negative development in the relevant economic environment will occur.

#### *8.2.2.1.4 Factor competition*

Biofrontera Group faces competition mainly from one PDT drug in Europe, Metvix®, and another PDT drug in the US, Levulan Kerastick®. Since only smaller revenues are forecasted in the US in 2017, US competition will not have a major influence on Biofrontera Group's revenue development. In Europe however, Metvix® has a broader label which includes basal cell carcinoma (BCC) as an indication and has recently also been able to extend the label to daylight therapy. Although Biofrontera Group's product has significantly better clinical efficacy in comparable indications (actinic keratoses), Biofrontera Group cannot guarantee that Metvix® will not be able to regain market share due to changing prescriptions and uses of drugs by dermatologists, in particular when daylight therapy is used rather than performing PDT under a lamp.

#### *8.2.2.1.5 Factor Ownership*

At the time of preparation of the forecast the Issuer assumed that the current shareholder structure will remain stable and any smaller changes will not influence the strategy of the operating business. The largest shareholder holds approx. 25 % of the Issuer's share capital. While the German Federal Constitutional Court has ruled the current provisions regarding loss of tax carry-forwards due to changes in ownership unconstitutional, amended legislation may still lead to situations where an

increase of the investment of the Issuer's major shareholder beyond 25% may lead to a reduction or even complete loss of the Issuer's income and trade tax loss carry-forwards.

#### 8.2.2.2 Factors that can be influenced to a limited extent

##### 8.2.2.2.1 *Factor price development*

The Issuer assumes that no major changes of prices or mandatory rebates for pharmaceutical products in Europe will occur. In all European countries in which Biofrontera Group's products are available, prices for prescription drugs are set and maintained by governmental authorities. The Issuer further assumes that prices actually achieved for its products in the US will not substantially deviate from price assumptions made in the forecast.

##### 8.2.2.2.2 *Factor drug prescriptions*

Dermatologists have various options to treat actinic keratoses and it is entirely their own decision based on their assessment of the medical need which option they choose. Biofrontera Group can advertise clinical and other advantages to dermatologists only to a limited extent. The Issuer assumes that the number of prescriptions of products will continue to grow compared to the number of prescriptions in the previous year.

##### 8.2.2.2.3 *Sales revenues*

In April 2017 the following forecast report has been published in the Issuer's 2016 annual report: "For the 2017 financial year, Biofrontera expects to achieve sales revenue of approximately EUR 14 million to EUR 18 million. In Germany and other European countries outside Germany, the competitive situation for Biofrontera has changed considerably due to the market launch of a medication for daylight PDT identical to Metvix®. We nevertheless anticipate a resumption of slight growth in 2017 in both Germany and Europe. In the USA, we expect a marked increase in sales revenues in 2017, especially as initial system-related problems with reimbursing the medication have meanwhile largely been resolved. The receipt of an individual reimbursement code for the medication Ameluz® – to be activated prospectively in January 2018 – will significantly simplify and accelerate the acquisition of market shares and related sales revenue growth. Overall, however, sales growth remains very difficult to forecast, generating a considerable fluctuation range of achievable revenues."

Update: in May 2017, the following forecast update has been published in the Issuer's 2017 Q1 report: "Among other elements, the Management Board consequently expects sales revenue for the year of approximately EUR 14-18 million."

Update: in August 2017, the following forecast update has been published in the Issuer's 2017 H1 report: "Total revenue are expected to be at the lower end of the outlook range, depending on sales development in the US maybe even slightly below the range."

Explanation: the Issuer explained this assumption as follows: „The competitive situation has stabilised for Biofrontera in Germany as well as in other European countries. From today's perspective, sales revenues in these regions in the full 2017 year will lie within the range of expectations. In the USA, we anticipate continuous sales revenue growth during 2017, although initial system-related difficulties in the reimbursement of the medication through a so-called Miscellaneous Code prompt the expectation of somewhat slower sales revenue growth than previously anticipated. The receipt of an individual reimbursement code for the medication Ameluz® in January 2018 will significantly simplify and accelerate the acquisition of market shares and related sales revenue growth. Overall, however, sales growth remains very difficult to forecast, continuing to generate a considerable fluctuation range of achievable revenues.“

Update: In November 2017, the following forecast update has been published in the Issuer's 2017 Q3 report: "We assume sales revenue for the year of around EUR 12 million and a net result for the year of EUR -18 million."

Explanation: the Issuer explains this assumption as follows: "Business trends in the third quarter of the 2017 financial year confirm the assessment that the Management Board already communicated in the half-year report, whereby sales revenues might lie below the 2017 financial year forecast published on 12 April 2017 of at least EUR 14 million. Sales revenues in October and November already point to a pleasing trend turnaround, with sales revenues of approximately EUR 1.5 million being generated in October alone. This performance will prospectively prove insufficient, however, to meet the full-year forecast."

#### 8.2.2.2.4 *Factor Research and development expenses*

In April 2017 the following forecast report has been published in the Issuer's 2016 annual report: "To extend the range of indications, Biofrontera will continue to make significant investments in research and development as well as in regulatory affairs in 2017. The development and approval costs will amount to approximately EUR 6 to 7 million. In 2017, Biofrontera will also invest in further expanding its sales and marketing organization, predominantly in the USA, as a consequence of which sales and marketing costs will increase further compared with 2016 and amount to a total of between approximately EUR 18 million and EUR 21 million."

Update: in August 2017, the following forecast update has been published in the Issuer's 2017 H1 report: "The forecast for development and approval costs remains at between approximately EUR 6 million and EUR 7 million."

#### 8.2.2.2.5 *Factor operating expenses*

In April 2017 the following forecast report has been published in the Issuer's 2016 annual report: "Administrative costs will rise only slightly compared with 2016 and stand at around between EUR 3 million and EUR 4 million." Biofrontera Group's operating expenses other than Research and Development mainly include personnel expenses, fees for legal and audit and other advisors as well as costs incurred for marketing purposes. For the purpose of forecast the Issuer has taken into consideration the personnel as of to date including any planned changes, which in particular include the planned hiring of new personnel in the US. Assumption has been made that Biofrontera Group will be able to hire all planned personnel and that salary levels will be within the planned range.

Update: in August 2017, the following forecast update has been published in the Issuer's 2017 H1 report: "The establishment of the sales and marketing organisation in the USA is largely occurring to plan, so that sales and marketing costs remain largely unchanged compared with the last forecast report at between approximately EUR 18 million and EUR 21 million. Compared with the last forecast, administrative costs will rise slightly due to additional costs for financing measures, and amount to between around EUR 4 million and EUR 5 million."

#### 8.2.2.2.6 *Factor interest expenses*

In April 2017 the following forecast report has been published in the Issuer's 2016 annual report: "The financial result reflects the interest payments and compounding of interest applying the effective interest method for the still outstanding warrant bond. For this reason, 2017 will represent an improvement compared with 2016."

#### 8.2.2.2.7 *Factor Other income*

In May 2016 the following forecast report has been published in the Issuer's 2015 annual report: "The reimbursement of the PDUFA fee by the FDA will be shown under "Other Income"." The 2016 figures and thus 2016 forecast contain the reimbursement of PDUFA fee with amount of EUR 2.1 million in other income.

This forecast remains unchanged compared to the forecast contained in 2015 Annual Report.

### 8.2.2.3 Factors that can be influenced

#### 8.2.2.3.1 *Factor once only effects*

The forecast includes costs and payments made as well as income received to date. The Issuer points out that the refund of the PDUFA fee amounting to EUR 2.1 million is a one time only effect in 2016.

#### 8.2.2.3.2 *Other explanations*

Since the forecast report includes a period in the future and is based on assumptions relating to future uncertain events and acts (factors) it is connected with significant uncertainty. Therefore it is possible that the actual net income for the 2017 financial year will deviate significantly from the forecasted net income.

Leverkusen, 24 January 2018

|                           |                         |                          |
|---------------------------|-------------------------|--------------------------|
| Prof. Dr. Hermann Lübbert | Thomas Schaffer         | Christoph Dünwald        |
| Chief Executive Officer   | Chief Financial Officer | Chief Commercial Officer |

### **8.3 Auditors' report**

“Auditor’s Report

To Biofrontera AG, Leverkusen

We have audited whether the profit forecast prepared by Biofrontera AG, Leverkusen, for the period from January 1, 2017 to December 31, 2017, last updated in November 2017, has been properly compiled on the basis stated in the explanatory notes to the profit forecast and whether this basis is consistent with the accounting policies of the company. The profit forecast comprises the forecast profit after tax for the period from January 1, 2017 to December 31, 2017 and explanatory notes to the profit forecast.

The preparation of the profit forecast including the factors and assumptions presented in the explanatory notes to the profit forecast is the responsibility of the company’s management.

Our responsibility is to express an opinion based on our audit on whether the profit forecast has been properly compiled on the basis stated in the explanatory notes to the profit forecast and whether this basis is consistent with the accounting policies of the company. Our engagement does not include an audit of the assumptions identified by the company and underlying the profit forecast or an audit of the historical financial information contained in the explanatory notes.

We conducted our audit in accordance with IDW Prüfungshinweis: Prüfung von Gewinnprognosen und -schätzungen i.S.v. IDW RH HFA 2.003 (IDW PH 9.960.3) (IDW Auditing Practice Statement: The Audit of Profit Forecasts and Estimates in accordance with IDW AcPS AAB 2.003 (IDW AuPS 9.960.3)) issued by the Institut der Wirtschaftsprüfer in Deutschland e.V. (Institute of Public Auditors in Germany) (IDW). Those standards require that we plan and perform the audit such that material errors in the compilation of the profit forecast on the basis stated in the explanatory notes to the profit forecast and in the compilation of this basis in accordance with the accounting policies of the company are detected with reasonable assurance.

As the profit forecast relates to a period not yet completed and is prepared on the basis of assumptions about future uncertain events and actions, it naturally entails substantial uncertainties. Because of these uncertainties it is possible that the actual profit of the company for the period from January 1, 2017 to December 31, 2017 may differ materially from the forecast profit.

We believe that our audit provides a reasonable basis for our opinion.

In our opinion, based on the findings of our audit, the profit forecast has been properly compiled on the basis stated in the explanatory notes to the profit forecast. This basis is consistent with the accounting policies of the company.

Düsseldorf, 24 January 2018

Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft

|                       |                       |
|-----------------------|-----------------------|
| Martin Feix           | Dr. Thomas Senger     |
| Wirtschaftsprüfer/CPA | Wirtschaftsprüfer     |
| German Public Auditor | German Public Auditor |

## 9. Business overview

### 9.1 Principal activities

Biofrontera Group is an international biopharmaceutical enterprise 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 Group's approved products focus on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer (also "**AK**") in Europe and the United States, as well as the treatment of basal cell carcinoma (also "**BCC**") in the EU. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots. Because of their location and appearance, actinic keratoses are often cosmetically unappealing.

Biofrontera Group's principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy (also "**PDT**" and as PDT with Ameluz® "**Ameluz® PDT**"). Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or



poor cosmetic outcome. A major advantage of treating actinic keratosis and basal cell carcinoma with photodynamic therapy (as opposed to other common treatments such as surgery and cryotherapy) is that it is a non-invasive alternative that can have better cosmetic results, *i.e.*, removal of tumors without leaving clearly visible scarring.

In addition, Biofrontera Group has developed its own PDT lamp, BF-RhodoLED®, for use in combination with Ameluz®. The BF-RhodoLED® lamp was approved as a medical device in the EU in November 2012 and is approved for sale in all EU countries, although the use of the BF-RhodoLED® lamp is not required to be used in combination with Ameluz® in the EU or Switzerland.

In May 2016, Biofrontera Group received approval from the U.S. Food and Drug Administration (“*FDA*”), for US marketing of Ameluz® in combination with photodynamic therapy using the BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Group launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the US in October 2016.

## **9.2 Markets**

Biofrontera Group currently sells Ameluz® in 12 countries in Europe and in the U.S., and expects to commence sales of Ameluz® in Israel in the second half of 2017. Biofrontera Group’s principal markets are Germany, the United States and, to a lesser degree, other European countries. In the first half of 2017, Biofrontera Group generated a turnover of approx. EUR 1.1 million in Germany, and approx. EUR 2.39 million in the US, as well as EUR 0.732 million in other European countries. A further turnover of EUR 0.785 million was generated in fees for development projects, *i.e.* outside of sales.

## **9.3 Products**

### **9.3.1 Ameluz®**

Biofrontera Group’s principal marketed product is Ameluz®. Ameluz® is used in photodynamic therapy to selectively remove tumor cells. Biofrontera Group is currently selling Ameluz® in the U.S. and in 12 countries in Europe, and also expects to commence sales of Ameluz® in Israel in the second half of 2017. Biofrontera Group outsources the production of Ameluz® to a third party contract manufacturer in Switzerland.

#### **9.3.1.1 Mechanism**

In general, photodynamic therapy is a two-step process:

- the first step is the application of a drug known as a “photosensitizer,” or a pre-cursor of this type of drug, which tends to collect in cancerous cells; and



- the second step is activation of the photosensitizer by controlled exposure to a selective light source in the presence of oxygen.

During this process, energy from the light activates the photosensitizer. In photodynamic therapy, the activated photosensitizer transfers energy to oxygen molecules found in cells, converting the oxygen into a highly energized form known as “singlet oxygen,” which destroys or alters the sensitized cells.

The longer the wavelength of visible light, the deeper into tissue it penetrates. Different wavelengths, or colors of light, including red and blue light, may be used to activate photosensitizers. The selection of the appropriate color of light for a given indication is primarily based on two criteria:

- the desired depth of penetration of the light into the target tissue; and
- the efficiency of the light in activating the photosensitizer.

Red light penetrates more deeply into tissues than blue light, and is therefore generally better suited for treating cancers and deeper tissues. Different photosensitizers do not absorb all wavelengths (colors) of visible light in the same manner. For any given photosensitizer, some colors are more strongly absorbed than others. Blue light requires less energy to activate the molecule than red light, but it does not penetrate deeply into tissues, so it is generally better suited for treating superficial lesions.

Photodynamic therapy can be a highly selective treatment that targets specific tissues while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. The most common side effect of photosensitizers that are applied topically or taken systemically is temporary skin sensitivity to bright light. Treatment is generally well tolerated but tingling discomfort or pain is common during PDT. In Biofrontera Group’s Phase III trials, the resulting redness and/or inflammation resolved within 1 to 4 days in most cases; in some cases, however, it persisted for 1 to 2 weeks or even longer. Patients undergoing photodynamic therapy treatments are usually advised to avoid direct sunlight and/or to wear protective clothing and sunscreen for some days after the treatment. Patients’ indoor activities are generally unrestricted except that they are told to avoid bright lights. The degree of selectivity and period of skin photosensitivity varies among different photosensitizers and is also related to the drug dose given. Unless activated by light, photosensitizers have no direct photodynamic therapy effects.

#### 9.3.1.2 Applications

In December 2011, Ameluz® 78 mg/g Gel received a centralized European regulatory approval by the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. In the EU, Ameluz® is to be used in combination with exposure to a red light source (although the approved labelling does not specify the light source). Biofrontera Group launched the

commercialization of Ameluz® for the treatment of actinic keratosis in Germany for this indication in February 2012 followed by other EU countries during the following two years.

In November 2015, Biofrontera Group's license partner Louis Widmer SA obtained approval to market Ameluz® in Switzerland for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. In April 2016, Biofrontera Group's licensee Perrigo Israel Agencies Ltd. obtained approval to market Ameluz® in Israel for the same indication. Biofrontera Group launched the commercialization of Ameluz® in Switzerland in April 2016 and expects to launch the commercialization of Ameluz® in Israel in the second half of 2017.

In May 2016, Biofrontera Group received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using Biofrontera Group's BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Thus, in the U.S., Ameluz® is to be used in combination with exposure to light using Biofrontera Group's BF-RhodoLED® lamp. Biofrontera Group launched the commercialization of Ameluz® and BF-RhodoLED® for the treatment actinic keratosis in the U.S. in October 2016.

In September 2016, the European Commission approved Ameluz® for the photodynamic therapy treatment of field cancerization following a prior recommendation of the European Medicines Agency ("EMA"). This decision was based on a field-directed Phase III trial during which the skin rejuvenating effects of Ameluz® were also studied. The skin rejuvenation results of this trial are included in the authorized EU product information.

Biofrontera Group initiated efforts to extend indications for Ameluz® to include basal cell carcinoma in 2014. Biofrontera Group conducted Phase III clinical testing in direct comparison with the European competitor product Metvix®. Biofrontera Group completed patient recruitment in May 2015 and the last patient concluded the clinical part of the trial in November 2015. Biofrontera Group will have a 5-year follow-up period for all patients, of which 6-month and 12-month data are currently available. Biofrontera Group published the results of the trial in January 2016, which demonstrated clinical efficacy of Ameluz® for non-aggressive forms of basal cell carcinoma. In comparison with the competitor product Metvix®, in the clinical trials Ameluz® demonstrated generally higher clearance rates, especially for thicker and nodular carcinomas and significant non-inferiority of the clinical endpoint, which was total patient clearance of all basal cell carcinomas. These trial results demonstrated to the EMA that Ameluz® is a viable treatment option for superficial and nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome, which resulted in approval of this indication in the EU in January 2017.

Biofrontera Group is also seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy (*i.e.*, using natural daylight to activate the drug), which Biofrontera Group applied for in the second quarter of 2017. Biofrontera Group believes that if this approval can be obtained, Biofrontera

Group may increase the market potential of Ameluz® in the EU since Ameluz® could be used without doctor's office procedures, which procedures can render photodynamic therapy treatment in European markets commercially unattractive due to lack of reimbursement.

### **9.3.2 BF-RhodoLED® Lamp**

Biofrontera Group's BF-RhodoLED® is a red light lamp specifically designed for photodynamic therapy, and uses LEDs emitting red light at a wavelength of approximately 635 nm to activate the photosensitizer. The Issuer believes light emitted at this wavelength is effective for photodynamic therapy illumination with Ameluz® or other medications containing ALA or methyl ALA. The red light emitted by the BF-RhodoLED® lamp is outside the infrared range, reducing the likelihood for discomfort from warming. Other light wavelengths, including the blue range, can also activate the photosensitizer, but penetrate less deeply into tissues as compared to red light. Biofrontera Group manufactures the BF-RhodoLED® lamp at its own manufacturing facility in Germany.

The Issuer believes the BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity of design, user-friendliness and energy efficiency. The BF-RhodoLED® lamp contains a fan used to blow air over the treated skin surface and power settings for the fan. In the model used in the EU, the lamp also allows adjustment of the light intensity during photodynamic therapy in order to reduce any discomfort experienced during the treatment. The BF-RhodoLED® lamp has been CE-certified since November 2012 and is currently distributed throughout the EU. The lamp is approved in the U.S. by the FDA as a combination product for use in treatment with Ameluz®.

Biofrontera Group has been performing the final assembly of the BF-RhodoLED® lamp at its facilities in Leverkusen, Germany since July 2016 and, thus, is considered the responsible manufacturer by the FDA.

## **9.4 Indications**

### **9.4.1 Actinic keratoses**

#### **9.4.1.1 Nature of actinic keratoses**

Actinic keratoses are superficial potentially pre-cancerous skin lesions caused by chronic sun exposure that may, if left untreated, develop into a form of potentially life-threatening skin cancer called squamous cell carcinoma. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots.

According to The Skin Cancer Foundation, actinic keratosis is becoming a widespread disease, with more than 58 million people affected in the U.S. alone. According to The Skin Cancer Foundation, if

left untreated, up to 1 percent of actinic keratosis lesions develop into squamous cell carcinomas every year. On average, this transformation into squamous cell carcinoma occurs within two years of formation of the initial actinic keratosis lesion.

Squamous cell carcinoma is an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers (the epidermis). Squamous cell carcinoma often appear as scaly red patches, open sores, elevated growths with a central depression, or warts; and they may crust or bleed. They can become disfiguring and sometimes deadly if allowed to grow. According to The Skin Cancer Foundation, squamous cell carcinoma has been the second most common form of skin cancer, but its incidence has been rapidly increasing. According to The Skin Cancer Foundation, more than one million cases of squamous cell carcinoma are diagnosed each year in the U.S. alone, and it has been estimated that as many as 8,800 people die from the disease each year in the U.S. alone.

Because actinic keratosis can develop into squamous cell carcinomas, actinic keratosis is classified by The European Academy of Dermatology and Venereology and other international treatment guidelines as a tumor that requires treatment, and the international treatment guidelines list photodynamic therapy as the “gold standard” for the removal of actinic keratoses, particularly for patients with large keratotic areas.

Actinic keratosis was recognized as an occupational disease by the Federal Ministry of Labor and Social Affairs in Germany in 2013. As a result of such recognition, occupational insurance associations in Germany must cover, for the duration of the patients' lives, the treatment costs of patients who have worked predominantly outdoors for extended periods of time and who meet certain other criteria. In Germany since March 2016, photodynamic therapy has been included as an approved treatment option for occupational actinic keratosis, which means it can be reimbursed by the government.

#### 9.4.1.2 Treatment of Actinic Keratosis

Actinic keratosis is a disease that is most frequent in the Caucasian, light-skinned population. It has been estimated that actinic keratosis affects up to 10% of the entire Caucasian population worldwide. Only a fraction of these patients are currently being treated. Actinic keratoses are treated using a wide range of methods. The traditional methods of treating actinic keratoses are:

- cryotherapy, or the deep freezing of skin;
- simple curettage;
- self-applied topical prescription products; and
- combination of medication with photodynamic therapy.

Although any of these methods can be effective, each has limitations and can result in significant side effects.

Cryotherapy is non-selective (meaning it cannot target specific tissues but affects all tissues in the area of application), can be painful at the site of freezing, and can cause blistering and loss of skin pigmentation, leaving temporary or permanent white spots. In addition, because there is no standardized treatment protocol, results are not uniform.

Topical prescription products, such as 5-fluorouracil cream, or 5-FU, can be highly irritating and requires twice-a-day application by the patient for approximately 2 to 4 weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment, up to several weeks of healing may be required. Imiquimod or diclofenac, other topical prescription products, require extended applications of cream, lasting up to 3 or 4 months, during which the skin is often very red and inflamed. Treatment with ingenol mebutate is faster, requiring application for only a few days, but side effects can be long-lasting and this drug has been labeled with a black-box warning by the FDA.

Surgery is generally most useful for one or a few individual lesions, but not for a large number of lesions, and it leaves permanent scars.

#### *9.4.1.2.1 European Markets*

The total actinic keratosis drug market in Europe is currently approximately EUR 120 million, with about EUR 22 million for PDT drugs. In Europe, to the knowledge of the Issuer, most actinic keratosis patients are treated with various available medications, which can be assessed through the number of prescriptions. Throughout Europe, there are more than 2 million prescriptions written per year for actinic keratosis drugs, and the number of prescriptions has been growing by about 10% annually over the past four years. The Issuer estimates that about 33% of all prescriptions for actinic keratosis drugs in Europe are written in Germany, followed by the UK (15%), France (12%), Italy (12%), Spain (10%) and Switzerland (3%). The remaining European countries account for approximately 15% of prescriptions.

Only a minor part of all actinic keratosis prescriptions, about 120,000 in 2016, representing sales of EUR 22 million, are for PDT drugs. Thus, PDT drugs are prescribed for a relatively low percentage of treatments for actinic keratosis, notwithstanding the fact that clinical trials have demonstrated that photodynamic therapy achieves the highest clearance rates. The Issuer believes that, in the Europe, the complexity of photodynamic therapy's treatment procedure and the time required by medical practices to administer it have historically prevented significant market penetration in the statutory health insurance sector in Europe. Topical prescription product creams often receive reimbursement and do not require an office based procedure, whereas photodynamic therapy requires a procedure that, to date, is not reimbursed in all markets in Europe. With the advent of daylight PDT, which eliminates

the procedures in doctor's offices and allows easier reimbursement (Biofrontera Group has filed an approval application in the EU for daylight PDT), the Issuer sees the potential for PDT to significantly grow its share of the actinic keratosis market in Europe. The PDT sector was growing slightly faster, by about 15% per year, than the total actinic keratosis market, but still represents below 6% of all prescriptions for actinic keratosis in Europe. This market size may, however, be a slight underestimation since in many countries PDT drugs may be sold directly into hospitals and therefore are not tracked by regular market research sources. Since PDT drugs generally have a higher price than the self-applied topical drugs, their percentage of revenues is higher than that of prescription numbers (18.3% vs. 5.7%, respectively).

Available PDT drugs for treatment of actinic keratosis in Europe include Ameluz® gel, Metvix® cream, AlaCare® adhesive plaster and Luxerm® cream. Metvix® has been on the market since 2002, and is the most frequently used PDT drug for treatment of actinic keratosis throughout the EU. Metvix® is approved for treatment with a red light source and contains methylester, which is metabolized to 5-ALA in the tissue, as its active ingredient. As with Ameluz®, in the treatment of actinic keratosis, Metvix is used in a PDT treatment once, and the PDT treatment is repeated after several weeks if residual lesions remain. In Biofrontera Group's phase III trial, the efficacy of Ameluz® was compared with that of Metvix® and showed significant superiority in the treatment of actinic keratosis. AlaCare® is a 2x2 cm plaster that has low market share because of its limited size of treatment area. Luxerm is identical to Metvix, but its use is restricted to daylight PDT. It is on the market only in Germany, and was launched in 2016.

Throughout Europe, Metvix® has 74% market share among PDT treatments for treatment of actinic keratosis, followed by Ameluz with 21%, Luxerm with 3% and AlaCare with 2%. Since commercial launch in Germany (where Biofrontera Group's sales force has been most active), the market share of Ameluz® in the segment of photodynamic therapy drugs for treatment of actinic keratosis dispensed by German public pharmacies had been over 75%. In recent months, however, Biofrontera Group's market share has fallen to approximately 60%. The Issuer believes this decline resulted primarily from the introduction to the market of the medication Luxerm® in 2016. Using the recently completed Phase III trial, Biofrontera Group has filed for label extension in the EU for the treatment of actinic keratosis using Ameluz® and daylight PDT, which would eliminate the need for an office-based procedure in connection with treatment using Ameluz® (the medication can be administered by the patient). The Issuer believes that Biofrontera Group may obtain approval as early as the first half of 2018, although there is no guarantee that Biofrontera Group will receive approval for this label extension. The Issuer believes that daylight photodynamic therapy products will play an increasingly important role in Europe in the future and will begin to be prescribed as an alternative to less effective, self-applied, topical prescription product creams (which have historically been market leaders in the EU in treating actinic keratosis).



In Spain market share of Ameluz® for treatment of actinic keratosis has been growing from less than 5% in 2014 to 12% in 2015 and 23% in 2016.

Most of the prescriptions in Europe for treatment of actinic keratosis are for self-applied topical drugs, for which the driver seems to be the minimal amount of time required by the doctor. Almost half of all prescriptions are for Solaraze (45%), which according to a meta-analysis of clinical trials by Vector and Tolley (2014) has a rather low efficacy. This reinforces the Issuer's belief that another driver, such as time spent in consultation, may determine treatment selection besides efficacy. Solaraze prescriptions for actinic keratosis are followed by Aldara (18%), Picato (16%) and Actikerall (7%).

#### *9.4.1.2.2 US market*

The actinic keratosis market in the U.S. differs greatly from the European market, since the U.S. reimbursement system generally has favored procedures, for which physicians in Europe may not get paid or reimbursed. The most frequently used treatment option for actinic keratosis is cryotherapy. In 2013, Medicare alone paid for 5.977 million actinic keratosis patients treated with cryotherapy. This had been growing by 2-3% per year since 2008. If the number is extrapolated to 2016 with an assumed 2% growth rate, the Issuer estimates that about 6.4 million Medicare patients were treated with cryotherapy in 2016. An analysis of "National Ambulatory Medical Care Survey" and "Medicare Current Beneficiary Survey" data with respect to the frequency and cost of actinic keratosis treatment concluded that about 60% of actinic keratosis patients were covered by Medicare, and 40% of treatments are reimbursed by private payers during the period from 1998 through 2000 (Dermatology Surgery 2006;32(8):1045-9). Thus, the Issuer assumes that the above number of cryotherapies for Medicare patients represents only 60% of all cryotherapy treatments performed in the U.S. in the relevant year, so the number of cryotherapies for Medicare patients should be divided by 0.6 in order to estimate the total number of cryotherapy treatments in that year.

In the U.S., Levulan® is approved for use in combination with PDT with a blue light source. Levulan® contains 5-aminolevulinic acid (5-ALA) as its active ingredient. As with Ameluz®, in the treatment of actinic keratosis, Levulan® is used in a PDT treatment once, and the PDT treatment is repeated after several weeks if residual lesions remain. Sun Pharma has reported annual Levulan revenues in 2016 of \$106 million. With an approximate annual average sales price of \$309 per Levulan Kerastick, this equates to 343,000 prescriptions.

The Issuer estimates that there were an additional 1.65 million prescriptions for self-applied topical drugs in the U.S. for the treatment of actinic keratosis. These prescriptions are distributed over multiple products, the most frequently prescribed ones are drugs with the active ingredient 5-fluorouracil (44% generic plus 4% branded), followed by imiquimod drugs (31%), diclofenac drugs (16%) and ingenol mebutate drugs (5.5%).

Altogether, the cryotherapy treatments and the topical products including PDT drugs add up to an estimated 12.6 million treatments for actinic keratosis in the U.S. in 2016. According to these numbers, PDT is only applied in about 3% of all actinic keratosis treatments, and there is substantial market potential and room for growth.

The Issuer believes that opportunities for Ameluz® sales growth for treatment of actinic keratosis in the US market are to replace Levulan® Kerastick as the leading PDT product in the current PDT market sector for actinic keratosis treatment, and subsequently to grow the PDT market as a first-option therapy as compared to cryotherapy and self-applied topical products.

#### **9.4.2 Basal Cell Carcinoma**

##### **9.4.2.1 Nature of basal cell carcinoma**

Basal cell carcinomas are abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the deepest layer of the epidermis (the outermost layer of the skin). Basal cell carcinomas often appear as open sores, red patches, pink growths, shiny bumps or scars and are typically caused by accumulated sun exposure.

Basal cell carcinomas are the most common invasive tumors affecting humans, accounting for approximately 50-80 percent of all invasive skin cancers worldwide. Approximately 30 percent of all Caucasians develop at least one basal cell carcinoma in their lifetime, and cases are increasing rapidly worldwide, which is believed to be caused by increased exposure to ultraviolet light. More than 4 million cases of basal cell carcinoma are diagnosed in the U.S. alone each year. Although basal cell carcinoma rarely spreads to other parts of the body and becomes life-threatening, it can be disfiguring if not treated promptly.

##### **9.4.2.2 Treatment of basal cell carcinoma**

The most common treatment for basal cell carcinoma in the EU and U.S. is surgical removal. In many European countries, dermatology specialists are hospital-based and, as a result, basal cell carcinoma is most commonly treated by hospital surgery in such European countries, which is rarely the case for actinic keratosis. The treatment of basal cell carcinoma by a surgical procedure can result in high cost and clearly visible scarring. But thin, non-aggressive basal cell carcinomas can also be treated with photodynamic therapy. The advantage of treating basal cell carcinoma with photodynamic therapy is that it is a non-invasive alternative that can have better cosmetic results, *i.e.*, removal of tumors without leaving clearly visible scarring.

According to a market study published in 2014 by Technavio, the international market for actinic keratosis medication is expected to grow by approximately 8% annually, from approximately \$546 million in 2013 to approximately \$942 million in 2020. During this same period, the global



market for basal cell carcinoma medication is expected to grow from approximately \$236 million in 2013 to nearly \$5 billion in 2020, because of the availability of new drugs (such as Ameluz®), which would likely mean that fewer patients will undergo surgery for treatment of basal cell carcinoma.

## **9.5 Sales, marketing and distribution**

Biofrontera Group currently sells Ameluz® in 12 countries in Europe and in the U.S., and expects to commence sales of Ameluz® in Israel during the second half of 2017.

### **9.5.1 Sales, marketing and distribution in Europe and Israel**

With its central European approval, Ameluz® for the photodynamic therapy treatment of actinic keratosis and basal cell carcinoma, can be sold and distributed in all EU countries as well as in Norway, Iceland, and Liechtenstein. Biofrontera Group has marketed and sold Ameluz® to dermatologists in Germany and, since March 2015, also in Spain through its own field sales force. Biofrontera Group sells Ameluz® in other countries within the European Union and in Switzerland through license partners, and plans to sell in Israel through a license partner. In the UK, Biofrontera Group is currently preparing an own sales operations after terminating a contract with a local marketing company.

In many European countries, the price and the medical reimbursement status have to be defined prior to market launch, which can be a lengthy process. To date, in Europe Biofrontera Group or the license partners have commenced sales in Germany, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway, Slovenia, the UK and Switzerland. The medication is available in these countries at a pharmacy retail price of between approximately EUR 150-EUR 270 per 2 gram tube.

In the EU, distribution to public pharmacies generally takes place via pharmaceutical wholesalers, whereas hospital pharmacies may also be supplied directly. In addition to regular visits by field sales force to dermatologists, Biofrontera Group has since presented Ameluz® at major dermatological conferences both in Germany and in other European countries.

Biofrontera Group has a license and supply agreement with Desitin Arzneimittel GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Denmark, Sweden, and Norway; a license and supply agreement with Bipharma B.V. to market and sell Ameluz® and the BF-RhodoLED lamp in Belgium, the Netherlands and Luxembourg; and a license and supply agreement with Pelpharma Handels GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Austria.

Biofrontera Group terminated a marketing collaboration agreement with Spirit Healthcare Limited to market Ameluz® in the UK and Ireland in July 2015, and is currently preparing to commence own sales activities in the UK.

Biofrontera Group also terminated a marketing agreement with PHA Pharmed d.o.o. in Slovenia, and intends to terminate distribution in this country.

Biofrontera Group initially marketed and sold Ameluz® in Spain pursuant to an agreement with Allergan SA. After termination of this agreement, since March 2015 Biofrontera Group has marketed and sold its products in Spain through its branch, Biofrontera Pharma GmbH sucursal en España.

Biofrontera Group has a license and supply agreement with Louis Widmer SA in which it has granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Switzerland and Liechtenstein. Biofrontera Group has a license and supply agreement with Perrigo Israel Agencies Ltd. in which it has granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Israel, the West Bank and the Gaza Strip. In these regions, the licensees were required to obtain independent regulatory approvals in collaboration with Biofrontera. In Switzerland, the regulatory approvals for Ameluz® and reimbursement were issued in December 2015 and commercial launch commenced in the beginning of 2016. In Israel, regulatory approval for Ameluz® was granted by the Israeli health agency in April 2016, reimbursement for treatment with Ameluz® of immunosuppressed patients was subsequently granted, and the Issuer expects commercial launch in Israel to commence during the second half of 2017.

In these agreements with sales partners, Biofrontera Group often (but not always) received an initial up-front payment. The sales partners purchase Ameluz® at a price that is linked to their own anticipated sales price. Biofrontera Group's share of the sales price varies, depending on the up-front payment as well as market conditions within each country or region, ranging from 35% to 60% of net revenue.

#### **9.5.2 Sales, marketing and distribution in the U.S.**

Biofrontera Group decided to market and sell Ameluz® in combination with BF-RhodoLED® for the treatment of actinic keratosis in the U.S. with its own sales force, and launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in October 2016. Prior to launch, and with the help of a consulting firm specializing in market access, Biofrontera Group analyzed the reimbursement mechanisms for photodynamic therapy in the U.S. healthcare system. Ameluz® is distributed as a buy-and-bill drug that is purchased by the dermatologist, rather than distribution through pharmacies.

Sales in the U.S. are made through a wholly-owned subsidiary, Biofrontera Inc., a Delaware corporation, which was established in March 2015. Based on the Issuer's experience, Biofrontera Group concluded that it could most effectively market its products in the U.S. by using an own sales force, which can be trained to sell Ameluz® in combination with the BF-RhodoLED® lamp and related procedure. During 2016, Biofrontera Group hired 26 employees for the U.S. marketing and sales efforts, and launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016. Biofrontera Group has filled the key positions for the U.S.

operations with qualified and experienced employees, and expects to continue to fill positions and build a field sales force for the market. Several employees have joined from competitors and, as a result, have specific experience with the photodynamic therapy market sector, including experience in selling medication as a buy-and-bill combination product. This is particularly helpful because, in the U.S., Ameluz® is sold in combination with the BF-RhodoLED® photodynamic therapy lamp.

## **9.6 Competition**

The following description of the competitive environment of Biofrontera Group is based on the estimate of the management board of Biofrontera Group.

### **9.6.1 Competition in the EU**

#### **9.6.1.1 Competing PDT products**

There are a few other companies that are selling photodynamic therapy agents other than Ameluz® for the treatment of actinic keratoses and certain other skin conditions. The major competitor in the EU is methyl aminolaevulinate (160mg/g) (MAL) Metvix®/Metvixia®, a drug owned and distributed by Galderma S.A., which is used in photodynamic therapy with red light. Its approved indications include: the treatment of thin or non-hyperkeratotic and non-pigmented actinic keratoses on the face and scalp when other therapies are considered less appropriate; the treatment of superficial and/or nodular basal cell carcinoma unsuitable for other available therapies due to possible treatment related morbidity and poor cosmetic outcome, such as lesions on the mid-face or ears, lesions on severely sun damaged skin, large lesions, or recurrent lesions; and the treatment of squamous cell carcinoma in situ (Bowen's disease) when surgical excision is considered less appropriate. Metvix is indicated in adults above 18 years of age. Historically, Biofrontera Group lost sales of Ameluz® in the EU to Metvix because Metvix was approved in the EU to treat both actinic keratosis and basal cell carcinoma. Since obtaining the indication extension to treat basal cell carcinoma in the EU in 2016, the Issuer expects improved sales of Ameluz® in the EU because of Biofrontera Group's product's generally higher clearance rates, especially for thicker and nodular carcinomas, as demonstrated in clinical trials.

Metvix® has also recently been approved in the EU for use in daylight photodynamic therapy for which it is sold by Galderma under the brand name Luxerm® in Germany and Luxera® in other European countries, which gives that drug a competitive advantage compared to Ameluz®, as Ameluz® is not yet approved to be used in daylight photodynamic therapy to treat actinic keratosis. Biofrontera Group has applied to extend the indication to daylight photodynamic therapy in the EU and believes that this extension may be received as early as the first half of 2018 to better compete with Metvix® and Luxerm®, but there can be no assurance that this will be the case.

A patch containing 5 ALA (Alacare®), which is owned and sold by Galderma, is approved for the treatment of mild actinic keratosis in a single treatment session in combination with red light without pretreatment of the lesion.

#### 9.6.1.2 Competing treatment concepts

In addition, Biofrontera Group also competes with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions, including: Efudex® (5 fluorouracil), sold by Valeant; Solaraze® (diclofenac sodium), sold by Almirall; ALDARA® and Zyclara®(imiquimod), sold by Meda Pharma; Picato® (Ingenolmebutat), sold by LEO Pharma; and Actikerall® (5-fluorouracil and salicylic acid) sold by Almirall.

The Issuer believes that only a small proportion of patients in the EU who could be treated with medication in combination with photodynamic therapy are currently being so treated because dermatologists in the EU favor topical prescriptions, which require the least work from medical practitioners (since no office procedure is required). In the EU, cryotherapy is not a common practice due of its limited efficacy, high recurrence rates and the lack of reimbursement. Photodynamic therapy for actinic keratosis is not reimbursed in all markets in the EU. Particularly in those countries where dermatology is mostly a hospital based discipline, dermatologists typically treat basal cell carcinoma (and not actinic keratosis). The Issuer expects sales of Ameluz® to increase in the EU because of the higher efficacy rate demonstrated in clinical trials, better cosmetic results compared to other treatment options, and the extension of indications to field cancerization and basal cell carcinoma in addition to actinic keratosis.

In addition, the Issuer expects to extend indications in the EU for Ameluz® to include daylight photodynamic therapy in the first half of 2018 to better compete with Metvix® and Luxerm®. Approval for daylight photodynamic therapy would also allow to more effectively compete with other topical prescription drugs, which are widely used in Europe. If the indication is not so extended, then it will be difficult for Ameluz® to effectively compete with Metvix® and other drugs in the EU.

#### ***9.6.2 Competition in the US***

In the U.S., dermatologists have favored cryotherapy to treat actinic keratosis because of a favorable reimbursement regime, which may be under review by the Center for Medicare and Medicaid Services (CMS). The photodynamic therapy market in the U.S. for actinic keratosis treatment only represented an estimated three percent of the actinic keratosis treatments during 2016, representing sales of over \$100 million after rapid growth in previous years. Treatment guideline pressure towards field-directed therapy may also help support sales of photodynamic therapy treatments.

In the U.S., treatment of actinic keratosis with Ameluz® in combination with the BF-RhodoLED® red light device competes with one approved photodynamic therapy drug for actinic keratosis used in

combination with a blue light lamp. In addition, Biofrontera Group also competes with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions similar to those listed above, as well as cryotherapy with liquid nitrogen.

Because the approval for Ameluz® in the U.S. covers not only lesion-directed treatment, but also field-directed therapy, the approval provides Biofrontera Group with the ability to provide broader treatment possibilities compared to certain competitor products.

Both Ameluz® and Levulan® are FDA-approved for the photodynamic treatment of mild-to-moderate actinic keratoses on the face and scalp. The Ameluz® approval covers both lesion-directed and field-directed treatment, while the Levulan® approval is restricted to lesion-directed treatment. Ameluz® consist of 10% 5-aminolevulinic acid in a nanoemulsion gel formulation that can be easily applied. Levulan® is a 20% alcoholic solution that comes in a 2-compartment stick (Kerastick®), in which the two glass containers have to be broken and mixed by the doctor, followed by application with a ball point at the end of the stick. Both drugs are combination products, but with completely different lamp systems, and their labels require different posologies. While Ameluz® is applied for 3 hours under occlusion prior to a 10 minute illumination with the red-light lamp BF-RhodoLED®, Levulan® requires a 14-18 hour incubation without occlusion prior to a 16 minute and 40 second illumination with the blue lamp Blu-U®. Before Ameluz® application, crusts are removed and the treatment field is gently roughened, which is not done in a treatment with Levulan®.

## **9.7 Regulatory environment**

### **9.7.1 European regulatory environment regarding drugs**

In the European Economic Area (“*EEA*”) medicinal products can only be commercialized after obtaining a marketing authorization (“*MA*”). There are two types of marketing authorizations:

The Community MA, which is issued by the European Commission in the so-called Centralized Procedure, based on the opinion of the EMA Committee for Medicinal Products for Human Use (CHMP), is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

Biofrontera Group has received Community MA for Ameluz® in November 2011.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope

of the Centralized Procedure. Biofrontera Group currently does not have products which are subject to National MAs.

### **9.7.2 European regulatory environment regarding medical devices**

The advertising and promotion of Biofrontera Group's products in the EEA is subject to the provisions of the Medical Devices Directive, the Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation in the EEA countries governing the advertising and promotion of medical devices. The European Commission has submitted a Proposal for a Regulation of the European Parliament and the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, to replace, inter alia, Directive 93/42/EEC and to amend regulations regarding medical devices in the European Union, which could result in changes in the regulatory requirements for medical devices in Europe. In Germany, the advertising and promotion of medical products can also be subject to restrictions provided by the German Act Against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb) and the law on the advertising of medicines (Heilmittelwerbegesetz), criminal law, and some codices of conduct with regard to medical products and medical devices among others. These laws may limit or restrict the advertising and promotion of medical products to the general public and may impose limitations on Biofrontera Group's promotional activities with healthcare professionals.

In the EEA, Biofrontera Group is required to obtain so-called Certificates of Conformity before drawing up an EC Declaration of Conformity and affixing the CE Mark of conformity to medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval (see below) although others, such as Brazil, Canada and Japan require separate regulatory filings.

### **9.7.3 US regulatory environment regarding drugs**

Any drug products for which Biofrontera Group receives FDA approvals – at this time, Ameluz® - are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among other requirements, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.



In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval. Biofrontera Group is relying exclusively on manufacturing partner's facilities for the production of clinical and commercial quantities of Biofrontera Group's products in accordance with cGMP regulations, which has not yet been cGMP approved. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented and development of and submission of data to support the change. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, as well as, possibly, the development and submission of data to support the change.

The FDA also may require post-approval trials and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures.

#### **9.7.4 US regulatory environment regarding medical devices**

After a medical device is placed on the market in the US, regardless of its classification or premarket pathway, numerous regulatory requirements apply. These include:

- establishing establishment registration and device listings with the FDA;
- Quality System Regulation, or QSR, which requires manufacturers, including third party manufacturers and certain other parties, to follow stringent design, testing, process control,

documentation, CAPA, complaint handling and other quality assurance procedures, as applicable;

- labeling statutes and regulations, which prohibit the promotion of products for uncleared or unapproved, or off-label, uses and impose other restrictions on labeling;
- clearance or approval of product modifications that could affect safety or effectiveness or that would constitute a change in intended use;
- medical device reporting regulations;
- corrections and removals reporting regulations
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish additional safety or efficacy data.

The FDA has broad post-market and regulatory enforcement powers. The agency may conduct announced and unannounced inspections to determine compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of subcontractors. Failure by Biofrontera Group or its suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions and related consequences

#### **9.7.5 Reimbursement**

Sales of Biofrontera Group's products will depend, in part, on the extent to which the products will be covered by third party payors, such as government health care programs, statutory health insurances, and commercial insurance and managed healthcare organizations. These third party payors are increasingly reducing reimbursements for medical products and services and there is no guarantee that Biofrontera Group will be able to obtain reimbursement at all for any future products.

In particular in the U.S., as the market to be envisaged to be most important to Biofrontera Group, treatment of actinic keratosis with Ameluz® in combination with BF-RhodoLED® photodynamic therapy lamp is eligible to be reimbursed by the U.S. federal government's Medicare program through Part B, which means that dermatologists purchase the drug to treat a patient in combination with BF-RhodoLED® photodynamic therapy lamp and the doctors can be reimbursed for the cost of the drug after its use to treat a patient. This differentiates Ameluz® from drugs that are reimbursed through the U.S. federal government's Medicare Program through Part D and distributed through pharmacies. As a result, "Part B" drugs tend to have lower prices than "Part D" drugs, since doctors must have the financial wherewithal to purchase the drugs before treating the patients. Problems with reimbursement can become a serious issue for doctors since they are personally liable for the cost of the drugs if they are not reimbursed. For a drug to be eligible for reimbursement by Medicare, a pharmaceutical company usually must obtain a permanent "J-code" for the drug that can be applied for in January



following the year of a drug's approval. The process for applying and obtaining a permanent "J-code" typically takes approximately one year. Biofrontera Group applied for a "J-code" for Ameluz® in January 2017, and expects to receive a permanent "J-code" in January 2018. Until then, doctors making reimbursement claims must apply for reimbursement by use of a "miscellaneous" code. The use of the "miscellaneous J-code" for a new drug creates additional administrative hurdles and delay for the doctors to get reimbursed, especially after launch, when payers are not yet familiar with claims for the new drug. Biofrontera Group believes that doctors using Ameluz® during its launch phase in the U.S. may have suffered delays in reimbursement because of lack of a permanent "J-code". More recently, Biofrontera Group believes that the coding and reimbursement process for doctors in the U.S. treating actinic keratosis patients with Ameluz® is becoming smoother and Biofrontera Group expects to obtain the permanent "J-code" in January 2018.

## **9.8 Trends**

### ***9.8.1 Recent trends since the end of the last fiscal year***

In January 2017, the European approval of Ameluz® was extended to treatment of basal cell carcinoma. The Issuer expects this to improve the market standing of Ameluz®.

In January 2017, the Issuer placed a convertible bond in an amount of EUR 5 million (Convertible Bond 2022 referred to above). Furthermore, the Issuer entered into a facility loan agreement with the European Investment Bank in May 2017, under which the Issuer has the right to draw down EUR 10 million immediately and further EUR 10 million pending fulfillment of certain milestones. An amount of EUR 10 million was drawn down in July 2017. The Issuer expects that these financing measures provide more liquidity and allow for more investments.

### ***9.8.2 Recent trends expected to influence the Issuer***

Marketing activities by competitors have made the so-called daylight therapy more popular. With daylight therapy, a patient does not need to be treated with a lamp, but the agent in the PDT drug is activated by daylight. This may reduce discomfort to the patient and effort to the treating doctor. The competitor drug Luxerm®, which is identical to Metvix® but only approved for treatment in daylight therapy, has sold more units in July 2017 than all other PDT drugs together.

In May 2017, Biofrontera filed for extension of the European approval of Ameluz® to daylight therapy in order to improve competitiveness.

## **9.9 Dependencies**

The Issuer and Biofrontera Group are dependent on several factors which are material for the Issuer's and Biofrontera Group's business and profitability.

As a pharmaceutical research, development and distribution enterprise, Biofrontera Group strongly depends on its intellectual property to protect both the unique technology underlying its products, as well as the brand identity of the products. The respective IP is set out under 9.10.

Furthermore, Biofrontera Group is dependent on the continued performance of certain agreements. These agreements are set out under 9.11.

### **9.10 Intellectual Property**

The most relevant intellectual properties relate to the Biofrontera brand, the Ameluz® technology and brand, and the Belixos® technology and brand:

#### ***9.10.1 Biofrontera brand***

The Biofrontera brand is protected by the following word- and figurative marks:

| <b>Trademark</b>                                      | <b>Biofrontera (wordmark)</b>  |
|---|--|
| Registration number                                   | DE 30656877  |
| Registration date (priority)                          | 12.09.2006   |
| Protection period                                     | 30.09.2016   |
| Classes   | 1, 5, 35, 38, 42, 44   |
| Registration number of the international registration | IR 935601  |
| Registration international extension                  | 09.03.2007 (maintaining priority)  |
| Protection period of the international registration   | 09.03.2017   |
| National registrations                                | Chile (01,05)  |
| Protection period of the national registration        | 24.06.2018   |
| Granted   | Australia, Chile (Class 5,1), Singapore, European Union, Norway, USA, Syria, South Korea, Armenia, Japan |
| Pending   | Austria, China, Chile, Russian Federation, Iran  |

|   |   |
|---|---|
| <b>Trademark</b>                                      | <b>Biofrontera</b> (figurative mark)  |
| Registration number                                   | DE 302010066561   |
| Registration date (priority)                          | 21.10.2010  |
| Protection period                                     | 30.10.2020  |
| Classes   | 1, 5, 35, 42, 44, 45  |
| Registration number of the international registration | IR 1075749  |
| Registration international extension                  | 06.04.2011 (maintaining priority)   |
| Protection period of the international registration   | 06.04.2021  |
| Granted   | (Class 1, 5, 35, 42, 44, 45): Germany; (Classes 5): Norway, Australia, Russian Federation, South Korea, Syria, Armenia, Japan, USA, Singapore, Switzerland, China, European Union |

|                              |                                      |
|------------------------------|--------------------------------------|
| <b>Trademark</b>             | <b>Biofrontera</b> (figurative mark) |
| Registration number          | EM 927921                            |
| Registration date (priority) | 11.09.1998                           |
| Protection period            | 11.09.2018 (after prolongation)      |
| Classes                      | 05, 35, 42                           |

|                              |  |
|------------------------------|--|
| <b>Trademark</b>             | <b>Biofrontera</b> (figurative mark)                                 |
| Registration number          | (Trademark Switzerland) P-467208                                     |
| Registration date (priority) | 06.10.1998 (maintaining priority of trademark EM 927921: 11.09.1998) |
| Protection period            | 06.10.2018 (after prolongation)                                      |
| Classes                      | 5, 35, 42  |

### ***9.10.2 Ameluz® IP***

Ameluz® and the underlying technology is protected by the following marks and patents:

|   |   |
|---|---|
| <b>Trademark</b>                                      | <b>AMELUZ®</b> (wordmark)   |
| Registration number                                   | DE 302008040753   |
| Registration date (priority)                          | 24.06.2008  |
| Protection period                                     | 30.06.2018  |
| Classes   | 5   |
| Registration number of the international registration | IR 1031222  |
| Registration international extension                  | 23.12.2009  |
| Protection period of the international registration   | 23.12.2019  |
| Granted   | Argentina, Germany, European Union, Australia, Norway, Singapore, Russian Federation, USA, Syria, South Korea, Israel, Switzerland, Liechtenstein |
| Pending   | China, Canada   |

|  |  |
|--|--|
| <b>Trademark</b>   | <b>BF-RhodoLED®</b> (wordmark)   |
| Registration number  | DE 302011056690  |
| Registration date (Priority)                               | 17.10.2011   |
| Protection period  | 31.10.2021   |
| Classes  | 10   |
| Registration number of the international registration      | IR 1113422   |
| Registration international extension                       | 16.02.2012 (maintaining priority)  |
| Protection period of the international registration        | 16.02.2022   |
| Countries for which international extension has been filed | Armenia, Australia, China, European Union, Iran, Japan, Norway, Russian Federation, Singapore, Switzerland, South Korea, Syria, USA.                           |
| National registrations                                     | Israel, Canada   |
| Granted  | Armenia, Germany, Australia, Singapore, Norway, European Union, South Korea, Canada, Russian Federation, China, USA, Switzerland, Japan, Israel, Liechtenstein |
| Pending  | Syria, Iran  |

|  |   |
|--|---|
| <b>Trademark</b>   | <b>RHODOLED®</b> (wordmark)   |
| Registration number  | DE 302011056689   |
| Registration date (Priority)                               | 17.10.2011  |
| Protection period  | 31.10.2021  |
| Classes  | 10  |
| Registration number of the international registration      | IR 1111189  |
| Registration international extension                       | 16.02.2012 (maintaining priority)   |
| Protection period of the international registration        | 16.02.2022  |
| Countries for which international extension has been filed | Armenia, Australia, China, European Union, Japan, Norway, Russian Federation, Singapore, Switzerland, South Korea, Syria, USA             |
| National registrations                                     | Israel, Canada  |
| Granted  | Armenia, Germany, Singapore, Australia, Norway, Japan, Syria, Canada, China, South Korea, USA, Russian Federation, European Union, Israel |
| Pending  | Iran  |

|   |                             |
|---|-----------------------------|
| <b>Trademark</b>                                      | <b>Nanoxosan</b> (wordmark) |
| Registration number                                   | DE 302009017727             |
| Registration date (priority)                          | 23.03.2009                  |
| Protection period                                     | 31.03.2019                  |
| Classes   | 5, 1, 3                     |
| Registration number of the international registration | IR 1027173                  |
| Registration international extension                  | 12.11.2009                  |
| Protection period of the international registration   | 12.11.2019                  |
| Granted   | Germany                     |
| Pending   | Austria, Switzerland        |

|   |                              |
|---|------------------------------|
| <b>Trademark</b>                                      | <b>BF-200 ALA</b> (wordmark) |
| Registration number                                   | DE 302008017906              |
| Registration date (priority)                          | 17.03.2008                   |
| Protection period                                     | 17.03.2018                   |
| Classes   | 5, 1, 3                      |
| Registration number of the international registration | IR 1027173                   |
| Registration international extension                  | 09.09.2008                   |
| Protection period of the international registration   | 09.09.2018                   |
| Granted   | Germany                      |
| Pending   | Austria, Switzerland         |

|                              |                          |
|------------------------------|--------------------------|
| <b>Trademark</b>             | <b>Dynala</b> (wordmark) |
| Registration number          | DE 302008040755          |
| Registration date (priority) | 24.06.2008               |
| Protection period            | 30.06.2018               |
| Classes                      | 5                        |
| Granted                      | Germany                  |

|                              |                            |
|------------------------------|----------------------------|
| <b>Trademark</b>             | <b>Lumixeen</b> (wordmark) |
| Registration number          | DE 302008040756            |
| Registration date (priority) | 24.06.2008                 |
| Protection period            | 30.06.2018                 |
| Classes                      | 5                          |
| Granted                      | Germany                    |

|   |   |
|---|---|
| <b>Patent</b>   | <b>Nanoemulsion</b> (used in „Ameluz®“)   |
| <u>International PCT application through WIPO</u><br>(based on an European Patent Office application) |   |
| PCT-application number  | PCT/EP2007/011404   |
| PCT-application date  | 21.12.2007  |
| Priority  | 22.12.2006  |
| Priority number   | 06026698.8 (European Patent Office)   |
| Patents granted (end of protection 21.12.2027)  | European Patent Office, South Africa, China, Mexico, New Zealand, Singapore, Ukraine, Australia, Russia, Japan, Belarus, India, Canada, Chile |
| National examination initiated  | United Arab Emirates, Brazil, Hong Kong, Israel, USA, Uruguay, Argentina, Paraguay  |

|   |  |
|---|--|
| <b>Patent</b>                                     | <b>Nanoemulsion of 5-Aminolevulinic Acid</b>   |
| <u>International PCT application through WIPO</u> |  |
| PCT-application number                            | PCT/EP1999/008711  |
| PCT-application date                              | 12.11.1999   |
| Priority  | 12.11.1998   |
| Priority number                                   | DE19852245   |
| Patents granted (end of protection 12.11.2019)    | European Patent Office (Belgium, Austria, Switzerland, Ireland, Luxembourg, Portugal, Germany), USA, Canada, Australia, Israel |

### ***9.10.3 Belixos® IP***

Belixos® and the underlying technology is protected by the following marks and patents:

|   |  |
|---|--|
| <b>Trademark</b>                                      | <b>Belixos®</b> (Wordmark)   |
| Registration number                                   | DE 302009060491  |
| Registration date (Priority)                          | 14.10.2009   |
| Protection period                                     | 31.10.2019   |
| Classes   | 3  |
| Registration number of the international registration | IR 1033935   |
| Registration international extension                  | 10.02.2010 (maintaining priority)  |
| Protection period of the international registration   | 10.02.2020   |
| National registrations                                | Iraq, Yemen, Kuwait, Lebanon, Libya, Qatar, Saudi Arabia, Tunisia, United Arab Emirates.   |
| Granted   | Armenia, Germany, European Union, Singapore, Lebanon, Australia, USA, Algeria, Bahrain, Egypt, Morocco, Sultan Oman, Sudan, Norway, Kuwait, Tunisia, United Arab Emirates, Japan, Yemen, Brazil, Iran, Iraq, Russian Federation, Saudi Arabia, South Korea |
| Pending   | China, Syria, Switzerland, Libya, Qatar  |

|   |  |
|---|--|
| <b>Trademark</b>                                      | <b>Belixos®</b> (wordmark)   |
| Registration number                                   | DE 302008040757  |
| Registration date (priority)                          | 24.06.2008   |
| Protection period                                     | 30.06.2018   |
| Classes   | 5  |
| Registration number of the international registration | IR 1007314   |
| Registration international extension                  | 27.05.2009   |
| Protection period of the international registration   | 27.05.2019   |
| National registrations                                | Israel, Canada   |
| Protection period of the national registrations       | 01.06.2019, 28.09.2027   |
| Granted   | Germany, Australia, Singapore, Norway, USA, European Union, Russian Federation, Argentina, Canada, South Korea |
| Pending   | Switzerland, China, Israel, Japan, Syria, Iran   |



|                              |   |
|------------------------------|---|
| <b>Trademark</b>             | <b>Natural heritage with herbal biocolloids (colored) (figurative mark)</b> |
| Registration number          | EM 012224192  |
| Registration date (priority) | 15.10.2013  |
| Protection period            | 15.10.2023  |
| Classes                      | 03  |
| Granted                      | EU (Classes 3,5,10), Japan, Australia, Singapore, USA, Switzerland          |
| Pending                      | Brazil  |

|                              |   |
|------------------------------|---|
| <b>Trademark</b>             | <b>Natural heritage with herbal biocolloids (black / white) (figurative mark)</b> |
| Registration number          | EM 012224218  |
| Registration date (priority) | 15.10.2013  |
| Protection period            | 15.10.2023  |
| Classes                      | 03  |
| Granted                      | European Union, Japan, Australia, Singapore, USA, Switzerland                     |
| Pending                      | Brazil  |

|                              |                                |
|------------------------------|--------------------------------|
| <b>Trademark</b>             | <b>Gefühlt mir (word mark)</b> |
| Registration number          | EM 012224267                   |
| Registration date (priority) | 15.10.2013                     |
| Protection period            | 15.10.2023                     |
| Classes                      | 03, 05, 10                     |
| Granted                      | European Union, Switzerland    |

|                               |   |
|-------------------------------|---|
| <b>Patent</b>                 | <b>Pharmaceutical and/or cosmetic composition for treating the skin</b> |
| <u>USA-Patent application</u> |   |
| Application number            | 61322524  |
| Application date              | 09.04.2010  |
| Priority                      | 09.04.2010  |
| Status of proceedings         | Application is published and under examination.                         |

|                             |   |
|-----------------------------|---|
| <b>German utility model</b> | <b>Pharmaceutical and/or cosmetic composition for treating the skin</b>                                       |
| Application number          | DE 20 2010 004 750.1  |
| Application date            | 09.04.2010  |
| Publication date            | 01.12.2011  |
| Period of protection        | Period of protection is prolonged to 6 years from application. Prolongation until up to 10 years is possible. |

#### **9.10.4 Migraine IP**

The migraine related product candidate BF-1 is protected by the following IP:

|   |  |
|---|--|
| <b>Patent</b>                                     | <b>Derivatives of 4-(Thio- or Seleno-xanthene-9-ylidene)- Piperidine or Acridine and its use as a selective 5-HT<sub>2B</sub> Receptor</b>   |
| <u>International PCT application through WIPO</u> |  |
| PCT-application number                            | PCT/EP2002/011817  |
| PCT-application date                              | 23.10.2002   |
| Priority  | 25.10.2001   |
| Priority number                                   | 01125527.0 (European Union)  |
| Patents granted (end of protection 23.10.2022)    | European Union (Austria, Switzerland, Germany, Denmark, Spain, France, United Kingdom, Italy, Netherlands, Sweden, Turkey), Australia, USA, South Africa, Russia, China, USA(CIP), India, South Korea, Japan, Canada |

|  |  |
|--|--|
| <b>Patent</b>                                      | <b>Antimigraine compounds and their use</b>  |
| <u>International PCT- application through WIPO</u> |  |
| PCT- application number                            | PCT/EP2013/052060  |
| Designated states                                  | All PCT-member states are designated.  |
| Status of proceedings                              | International research report completed. National proceedings in USA and European Union. |

### **9.11 Material Agreements**

#### **9.11.1 Manufacturing and research agreements**

Biofrontera Group and Glaropharm AG have entered into manufacturing agreement dated 1 April 2009 for the manufacture and delivery of Ameluz® and Belixos®, pursuant to which

Biofrontera Pharma GmbH has pledged to purchase its total requirements for the first five years and thereafter 80 per cent of its requirements for another two years exclusively from Glaropharm for the products currently marketed under the trade names “Ameluz®” and “Belixos®” for the European market. Glaropharm agreed to produce the products according to a quality assurance agreement concluded between the two parties and will guarantee that the products are manufactured in accordance with the rules and regulations of Switzerland and the European Union and that Glaropharm has all the necessary permits and licenses required for manufacturing. Biofrontera is largely dependent on Glaropharm to produce the products.

A service agreement dated 25 September 2013 was entered into between Biofrontera Bioscience GmbH and Accovion GmbH (“*Accovion*”) concerning project management of a clinical research program. Accovion will provide services under the contract including project management, clinical monitoring, data management, programming of biostatistics and the drawing up of medical assessments and their publication. The agreement is valid until the fulfillment of all project related commitments assigned to Accovion. The study period is 74 months. Accovion and Biofrontera Bioscience GmbH may terminate the project on 30 days’ notice. Biofrontera Bioscience GmbH is exclusively entitled to any intellectual property rights arising in connection with the project. Under the terms of the contract, current estimated costs are between approximately EUR 1.7 million and EUR 2.2 million for Accovion and up to approximately EUR 220,000 in pass-through costs. The total commercial volume of this contract over the entire term is estimated at EUR 2,400,000 plus up to EUR 300,000 for additional consulting services.

In July 2016, the Issuer agreed on a research partnership with Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera Group’s proprietary nanoemulsion technology are to be researched. Ameluz® was developed with a similar strategy. The nanoemulsion technology stabilized the active substance and improved skin penetration, leading to greater clinical efficacy. According to the agreement, Maruho will bear all costs connected with the exploratory research of for new product candidates. It is planned that Maruho will be the owner of the new products and that Biofrontera will receive the license to market in Europe. In some cases of a change of control Maruho has the right but not an obligation to terminate the cooperation agreement. This development partnership generated revenue of EUR 785 thousand in the first half of 2017.

#### **9.11.2 EIB Credit Facility**

On 19 May 2017, the Issuer entered into a finance contract with the European Investment Bank (EIB) (“*EIB Credit Facility*”), whereby EIB has committed to lend an amount of up to EUR 20 million to the Issuer. The loan terms of the EIB Credit Facility specify that the amounts drawn shall be used to finance up to approximately 50% of specified research and development expenses forecast to be made by Biofrontera Group between 2017 and 2020. The key terms of the EIB Credit Facility are as follows:

The EIB Credit Facility can be drawn in tranches of EUR 5 million, each of which matures 5 years from the scheduled date of disbursement for the relevant tranche. The final availability date for the EIB Credit Facility is 19 May 2019. At the date of this prospectus, the Issuer has drawn down two tranches in an amount of EUR 10 million. The two remaining tranches of EUR 5 million require the following milestones to be reached: (i) revenues of EUR 15 million on a 12-months rolling basis, and (ii) revenues of EUR 35 million on a 12 months rolling basis and a raise of at least EUR 5 million in equity.

There are three components to the interest the Issuer pays under the EIB Credit Facility: (i) floating interest payments each quarter based on a rate per annum equal to EURIBOR plus 4.00%; (ii) deferred interest payable in full when the relevant tranche matures, which accrues at a rate of 6.0% per annum; (iii) “performance participation interest” linked to the development of the market capitalization of the Issuer, payable in full when the relevant tranche matures, in an amount equal to the product of (x) the percentage that EIB would hold in the shares of the Issuer if EIB had acquired shares at the disbursement date of the respective tranche instead of granting the loan (notional equity proportion) multiplied by (y) the Issuer’s market capitalization on the maturity date of the respective tranche. For the tranches -drawn down by the Issuer, the notional equity proportion is 0.64% in total. This last component effectively reflects the increase in value that an equity investment in an equal amount of the debt investment by EIB would have had (and, for the avoidance of doubt, is therefore solely linked to the development of the Issuer’s market capitalization and not to other performance indicators).

The EIB Credit Facility provides for certain covenants. In particular, the Issuer may generally not incur additional third-party debt of more than EUR 1 million without EIB consent. Furthermore, the Issuer has – inter alia – agreed to refrain from granting securities, loans and guarantees as well as from disposing of assets or subsidiaries or changing its business. The Issuer is further under an obligation to report on the research to be financed by the EIB Credit Facility.

In certain events of default, EIB may request an immediate repayment of the EIB Credit Facility.

### **9.11.3 ADS Agreement**

In the context of the potential US Offer, the Issuer has entered into an agreement regarding the creation of so-called American Depositary Shares (“**ADSs**”). ADSs are certificates that that can be traded on US exchanges, and represent non-US securities, in particular shares. ADSs may be securitized in certificates referred to as American Depositary Receipts (“**ADRs**”). The terms ADR and ADS are widely used interchangeably. ADSs are created by a US financial institute (the depositary) issuing the ADRs. Prior to the issue, shares in a sufficient amount to cover the ADSs are deposited with a custodian for the account of the depositary.

In the context of the envisaged US Offer, the Issuer has entered into an agreement regarding the creation of ADSs with the Bank of New York Mellon Corp., 225 Liberty Street, New York, NY

10286, United States acting as depositary (“*Depositary*”), with Bank of New York Mellon SA/NV, Asset Servicing, Niederlassung Frankfurt am Main; Friedrich-Ebert-Anlage 49, 60308 Frankfurt am Main, acting as custodian (“*Custodian*”) (“*ADS Agreement*”).

This prospectus does not apply to the ADSs or the ADRs. The ADSs and the ADRs are exclusively offered in the US in the context of a private placement.

## **9.12 Investments**

The Issuer’s investments in the period covered by the historical financial information were centered around research and development activities. The research and development expenses mainly consist of expenses incurred in developing, testing, manufacturing and seeking regulatory approval relating to both the admission process with the FDA as well as the indication extension to the treatment of basal cell carcinoma with the EMA. Details regarding investments made are set out below under 9.13.

No significant investments in property, plant and equipment were made during the period covered by the historical financial information.

The Issuer is making ongoing investments into research activities under the research agreement with Maruho. These activities are on an ongoing basis, with no fixed sum budgeted to them.

The Issuer has not resolved on specific material investments at the date of this prospectus.

## **9.13 Research and development**

### ***9.13.1 Fiscal year 2015***

The research and development amounted to EUR 6,204 thousand in the 2015 financial year. The investment in research and development to extend the range of indications and obtain approval for Ameluz® in the USA remained constant compared to the previous year, but in addition, a submission fee (“*PDUFA fee*”) of EUR 2,072 thousand was paid for the submission of the approval application to the FDA. This fee was refunded by the FDA in March 2016.

Research in the fiscal year 2015 was focused on a phase-III clinical study for the extension of the indication of Ameluz® to the treatment of BCC. The clinical trials were completed in November 2015, and the results became available in January 2016. As a result of the study, the approval was extended to the treatment of BCC in January 2017.

### ***9.13.2 Fiscal year 2016***

In 2016, Biofrontera Group has continued to invest in research and development and the further development of its products. Research and development costs amounted to EUR 4,640 thousand, a reduction of EUR 1,564 thousand, or 25%, as compared to 2015. The decrease mainly reflects the

EUR 2,072 thousand submission fee (PDUFA fee) paid upon submission of the application for approval to the FDA during the first half of 2015. The FDA reimbursed this fee in March 2016.

In June 2016, Biofrontera Group launched a phase-III clinical study with Ameluz® in daylight therapy. The last patient completed the trial in December 2016.

In July 2016, Biofrontera Group agreed a research partnership with Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera Group's proprietary nanoemulsion technology are to be researched (for details, see above 9.11).

### **9.13.3 Fiscal year 2017**

In the current fiscal year, Biofrontera Group completed a phase-III-study regarding daylight therapy, and filed an application regarding the extension of the approval of Ameluz® for daylight treatment to the European Commission. The increase of research costs EUR 2,185 thousand is mainly due to the research partnership with Maruho, which requires increased research activities.

### **9.14 Environmental issues**

Biofrontera Group does not hold property, plants or equipment that might cause environmental issues.

### **9.15 Legal and arbitration proceedings**

During the period of the previous twelve months, no governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Issuer is aware) have nor have had in the past any significant effects on the Issuer and/or Biofrontera Group's financial position or profitability.

The Issuer wishes to note, though, that Deutsche Balaton AG brought a lawsuit for rescission and nullity against the resolutions passed by the Issuer's annual general meeting on 24 May 2017 under agenda item 2 (resolution concerning the discharge of the management board members for the 2016 financial year) and agenda item 6 (resolution concerning adding a new section 7 (3b) to the Issuer's articles of association (authorized capital II with the possibility to exclude subscription rights for fractional amounts and pursuant to sec. 186 (3)(4) of the German Stock Corporation Act)). The lawsuit pending before the Cologne District Court is registered under file reference 82 O 66/17. In the opinion of the Issuer, the lawsuit is not merited. Even if the claimant was successful, the results are not expected to have a significant effect on the Issuer or Biofrontera Group's financial position or profitability.

### **9.16 Significant change in the Issuer's financial or trading position**

Since Biofrontera Group is currently not generating profits, Biofrontera Group's working capital and equity are significantly lower than on 30 June 2017, i.e. the end of the last financial period for which audited financial information or interim financial information have been published.

No further significant change in the Issuer's or Biofrontera Group's financial or trading position has occurred since 30 June 2017, i.e. the end of the last financial period for which audited financial information or interim financial information have been published.

## **10. Tax**

### **10.1 General responsibility for withholding tax**

When paying out dividends, the Issuer is generally obliged to levy withholding tax (*Kapitalertragsteuer*) at a rate of 25% on the amount of the distribution. A solidarity surcharge of 5.5% is also levied on the withholding tax amount, resulting in a total withholding of 26.375% (plus church tax, if any). The Issuer assumes liability for withholding of taxes from sources on distributions, in accordance with statutory provisions. This means that the Issuer is released from liability for the violation of its legal obligation to withhold and transfer the taxes from the sources if it provides evidence that it has not breached its duties intentionally or grossly negligent.

### **10.2 Taxation in Germany**

The following sections describe a number of key German taxation principles that may be relevant to purchasing, holding or transferring the shares. The information provided does not constitute a comprehensive or definitive explanation of all possible aspects of taxation in this area. This summary is based on applicable German tax law as of the date hereof, including the double taxation treaties that Germany has concluded with other countries. It should be noted that the legal situation may change, including, in certain cases, with retroactive effect.

Persons interested in purchasing shares should seek advice from their own tax counsel regarding the tax implications of purchasing, holding, disposing, donating and bequeathing shares, and the regulations on reclaiming previously withheld withholding tax (*Kapitalertragsteuer*). Due consideration to a shareholder's specific tax-related circumstances can only be given within the scope of an individual tax consultation.

#### **10.2.1 Taxation of the Issuer**

The earnings of entities with seat or place of management in Germany are subject to corporate income tax of 15.0% plus a solidarity surcharge (*Solidaritätszuschlag*) of 5.5% of this amount (that is, a total

tax rate of 15.825%). In addition, income generated at their German permanent establishments is also usually subject to trade tax of between 7.0% and 17.5%, depending on the multiplier applied by the relevant municipal authority. Trade tax is generally based on the taxable income as determined for corporate income tax purposes taking into account, however, certain add-backs and deductions.

In principle, dividends that a company receives from German or foreign corporations are effectively 95% exempt from corporate tax. An amount equal to 5% of such receipts are treated as non-deductible business expenses and are subject to corporate tax (and solidarity surcharge (*Solidarit tszuschlag*) thereon) at a rate of 15.825%. However, dividends that the Issuer receives from German or foreign corporations after 28 February 2013, are no longer exempt from corporate tax (including solidarity surcharge thereon), if the Issuer holds a direct participation of less than 10% in the share capital of such corporation at the beginning of the calendar year (hereinafter in all cases, a “**Portfolio Participation**” – *Streubesitzbeteiligung*). The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the purpose of this rule. Losses on disposals are not tax deductible. Participations in the share capital of other corporations which the Issuer holds through a partnership, including co-entrepreneurships (*Mitunternehmenschaften*), are attributable to the Issuer only on a *pro rata* basis at the ratio of the interest share of the Issuer in the assets of relevant partnership.

The Issuer’s gains from the disposal of shares in a German or foreign corporation are in general effectively 95% exempt from corporate income tax (including the solidarity surcharge thereon), regardless of the size of the participation and the holding period. 5% of the gains are treated as non-deductible business expenses and are therefore subject to corporate income tax (plus the solidarity surcharge thereon) at a rate of 15.825%. Conversely, losses incurred from the disposal of such shares are generally not deductible for corporate income tax purposes. Currently, there are no specific rules for the taxation of gains arising from the disposal of Portfolio Participations.

In principle, profits derived from the sale of shares in another domestic and foreign corporation are treated in the same way for trade tax purposes as for corporate income tax. In contrast, dividends derived from German and foreign corporations are only effectively 95% exempt from trade tax, if, among other things, the company that is receiving the dividends has held or holds a stake of at least 15% in the share capital of the company making the distribution at the beginning or – in the case of foreign corporations – since the beginning of the assessment period. In the case of distributing companies domiciled in another member state of the European Union, a stake of 10% at the beginning of the assessment period is sufficient. Additional limitations apply with respect to shares in profits received from non-EU corporations and it is currently unclear whether and to what extent such additional limitations also apply to EU corporations. Otherwise, profits resulting from shares in corporations are fully subject to trade tax.



The earning-stripping rules (*Zinsschranke*) limit the degree to which interest expenses are tax deductible. Hence, for corporate income and trade tax purposes, if no exception to the rules on interest deduction limits applies, net interest expense is only deductible in an amount of up to 30% of attributable EBITDA for tax purposes (*verrechenbares EBITDA*) in the given fiscal year. Nondeductible interest expense can be carried forward. Attributable EBITDA that has not been fully utilised can be carried forward to and utilised in the subsequent five-year period if certain prerequisites are met. For the purpose of trade tax, however, the deductibility of interest expenses is further restricted: since 25% of the interest expense, to the extent it was deductible for income tax purposes and not subject to the interest deduction limits, is added back to compute the trade tax base, the deductibility amounts to only 75%.

While there is no limit on carrying over tax loss carryforwards, they can only be fully offset against taxable income up to €1 million in each year. In addition, 60% of the portion of taxable income exceeding this amount can be offset against existing and usable tax loss carryforwards; 40% is subject to corporate income tax and trade tax at the applicable rates.

If, directly or indirectly, more than 50% of a company's shares or voting rights are transferred to a purchaser (including parties related to the purchaser and a group of purchasers whose interests are aligned) or a similar transfer occurs within five years, all of the company's as yet unused loss carryforwards and interest carryforwards lapse and any losses accrued during the current fiscal year until the relevant transfer may not be offset against future profits. If, directly or indirectly, more than 25% up to and including 50% of the shares or voting rights are transferred to a purchaser (including parties related to the purchaser and a group of purchasers whose interests are aligned), the loss carryforwards, the interest carryforwards, or accrued losses pertaining to the current fiscal year are forfeited only in proportion to the shares or voting rights transferred.

### **10.2.2 Taxation of Shareholders**

Shareholders of the Issuer are subject to taxation in connection with the holding of shares (see “—*Taxation of Dividends*”), the disposal of shares (see “—*Taxation of Capital Gains*”) and the gratuitous transfer of shares (see “—*Inheritance and Gift Tax*”).

#### **10.2.2.1 Taxation of Dividends**

When paying out dividends, the Issuer is generally obliged to levy withholding tax (*Kapitalertragsteuer*) at a rate of 25% on the amount of the distribution. A solidarity surcharge of 5.5% is also levied on the withholding tax amount, resulting in a total withholding of 26.375% (plus church tax, if any). The assessment basis for the withholding tax is the dividend approved by the general shareholders' meeting.

The withholding tax is generally withheld regardless of whether and to what extent the dividend is exempt from tax at the shareholder's level and whether the shareholder is a resident of Germany or elsewhere. If shares – as it is the case with the shares in the Issuer – are admitted to be held in collective safe custody (*Sammelverwahrung*) with a central securities depository (*Wertpapiersammelbank*) pursuant to § 5 German Act on Securities Accounts (*Depotgesetz*) and are entrusted to such central securities depository for collective safe custody in Germany, the withholding tax is withheld and discharged for the account of the shareholders by the domestic credit or financial services institution (*inländisches Kredit- oder Finanzdienstleistungsinstitut*) (including domestic branches of foreign credit and financial services institutions), by the domestic securities trading company (*inländisches Wertpapierhandelsunternehmen*) or the domestic securities trading bank (*inländische Wertpapierhandelsbank*) which keeps and administers the shares and disburses or credits the dividends or disburses the dividends to a foreign agent or by the central securities depository to which the shares were entrusted for collective safe custody if the dividends are disbursed to a foreign agent by such central securities depository (hereinafter referred to jointly or separately as “Dividend Paying Agent”). The Issuer assumes responsibility for the withholding of taxes (with the exception of church tax) on distributions, in accordance with statutory provisions. This means that the Issuer is released from liability for the violation of its legal obligation to withhold and transfer the taxes if it provides evidence that it has not breached its duties intentionally or through gross negligence.

However, if monies from the tax contribution account (*steuerliches Einlagekonto*) are to be used for the distribution, the dividend payment is generally, subject to certain prerequisites, tax exempt and not subject to withholding tax. Nevertheless, dividends lower the acquisition costs of the shares, which may result in a greater amount of taxable capital gain upon the shareholder's sale of the shares. To the extent that dividends from the tax-recognised contribution account exceed the then lowered acquisition costs of the shares, a capital gain is recognised by the shareholder, which may be subject to tax in accordance with the provisions outlined below.

In the case of dividends paid to a company domiciled in another European Union member state and subject to the Council Directive 2011/96/EU dated 30 November 2011 (the “**Parent- Subsidiary Directive**”), upon request and provided that other conditions are also met, including, e.g. the minimum holding requirement of 10% and substance requirements of the German anti-treaty shopping rules, the withholding tax is reduced to zero. The same applies to dividends paid to a permanent establishment of such company located in another European Union member state and to dividends paid to a permanent establishment of a German parent company located in another European Union member state if the shares in the Issuer are classified as business assets of the respective permanent establishment for tax purposes. In certain additional cases, companies domiciled in another European Union or European Economic Area member state may be entitled to a refund of withholding tax, even though the minimum holding requirements of the Parent-Subsidiary Directive are not met.

In the case of dividends paid to other foreign shareholders, a reduced withholding tax rate may be applied (usually a rate of 15%) if the respective shareholder can claim the benefits of a double taxation treaty concluded between its country of residence and Germany and assuming other conditions are met, including substance requirements of the German anti-treaty shopping rules.

The reduction of the withholding tax rate generally does not affect the obligation to comply with withholding obligations. However, an application may be filed with the Federal Central Tax Office (*Bundeszentralamt für Steuern*) for a refund of the difference between the withholding tax withheld and the maximum rate stipulated in the double taxation treaty or the zero rate of the Parent-Subsidiary Directive. The shareholder must submit a certificate, issued by the institution that withheld the tax, together with the completed application form to receive a refund. Alternatively, withholding tax does not have to be withheld if, prior to the distribution, the tax authorities have issued a (partial) exemption certificate upon application. If dividends are paid to corporations with limited tax liability in Germany, that is, corporations with no seat and no place of management in Germany, then two-fifths of the withholding tax withheld as well as two-fifths of the solidarity surcharge thereon at source can be refunded, subject to certain restrictions. This refund is permissible irrespective of the applicability of any double taxation treaty or the fulfilment of the requirements set forth in the Parent-Subsidiary Directive. Nevertheless, certain conditions have to be met, including substance requirements of the German anti-treaty shopping rules. The foreign corporation must file an application form with the Federal Central Tax Office (*Bundeszentralamt für Steuern*).

#### 10.2.2.1.1 *Shareholders Tax Resident in Germany*

##### Shares Held as Part of the Private Assets of Individuals

The tax liability applicable to dividend payments to individual shareholders who are German tax residents and who hold shares as part of their private assets is generally satisfied by withholding a flat tax (*Abgeltungsteuer*) of 25% plus solidarity surcharge of 5.5% thereon, resulting in a total tax rate of 26.375% (plus church tax, if any) as described above (see “—*Taxation of Dividends*”). Income-related expenses incurred in connection with private investment income are not tax deductible. The only deduction that may be made is an annual flat-rate savings allowance of €801 (€1,602 for joint-filing spouses) on all private capital income. Shareholders may apply for the whole amount of their capital income, including dividends, to be taxed at the income tax rate based on their personal circumstances instead of the flat-rate withholding tax if this results in a lower tax liability. In such cases, it is also not possible to deduct any income-related expenses other than the flat-rate savings allowance. Furthermore, dividend income can only be offset by losses from capital income, except for losses generated by the disposal of shares. Shareholders may be liable for church tax, which is generally determined by means of an income tax assessment. However, shareholders may generally request that the domestic paying agent (the “**Domestic Paying Agent**”) withholds church tax in order to satisfy

this church tax liability. With regards to capital gains received after 31 December 2014, the Act on the Implementation of the Recovery Directive (*Beitreibungsrichtlinie- Umsetzungsgesetz*) of 7 December 2011 provides for an automatic procedure for deduction of church tax by way of withholding unless the shareholder has filed a blocking notice (*Sperrvermerk*) with the Federal Central Tax Office.

Individual shareholders who privately hold, directly or indirectly, an interest of at least 25% in the Issuer, and shareholders who privately hold, directly or indirectly, at least 1% in the Issuer and work for the Issuer, may request an exemption from the flat-rate withholding tax. In this case, 60% of the dividends paid to the shareholder is subject to income tax according to the applicable rate plus solidarity surcharge. Expenses incurred in connection with dividend income are generally 60% tax-deductible. The levied withholding tax is offset against the income tax and any excess withholding is refunded. Dividend payments that are made using funds from the tax contribution account (*steuerliches Einlagekonto*) are generally, subject to certain prerequisites, tax exempt.

Through 2014, shareholders who pay church tax and hold shares as private assets may request the Domestic Paying Agent that pays out their capital investment income to withhold their church tax according to the church tax legislation of their state and remit it to the relevant tax authority. As of 1 January 2015, entities required to collect withholding taxes on capital investment income are required to likewise withhold the church tax on shareholders who pay church tax, unless the shareholder objects in writing to the German tax authorities sharing his private information regarding his affiliation with a denomination. If church tax is withheld and remitted to the tax authority as part of the withholding tax deduction, then the church tax on the dividends is also deemed to be discharged when it is deducted. The withheld church tax cannot be deducted in the tax assessment as a special expense; however, 26.375% of the church tax withheld on the dividends is deducted from the withholding tax (including the solidarity surcharge) withheld by the Issuer. If no church taxes are withheld along with the withholding of capital gains tax, the shareholder who pays church tax is required to report his dividends in his income tax return. The church tax on the dividends will then be imposed during the assessment.

### **Shares Held as Part of the Business Assets of Corporations**

Dividends paid to corporations that are German tax residents are generally exempt from tax, provided that the incorporated entity holds a direct participation of at least 10% in the share capital of the company that is paying the dividend at the beginning of the calendar year in which the dividends are paid. The acquisition of a participation of at least 10% in the course of a calendar year is deemed to have occurred at the beginning of such calendar year for the purpose of this rule. Participations in the share capital of the company which a corporate shareholder holds through a partnership, including co-entrepreneurships (*Mitunternehmenschaften*), are attributable to such corporate shareholder only on a *pro rata* basis at the ratio of the interest share of the corporate shareholder in the assets of relevant partnership. However, 5% of the tax-exempt dividends are treated as non-deductible operating

expenses and are subject to tax. Business expenses actually incurred in connection with dividend income from a tax perspective are generally tax-deductible. For trade tax purposes, dividends are only exempt as described above if the entity that is receiving the dividends held a stake of at least 15% in the share capital of the Issuer at the beginning of the assessment period. Otherwise, the dividends will be fully subject to trade tax. The withholding tax withheld is offset against the corporate income tax due and any excess withholding is refunded. The same applies to the solidarity surcharge, which is levied in addition to the corporate income tax. Dividend payments that are made using funds from the tax contribution account (*steuerliches Einlagekonto*) are generally, subject to certain prerequisites, tax-exempt.

#### **Shares Held as Part of the Business Assets of Sole Proprietors**

60% of the dividends paid to individuals who are German tax residents and who hold shares as part of their business assets is subject to income tax according to the applicable rate. A solidarity surcharge of 5.5% of this amount also applies. The levied withholding tax is offset against the personal income tax due and any excess amount is refunded. The same applies to the solidarity surcharge. Business expenses incurred in connection with dividend income from a tax perspective are generally only 60% tax-deductible. The dividends are also subject to trade tax, which is fully or partly credited towards the individual's income tax by a lump-sum method. The dividends are exempt from trade tax, provided that the shareholder held at least 15% of the Issuer's share capital at the beginning of the relevant assessment period. Dividend payments that are made using funds from the tax contribution account (*steuerliches Einlagekonto*) are generally, subject to certain prerequisites, tax-exempt.

#### **Shares Held as Part of the Business Assets of a Commercial Partnership**

Income tax or corporate income tax (including solidarity surcharge) is not levied at the level of the partnership (*Mitunternehmerschaft*) but rather at the level of the respective partner. The level of taxation for each partner depends on whether the partner is a corporation or an individual. If the partner is a corporation, the dividends contained in its profit share are taxed in accordance with the principles applicable to corporations (see “—*Shares Held as Part of the Business Assets of Corporations*” above). If the partner is an individual and the shares are held as business assets of the partnership, dividends contained in their profit share are taxed in accordance with the principles applicable to sole proprietors (see “—*Shares Held as Part of the Business Assets of a Sole Proprietor*” above). Subject to certain conditions, an individual partner may request that its personal income tax be lowered for earnings not withdrawn from the partnership. If the partnership is liable for trade tax, it is levied at the level of the partnership. If an individual holds an interest in the partnership, the proportionate trade tax may be credited fully or partly towards the individual's income tax by means of a lump-sum method.

#### **Shares Held as Part of the Assets of Certain Companies in the Financial and Insurance Sector**

The tax exemption applicable to dividends does not apply to dividends paid to certain companies in the financial and insurance sector.

Dividends from shares that are, pursuant to Article 4 no. 86 of the Commission Regulation 575/2013 of 26 June 2013, part of the trading books of banks and financial services institutions, as well as dividends from shares that are acquired by certain financial enterprises in the meaning of the German Banking Act (*Gesetz über das Kreditwesen*) with the aim of generating a short-term proprietary trading profit, are fully liable for corporate income tax (plus solidarity surcharge). If the stake held at the beginning of the relevant assessment period is 15% or higher, subject to certain conditions, the dividends can be fully exempted from trade tax. Dividends from shares that are classified as investments in the case of life insurers, health insurers and pension funds are fully subject to corporate income tax and trade tax. However, an exemption to the foregoing, and thus a 95% effective tax exemption, applies to dividends obtained by the aforementioned companies, to which the Parent-Subsidiary Directive applies.

#### *10.2.2.1.2 Shareholders Tax Resident Outside Germany*

Dividends paid to shareholders who are not German tax residents (individuals and corporations) are generally subject to German taxation.

If the shares are held as part of business assets in Germany (that is, via a permanent establishment or as part of business assets for which a permanent representative in Germany has been appointed), the provisions outlined above with respect to the taxation of shareholders that are German tax residents principally apply accordingly. The withholding tax and solidarity surcharge that is withheld at source and remitted to the German tax authorities will be credited towards the shareholder's income tax or corporate income tax liability or refunded in the amount of any excess paid. In all other cases, the tax liability of the dividends is settled via the withholding tax plus the solidarity surcharge (which may be reduced pursuant to an applicable double taxation treaty, the Parent-Subsidiary Directive or under national tax laws).

#### *10.2.2.2 Taxation of Capital Gains*

##### *10.2.2.2.1 Shareholders Tax Resident in Germany*

###### *Shares Held as Part of the Private Assets of Individuals*

Capital gains are classified as income from capital investments and are subject to income tax (plus solidarity surcharge and church tax, if any) irrespective of how long the shares have been held. If the shares are held in custody or administered by a domestic credit institution, domestic financial services institution, domestic securities trading company or a Domestic Paying Agent, including domestic branches of foreign credit institutions or financial service institutions, or if such an office executes the



disposal of the shares and pays out or credits the capital gains, the tax on the capital gains will in general be discharged for the account of the seller by the Domestic Paying Agent imposing the withholding tax on investment income at the rate of 25% (plus 5.5% solidarity surcharge, resulting in a total withholding of 26.375%, and church tax, if any) in the case of shares held as private assets. The taxable capital gain is calculated by deducting the acquisition costs of the shares and the expenses directly related to the disposal from the proceeds of the disposal.

A shareholder's income tax and solidarity surcharge liability is generally satisfied through the withholding of the withholding tax. Shareholders may, however, request that a tax assessment be carried out on their income from capital investments if this results in a lower tax liability. Income from capital investments may be reduced only by a flat-rate savings allowance of €801 (€1,602 for joint-filing spouses); it is not possible to further deduct income-related expenses actually incurred except for expenses incurred directly in connection with the disposal. Capital gains generated by the disposal of shares can be offset against any type of losses from capital investment income while capital losses incurred on the disposal of shares can only be offset against capital gains from the disposal of shares.

Through 2014, shareholders who pay church tax and hold shares as private assets may request the Domestic Paying Agent that pays out their capital investment income to withhold their church tax on the capital gain according to the church tax legislation of their state and remit it to the relevant tax authority. As of 1 January 2015, entities required to collect withholding taxes on capital investment income are required to likewise withhold the church tax on shareholders who pay church taxes, unless the shareholder objects in writing to the German tax authorities sharing his private information regarding his affiliation with a denomination. If church tax is withheld and remitted to the tax authority as part of the withholding tax deduction, then the church tax on the capital gain is also deemed to be discharged when it is deducted. The withheld church tax cannot be deducted in the tax assessment as a special expense; however, 26.375% of the church tax withheld on the capital gain is deducted from the withholding tax (including the solidarity surcharge) withheld by the Issuer.

If the shareholder making the disposal – or, in the event of a sale of shares acquired without consideration, its legal predecessor – held a direct or indirect stake of at least 1% in the Issuer's share capital at any time in the five years preceding the disposal, any capital gains realised are deemed to be trading income such that the withholding tax levied on the capital gains does not satisfy the tax liability. The capital gains are 60% taxable at the individual tax rate of the shareholder. The withholding tax and solidarity surcharge withheld are credited towards the shareholders' tax liability or refunded in the amount of any excess paid on their tax assessment.

#### **Shares Held as Part of the Business Assets of an Incorporated Entity**

Gains from the disposal of shares held by incorporated entities that are German tax residents are generally not subject to withholding tax and are in principle exempt from corporate income tax and trade tax. However, 5% of the capital gains are deemed non-deductible business expenses and are thus

subject to corporate income tax (plus solidarity surcharge) and – if the shares are held as part of the commercial business assets in Germany – to trade tax. Consequently, capital gains are generally 95% exempt from tax. As a rule, losses on disposals and other profit reductions in connection with the shares sold may not be deducted as business expenses.

#### **Shares Held as Part of the Business Assets of a Sole Proprietor**

Gains from the disposal of shares held by individuals are not subject to withholding tax if the disposal proceeds are part of the business income of a business based in Germany and the shareholder declares this fact to the Domestic Paying Agent on the designated official form. If the withholding tax and solidarity surcharge have been withheld, this does not satisfy the tax liability with respect to gains from the disposal of shares held as part of the business assets. Amounts withheld are instead credited towards the seller's income tax (plus solidarity surcharge) liability or refunded in the amount of any excess paid. 60% of the gains from the disposal of the shares is subject to income tax (plus solidarity surcharge and church tax, if any) at the individual tax rate of the shareholder and – if the shares are held as part of commercial business assets in Germany – to trade tax. The trade tax is (partially) credited to the shareholder's personal income tax by means of a lump-sum method. Generally, only 60% of the losses on disposals and business expenses commercially linked to the shares sold may be deducted.

#### **Shares Held as Part of the Business Assets of a Commercial Partnership**

Income tax or corporate income tax is not levied at the level of the partnership (*Mitunternehmerschaft*) but at the level of the respective partner. If shares are held as business assets of the partnership, taxation is determined as if the partner held a direct interest in the Issuer, according to the rules outlined above depending on whether the partner is a corporation (see “— *Taxation of Shareholders—Taxation of Dividends—Shareholders Tax Resident in Germany—Shares Held as Part of the Business Assets of Corporations*”) or an individual (see “— *Taxation of Shareholders—Taxation of Dividends—Shareholders Tax Resident in Germany—Shares Held as Part of the Business Assets of Sole Proprietors*”). Upon request and subject to further conditions, a partner that is an individual may, subject to certain conditions, have its personal income tax lowered for earnings not withdrawn from the partnership.

For a partnership, capital gains are subject to trade tax if the shares are part of the business assets of a German business operation of the partnership. 5% of these gains are subject to trade tax insofar as they relate to the profit share of a partner that is a corporation and 60% insofar as they relate to the profit share of a partner that is an individual. In the latter case, the trade tax is (partially) credited to the partner's personal income tax by means of a lump-sum method.

#### **Shares Held as Part of Assets of Certain Companies in the Financial and Insurance Sector**



Capital gains realised by certain companies in the financial and insurance sector are, as an exception to the aforementioned rules, fully taxable (see “—*Shares Held as Part of the Assets of Certain Companies in the Financial and Insurance Sector*” above). This applies to gains from the disposal of shares in the trading books of banks and financial services companies, to gains from the disposal of shares that were acquired by financial enterprises with the aim of generating a short-term proprietary trading profit, as well as to gains from the disposal of shares held as investments by life insurers, health insurers and pension funds.

#### 10.2.2.2.2 *Shareholders Tax Resident Outside Germany*

Gains from the disposal of shares held by shareholders that are not German tax residents as part of German business assets (that is, via a permanent establishment or as part of business assets for which a permanent representative in Germany has been appointed), are taxed in Germany principally according to the same provisions that apply to the taxation of shareholders that are German tax residents as described above.

Otherwise, capital gains realised by shareholders that are not German tax residents are taxable in Germany only if the shareholder making the disposal – or, in the event of shares acquired without consideration, their legal predecessor – held a direct or indirect stake of at least 1% in the Issuer’s share capital at any time in the five years preceding the disposal. As a general rule, double taxation treaties concluded by Germany often provide for full exemption from German taxation in such cases and assign fiscal jurisdiction to the shareholder’s country of residence. However, certain double taxation treaties contain special provisions for shareholdings in real estate companies subjecting the taxation of capital gains to the same rules applying to shareholders resident in Germany. If tax is levied in Germany and the shareholder is a corporation, generally no more than 5% of the capital gains will ultimately be subject to corporate income tax and the solidarity surcharge. In the case of individuals, by contrast, 60% of the gains from the disposal of the shares is subject to income tax (plus solidarity surcharge). Losses on disposals and other profit reductions or expenses incurred in connection with the shares may be deducted only to a limited extent in line with the principles outlined above. The German tax authorities have ruled that generally no withholding tax needs to be deducted by a Domestic Paying Agent in such cases. However, if the capital gain is subject to tax in Germany, the shareholder is required to file a tax return and pay such taxes.

#### 10.2.2.3 Inheritance and Gift Tax

The transfer of shares to another person upon death or as a gift is generally subject to German inheritance or gift tax in the following circumstances:

(i) the place of residence, customary place of abode, place of management or registered office of the testator, the donor, the heir, the donee or another acquirer is, at the time of the asset transfer, in Germany, or such person, as a German national, has not spent more than five consecutive years

outside of Germany without having a place of residence in Germany (this term is extended to ten years for German expatriates with U.S. residence);

(ii) the testator's or donor's shares were part of business assets for which there was a place of business in Germany or for which a permanent representative was appointed; or

(iii) the testator, at the time of death, or the donor with place of management or registered office in Germany, when the gift was made, held a direct or indirect interest of at least 10% of the Issuer's share capital either alone or jointly with other persons closely connected to them.

The small number of double taxation treaties regarding inheritance and gift tax that Germany has concluded to date generally provide for German inheritance or gift tax only to be levied in the cases under (i) and, subject to certain restrictions, in the cases under (ii). Special arrangements apply to certain German nationals and former German nationals living outside Germany.

#### 10.2.2.4 Other Taxes

No German capital transfer tax, value added tax, stamp duty or similar taxes are levied on the purchase or disposal of shares or other forms of share transfer. Wealth tax is currently not levied in Germany. However, an entrepreneur can opt to pay value-added tax on the sale of shares, despite being generally exempt from value-added tax, if the shares are sold to another entrepreneur for the entrepreneur's business

On 22 January 2013, the Council of the EU approved the resolution of the ministers of finance from 11 member states (including Germany) to introduce a financial transaction tax within the framework of enhanced cooperation. On 14 February 2013, the European Commission accepted the Proposal for a Council Directive implementing enhanced cooperation in the area of financial transaction tax. The plan focuses on levying a financial transaction tax of 0.1% (0.01% for derivatives) on the purchase and sale of financial instruments. The directive awaits the unanimous agreement of the 11 participating member states.

### **10.3 Taxation in Luxembourg**

The following information is of a general nature only and is based on the laws in force in Luxembourg as of the date of this prospectus. It does not purport to be a comprehensive description of all the tax considerations that might be relevant to an investment decision. It is included herein solely for preliminary information purposes. It is not intended to be, nor should it be construed to be, legal or tax advice. It is a description of the essential material Luxembourg tax consequences with respect to the Offering and may not include tax considerations that arise from rules of general application or that are generally assumed to be known to shareholders. This summary is based on the laws in force in Luxembourg on the date of this prospectus and is subject to any change in law that may take effect

after such date. Prospective shareholders should consult their professional advisors with respect to particular circumstances, the effects of state, local or foreign laws to which they may be subject, and as to their tax position. Please be aware that the residence concept used under the respective headings applies for Luxembourg income tax assessment purposes only. Any reference in the present section to a tax, duty, levy impost or other charge or withholding of a similar nature refers to Luxembourg tax law and/or concepts only. Also, please note that a reference to Luxembourg income tax encompasses corporate income tax (*impôt sur le revenu des collectivités*), municipal business tax (*impôt commercial communal*), a solidarity surcharge (*contribution au fonds pour l'emploi*), as well as personal income tax (*impôt sur le revenu*) generally. Corporate shareholders may further be subject to net wealth tax (“NWT”) (*impôt sur la fortune*) as well as other duties, levies or taxes. Corporate income tax, municipal business tax as well as the solidarity surcharge invariably apply to most corporate taxpayers resident in Luxembourg for tax purposes. Individual taxpayers are generally subject to personal income tax and the solidarity surcharge. Under certain circumstances, where an individual taxpayer acts in the course of the management of a professional or business undertaking, municipal business tax may apply as well.

### **10.3.1 Withholding Tax**

Dividend payments made to shareholders by a non-resident company, such as the Issuer, as well as liquidation proceeds and capital gains derived therefrom are not subject to a withholding tax in Luxembourg. Therefore, the Issuer does not assume liability for withholding taxes at the source.

### **10.3.2 Income Tax**

#### Luxembourg Resident Individuals

Dividends and other payments derived from the shares by resident individual shareholders, who act in the course of the management of either their private wealth or their professional/business activity, are subject to income tax at the progressive ordinary rate with a current top effective marginal rate of 40% (43.60% including the maximum 9% solidarity surcharge) depending on the annual level of income of individuals. A tax credit may be granted for foreign withholding taxes, provided that it does not exceed the corresponding Luxembourg tax. Under current Luxembourg tax law, 50% of the gross amount of dividends received by resident individuals from a company resident in a Member State and covered by Article 2 of the Council Directive 2011/96/EU of 30 November 2011, as amended the Parent-Subsidiary Directive, such as the Issuer, is exempt from income tax.

Capital gains realized on the disposal of the shares by resident individual shareholders, who act in the course of the management of their private wealth, are not subject to income tax, unless said capital gains qualify either as speculative gains or as gains on a substantial participation. Capital gains are deemed to be speculative and are subject to income tax at ordinary rates if the shares are disposed of

within six months after their acquisition or if their disposal precedes their acquisition. A participation is deemed to be substantial where a resident individual shareholder holds, either alone or together with his spouse or partner and/or minor children, directly or indirectly at any time within the five years preceding the disposal, more than 10% of the share capital of the Issuer. A shareholder is also deemed to transfer a substantial participation if he acquired free of charge, within the five years preceding the transfer, a participation that was constituting a substantial participation in the hands of the transferor (or the transferors in case of successive transfers free of charge within the same five year period). Capital gains realized on a substantial participation more than six months after the acquisition thereof are subject to income tax according to the half-global rate method (*i.e.*, the average rate applicable to the total income is calculated according to progressive income tax rates and half of the average rate is applied to the capital gains realized on a substantial participation). A disposal may include a sale, an exchange, a contribution or any other kind of alienation of the shares.

Capital gains realized on the disposal of the shares by resident individual shareholders, who act in the course of their professional/business activity, are subject to income tax at ordinary rates. Taxable gains are determined as being the difference between the price for which the shares have been disposed of and the lower of their cost or book value.

*Luxembourg Fully Taxable Resident Undertakings with a Collective Character and Luxembourg Permanent Establishments of Foreign Undertakings with a Collective Character or of Non-Resident Individuals*

Unless benefiting from a special tax regime, dividends and other payments made by the Issuer to a Luxembourg resident, a fully-taxable undertaking with a collective character or to a Luxembourg permanent establishment of a foreign undertaking with a collective character or of nonresident individuals are subject to income tax at their respective ordinary rates. Under current Luxembourg tax laws, 50% of the gross amount of dividends received from a company resident in a Member State and covered by Article 2 of the amended Parent-Subsidiary Directive, such as the Issuer, is exempt from income tax. A tax credit may further be granted for foreign withholding taxes, provided it does not exceed the corresponding Luxembourg corporate income tax on the dividends and other payments derived from the shares.

However, under the participation exemption regime, dividends derived from shares of an entity covered by Article 2 of the amended Parent-Subsidiary Directive, such as the Issuer, may be 30 exempt from income tax at the level when the shareholder is, at the time the dividend is made available to the shareholders, cumulatively, (i) the shareholder is (a) a fully taxable Luxembourg resident undertaking with a collective character, (b) a Luxembourg permanent establishment of a company covered by Article 2 of the amended Parent-Subsidiary Directive, (c) a Luxembourg permanent establishment of a foreign undertaking with a collective character in a country having a tax treaty with Luxembourg, or (d) a Luxembourg permanent establishment of a company limited by share capital or

a cooperative company resident in the EEA other than a Member State, (ii) the shareholder has held or commits itself to hold the shares of the distributing entity (*i.e.*, the Issuer) for an uninterrupted period of at least 12 months, (iii) during this uninterrupted period of 12 months, the shares represent a participation of at least 10% in the share capital of the Issuer or a participation of an acquisition price of at least €1.2 million, and (iv) the dividend is put at its disposal within such period. Liquidation proceeds may be exempt under the same conditions. Shares held through a tax transparent entity are considered as being a direct participation proportionally to the percentage held in the assets of the transparent entity.

Capital gains realized by (i) a Luxembourg fully-taxable resident undertaking with a collective character or (ii) the Luxembourg permanent establishment of a non-resident foreign undertaking with a collective character on the shares of the Issuer are subject to income tax at the maximum global rate of 29.22% in Luxembourg City, unless the conditions of the participation exemption regime, as described above, are satisfied except that the acquisition price must be of at least €6 million for capital gain exemption purposes. Shares held through a tax transparent entity are considered as a direct participation holding proportionally to the percentage held in the assets of the transparent entity.

Taxable gains are determined to be the difference between the price for which the shares have been disposed of and the lower of their cost or book value. Capital gains realized on the disposal of the shares by a non-resident individual holding the shares through a Luxembourg permanent establishment are subject to income tax at ordinary rates. Taxable gains are determined as being the difference between the price for which the shares have been disposed of and the lower of their cost or book value

### **10.3.3 Net Wealth Tax**

Shares held by a Luxembourg fully-taxable resident undertaking with a collective character or a Luxembourg permanent establishment of a foreign entity of the same type are subject to Luxembourg NWT (*impôt sur la fortune*) at the rate of 0.5% applied on its net assets as determined for NWT purposes. Net wealth is referred to as the unitary value (*valeur unitaire*), as determined on January 1 of each year. The unitary value is basically calculated as the difference between (a) assets estimated at their fair market value (*valeur estimée de réalisation* or *Gemeiner Wert*), and (b) liabilities vis-à-vis third parties, unless one of the exceptions mentioned below is satisfied.

Unless benefiting from a special tax regime, NWT will be levied on the shares in the hands of a Luxembourg fully taxable resident company or of a Luxembourg permanent establishment of a foreign company.

Further, in the case of a company covered by Article 2 of the amended EU Parent-Subsidiary Directive, such as the Issuer, the shares may be exempt for a given year, if the shares represent at the end of the previous year a participation of at least 10% in the share capital of the Issuer or a participation of an acquisition price of at least €1.2 million. The NWT charge for a given year can be

reduced if a specific reserve, equal to five times the NWT to save, is created before the end of the subsequent tax year and maintained during the five following tax years. The maximum NWT to be saved is limited to the corporate income tax amount due for the same tax year, including the employment fund surcharge, but before imputation of available tax credits.

#### **10.3.4 Other Taxes**

Under Luxembourg tax law, where an individual shareholder is a resident of Luxembourg for inheritance tax purposes at the time of his/her death, the shares are included in his/her taxable basis for inheritance tax purposes. Gift tax may be due on a gift or donation of the shares if the gift is recorded in a Luxembourg notarial deed or otherwise registered in Luxembourg.

## **11. Glossary**

|  |  |
|--|--|
| Accovion                                 | Accovion GmbH  |
| ADRs                                     | Securitizedizations of ADSs  |
| ADS                                      | American Depositary Shares   |
| ADS Agreement                            | Agreement regarding the creation of ADS between the Issuer, the Custodian and the Depositary   |
| AK                                       | Actinic keratoses  |
| Ameluz® PDT                              | Photodynamic therapy using Ameluz®   |
| Authorized Capital                       | Authorized capital of the Issuer's management board to increase the registered capital of the Issuer until 23 May 2022 with the approval of the supervisory board by up to EUR 6,000,000 by way of issuing, on one or several occasions, up to 6,000,000 no-par registered shares against contribution in cash and/or kind |
| BaFin                                    | Bundesanstalt für Finanzdienstleistungsaufsicht, the German Federal Financial Supervisory Authority  |
| Bankhaus Gebr. Martin Aktiengesellschaft | Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen  |
| BCC                                      | Basal cell carcinoma   |
| Biofrontera Group                        | Biofrontera AG with registered seat in Leverkusen, and business address Hemmelrather Weg 201, 51377 Leverkusen together with its subsidiaries  |

|                         |  |
|-------------------------|--|
| cGCP                    | current Good Clinical Practices  |
| cGMP                    | current good manufacturing practice  |
| Clearstream Banking AG  | Clearstream Banking Aktiengesellschaft, with registered seat in Frankfurt / Main, Germany, and business address Mergenthalerallee 61, 65760 Eschborn, Germany  |
| Conditional Capital I   | The conditionally increased registered capital of the Issuer, by up to EUR 4,137,201 by issuing up to 4,137,201 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each, under § 7(2) of the Issuer's articles |
| Conditional Capital II  | The conditionally increased registered capital of the Issuer, by up to EUR 500,000 by issuing up to 500,000 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each, under § 7(5) of the Issuer's articles     |
| Conditional Capital III | The conditionally increased registered capital of the Issuer, by up to EUR 542,000 by issuing up to 542,000 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each, under § 7(6) of the Issuer's articles     |
| Conditional Capital IV  | The conditionally increased registered capital of the Issuer, by up to EUR 1,814,984 by issuing up to 1,814,984 new registered no-par shares with a participation in the Issuer's registered capital of EUR 1.00 each, under § 7(8) of the Issuer's articles |
| Convertible Bond 2021   | The Issuer's subordinated convertible bond with a term until 31 December 2020, to be repaid on 1 January 2021  |
| Convertible Bond 2022   | The Issuer's subordinated convertible bond with a term until 31 December 2021, to be repaid on 1 January 2022  |
| CRO                     | Clinical research organization   |
| Custodian               | Bank of New York Mellon SA/NV, Asset Servicing, Niederlassung Frankfurt am Main; Friedrich-Ebert-Anlage 49, 60308 Frankfurt am Main, acting as custodian   |
| Defined Term            | Definition   |
| Depository              | Bank of New York Mellon Corp., 225 Liberty Street, New York, NY 10286,   |



|                            |   |
|----------------------------|---|
|                            | United States   |
| EEA                        | European Economic Area  |
| EIB                        | European Investment Bank  |
| EIB Credit Facility        | The finance contract with EIB entered into in May 2017  |
| EMA                        | European Medicines Agency   |
| FDA                        | U.S. Food and Drug Administration   |
| Global Share Certificates  | The global share certificate or certificates representing the New Shares, to be deposited with Clearstream Banking AG   |
| Issuer                     | Biofrontera AG with registered seat in Leverkusen, and business address Hemmelrather Weg 201, 51377 Leverkusen  |
| J-code                     | A code in the US health system that facilitates reimbursements for doctors subscribing a drug   |
| Lang & Schwarz Broker GmbH | Lang & Schwarz Broker GmbH with seat in Düsseldorf, Breite Str. 34, 40213 Düsseldorf  |
| MA                         | Marketing Authorization   |
| Maximum Subscription Price | EUR 4.50  |
| NAV                        | Net Asset Value   |
| New Shares                 | 6,000,000 new, no-par registered shares, representing a total notional participation in the registered share capital of the Issuer of EUR 6,000,000, with the German Securities Identification Number WKN 604611 and the International Securities Identification Number ISIN DE0006046113       |
| Offer                      | The public offering of 6,000,000 New Shares from the capital increase resolved on 29 January 2018 by the management board, with the approval of the supervisory board dated the same day, against capital contributions in cash, with dividend rights from 1 January 2017 and ISIN DE0006046113 |
| PDT                        | Photodynamic therapy  |
| Prime Standard             | Regulated market with simultaneous admission to the sub-segment of the regulated market with additional post-admission obligations of the Frankfurt   |



|                              |   |
|------------------------------|---|
|                              | Stock Exchange  |
| Private Placement”.          | The offer of any New Shares which are not subscribed for in the context of the execution of subscription rights including the residual amounts resulting from the subscription ratio to investors selected and addressed by the Issuer in Germany, Luxembourg and in other countries                          |
| QSR                          | The FDA’s Quality System Regulation   |
| Securities Act               | U.S. Securities Act 1933 as amended from time to time   |
| Share Loan Service Agreement | Agreement between the Issuer, Lang & Schwarz Broker GmbH and Maruho Deutschland GmbH regarding the loan of shares   |
| Stock Option Program 2015    | The stock option program implemented under the authorization of the general meeting of the Issuer of 28 August 2015   |
| Subscription Offer           | Admission of Lang & Schwarz Broker GmbH to subscribe and take over up to 6,000,000 New Shares at an issue price of EUR 1.00 per New Share, together with the obligation to offer the New Shares to the shareholders for subscription  |
| Subscription Period          | Period from 30 January 2018 to 12 February 2018   |
| Subscription Price           | Price per New Share, expected to be determined on 9 February 2018, taking into account offers received from institutional investors in a bookbuilding process. The Subscription Price will be published presumably on 9 February 2018 as an ad hoc release and on the same day in the German Federal Gazette. |
| US Offer                     | The sponsored Level-III-program under which ADSs will be offered in the US  |
| WKGT                         | Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, Johannstr. 39, 40476 Düsseldorf, Germany   |

## F. Financial Information

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**F.1 Audited IFRS group accounts 2016**

## **F.1.1) Combined management report as of 31 December 2016**

### ***Basis of the Group***

#### ***Group structure***

This report describes the business performance of the Group (hereinafter also referred to as "Biofrontera" or the "Biofrontera Group") for the 2016 financial year. The Group consists of the parent company Biofrontera AG and five wholly owned direct subsidiaries – Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc. Biofrontera Inc. has its registered office in Wilmington, Delaware, USA. All the other companies are based at the parent company's seat in Leverkusen, Germany.

The listed public stock corporation ("Aktiengesellschaft" in German, abbreviated "AG") performs a holding company function in the group of companies and ensures the necessary financing for the Group. Biofrontera Bioscience GmbH undertakes the research and development tasks for the Group and is the holder of patents and the approval for Ameluz®. Based on a licence agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH (which is also the holder of the approval for BF-RhodoLED®) is responsible for the manufacturing and also the further licensing and marketing of the Biofrontera Group's approved products.

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH were established as additional wholly-owned subsidiaries of Biofrontera AG in December 2012. The purpose of both companies is to pursue the further development of pipeline products that do not form part of Biofrontera's core business and consequently cannot be sufficiently financed as part of normal business development. The product BF-derm1 to treat severe chronic urticaria is now the responsibility of Biofrontera Development GmbH, while the product BF-1 for the prophylactic treatment of migraines is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products can be uncoupled from the normal Group financing.

Biofrontera Inc. is responsible for US marketing of the Biofrontera Group's approved products.

### ***Group strategy***

The strategic objective of the Biofrontera Group is the global positioning as a pharmaceuticals company specialising in dermatology. Focus areas of activity include further expanding our products' sales, especially in the USA, as well as extending the approvals of Ameluz® to include further indications to enhance its market potential.

Biofrontera is the first smaller German company to receive centralised approval for a completely independently developed medication marketed under the Ameluz® brand. Since its launch in February 2012, Biofrontera has been deploying its own sales force to market Ameluz® among dermatologists in Germany, as well as in Spain since March 2015. Ameluz® is also available in the United Kingdom, although Biofrontera will not actively market it there until the start of the coming financial year, after the expansion of approval in January 2017 to include basal cell carcinoma (BCC). Licensing partners distribute the drug in other European Union countries, as well as in Israel and Switzerland. In July, the European Medicines Agency (EMA) issued a positive recommendation to improve Ameluz® to treat field cancerisation. The European Commission issued the effective expansion of the approval in September 2016. As the skin-rejuvenating effects of Ameluz® were also measured in the study on field-directed treatment that was conducted for this purpose, these results have also been included in the approved new product information.

In May 2016, the US Food and Drug Administration (FDA) issued US approval for Ameluz® in combination with the BF-RhodoLED® lamp for the lesion-directed and field-directed PDT (photodynamic therapy) of actinic keratosis. In early July 2015, the company had submitted a new drug application (NDA) to the FDA. As Ameluz® and BF-RhodoLED® had to be approved as a combination of a drug and a medical device in the USA, the approval application there proved to be unusually complex. The FDA conducted extensive investigations and inspections in the subsequent months. The approval for both lesion-directed and field-directed treatment of mild to moderate actinic keratoses on the face and scalp was then issued without conditions. The world's largest healthcare market is consequently open to Biofrontera. A US subsidiary, Biofrontera Inc., based in Wilmington, Delaware, has been set up to market in the USA. All requisite structures were created for the market launch in the USA, which occurred in October 2016. Ameluz® for the US market is produced in Switzerland and imported into the USA. The PDT lamp for the US market is also produced at Biofrontera's headquarters in Leverkusen, Germany.

Biofrontera has thereby established itself as an internationally operating specialist pharmaceutical company. The Group strategy focuses in the short term on further expanding business in Europe and

the USA, as well as on the indication expansion for basal cell carcinoma, which occurred in the EU in January 2017, and which is now also aimed for in the USA.

The indication expansion for Ameluz® to treat BCC was initiated in 2014. The Phase III clinical testing was conducted in direct comparison with competitor product Metvix®. Patient recruitment was completed in May 2015 and the last patient completed the clinical part of the trial in November 2015. This is followed by a 5-year follow-up period for all patients. The results of the trial have been available since January 2016 and prove that Ameluz® is highly clinically effective for the BCC indication. The recently published recurrence rates after 12 months confirm the better efficacy of Ameluz®. In comparison with competitor product Metvix®, it demonstrated significantly higher healing rates, especially with thicker and nodular BCCs. Despite statistically significant inferiority in the treatment of mild and moderate actinic keratosis on the face and scalp, as well as the restriction of its approval as a second therapy option with its approval to treat BCCs, Metvix® had enjoyed a big competitive advantage compared with Ameluz® to date. Especially in those European countries where dermatologists are based mainly in hospitals and fewer independent practices exist, the market opportunities for Ameluz® had been significantly reduced by the previous lack of approval for BCC. The company applied to the EMA in July 2016 for an indication expansion of Ameluz® for basal cell carcinoma, which the European Commission issued in January 2017. Biofrontera hopes for a significantly improved market position from this new indication.

The 2016 business year was a quite crucial year for Biofrontera, when it made preparations for a successful future. Given this, and the related challenges for Biofrontera, the Group also strengthened its personnel base. Along with hiring appropriate staff in the USA, the German organisation also needed to grow slightly, as many tasks for the USA are performed from Germany, and the development partnership with Maruho also ties up personnel capacities.

## ***Products***

### **Ameluz®**

Ameluz® 78 mg/g Gel ("love the light" – development name: BF-200 ALA) received a first centralised European approval for the treatment of mild and moderate actinic keratoses on the face and scalp in December 2011. Its superiority compared to its direct competitor product Metvix® was demonstrated for this indication during Phase III development. Actinic keratoses are superficial forms of skin cancer, and a risk exists that they can spread to deeper layers of skin. The combination of Ameluz® with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European Medicines Agency (EMA)

explicitly mentions the significant superiority of Ameluz® for removing all a patient's keratoses compared to its direct competitor product.

In the Phase III approval trials, Ameluz® showed excellent healing rates and demonstrated marked and statistically significant superiority compared to the approved comparator product tested in parallel. In the first Phase III trial in which the drug was combined with an LED lamp, in 87% of patients treated with Ameluz®, all keratoses were completely removed, and in terms of the number of individual keratosis lesions, as many as 96% were completely eradicated (all the values stated are ITT – intent to treat – values). In the second Phase III approval trial, the effectiveness of Ameluz® was tested in comparison with the approved standard medication. The results of the trial provided evidence that Ameluz® was clearly superior to the competitor product already available in Europe at the time. Based on the average for all lamps, Ameluz® resulted in the complete healing of actinic keratoses in 78% of patients, whereas the approved competitor product achieved a healing rate of only 64%. With LED lamps, the healing rates increased to 85% for Ameluz® and 68% for the competitor product. The side effect profile was comparable for both products.

As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which also required the entire company to be certified pursuant to the ISO 9001 and ISO 13485 standards. In preparation for the approval in the USA, a Phase III trial was performed with a combination of Ameluz® and BF-RhodoLED®. With this combination, 91% of patients were cleared from all keratoses, and in terms of the number of individual lesions, 94% were completely removed after treatment (99.1% of mild and 91.7% of moderate lesions).

The patients treated in the field therapy trial were observed by the trial doctors over the course of a year after the final treatment. Here, the long-term nature of the pharmaceutical effect of Ameluz® was analysed in terms of effectiveness, safety and cosmetic result. A total of 63.3% of the patients who were initially completely asymptomatic were still asymptomatic a year later. The long-term effectiveness achieved applying field-directed therapy consequently lies in the data range already observed in previous long-term studies on lesion-directed PDT with Ameluz®.

As it has been widely reported in the specialist literature that PDT enjoys pronounced skin-rejuvenating properties, particularly in the case of sun-damaged skin, and in this trial – for the first time in a Phase III trial of PDT anywhere in the world – the drug was applied over large surface areas (field-directed therapy), the cosmetic result was measured without taking the disappearance of the

keratotic lesions into account. All the parameters that were tested improved significantly as a result of the treatment. An improvement in the skin appearance of patients treated with Ameluz® observed immediately after PDT continued to develop during the follow-up period. Before PDT, only 14.8% of patients had no impairments to the surface of the skin. Whereas twelve weeks after the last PDT, 63% of patients were already free of such cosmetic damage, this percentage rose after a year to 72.2%. Similar results were also observed for pigment disorders. Before PDT, hyperpigmentation occurred in 59.3% and hypopigmentation in 46.3% of patients, with 48.1% exhibiting irregular pigmentation. Twelve weeks after Ameluz® PDT, these rates initially fell to 42.6%, 29.6% and 29.6%, and decreased over the course of a year to 24.1%, 11.1% and 18.5%. These results clearly show that the skin rejuvenation effect achieved using photodynamic therapy with Ameluz® is long-lasting, and the repair processes triggered by the therapy remain active for at least 12 months.

The results on skin-appearance improvement have meanwhile been included in the official product information in the EU.

Both of the Phase I trials required by the American approval authority, the FDA, were also already completed in 2015. These clinical trials were initiated with a total of approximately 240 patients or test persons to add the safety data required for registration in the USA to the European approval package for Ameluz®. Specifically, one of the trials was a sensitisation study, which determines the potential of Ameluz® to trigger allergies, and the other was a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz®, aminolevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, in other words, the application of a complete tube onto the defective skin. No safety concerns were identified in either of the trials.

Actinic keratosis is classified as a tumour that requires treatment, and the international treatment guidelines list photodynamic therapy as the gold standard for the removal of actinic keratoses, particularly for patients with large keratotic areas. The latest statistics show that actinic keratosis is becoming a widespread disease, with up to 8 million people affected in Germany alone, with a marked uptrend. A total of even as many as 58 million individuals are estimated to suffer actinic keratosis in the USA. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this happens to the relevant lesions within two years on average. The fact that doctors are consequently taking actinic keratosis increasingly seriously is illustrated by the fact that actinic keratosis has been recognised in Germany as an occupational disease since summer 2013. Since then, occupational insurance associations have been obligated to cover the treatment costs of patients who have mainly worked outdoors for a long time and who fulfil certain criteria, for the



duration of these patients' lives. The related payment modalities were set in March 2016, with PDT being included as a treatment method. PDT can be used to treat actinic keratosis in the context of an occupational disease, and can be billed accordingly.

At present, actinic keratoses are treated using a wide range of methods. Lesions are treated, sometimes for weeks, with topical creams, which are often ineffective, or the diseased skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often leads to scar formation or permanent pigment disorders, besides offering little efficacy.

The market for topical creams continues to report constant growth, and medicinally and legally questionable PDT formulations continue to be used in Germany. Because Ameluz® is the market leader among independent dermatologists in Germany in the PDT proprietary medicinal product market, a significant increase in sales can and must result from the aforementioned sectors.

The overall advantages of Ameluz® in terms of effectiveness, handling, user-friendliness and skin rejuvenation effects, as well as the high healing rates of PDT in the treatment of actinic keratoses, will increasingly bring this treatment option to the attention of dermatologists over the next few years. This will be helped by the recent expansion of the range of indications to include basal cell carcinoma, as the vast majority of PDT treatments are conducted for this indication, particularly in the UK and Spain.

Biofrontera has conducted a Phase III trial for the extension of the European approval to include the BCC indication. BCCs are the most common invasive tumours that affect humans and account for approximately 50% to 80% of all skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in the USA but this can lead to clearly visible scarring, whereas treatment with PDT, which is an alternative particularly in the treatment of thin BCCs, gives rise to excellent cosmetic results. In the pivotal Phase III trial, a total of 278 patients were treated. This trial was under the clinical management of Prof. Colin Morton (UK) and Prof. Markus Szeimies (Germany) and was conducted at 27 clinical trial centres in England and Germany. Patient recruitment for the trial, which was conducted in direct comparison with the competitor product Metvix®, was completed in May 2015 and the last patient completed the trial in November 2015. The trial's results have been available since January 2016. The results confirm the company's positive expectations. In the clinical trial, the effectiveness and safety of Ameluz® were compared with that of Metvix®, a drug already approved in the EU for the treatment of BCC. Non-

aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved the complete elimination of all BCCs from the patient in 93.4% of cases compared to 91.8% with Metvix®. Greater differences occurred with thicker BCCs. For example, 89.3% of nodular carcinomas were removed entirely with Ameluz®, and just 78.6% with Metvix®. Recurrence rates after 12 months were higher for Metvix® than for Ameluz®.

Based on the results of this Phase III trial, Biofrontera applied to the European regulator in July 2016 for approval to treat BCC with Ameluz®, which the European Commission issued in January 2017.

Between June and September 2016, patients were treated as part of a Phase III clinical trial, in which the efficacy and safety of Ameluz® in combination with PDT in daylight were measured in comparison with Metvix® in treating mild and moderate actinic keratosis. This comparative, randomised, observer-blind multicentre trial was conducted at seven trial centres in Spain and Germany with a total of 52 patients. Each patient had between 3 and 9 mild to moderate actinic keratoses (Olsen grades 1 and 2) on each of two comparable treatment areas on the face and/or scalp. The selection medication for the respective treatment side was random. The last patient completed the clinical phase of the trial in December 2016. The trial's results prove the non-inferiority (relevant from a regulatory standpoint) of Ameluz® compared with Metvix®. All relevant secondary endpoints produced comparable or higher cure rates for Ameluz® in relation to Metvix®.

Daylight PDT comprises a favourable and pain-free alternative to PDT treatment with a special lamp. Here, the topically applied medication is activated by natural or artificial daylight. The clinical endpoint of the trial is the total cure rate for all lesions on each treatment side 12 weeks after treatment. The secondary clinical endpoint comprises determining medication safety and additional efficacy parameters. The trial was jointly directed by Dr. Susana Puig, Research Director at the Biomedical Research Institute August Pi i Sunyer and professor at the University of Barcelona as the main research director in Spain, and Prof. Thomas Dirschka, founder of the private dermatology practice CentroDerm as the main research director in Deutschland. As treatment in daylight PDT does not need to be administered at a physician's practice it competes directly with the self-applied topical medications that are much more widely disseminated in Europe, and is consequently also reimbursed by statutory healthcare funds in Germany.

## **BF-RhodoLED®**

BF-RhodoLED® is a lamp designed for PDT, and utilises LEDs emitting red light at a wavelength of approximately 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. In the European version, light energy and fan power settings can be adjusted during a PDT treatment session to reduce any pain caused by the treatment. No other lamp on the market offers comparable power and flexibility. BF-RhodoLED® has been CE-certified since November 2012 and is distributed throughout the EU. For marketing in the USA, the final assembly of the PDT lamp was relocated to Biofrontera's premises, and Biofrontera itself has been performing final assembly since July 2016. From the FDA's perspective, Biofrontera is consequently the manufacturer responsible for the product.

## **Belixos®**

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated skin. The biocolloid technology patented by Biofrontera, which optimises epidermal penetration, makes the products unique: pure plant biocolloids are combined with medicinal plant extracts to form an extraordinary combination of active substances with proven depth penetration, drawing together the best of nature and science.

Belixos® Creme rapidly and reliably soothes itching and is the ideal basic treatment for inflamed, reddened and flaky skin. It soothes the skin, reduces scratching and allows the skin to regenerate naturally. Belixos® Creme, which has been available since 2009, has consequently proved particularly useful as an effective basic treatment for atopic dermatitis and psoriasis.

Over the past two years, other specialist regenerative cosmetic products for skin problems have been developed. The typical deep yellow colour is the unmistakable mark of quality. This is derived from the traditional medicinal plant extract obtained from the roots of *Mahonia aquifolium*. Belixos® products use only natural active substance extracts with clinically proven effects.

Belixos® Liquid is an innovative scalp tonic with a practical pipette for dosing, which soothes scalps irritated by psoriasis or eczema, for example, and restores their balance. For itchy and flaky scalps, a combination of anti-inflammatory mahonia, moisturising oats, irritation-relieving panthenol and a special zinc PCA complex is used.

Belixos® Gel is specially cosmetically formulated for skin that is inflamed, reddened and prone to skin blemishes, providing an effective treatment for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin and regulates sebum.

Belixos® Protect is a modern daily care product specially developed for sun-damaged skin. With its skin-regenerative properties deriving from highly concentrated niacinamide, it leaves skin smooth and helps repair damaged skin. It also contains UVA and UVB broad spectrum protection with SPF15 to protect against further light-induced skin ageing and hyperpigmentation.

Belixos® to go is a roll-on acute care product available since July 2016, which utilises a highly precise stainless steel ball to deliver care for itchy skin, insect bites and minor skin irritations. Anti-inflammatory mahonia, calming beach chamomile and the anti-irritative Sepicalm S Complex lead to faster relief for irritations and inflammation.

Belixos® products are manufactured according to stringent quality and environmental regulations. They are free of paraffins, parabens, ethyl alcohol, animal products, dyes and fragrances that may have negative dermatological effects. Its skin compatibility was certified as "very good" by the independent Dermatest Institute. Belixos® is obtainable in selected pharmacies, dermatological institutes and from the online retailer Amazon.

### ***Sales and markets***

With its central European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland and Liechtenstein. In many European countries, however, price and reimbursement status have to be defined before market launch, which can be a very protracted process. To date In Europe, the company has commenced sales and distribution in Germany, the UK, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway, Switzerland and Slovenia. The drug is available in these countries at a pharmacy retail price of between just under EUR 200 and approximately EUR 270 per 2g tube.

Ameluz® is marketed in Germany and, since March 2015, also in Spain by Biofrontera's own field sales force, and in other European countries through marketing partners. Biofrontera is preparing its

own sales operation in the UK, having already terminated its contract with a local marketing company on 31 July 2015. Biofrontera also conducts sales in Slovenia, with a local company supporting it in marketing.

Distribution to public pharmacies generally occurs through pharmaceutical wholesalers, whereas hospital pharmacies are also supplied directly. In addition to regular visits by the field sales force to dermatologists, Biofrontera has presented Ameluz® at major dermatological conferences in Germany and other European countries since it was launched on the market. The feedback from dermatologists has been extraordinarily positive. The market share of Ameluz® in the segment of PDT medications made available by public-sector German pharmacies has long been constant at above 70%, but over the past months of 2016 has reduced proportionally a little again due to the launch of a daylight PDT product identical to Metvix®. Nonetheless, all PDT products together command only a small share of the overall market for preparations to treat actinic keratosis, because only approximately 5% of patients are treated with proprietary medicinal products for PDT. Although PDT achieves the highest healing rates by far, the complexity of the treatment and time required by medical practices to administer it have hindered significant market penetration in the statutory health insurance sector area to date. A film about PDT can be viewed on YouTube, in German at (<http://www.youtube.com/watch?v=aK4a3R5kqMA>, and in English at <http://www.youtube.com/watch?v=2xE08DWCO8o>).

The treatment of actinic keratosis with daylight therapy will play an ever greater role in Europe in the future. Competitor medication Metvix® has already received one approval for this indication, and since recently has been marketed specially for the daylight application under another brand name. Statutory healthcare funds reimburse the treatment as this approach dispenses with additional PDT treatment work in physicians' practices, and patients apply the medication themselves. It can be expected that in the future daylight PDT will gain market shares that to date have been reserved for self-applied topical creams. Biofrontera successfully concluded a Phase III clinical trial on daylight PDT in January 2017, and having submitted the application for approval in the second quarter of 2017 also expects to receive approval for it during the first half of 2018.

Approval for BCC is a prerequisite for the widespread use of Ameluz® in hospitals, as BCC is mainly treated there, whereas this is only quite rarely the case for actinic keratosis. This indication plays an essential role in the breakthrough of Ameluz® especially in European countries outside Germany where dermatologists work mainly in hospitals. BCCs are the most common invasive tumours that affect humans and account for 50% to 80% of all invasive white skin cancers. Around 30% of all

Caucasians develop at least one BCC in their lifetime, and this is a rapidly growing trend worldwide due to increased exposure to UV light. BCCs are mostly removed surgically, although this can result in unattractive scar formation. Treatment with PDT is a highly effective alternative which also leads to excellent cosmetic results. According to a market study published in 2014 by Technavio, the international market for actinic keratosis medications is expected to grow by approximately 8% annually, from approximately USD 546 million USD 942 million in 2020. However, the market for BCC medications is expected to grow to a multiple of its current size, from approximately USD 236 million today to nearly USD 5 billion over the same period, because the availability of new drugs (Ameluz® is also mentioned in this context) will mean that fewer and fewer patients undergo operations.

In Denmark, Sweden and Norway, Ameluz® is marketed by Desitin Arzneimittel GmbH, in Benelux by Bipharma N.V., and in Austria by Pelpharma Handels GmbH. In Slovenia, Biofrontera conducts its own sales and distribution activities, and is supported in its marketing activities by PHA Farmed Consultancy s.p. The cooperation with Spirit Healthcare in the UK was terminated by Biofrontera as of 31 July 2015, and Biofrontera is currently preparing to set up its own sales operation in the UK. Sales in Spain were initially handled by Allergan SA, but since March 2015 Biofrontera has marketed its products itself in Spain through its own branch operation, Biofrontera Pharma GmbH sucursal en España. Louis Widmer SA has been granted the Ameluz® distribution licence for Switzerland and Liechtenstein, and the Ameluz® distribution licence for Israel has been allocated to Perrigo Israel Agencies Ltd. It was necessary to undergo an independent approval process in these countries, which was conducted by the aforementioned distribution partners in collaboration with Biofrontera. In Switzerland, both the approval and the reimbursement approval were issued in December 2015. Market launch occurred at the start of 2016. In Israel, the Israeli health authorities issued approval for Ameluz® in April 2016. Reimbursement by healthcare insurance funds was approved for immunosuppressed patients. Marketing is expected to start in the coming months.

The contracts with the respective sales partners have been concluded in such a way that Biofrontera has received no downpayment, or only a modest downpayment, and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their own sales price. Biofrontera's share of the sales price varies considerably depending on the market conditions in each country, ranging from 35% to 60% of net sales.

Biofrontera launched Ameluz® in the US market in October 2016. In advance, with the help of a consulting firm specialising in market access and a team of medical advisors, a start was made with

analysing the actinic keratosis drug market and reimbursement systems in the American healthcare system. For this, Biofrontera also drew on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick®. Marketing in the USA is occurring through the company's own subsidiary, Biofrontera Inc., which was founded for this purpose in March 2015. Very qualified and experienced local staff were hired for important key positions in the USA, with hiring continuing. Most of the staff have switched from direct competitors to join Biofrontera. As the drug and the lamp are approved as a combined product in the USA, the speed of market penetration in the USA will also depend in part on the speed of placing the BF-RhodoLED® PDT lamps. Until an individual reimbursement code is issued – which Biofrontera applied for in January 2017 and will prospectively come into force in January 2018 – Ameluz® is being reimbursed in the USA through a so-called miscellaneous code. Although this is a normal procedure for any newly launched medication due to the prescribed application periods, this still makes it difficult to process reimbursement in physicians' practices, and is consequently continuing to hamper sales revenue growth in 2017.

### ***Further development projects***

In July 2016, the company agreed a research partnership with Maruho Co., Ltd, ("Maruho"), a Japanese company specialising in dermatology, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. Ameluz® was developed with a similar strategy. The nanoemulsion technology stabilised the active substance and improved skin penetration, leading to greater clinical efficacy. According to the agreement, Maruho will bear all costs connected with the exploratory research of for new product candidates. It is planned that Maruho will be the owner of the new products and that Biofrontera will receive the licence to market in Europe. In some cases of a change of control Maruho has the right but not an obligation to terminate the cooperation agreement.

### **Patent and trademark developments since 31 December 2015**

#### **Nanoemulsion**

The patent was issued in Europe on 21 September 2016 (Bulletin 2016/38). Regional phases were launched in Europe for Switzerland, Germany, Spain, France, the UK and Italy.

The Chilean and Israeli share of the patent has also been issued.

A further office action has also been issued in the USA for the "nanoemulsion" patent (PCT/EP2007/011404), to which a response was provided to deadline.

### **Migraine**

An information disclosure statement was submitted to the United States Patents and Trademark Office (USPTO) for the patent "Antimigraine compounds and their use" (US Patent Application No. 14/765,176). An office action was also issued that was answered to deadline in November 2016.

### **Belixos®**

The patent "Pharmaceutical and/or cosmetic composition for treating the skin" (US Patent Application No. 13/081,737) is not being pursued further.

### **Brand development**

The European Community trademark "Daylight-PDT" (Number 014943518) is not being pursued further.

### ***Steering system***

The Management Board manages Biofrontera AG, and is responsible for and supervises the operating business. The Management Board receives and reviews internal management reports to this end.

Sales revenue forms the central management metric in the context of such reporting, which is reported by product and region.

Change in liquidity are also utilised as an important key indicator and management metric, and are monitored on a daily basis. Liquidity is defined as the sum of the cash position and bank deposits. Further Research- and development costs as well as equity form important management metrics.

### **Key financial performance indicators**

Sales revenue



Internal steering focuses on sales revenue trends. Consolidated sales revenue comprises sales to both wholesalers and physicians and clinics, as well as sales to our licensing partners.

As medications in Germany are not sold directly to patients, the company also receives data about pharmacies' sales, reported by regional segments, enabling an analysis of prescription trends in Germany.

#### Liquidity

A daily summary of all funds held on bank accounts is prepared in order to monitor liquidity.

#### **Key non-financial performance indicators**

##### Number of employees

Personnel figures (measured in terms of full-time equivalents/FTEs) represents a further relevant management metric. In the recruitment of personnel, the company focuses primarily on staff possessing the requisite qualifications and expertise to reach the objectives that are set in the operative and administrative areas. Personnel costs are always monitored on the basis of normal salary levels for the sector.

This steering system is applied on a consolidated basis so the entire Group is managed according to standard systems.

#### ***Economic and business report for the 2016 financial year for the Biofrontera Group:***

- Sales revenue: at EUR 6.1 million (prior-year period: EUR 4.1 million), year-on-year sales revenue growth of 48%. First significant sales revenues in the USA as well as sales revenues from the development partnership with Maruho
- Operating result: EUR -11.8 million (prior-year period: EUR -10.2 million)
- Consolidated loss before tax: EUR -10.6 million (prior-year period: EUR -11.2 million)
- Cash and cash equivalents as of 31 December: EUR 15.1 million (previous year: EUR 4.0 million)

- Undiluted earnings per share amounted to EUR -0.36 (previous year: EUR -0.48)

## ***Biofrontera Group financial position and performance***

### **Sales revenue**

The Biofrontera Group generated total sales revenue of EUR 6,130 thousand in the 2016 financial year, equivalent to an increase of more than 48% compared with the previous year's level (EUR 4,138 thousand). Sales revenue in Germany of EUR 2,515 thousand reflected a reduction compared with the previous year's EUR 3,028 thousand. In European countries outside Germany, sales revenue reported a marked increase of 20% to reach EUR 1,247 thousand (previous year: EUR 1,040 thousand). Sales revenue in the USA stood at EUR 1,153 thousand (previous year: EUR 0 thousand). The development projects with Maruho generated EUR 1,177 thousand in the reporting period (previous year: EUR 0 thousand). Licence revenue (one-off payments) amounted to EUR 40 thousand in the 2016 financial year (previous-year period: EUR 70 thousand). Based on disclosure changes in accordance with BilRuG Biofrontera AG has, in its individual statutory financial report, recorded revenues of EUR 2,038 thousand (previous year: EUR 1,814 thousand) for the first time.

### **Cost of sales, gross profit**

The gross profit on sales improved from EUR 2,902 thousand in the 2015 financial year to EUR 4,478 thousand in the 2016 financial year. The gross margin increased to 73%, compared to 70% in the same period in the previous year.

The cost of sales amounted to EUR 1,652 thousand, or 27% of the sales revenue, improving relative to sales revenue compared with the previous year (EUR 1,236 thousand, or 30%).

### **Development costs**

Biofrontera has also continued to invest in research and development and the further development of its products. Research and development costs amounted to EUR 4,640 thousand in the 2016 financial year, a reduction of EUR 1,564 thousand, or 25%, year-on-year. The decrease mainly reflects the EUR 2,072 thousand submission fee (PDUFA fee) paid upon submission of the application for approval to the FDA during the first half of 2015. The FDA reimbursed this fee in March 2016, with the credit being reported under the other income item.

### **Sales and marketing costs**

Sales and marketing costs amounted to EUR 8,763 thousand in the 2016 financial year, a significant increase of EUR 4,593 thousand to more than double the previous year's level (EUR 4,170 thousand). Sales and marketing costs include the costs of our own field sales team in Germany, Spain and the USA, as well as marketing expenses. The increase is chiefly attributable to expenses for the start-up of sales activities and to establish sales structures in the USA.

### **Administrative costs**

Administrative costs increased by EUR 94 thousand year-on-year to EUR 2,853 thousand in the 2016 financial year (previous year: EUR 2,759 thousand). Financing costs shown under administrative costs include primarily consultancy and placement fees in connection with support in the search for investors.

### **Financial result**

The financial result consists primarily of the interest payable for the 2009/2017 warrant bond (EUR 463 thousand, previous year: EUR 439 thousand) and for the 2011/2016 warrant bond placed in 2011 (EUR 727 thousand, previous year: EUR 727 thousand), calculated using the effective interest method. The aforementioned interest expenses on the warrant bond 2009/2017 of EUR 463 thousand (previous year: EUR 439 thousand) include the opposite effect of EUR 204 thousand (previous year: EUR 193 thousand) from the repurchase of part of the warrant bond on 28 February 2014.

The interest on Warrant Bond I for the 2015 financial year was paid at the end of December 2015, and the interest on Warrant Bond II was paid at the beginning of January 2016. The interest for the 2016 financial year for Warrant Bond I was paid at the start of January 2017. In December 2016, Warrant Bond II was repaid early at par plus accrued interest.

### **Other income and expenses**

The submission fee paid to the FDA in 2015 (PDUFA fee) was reimbursed in an amount of EUR 2,140 thousand in March 2016 after a "small business waiver" was granted. This fee was reported under research and development costs in the income statement for 2015. The reimbursement is reported under other income. The individual statutory accounts of Biofrontera AG show other operational income of EUR 298 thousand (previous year: EUR 55 thousand) and other operational

expenses of EUR 1,060 thousand (previous year: 492 thousand) after reclassification in accordance with BilRuG.

### **Investments**

The additions to intangible assets and to property, plant and equipment in the reporting period arise mainly from the purchase of special software (EUR 20 thousand; previous year: EUR 0), right-of-use assets connected with the prototype of the PDT lamp (EUR 36 thousand; previous year: EUR 26 thousand), laboratory devices (EUR 290 thousand; 2015: EUR 35 thousand) and fixtures and equipment (EUR 117 thousand; 2015: EUR 42 thousand). The asset disposals with costs totaling EUR 66 thousand (previous year: EUR 20 thousand) resulted primarily from sales of the rental lamps in an amount of EUR 52 thousand (previous year: EUR 20 thousand).

### **Inventories**

Inventories stand at EUR 3,646 thousand (previous year: EUR 1,534 thousand). These included: finished products (Ameluz®) amounting to EUR 751 thousand, BF-RhodoLED® lamps recorded in the inventories amounting to EUR 1,001 thousand and Belixos® products amounting to EUR 67 thousand as well as work in progress, and raw materials and supplies reported at EUR 1,827 thousand.

### **Receivables**

Trade receivables increased by EUR 729 thousand, from EUR 895 thousand as of 31 December 2015 to EUR 1,624 thousand, due to the higher level of sales revenue in the 2016 financial year.

### **Share capital**

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 37,722,433.00 on 31 December 2016. It was divided into 37,722,433 registered shares with a nominal value of EUR 1.00 each. The share capital amounted to EUR 25,490,430.00 on 31 December 2015, and was increased during the course of 2016 financial year initially by a capital increase in February 2016 by an amount of EUR 2,357,384.00, divided into 2,357,384 registered shares, a capital increase in April 2016 of EUR 2,499,999.00, divided into 2,499,999 registered shares, and a further capital increase in November 2016 of EUR 5,012,950.00, divided into 5,012,950 registered shares.

As part of the capital increase implemented in February 2016, the company's share capital was increased against cash capital contributions by EUR 2,357,384.00 through issuing 2,357,384 new ordinary registered shares from authorised capital. Shareholders' subscription rights were excluded for this capital increase. The new shares were offered to selected institutional investors at an issue price of EUR 1.90 per new share, consequently for a total issue amount of EUR 4,479,029.60. These shares were fully placed. The net issue proceeds amounted to EUR 4.4 million.

As part of the capital increase implemented in April 2016, the company's share capital was increased against cash capital contributions by EUR 2,499,999.00 through issuing 2,499,999 new ordinary registered shares from authorised capital. Statutory subscription rights were granted to the shareholders. An "additional subscription" was also offered. In other words, shareholders exercising subscription rights could apply to subscribe for unsubscribed new shares at the subscription price. The subscription price per share amounted to EUR 2.00. The net issue proceeds amounted to EUR 4.9 million.

As part of the capital increase implemented in November 2016, the company's share capital was increased against cash capital contributions by EUR 5,012,950.00 through issuing 5,012,950 new ordinary registered shares from authorised capital. The new shares are dividend-entitled from 1 January 2016. Statutory subscription rights were granted to the shareholders in a 6:1 ratio at the subscription price. The subscription price per new share amounted to EUR 3.00. The net issue proceeds amounted to EUR 14.7 million.

In November 2016, 49,990 subordinated convertible 2016/2021 bonds were issued in a total nominal amount of EUR 4,999,000 ("convertible bond"). The bonds were issued at a subscription price of 100% of the nominal value per bond in a denomination of EUR 100.00 per bond, and were fully placed. Shareholders were granted indirect subscription rights to the bonds. The conversion price amounted initially to EUR 3.00 per share, EUR 4.00 per share from 1 January 2017 and EUR 5.00 per share from 1 January 2018. Shareholders were granted statutory subscription rights in a 607:1 ratio at an issue price of EUR 100.00 per bond. The complete issue volume amounted to EUR 5.0 million.

The exercising of warrant rights from the 2011/2016 warrant bond generated issue proceeds of EUR 2.2 million in the 2016 financial year.

### **Group equity and company equity**

The Group has equity amounting to EUR 15,842 thousand on the basis of IFRS accounting principles.

Biofrontera AG has equity of EUR 95,566 thousand as of 31 December 2016 on the basis of accounting policies pursuant to the German Commercial Code (HGB) (previous year: EUR 65,496 thousand). Overindebtedness in the meaning of insolvency law does not exist at the two subsidiaries Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH, as positive going concern forecasts exist for both companies. The net loss incurred for the year for Biofrontera AG amounts to EUR -1,962 thousand (previous year: EUR -7,263 thousand).

### **Financial position**

The company's capital management body regularly reviews the equity ratio of both the Group and the parent company. The management's objective is to ensure an appropriate equity base within the framework of capital market expectations, and creditworthiness in relation to national and international business partners. The company's Management Board ensures that all Group companies have sufficient equity and debt funding at their disposal.

Cash flow from operating activities reduced year-on-year from EUR -9,717 thousand to EUR -10,740 thousand in 2016.

Cash flow from investing activities diminished by EUR 472 thousand to EUR -455 thousand, especially due to capital expenditure, which increased by EUR 304 thousand to EUR 485 thousand.

Cash flow from financing activities improved by EUR 17,212 thousand year-on-year, from EUR 5,150 thousand to EUR 22,362 thousand. This change arises particularly from the proceeds of new share issues generating EUR 24.2 million of issue proceeds. In the prior-year period, two capital increases with issue proceeds totalling EUR 6.3 million were implemented.

The company was able to meet its payment obligations at all times, but will continue to depend on additional financing measures in the future. To date, Biofrontera has always succeeded in providing the necessary financing for its business operations through injections of equity. As a result of the capital increases implemented in February, April and November 2016, the company currently has sufficient liquidity at its disposal. However, the planned investments in marketing in the USA and obligations arising from the warrant bond that was issued will necessitate further capital measures during the course of the 2017 financial year.

On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can continue to be secured. Should – contrary to expectations – these valid estimates not be realised, a going concern risk would ensue.

**Target attainment in 2016:**

|                                | Outlook for 2016       | Target attainment as 31 December 2016 |
|--------------------------------|------------------------|---------------------------------------|
| Group sales revenue            | EUR 6 to 7 million     | EUR 6.1 million                       |
| Research and development costs | EUR 4 to 5 million     | EUR 4.6 million                       |
| Consolidated result before tax | EUR -11 to -12 million | EUR -10.6 million                     |

Biofrontera reached all its financial targets in 2016. The previous year's forecast was for sales revenue of between EUR 6 million and EUR 7 million. A reduction in sales revenue in Germany was more than offset by sales revenue generated from the development projects with Maruho. Sales revenues in European countries outside Germany were as expected. Initial revenues of EUR 1.2 million were achieved in the USA during the final quarter of the financial year under review.

Biofrontera also made significant investments in research and development in 2016, including in the "regulatory affairs" area. Research and development costs of EUR 4.6 million were in line with budget.

The consolidated result before tax of EUR -10.6 million was also slightly improved compared with the forecast.

***Personal matters***

**Management Board**

The Management Board consists of Prof. Hermann Lübbert (Chief Executive Officer), Mr. Thomas Schaffer (Chief Financial Officer) and Mr. Christoph Dünwald (Chief Commercial Officer).

The remuneration of the Management Board members consists of a fixed salary that is paid in twelve equal monthly instalments. In addition, an annual performance-based bonus exists for the Management Board members, as well as a long-term remuneration component consisting of participation in the company's share option programme. Company cars are also available to the directors for business and private use.

## Staff

As of 31 December 2016, 94 employees worked for the Biofrontera Group (previous year: 58). Of these, 20 were employed at Biofrontera AG (previous year: 17), 9 at Biofrontera Bioscience GmbH (previous year: 6) and 41 at Biofrontera Pharma GmbH including the Spanish office (previous year: 34). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. Biofrontera Inc. employed a total of 24 staff (previous year: 1).

## Employee stock option programme 2010

In order not to be at a disadvantage in the future in recruiting and retaining staff, the company must continue to be able to offer share and/or securities-based remuneration. Moreover, in accordance with the German Act regarding the Appropriateness of Management Board Remuneration (VorstAG), such schemes must be linked to the company's long-term performance and profitability. As the stock option programme approved by the Annual General Meeting of the company on 24 May 2007 could not be utilised, the Annual General Meeting held on 2 July 2010 granted the Management and Supervisory boards the authorisation to issue, within the next 5 years, up to 839,500 options to directors and employees. Further related provisions were specified in the invitation to the Annual General Meeting and are available on the company's website. The issue of the first tranche of these options is described in the consolidated financial statements for the financial year ending 31 December 2010. The second tranche occurred in calendar 2011 and is described in the consolidated financial statements for the financial year ending 31 December 2011. In the first half of 2012, a further 116,500 options were issued at an exercise price of EUR 3.30 and EUR 4.09 respectively each (third tranche). On 2 September 2013, 179,500 options were issued with an exercise price of EUR 3.373 each (fourth tranche). In a further tranche (fifth tranche) on 2 April 2014, a total of 159,350 options were issued at an exercise price of EUR 3.43 each. A total of 137,250 options were forfeited by employees leaving the company. A further 106,400 options (from the first tranche) lapsed because the exercise conditions were not met. The cost expensed in the reporting period amounted to EUR 62 thousand (previous year: EUR 103 thousand).



The authorisation to issue options under the 2010 share option programme ended on 1 July 2015. By resolution of the Annual General Meeting on 28 August 2015, the Conditional Capital III provided to service options under this programme was reduced to EUR 542,400.00.

Employee stock option programme 2015

After the end of the 2010 employee share option programme, the company's Annual General Meeting on 28 August 2015 authorised the Management and Supervisory boards until 27 August 2020 to issue to Management Board members and employees up to 1,814,984 subscription rights to up to EUR 1,814,984 of the company's ordinary registered shares according to the more detailed specifics of the authorisation resolutions. Further related provisions were specified in the invitation to the Annual General Meeting and are available on the company's website (2015 option programme).

On 18 April 2016, a total of 425,000 options were issued for the first time from the potential 1,814,914 share options (exercise price: EUR 2.49 per option). On 1 December 2016, a further 130,500 options (second tranche) were issued with an exercise price of EUR 3.28 each. A total of 7,500 options were forfeited by employees leaving the company. Due to the blocking period, no options have yet been exercised or forfeited. As a consequence, 1,259,483 options are still outstanding on 31 December 2016. The expenditure recognised in the reporting period was EUR 49 thousand (previous year: EUR 0). No previous year's figures exist as the share option programme was not set up until the 2015 financial year.

**Supervisory Board**

As a result of the resolution passed by the Annual General Meeting held on 31 May 2016, the Supervisory Board has consisted of the following members since 31 May 2016, with these members acting as representatives of the shareholders:

- Dr. Ulrich Granzer      Supervisory Board Chairman, Owner and Managing Director of Ulrich Granzer Regulatory Consulting & Services, resident in Munich, Germany
- Jürgen Baumann      Deputy Supervisory Board Chairman, management consultant, resident in Monheim
- John Borer              Head of Investment Banking at The Benchmark Company LLC, New York, USA, resident in Jersey City, NJ, USA

Hansjörg Plaggemars Management Board member of Deutsche Balaton Aktiengesellschaft, Heidelberg, resident in Stuttgart

Mark Reeth Attorney, resident in Frederick, MD, USA

Kevin Weber Principal of Skysis, LLC, Scottsdale, AZ, USA, resident in Scottsdale, AZ, USA

The Supervisory Board members held the following other supervisory board positions and positions on comparable domestic and foreign boards during the reporting period:

Hansjörg Plaggemars OOC CTV Verwaltungs GmbH, Managing Director

Stellar Diamonds plc, Non-Executive Board Member

Carus Grundstücksgesellschaft am Taubenfeld AG, Supervisory Board Chairman

Eurohaus Frankfurt AG, Supervisory Board Chairman

Youbisheng Greenpaper AG i.L., Supervisory Board Chairman

Ming Le Sports AG, Supervisory Board Chairman

Nordic SSW 1000 Verwaltungs AG, Supervisory Board Chairman

Balaton Agro Invest AG, Deputy Supervisory Board Chairman

Carus AG, Deputy Supervisory Board Chairman

Deutsche Balaton Immobilien I AG, Supervisory Board member

Ultrasonic AG i.L., Supervisory Board member

In the 2016 financial year, compensation paid to Supervisory Board members amounted to EUR 113 thousand (previous year: EUR 113 thousand). The compensation transactions are classified as short-term employee benefits as per IAS 24.17(a).

## ***Risk, opportunity and forecast report***

### ***Risk and opportunity report***

#### **Risk management system**

Biofrontera's management deploys a comprehensive risk management system to counter risks within the Group.

The risk and opportunity management system for the Biofrontera Group applies equally to Biofrontera AG. By virtue of its holding company function, Biofrontera AG controls all the legally independent entities within the Biofrontera Group. For this reason, risks and opportunities must be assessed on a standard basis across the entire Group.

The primary objective of the Biofrontera Group is to achieve sustainable and long-term growth while increasing the company's value continuously. Risk management plays a major role in achieving this objective. Risk management at Biofrontera involves the identification of risks that could lead to lasting or significant harm to the company's financial position and performance, as well as the responsible analysis and monitoring of such risks and initiation of suitable countermeasures. This requires the establishment of guidelines, organisational structures and measuring and monitoring processes that are specifically geared to the Biofrontera Group's activities.

Correspondingly detailed risk prevention measures are essential to fully exploit the opportunities arising from Biofrontera's business activities. In the 2016 financial year, Biofrontera's existing risk management structures were further developed to reflect the quality management system required for pharmaceutical manufacturers and businesses as well as medical device manufacturers. This system incorporates sales and marketing activities, as well as the international responsibilities of licence holders with regard to the manufacture and sale of drugs, medical devices and cosmetics.

#### **The management of opportunities and risks at Biofrontera**

The Biofrontera Group's risk management system is integrated into the Group's corporate processes and decision-making processes, thereby forming an integral element of planning and controlling processes Group-wide. Risk management and control mechanisms are coordinated with each other. They ensure that risks relevant to the company are identified and assessed at an early stage, while at the same time enabling the company to respond rapidly to potential opportunities.

Risk management at Biofrontera is organised both locally and centrally. Opportunities and risks are regularly identified, evaluated and analysed at all hierarchical levels. All Group management staff are involved in Group-wide risk policy and associated reporting. This includes the Management Board, the Group companies' managing directors, and process and project managers.

The Risk Management Team headed by the Chief Executive Officer is responsible for the centrally organised risk management system. It coordinates the individual management bodies and ensures they receive their information continuously and promptly. The Risk Management Team is also responsible for the continuous monitoring of risk profiles, for initiating risk prevention measures, and for corresponding monitoring instruments. The Biofrontera Group management holds regular meetings at which the Group's central and operational departments exchange information relevant to risk management at all levels.

The Risk Management Officer, who is also a member of the Risk Management Team, is the Group-wide contact individual. If unexpected risks arise, he/she immediately initiates the necessary steps to counteract them.

He/she is responsible for developing the risk management system, and for ensuring it is properly documented in the risk manual. Furthermore, the Risk Manager sets uniform standards and ensures that similar types of risk management processes are implemented throughout the Biofrontera Group. Regular analysis of key business performance figures helps to ensure that any possible discrepancies from expected performance levels can be identified and assessed at an early stage, allowing necessary countermeasures to be adopted in good time. Overall monitoring is conducted in relation to the sales activities for Ameluz®, including the PDT lamp, and Belixos®. Risk planning and identification in this area are performed in collaboration with the relevant unit managers. The structure and function of the early risk detection system are assessed by the auditor.

### **Risks and opportunities relating to future business development and growth**

The Biofrontera Group is endeavouring to achieve its strategic objectives, especially the establishment of its own sales operation in some countries, the identification of sales partners, and approval of development projects. It has already obtained not only European but also especially US approval for Ameluz®, giving it the opportunity to grow rapidly and become very profitable.

In addition to general risks, such as market developments and the competitive situation, the company is also exposed to specific risks associated with the pharmaceutical and biotechnology sectors.

It is possible that the product Ameluz® will not prove to be successful in competition with other treatment options for actinic keratosis or BCC. Despite the greater effectiveness of Ameluz®, doctors may resort to other products more often than expected because of the higher treatment costs associated with PDT, for which they frequently do not obtain any, or only insufficient, remuneration from the healthcare systems.

Biofrontera is required to make recourse to suppliers to manufacture its products, and changing such suppliers would entail protracted regulatory processes. Problems at, or with, such suppliers can place a burden, or incapacitate, the company's ability to deliver its products and services, which would lead to a shortfall in revenues. Biofrontera endeavours to minimise such dependencies by establishing alternative suppliers.

No guarantee exists that a product will be launched on the market at the end of a project's development period – which is 6 to 10 years on average. A lack of success in the individual development steps could incur additional costs, cause project delays or even bring project development to a complete halt. It is possible that none, or only some, of the funds invested will be recouped in sales revenue.

The company tries to counterbalance these risks, to some extent, by selecting projects with relatively attractive risk profiles, by setting up a project control and reporting system, and by drawing on the outstanding professional expertise of the Supervisory Board members. The project control system represents the entire development process in detail right up to approval, making it possible to analyse the effects that even small changes or delays – with clinical trials, for example – can have on the development process and on its costs. This makes it possible to precisely observe the development risk associated with individual projects and take the steps necessary to minimise the development risk.

Due to the existing loss situation and uncertainties relating to future business expansion, the company's survival will depend substantially on further cash injections from shareholders or other capital investors. Investors' acceptance of this industry and its associated risks as well as the special accounting characteristics and overall fiscal conditions is of great importance in this context. The company cannot influence such circumstances, although they are of crucial importance for the company during its development phase and when it is reliant on the financial markets for injections of the equity it requires.

## Patent protection

Patents guarantee the protection of our intellectual property. If our products are marketed successfully, the resultant profits can be deployed for sustainable ongoing investment in research and development activities. Due to the long intervening period between the patent application and the launch of a product, Biofrontera generally has only a few years to earn a suitable income from its intellectual work. This makes it all the more important for the Group to obtain effective and secure patent protection. The majority of our products are subject to patent protection. If a patent expires, or we cannot defend it successfully, we generally face the prospect of increased competition and price pressure resulting from the market entry of generic drug suppliers. Moreover, third-party claims regarding Biofrontera's potential infringement of patents or other protective rights may hinder or completely prevent the development or manufacturing of certain products, and may obligate us to pay damages or royalties to third parties. Our patent department regularly reviews the current patent situation, in cooperation with the relevant operational departments, and monitors possible patent infringement attempts, so that it can take suitable legal steps if necessary. We consider it unlikely that patent risks will arise. Biofrontera is not aware of any patent infringement claims lodged by third parties.

## Products and product stewardship

Biofrontera assesses potential environmental and health risks associated with a product along the entire value chain. This includes every stage from research and development to disposal, including production, marketing and customer use. Although comprehensive trials are conducted prior to approval/registration, it is possible that some or all of our products will subsequently be withdrawn from the market for various reasons, including the emergence of unexpected side effects. Sales may be stopped voluntarily or as a consequence of legal or official measures. Possible payments of damages associated with the aforementioned risks could exert a considerable negative effect on the company's financial results. As no previously unknown drug side effects have appeared, we consider it highly improbable that risks of this kind will arise.

## Purchasing

Purchase prices for raw materials may vary considerably, and they cannot always be passed on to our customers through price adjustments due to regulated drug prices. The safety and tolerance of our products, and protection of our employees and of the environment, form key priorities. Risks associated with the manufacturing, bottling, storage and transportation of products may result in personal injury or material or environmental damage, and may give rise to an obligation to pay

damages. Here Biofrontera is dependent to some extent on individual suppliers. Using our own audit and monitoring system, we regularly ensure that the manufacturing conditions at our most important suppliers meet the required standard. This enables us to avoid such risks and damages. We have already established two suppliers of the agent aminolevulinic acid, whose manufacturing processes have been approved by the EMA. Biofrontera is the owner of the Drug Master File for one of the two manufacturers. This will ensure the long-term supply security of aminolevulinic acid. We have also established our own production facilities for the final assembly and final quality control of the BF-RhodoLED® lamp to reduce our dependence on suppliers in this area too.

### Employees

Qualified and dedicated staff are a key prerequisite for the company's success. Competitive compensation and extensive training and development opportunities are essential to this end. We also pursue a diversity-orientated personnel policy to exploit the labour market's full potential. To date, Biofrontera has always succeeded in acquiring the qualified staff necessary for the company, so the company also regards this area as bearing a low risk.

### Information technology

The Group's business processes and internal and external communication are increasingly based on global IT systems. A significant technical malfunction or total failure of IT systems could result in severe impairment of our business processes. It is of fundamental importance to us that both internal and external data remain confidential. If the confidentiality, integrity or authenticity of data or information were to be lost, the manipulation and/or uncontrolled outflow of data and know-how could arise. We have adopted appropriate measures to counteract this risk, such as a comprehensive authorisation concept. The measures adopted by the company have always proven adequate to date, so such risk is to be regarded as low.

### Law and compliance

The Group may be subjected to litigation or legal proceedings in the future. In particular, this includes risks arising from product liability, antitrust law, competition law, patent law, tax law and environmental protection. Inquiries and investigations on grounds of possible infringements of statutory or regulatory provisions may result in criminal and civil sanctions, including considerable fines or other financial disbenefits, and these may harm the company's reputation and ultimately have a negative effect on the company's success and performance.

## Liquidity risk

Liquidity risks arise from the possibility that the Group will be unable to fulfil existing or future payment obligations due to not having sufficient funds. We calculate and manage the liquidity risk in our weekly and medium-term liquidity planning sessions. Payment obligations arising from financial instruments are defined separately in the consolidated financial statements based on their due dates.

To ensure payment security, cash and cash equivalents are kept available so that all the Group's scheduled payment obligations can be fulfilled on their respective due dates. The level of this liquidity reserve is reviewed regularly and adjusted to current circumstances where necessary.

The company was able to meet its payment obligations at all times, but will continue to depend on additional financing measures in the future. To date, Biofrontera has always succeeded in providing the financing needed for its business operations through injections of equity. As a result of the capital increases implemented in February, April and November 2016, and the issue of subordinated convertible bonds in January 2017, the company currently has sufficient liquidity at its disposal. Until breakeven is reached, however – particularly through obtaining approval in the USA – until the planned investments are made in marketing in the US and until obligations from the issued option bond are met, further capital measures will be required during the 2017 financial year. Such capital measures can comprise equity or debt financing.

On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that it can continue to secure the liquidity it requires for its business activities. Should – contrary to expectations – these valid estimates not be realised, a going concern risk would ensue.

## Litigation

In August 2016, the Cologne District Court served on the company a lawsuit from a shareholder dated 30 June 2016. The lawsuit brought charges for nullity, alternatively rescission, of some of the resolutions passed at the company's Ordinary AGM on 31 May 2016. In particular, the election of Mr. John Borer, Mr. Jürgen Baumann and Mr. Kevin Weber to the company's Supervisory Board was contested. A verbal negotiation meeting was held at the Cologne District Court on 4 November 2016. A further meeting to interview witnesses was held on 3 February 2017, also at the Cologne District Court. The plaintiff withdrew the lawsuit on 9 March 2017.



### ***Forecast report (outlook)***

Over the coming two years, Biofrontera will continue to invest considerable funds in new indication approvals for Ameluz® and to further expand sales of Ameluz® in the USA. Biofrontera has established its subsidiaries in the USA at great speed and will further strengthen the number and force of its staff there. To expand the management team, Mr. Randall Wilhoite was appointed Chief Operating Officer of Biofrontera Inc. in February 2017. Biofrontera will be present at the most important American dermatology conferences and will continue to aim for broad-based reporting about white skin cancer and Ameluz® among physicians and the general public. Preparations are currently underway for a so-called "pre-IND meeting" with the US regulator, the FDA. This meeting, in turn, is to form a preparation to expand the US approval to include the BCC indication. The extent to which the FDA sees the preconditions for the expanded approval as having been met by the data gathered in Europe is to be clarified at this meeting. Biofrontera has submitted an application for this meeting to the FDA, which will occur prospectively during the course of the second quarter of 2017. Only subsequently will it be possible to give a timing forecast relating to the expanded approval for BCC in the USA. To expand the approval to include daylight PDT in the EU, Biofrontera has concluded a corresponding Phase III trial with very good results. An application for the new indication is currently being prepared and should be submitted during the course of the second quarter of 2017. We anticipate the expanded approval for the new indication to be issued during the first half of 2018.

### **Forecast of key financial figures**

For the 2017 financial year, Biofrontera expects to achieve sales revenue of approximately EUR 14 million to EUR 18 million. In Germany and other European countries outside Germany, the competitive situation for Biofrontera has changed considerably due to the market launch of a medication for daylight PDT identical to Metvix®. We nevertheless anticipate a resumption of slight growth in 2017 in both Germany and Europe. In the USA, we expect a marked increase in sales revenues in 2017, especially as initial system-related problems with reimbursing the medication have meanwhile largely been resolved. The receipt of an individual reimbursement code for the medication Ameluz® – to be activated prospectively in January 2018 – will significantly simplify and accelerate the acquisition of market shares and related sales revenue growth. Overall, however, sales growth remains very difficult to forecast, generating a considerable fluctuation range of achievable revenues.

To extend the range of indications, Biofrontera will continue to make significant investments in research and development as well as in regulatory affairs in 2017. The development and approval costs will amount to approximately EUR 6 to 7 million. In 2017, Biofrontera will also invest in further expanding its sales and marketing organisation, predominantly in the USA, as a consequence of

which sales and marketing costs will increase further compared with 2016 and amount to a total of between approximately EUR 18 million and EUR 21 million. Administrative costs will rise only slightly compared with 2016 and stand at around between EUR 3 million and EUR 4 million.

No significant investments in property, plant and equipment are planned for 2017.

The financial result reflects the interest payments and compounding of interest applying the effective interest method for the still outstanding warrant bond. For this reason, 2017 will represent an improvement compared with 2016.

With the aforementioned conditions and forecasts, the company will achieve a consolidated result of EUR -14 million to EUR -17 million in 2017. The achievement of this result depends significantly on sales revenue trends.

### ***Remuneration report***

The total remuneration paid to members of the Management Board in the 2016 financial year and the total accumulated number of stock options issued to the Management Board were as follows as of 31 December 2016:

|                           |   |   |
|---------------------------|---|---|
| Prof. Dr. Hermann Lübbert | – Non-performance based salary component: | EUR 363 thousand (31 December 2015: EUR 370 thousand)   |
|                           | - Performance based salary component:     | EUR 72 thousand (31 December 2015: EUR 35 thousand)   |
|                           | - stock options                           | 231,850 (fair value when granted: EUR 366,435.50) (previous year: 151,850, fair value when granted: EUR 167,236); of which granted in 2016: 80,000 (2015: 0). |

|                   |   |   |
|-------------------|---|---|
| Thomas Schaffer   | – Non-performance based salary component: | EUR 213 thousand (31 December 2015: EUR 203 thousand)   |
|                   | - Performance based salary component:     | EUR 63 thousand (31 December 2015: EUR 28 thousand)   |
|                   | - stock options                           | 85,000 (fair value when granted: EUR 157,150) (previous year: 35,000, fair value when granted: EUR 32,650); of which granted in 2016: 50,000 (2015: 0). |
| Christoph Dünwald | – Non-performance based salary component: | EUR 236 thousand (31 December 2015: EUR 29 thousand)  |
|                   | - Performance based salary component:     | EUR 6 thousand (31 December 2015: EUR 0 thousand)   |
|                   | - stock options                           | 50,000 (fair value when granted: EUR 124,500) (previous year: 0, fair value when granted: EUR 0); of which granted in 2016: 50,000 (2015: 0).           |

All salaries/bonuses are classified as short-term employee benefits as defined in IAS 24.17 (a).

Company cars are also available to the directors for business and private use. The existing employment contracts stipulate that – depending on the achievement of targets to be mutually agreed – an annual bonus is payable. If the targets are exceeded, the maximum annual bonus payable is capped. If the targets are missed by a margin no greater than 30% (in other words, a level of at least 70% is achieved), the bonus payment is reduced straight-line. No bonus is payable if the targets are missed by a greater margin than this. The measurement factors are set at the end of each financial year for the following financial year in a mutually agreed target agreement.

Severance pay in the case of early termination of Management Board duties without good grounds is capped at twice the specified annual salary, and amounts to no more than the total remuneration due for the remaining period of the contract (severance cap). In case of a takeover bid in accordance with the German Securities Acquisition and Takeover Act (WpÜG) both the Chief Executive Officer and the Chief Financial Officer are eligible for severance payments in the amount of three annual salaries.

To further enhance the long-term incentive effect of variable compensation and consequently align it with the company's sustainable development and growth, the Management Board members have obligated themselves to hold as private assets ordinary shares in the company for share options granted from the 2010 share option programme for a three-year period beginning one month after the options' issue date ("restricted shares"), and thereby be invested in the company. The level of personal commitment is specified differently in detail for each member of the Management Board. An early sale of such restricted ordinary share must be reported immediately to the Supervisory Board Chair, and the company can request a return transfer of an equivalent number of stock options free of charge within a month of receiving such notification, with the most recently granted options being those that must be returned first (last in, first out). A return transfer is not required if the Management Board member can demonstrate that the sale of the restricted shares was necessary to meet pressing financial obligations. In 2010, the Chief Executive Officer was granted 35,000 options, and the other Management Board member was granted 20,000 options, and in 2011, the Chief Executive Officer was granted 30,000 options and the other Management Board member was granted 20,000 options on this basis. In 2012, a further 40,000 options were granted to the Chief Executive Officer, and an additional 25,000 options were granted to the other Management Board member. In the 2013 financial year, the Chief Executive Officer was granted 30,000 options, and the other Management Board member was granted 15,000 options, and in the 2014 financial year, 16,850 options were granted to the Chief Executive Officer, and 20,000 options were granted to the other Management Board member. No options were granted to the Management Board members in 2015. In the 2016 financial year, 80,000 options from the 2015 share option programme were granted to the Management Board Chairman (CEO), and the other Management Board members were each granted 50,000 options.

***Other disclosures pursuant to Sections 289 (4) and 315 (4) of the German Commercial Code (HGB)***

Management Board members are appointed and removed pursuant to Sections 84 and 85 of the German Stock Corporation Act (AktG). The composition of the Management Board is specified in more detail in Section 9 (3) of the bylaws. Pursuant to this, the Management Board must consist of one or more members. The Management Board comprises three individuals. The Supervisory Board

appoints Management Board members and determines their number. The Supervisory Board may appoint a Chief Executive Officer.

The employment contract of the Chief Executive Officer and that of the Chief Financial Officer include a compensation agreement in the form of a special right of termination, for example in the case of a takeover bid as defined in the German Securities Acquisition and Takeover Act (WpÜG).

Pursuant to Sections 119 (1) No. 5, 179 and 133 of the German Stock Corporation Act (AktG), amendments to the bylaws must be approved by a resolution of the Shareholders' General Meeting. Where legally permissible, a simple majority of the share capital represented at the vote is sufficient for such a resolution, in accordance with Section 179 (2) Clause 2 AktG in combination with Section 22 (2) of the bylaws, instead of the majority of three quarters of the represented share capital stipulated in Section 179 (2) Clause 1 AktG. Pursuant to Section 179 (1) Clause 2 AktG in combination with Section 22 (2) of the bylaws, the Supervisory Board is authorised to make changes that affect only the wording of the bylaws.

With regard to the repurchasing of shares, the Management Board is not subject to any restrictions beyond those specified in the German Stock Corporation Act (AktG).

### ***Accounting risk management system and internal control system***

In the section below, in addition to the risk management system already explained under the relevant subsection, the significant aspects of the internal control and risk management system relating to accounting processes for separate and consolidated financial statements, pursuant to Section 289 (5) of the German Commercial Code (HGB), as amended by the German Accounting Law Modernisation Act (BilMoG), are described.

The financial accounting process at Biofrontera AG aims to ensure that the figures and information provided in external accounting instruments (bookkeeping, components of the separate and consolidated financial statements, and the combined company and Group management report) are accurate and complete, and comply with the relevant legal requirements and bylaw provisions. The related existing structures and processes also include the risk management system and internal control measures relating to the financial accounting processes. In connection with the growing sales and

marketing activities, the internal accounting control system is subject to an ongoing monitoring and improvement process.

The risk management system aims to identify, assess and manage all the risks that could prevent the proper preparation of the separate and consolidated financial statements. Any risks identified must be assessed with regard to their influence on the separate and consolidated financial statements. The purpose of the internal accounting control system is to ensure that the process of compiling financial statements complies with all the relevant laws and regulations, by implementing appropriate guidelines, processes and controls to this end.

The risk management system and internal control system cover all the areas that are essential for the separate and consolidated financial statements and all the processes relevant to the preparation of the financial statements.

Significant aspects of accounting risk management and control include the clear assignment of responsibilities and controls for the compilation of financial statements, as well as transparent accounting standards. The two sets of eyes principle and separation of roles are also important control principles in financial accounting processes.

The Management Board assumes overall responsibility for the organisation of the internal control system. The quality management/controlling/risk management areas and the financial accounting department are responsible for the internal control system's coordinated subsystems.

### ***Takeover information***

### ***Trading platforms***

Biofrontera shares are traded under ticker symbol B8F and ISIN DE0006046113 in the Prime Standard segment of the Frankfurt Stock Exchange and on all other German stock exchanges. In addition, the shares were admitted for trading with the same stock ID number in the form of depositary interests (DI) on the Alternative Investment Market (AIM) of the London Stock Exchange until 18 February 2016.

## Shareholders

The numbers of shares held by the shareholders on 31 December 2016 based on shareholders' most recent mandatory disclosures are as follows:

|  | 31.12.2016<br>EUR | 31.12.2015<br>EUR |
|--|-------------------|-------------------|
| <p>Maruho Deutschland Co., Ltd.,<br/>Osaka Japan</p> <p>The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.</p>  | 7,631,586         | 4,467,143         |
| <p>Wilhelm Konrad Thomas Zours</p> <p>The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours:</p> <ul style="list-style-type: none"> <li>•DELPHI Unternehmensberatung AG</li> <li>•VV Beteiligungen AG</li> <li>•Deutsche Balaton AG</li> <li>•ABC Beteiligungen AG</li> <li>•Heidelberger Beteiligungsholding AG</li> </ul> | 3,400,907         | 1,053,154         |
| <p>Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany</p> <p>The share of voting rights is attributed to Universal-Investment GmbH through the company FEHO Vermögensverwaltungsgesellschaft.</p>   | 799,463           | 799,463           |

|            |            |            |
|------------|------------|------------|
| Free float | 25,890,477 | 19,170,670 |
| Total      | 37,722,433 | 25,490,430 |

### ***Share capital***

On 31 December 2016, the fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 37,722,433.00. It was divided into 37,722,433 registered shares, each with a nominal value of EUR 1.00.

As part of the capital increase implemented in February 2016, the company's share capital was increased against cash capital contributions by EUR 2,357,384.00 through issuing 2,357,384 new ordinary registered shares from approved capital. Shareholders' subscription rights were excluded for this capital increase. The new shares were offered to selected institutional investors at an issue price of EUR 1.90 per new share, consequently for a total issue amount of EUR 4,479,029.60. These shares were fully placed and the implementation of the capital increase was entered in the commercial register on 26 February 2016. The net issue proceeds amounted to EUR 4.4 million.

As part of the capital increase implemented in April 2016, the company's share capital was increased against cash capital contributions by EUR 2,499,999.00 through issuing 2,499,999 new ordinary registered shares from approved capital. Statutory subscription rights were granted to the shareholders. An "additional subscription" was also offered. In other words, shareholders exercising subscription rights could apply to subscribe for unsubscribed shares at the subscription price. The subscription price per share amounted to EUR 2.00. The capital increase was fully placed. The implementation of the capital increase was entered in the commercial register on 26 April 2016. The net issue proceeds amounted to EUR 4.9 million.

As part of the capital increase implemented in November 2016, the company's share capital was increased against cash capital contributions by EUR 5,012,950.00 through issuing 5,012,950 new ordinary registered shares from approved capital. The implementation of the capital increase was entered in the commercial register on 21 November 2016. Statutory subscription rights were granted to the shareholders in a 6:1 ratio. The subscription price per share amounted to EUR 3.00. The net issue proceeds amounted to EUR 14.7 million.



Also in November 2016, 49,990 subordinated convertible 2016/2021 bonds were issued in a total nominal amount of EUR 4,999,000 ("convertible bond"). The bonds were offered at a subscription price of 100% of the nominal value per bond in a denomination of EUR 100.00 per bond, and were fully placed. Shareholders were granted indirect subscription rights to the bonds. The conversion price amounted initially to EUR 3.00 per share, EUR 4.00 per share from 1 January 2017 and EUR 5.00 per share from 1 January 2018. Shareholders were granted statutory subscription rights in a 607:1 ratio at an issue price of EUR 100.00 per bond. The total issue volume amounted to EUR 5.0 million.

The Biofrontera AG shares were listed on the Regulated Market of the Düsseldorf Stock Exchange in 2006. In August 2012, the company's shares were also admitted to trading on the Regulated Market of the Frankfurt Stock Exchange in response to an application by the company. The company's shares are also traded on the Xetra computer trading system and all other German stock exchanges. On 3 June 2014, the share was admitted to the Prime Standard of the Frankfurt Stock Exchange and the AIM market of the London Stock Exchange. The listing on the AIM Market was discontinued as of 18 February 2016.

### ***Existing capital***

The company's share capital is conditionally increased by up to EUR 6,434,646.00 by the issuing of up to 6,434,646 new registered no par value ordinary shares (Conditional Capital I). The purpose of the conditional capital increase is (i) to ensure the granting of warrant rights and the agreement of warrant obligations in accordance with the bond conditions and (ii) to ensure the fulfilment of conversion rights and the fulfilment of conversion obligations in accordance with the bond conditions, which are issued, agreed and guaranteed by the company or its direct or indirect majority-owned subsidiaries (affiliated companies) in the period up to 27 August 2020, based on the authorisation of the Annual General Meeting of 28 August 2015. The conditional capital increase is to be implemented only in the event that financial instruments are issued based on the authorisation of the Annual General Meeting of 28 August 2015, and only insofar as the holders or creditors of financial instruments issued by the company exercise their warrant or conversion rights or fulfil their warrant or conversion obligations. The new shares carry dividend rights from the start of the financial year in which they are issued. The Management Board is authorised to determine the other details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board. The Supervisory Board is authorised to amend Section 7 of the bylaws in accordance with the use of conditional capital, and after the expiry of all warrant and conversion periods.

The share capital is conditionally increased by up to EUR 500,000.00 by the issuing of up to 500,000 new registered ordinary shares, each of which constitutes a share of EUR 1.00 of the share capital (no par value shares) (Conditional Capital II). The purpose of the conditional capital increase is to redeem warrant rights, pursuant to the warrant conditions, to the benefit of the holders of warrants from warrant bonds issued on the basis of the authorisation resolution of the Annual General Meeting of 17 March 2009. The new shares are issued at the warrant price set pursuant to the aforementioned authorisation resolutions (issue amount pursuant to Section 193 (2) No. 3 AktG). The conditional capital increase is to be implemented only in the event that warrant bonds are issued, and only insofar as that the holders of the warrants exercise their warrant rights, and the company does not use other sources for the required shares or replace them with a cash payment. The new shares issued by the exercise of the warrant right are dividend-entitled from the start of the financial year in which they are issued. The Management Board is authorised to determine the further details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board.

The company's share capital is conditionally increased by EUR 542,400 by the issuing of up to 542,400 no par value registered shares (Conditional Capital III). The purpose of the conditional capital increase is solely to fulfil the warrants granted up to 1 July 2015 on the basis of the authorisation of the Annual General Meeting of 2 July 2010. The conditional capital increase is implemented only insofar as holders of the issued warrants exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay cash settlement in order to fulfil the warrants. The new shares are dividend-entitled from the start of the financial year in which they are issued by the exercise of warrants.

The company's share capital is conditionally increased by up to EUR 2,494,890.00 by the issuing of up to 2,494,890 new ordinary registered no par value shares (Conditional Capital IV). The purpose of the conditional capital increase is to ensure the granting of warrant rights and the agreement of warrant obligations in accordance with the warrant bond conditions to holders or creditors of warrants from warrant bonds, or to ensure the fulfilment of conversion rights and the fulfilment of conversion obligations in accordance with the convertible bond conditions to holders or creditors of convertible bonds issued by the company in the period up to 9 May 2016 on the basis of the authorisation of the Annual General Meeting of 10 May 2011. The conditional capital increase is to be implemented only in the event that warrant or convertible bonds are issued, and only insofar as the holders or creditors of warrants or convertible bonds issued by the company on the basis of the authorisation of the Annual General Meeting of 10 May 2011 exercise their warrant or conversion rights or fulfil their warrant or conversion obligations (also in the event that a corresponding company voting right is exercised). The new shares are dividend-entitled from the start of the financial year in which they are issued. The

Management Board is authorised to determine the further details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board.

The company's share capital is conditionally increased by EUR 1,814,984.00 by the issuing of up to 1,814,984 no par value registered shares (Conditional Capital V). The purpose of the conditional capital increase is solely to fulfil the warrant rights granted up to 27 August 2020 on the basis of the authorisation of the Annual General Meeting of 28 August 2015. The conditional capital increase is implemented only insofar as holders of the issued warrants exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay cash settlement in order to fulfil the warrants. The new shares are dividend-entitled from the start of the financial year in which they are issued by the exercise of warrants. The Supervisory Board is authorised to amend Section 7 of the bylaws in accordance with the use of conditional capital and after the expiry of all warrant and conversion periods.

The capital measure implemented in January 2017 generated changes relating to Conditional Capital I as well as the corresponding authorisations of the Management Board. Further information on this can be found in the supplementary report.

***Corporate governance declaration pursuant to Section 289a HGB including the statement on the German Corporate Governance Code pursuant to Section 161 AktG***

Pursuant to Section 289a of the German Commercial Code (HGB), listed stock corporations are required to issue a declaration relating to their corporate governance. This must either be included in the management report or it must be published on the company's website. The current corporate governance declaration by Biofrontera AG and the corporate governance report are available on the company's website at [www.biofrontera.com](http://www.biofrontera.com) in the section "Investors", subsection "Corporate Governance".

Leverkusen, 05 April 2017

Biofrontera AG

Prof. Dr. Hermann Lübbert

Chief Executive Officer

Christoph Dünwald

Chief Sales and Marketing Officer

Thomas Schaffer

Chief Financial Officer

***Responsibility Statement***

***Affirmation of the legal representatives pursuant to § 37y of the German Securities Trading Act (WpHG) in conjunction with § 37w para. 2 no.3 WpHG***

We affirm that, to the best of our knowledge and in accordance with the applicable accounting principles, the consolidated financial statement gives a true and fair view of the financial position, cash flows and results from operations of the Group, and that the combined company and Group management report presents the business performance, including the business results and the position of the Biofrontera Group and of Biofrontera AG, in such a way that a true and fair view is conveyed, and that the main opportunities and risks relating to the anticipated performance of the Biofrontera Group and Biofrontera AG are described.

Leverkusen, 05 April 2017

Biofrontera AG

Prof. Dr. Hermann Lübbert

Christoph Dünwald

Thomas Schaffer

## F.1.2) Consolidated balance sheet as of 31 December 2016

Annex 1

Assets

| in EUR                          |     | 31 December 2016     | 31 December 2015    |
|---------------------------------|-----|----------------------|---------------------|
| <b>Non-current assets</b>       |     |                      |                     |
| Tangible assets                 | (1) | 644,710.75           | 372,834.23          |
| Intangible assets               | (1) | 1,251,882.75         | 1,901,927.93        |
|                                 |     | 1,896,593.50         | 2,274,762.16        |
| <b>Current assets</b>           |     |                      |                     |
| <b>Current financial assets</b> |     |                      |                     |
| Trade receivables               | (3) | 1,624,066.62         | 894,558.96          |
| Other financial assets          | (4) | 1,376,870.39         | 730,440.34          |
| Cash and cash equivalents       | (7) | 15,126,096.05        | 3,959,207.16        |
|                                 |     | 18,127,033.06        | 5,584,206.46        |
| <b>Other current assets</b>     |     |                      |                     |
| <b>Inventories</b>              |     |                      |                     |
| Raw materials and supplies      | (2) | 1,350,334.68         | 590,420.47          |
| Unfinished products             |     | 477,098.97           | 42,723.50           |
| Finished products and goods     |     | 1,818,889.76         | 900,505.05          |
| Income tax reimbursement claims | (5) | 32,980.20            | 32,220.80           |
| Other assets                    | (4) | 175,749.68           | 72,879.33           |
|                                 |     | 3,855,053.29         | 1,638,749.15        |
|                                 |     | 21,982,086.35        | 7,222,955.61        |
| <b>Total assets</b>             |     | <b>23,878,679.85</b> | <b>9,497,717.77</b> |

## Liabilities

| In EUR   |      | 31 December 2016     | 31 December 2015    |
|--|------|----------------------|---------------------|
| Equity   | (9)  |                      |                     |
| Subscribed capital   |      | 37,722,433.00        | 25,490,430.00       |
| Capital reserve  |      | 98,676,784.29        | 79,525,292.28       |
| Capital reserve from foreign currency conversion adjustments |      | (154,204.12)         | (1,188.65)          |
| Loss carry forward   |      | (109,823,695.69)     | (98,620,285.49)     |
| Net loss of the year   |      | (10,579,204.16)      | (11,203,410.20)     |
|  |      | 15,842,113.32        | (4,809,162.06)      |
| <b>Long-term liabilities</b>                                 |      |                      |                     |
| Long-term financial liabilities                              | (10) | 3,596,896.89         | 11,229,946.00       |
| <b>Current liabilities</b>                                   |      |                      |                     |
| <b>Current financial liabilities</b>                         |      |                      |                     |
| Trade payables   | (11) | 2,093,154.20         | 1,043,425.65        |
| Short-term financial debt                                    | (9)  | 274,424.06           | 830,174.00          |
| Other financial liabilities                                  | (13) | 58,458.32            | 37,622.28           |
|  |      | 2,426,036.58         | 1,911,221.93        |
| <b>Other current liabilities</b>                             |      |                      |                     |
| Income tax provision   | (8)  | 0.00                 | 0.00                |
| Other provisions   | (12) | 1,823,673.82         | 1,041,860.80        |
| Other current liabilities                                    | (13) | 189,959.24           | 123,851.10          |
|  |      | 2,013,633.06         | 1,165,711.90        |
|  |      | 4,439,669.64         | 3,076,933.83        |
| <b>Total liabilities</b>                                     |      | <b>23,878,679.85</b> | <b>9,497,717.77</b> |

### F.1.3) Consolidated statement of comprehensive income for the 2016 financial year

#### Annex 2

| In EUR   | Note | 01.01.-31.12.2016 | 01.01.-31.12.2015 |
|--|------|-------------------|-------------------|
| Sales revenue  | (15) | 6,130,270.09      | 4,137,917.39      |
| Cost of sales  | (16) | (1,652,247.11)    | (1,235,504.25)    |
| Gross profit from sales  |      | 4,478,022.98      | 2,902,413.14      |
| Operating expenses   |      |                   |                   |
| Research and development costs   | (17) | (4,640,324.84)    | (6,203,986.93)    |
| General administrative costs   | (19) | (2,853,053.95)    | (2,759,334.78)    |
| <i>thereof financing costs</i>   |      | (826,080.68)      | (264,924.08)      |
| Sales costs  | (18) | (8,763,405.57)    | (4,170,044.72)    |
|  |      | (16,256,784.36)   | (13,133,366.43)   |
| Loss from operations   |      | (11,778,761.38)   | (10,230,953.29)   |
| Interest expenses  | (20) | (1,207,022.19)    | (1,168,551.42)    |
| Interest income  | (20) | 2,935.14          | 9,225.68          |
| Other expenses   | (21) | (47,548.30)       | (32,046.20)       |
| Other income   | (21) | 2,451,192.57      | 218,915.03        |
|  |      | 1,199,557.22      | (972,456.91)      |
| Profit/loss before income tax  | (23) | (10,579,204.16)   | (11,203,410.20)   |
| Income tax   |      | 0.00              | 0.00              |
| Profit or loss for the period  | (23) | (10,579,204.16)   | (11,203,410.20)   |
| Expenses and income not included in profit/loss  |      |                   |                   |
| Items which may in future be regrouped into the profit and loss statement under certain conditions |      |                   |                   |
| Translation differences resulting from the conversion of foreign business operations               |      |                   |                   |
|  |      | (153,015.47)      | (1,188.65)        |
| Other income total   |      | (153,015.47)      | (1,188.65)        |
| Total profit/loss for the period   |      | (10,732,219.63)   | (11,204,598.85)   |
| Non-diluted (=diluted) earnings per share  | (22) | (0.36)            | (0.48)            |

### F.1.4) Statement of changes in equity for 2016

Annex 3

|   | Ordinary shares<br>number | Subscribed capital<br>EUR | Capital reserve<br>EUR | Capital reserve<br>from foreign<br>currency<br>conversion<br>adjustments<br>EUR | Accumulated loss<br>EUR | Total<br>EUR    |
|---|---------------------------|---------------------------|------------------------|---|-------------------------|-----------------|
| Balance as at 01 January 2015   | 22,196,570                | 22,196,570.00             | 76,402,715.36          | 0.00  | (98,620,285.49)         | (21,000.13)     |
| Capital increase  | 3,293,860                 | 3,293,860.00              | 3,515,382.80           | 0.00  | 0.00                    | 6,809,242.80    |
| Costs of equity procurement   | 0                         | 0.00                      | (495,769.88)           | 0.00  | 0.00                    | (495,769.88)    |
| Foreign currency conversion adjustment  | 0                         | 0.00                      | 0.00                   | (1,188.65)  | 0.00                    | (1,188.65)      |
| Increase in capital reserve from the stock option programme                               | 0                         | 0.00                      | 102,964.00             | 0.00  | 0.00                    | 102,964.00      |
| Net loss of the year  | 0                         | 0.00                      | 0.00                   | 0.00  | (11,203,410.20)         | (11,203,410.20) |
| Balance as at 31 December 2015  | 25,490,430                | 25,490,430.00             | 79,525,292.28          | (1,188.65)  | (109,823,695.69)        | (4,809,162.06)  |
| Capital increase  | 9,870,333                 | 9,870,333.00              | 14,647,544.60          | 0.00  | 0.00                    | 24,517,877.60   |
| Conversion from convertible bond 2016/2021  | 1,603,050                 | 1,603,050.00              | 3,231,341.65           | 0.00  | 0.00                    | 4,834,391.65    |
| Conversion from option bond 2011/2016   | 758,620                   | 758,620.00                | 1,486,895.20           | 0.00  | 0.00                    | 2,245,515.20    |
| Foreign currency conversion adjustment  | 0                         | 0.00                      | 0.00                   | (153,015.47)  | 0.00                    | (153,015.47)    |
| Costs of equity procurement   | 0                         | 0.00                      | (321,316.20)           | 0.00  | 0.00                    | (321,316.20)    |
| Changes in capital reserves pursuant to the issuance of the convertible<br>bond 2016/2021 | 0                         | 0.00                      | (4,247.24)             | 0.00  | 0.00                    | (4,247.24)      |
| Increase in capital reserve from the stock option programme                               | 0                         | 0.00                      | 111,274.00             | 0.00  | 0.00                    | 111,274.00      |
| Net loss of the year  | 0                         | 0.00                      | 0.00                   | 0.00  | (10,579,204.16)         | (10,579,204.16) |
| Balance as at 31 December 2016  | 37,722,433                | 37,722,433.00             | 98,676,784.29          | (154,204.12)  | (120,402,899.85)        | 15,842,113.32   |



### F.1.5) Consolidated cash flow statement for the 2016 financial year

Annex 4

| in EUR  | 01.01.-31.12.16        | 01.01.-31.12.15       |
|---|------------------------|-----------------------|
| <b>Cash flows from operations</b>   |                        |                       |
| Profit/loss for the period  | (10,579,204.16)        | (11,203,410.20)       |
| <b>Adjustments to reconcile profit/loss for the period to cash flow into operations</b> |                        |                       |
| Financial result  | 1,204,087.05           | 1,159,325.74          |
| Depreciation  | 830,779.04             | 811,681.84            |
| (Gains)/losses from disposal of assets  | 5,630.83               | 115.00                |
| Non-cash expenses and income  | (412,109.68)           | (22,203.75)           |
| <b>Changes in operating assets and liabilities</b>                                      |                        |                       |
| Trade receivables   | (729,507.66)           | (585,574.61)          |
| Other assets and income tax assets  | (870,059.80)           | (11,314.11)           |
| Inventories   | (2,112,674.39)         | (140,126.97)          |
| Trade payables  | 1,049,728.55           | 75,987.99             |
| Provisions  | 786,762.28             | 149,945.42            |
| Other liabilities   | 86,944.18              | 48,255.77             |
| <b>Net cash flow from operational activities</b>  | <b>(10,739,623.76)</b> | <b>(9,717,317.88)</b> |
| <b>Cash flows from investment activities</b>  |                        |                       |
| Purchase of intangible and tangible assets  | (484,537.07)           | (180,303.54)          |
| Interest received   | 2,935.14               | 183,978.17            |
| Revenue from sale of intangible and tangible assets                                     | 26,295.86              | 13,353.71             |
| <b>Net cash flow from (into) investment activities</b>                                  | <b>(455,306.07)</b>    | <b>17,028.34</b>      |
| <b>Cash flows from financing activities</b>   |                        |                       |
| Proceeds from the issue of shares   | 24,196,561.40          | 6,313,472.92          |
| Proceeds from conversions of convertible bonds 2016/2021                                | 4,830,144.41           | 0.00                  |
| Proceeds from conversions of option bond 2011/2016                                      | 2,245,515.20           | 0.00                  |
| Interest paid   | (841,603.24)           | (1,224,598.00)        |
| Increase/(decrease) in long-term financial debt   | (7,633,049.11)         | 455,647.62            |
| Increase/(decrease) in short-term financial debt  | (435,749.94)           | (394,424.00)          |
| <b>Net cash flows from financing activities</b>   | <b>22,361,818.72</b>   | <b>5,150,098.54</b>   |
| <b>Net increase (decrease) in cash and cash equivalents</b>                             | <b>11,166,888.89</b>   | <b>(4,550,191.00)</b> |
| Cash and cash equivalents at the beginning of the period                                | 3,959,207.16           | 8,509,398.16          |
| Cash and cash equivalents at the end of the period                                      | 15,126,096.05          | 3,959,207.16          |
| <b>Composition of financial resources at the end of the period</b>                      |                        |                       |
| Cash and cash balances and cheques  | 15,126,096.05          | 3,959,207.16          |

## **F.1.6) Notes to the consolidated financial statements as of 31 December 2016**

### ***Information about the company***

Biofrontera AG ([www.biofrontera.com](http://www.biofrontera.com)), registered in the commercial register of Cologne District Court, Department B under No. 49717, and its wholly-owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, all with head office at Hemmelrather Weg 201, 51377 Leverkusen, Germany, and Biofrontera Inc., which is based in Wilmington, Delaware, USA, research, develop and market dermatological products. The main focus is on the discovery, development and distribution of dermatological drugs and dermatologically tested cosmetics for the treatment and care of diseased skin. Biofrontera AG (hereinafter also the "company" or "Biofrontera") pursues this goal along with its subsidiaries. All the companies together form the "Biofrontera Group".

The Biofrontera Group was the first small German pharmaceutical company to receive centralised European and US drug approval for an independently developed drug, Ameluz®. In December 2011, Ameluz® was approved in Europe to treat light and moderate actinic keratosis. In September 2016, European approval was expanded to treat field cancerisation, and in January 2017 to treat basal cell carcinoma. In May 2016, the FDA issued approval in the USA for lesion-directed and field-directed treatment of actinic keratosis in combination with the red light lamp BF-RhodoLED®. In addition, a range of cosmetic products is to be expanded. The first product in this range, Belixos® Creme, was launched in the autumn of 2009. A hair tonic, Belixos® LIQUID, was introduced in the spring of 2014 and a Belixos® Gel skin care for rosacea and acne was launched at the beginning of December 2014. Belixos® Protect, a day cream with protective anti-aging properties designed especially for photodamaged skin, followed in July 2015, as well as in July 2016 Belixos® to go, a practical 5 ml roll-on applicator with a stainless steel roller, with simple and hygienic application leading to an immediate cooling effect for the affected skin. Two further clinical development projects, one a dermatological project and one for the prevention of migraines, have been spun off into dedicated subsidiaries and are not being actively pursued at the present time.

The product Ameluz® (development name BF-200 ALA), which was approved in Europe at the end of 2011, has been tested for European approval in one Phase II and two Phase III clinical trials to treat actinic keratosis. In preparation for approval in the USA, two Phase I trials and a further Phase III trial were conducted. Ameluz® consists of a combination of the drug aminolevulinic acid (ALA) and a patent-protected nanoemulsion (BF-200), with the latter chemically stabilising the ALA and enhancing its skin penetration. The clinical results regarding the treatment of actinic keratosis have shown its

clear superiority to the competitor product against which it was compared in the Phase III trials. An application for centralised European approval was submitted on 1 September 2010, and this approval was granted by the European Commission on 16 December 2011. Ameluz® has been sold in Germany since February 2012 and in several other European countries since autumn 2012. In September 2016, approval was expanded to treat field cancerisation, in other words, larger related areas permeated by tumour cells. Approval in the USA occurred on 10 May 2016, which now opens up the world's largest healthcare market to Biofrontera. Market launch occurred in October 2016. In addition, Biofrontera has carried out another Phase III trial for the treatment of basal cell carcinoma. This trial formed the basis for the expansion of the existing EU approval for this indication, which was issued in January 2017.

In November 2012, Biofrontera's BF-RhodoLED® PDT lamp received pan-European approval for use as a medical device and has since been sold in parallel with Ameluz®. In Europe, doctors can opt to use any of the lamps approved for PDT, whereas in the USA the approval of Ameluz® is combined with utilisation of the BF-RhodoLED® lamp. It is consequently approved as a combination product along with the drug.

In July 2016, the company agreed a research partnership with Maruho Co., Ltd. ("Maruho"), a Japanese company specialising in dermatology, in which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. This corresponds to the same strategy with which Ameluz® was also developed. The nanoemulsion technology stabilised the active substance and improved skin penetration, leading to greater clinical efficacy. This principle is also to be applied to other substances as part of the partnership with Maruho. According to the agreement, Maruho will bear all costs connected with the exploratory research of for new product candidates. It is planned that Maruho will be the owner of the new products and that Biofrontera will receive the licence to market in Europe.

The BF-derm1 project, which is currently not being actively pursued, was tested in a three-part Phase II trial for the treatment of chronic, antihistamine-resistant urticaria. The trial demonstrated the drug's good efficacy, which reduced the intensity of urticaria rashes and itching as well as reducing the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is an innovative substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007.

They show that the substance is almost completely absorbed in the intestine, and that it takes around two days for 50% of the substance to be broken down or excreted. These results are an excellent starting point for developing the substance for administration in tablet form.

The intention is to finance the development of both BF-derm1 and BF-1 independently of Biofrontera's normal budget by seeking funding providers who will benefit directly from the development of these products. For this reason, the two projects were acquired by Biofrontera AG and transferred as shareholder contributions to the two subsidiaries Biofrontera Development GmbH and Biofrontera Neuroscience GmbH, which were formed in December 2012. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is now the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products was uncoupled from the normal Group financing. As a result, the company's short-term financial plans can focus on the market launch of Ameluz® in North America and the extension of its range of indications, as well as the establishment of the Group as a specialist pharmaceutical company.

## ***Summary of significant accounting policies***

### Basis for preparation of the consolidated financial statements

The consolidated financial statements for Biofrontera AG for the financial year from 1 January 2016 to 31 December 2016 have been prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC), which are endorsed by the European Union (EU) and applicable on the balance sheet date. In addition, statutory provisions pursuant to Section 315a (1) of the German Commercial Code (HGB) have been complied with.

The assets and liabilities are recognised and measured in accordance with the IFRS that were mandatory on 31 December 2016.

Standards, amendments to standards and interpretations applied for the first time in the consolidated financial statements for 31 December 2016:

### Standards and interpretations requiring first-time mandatory application

| Standard / Interpretation   | First-time mandatory application as per IASB | First-time mandatory application in the EU |
|---|--|--|
| Amendments to IAS 19 "Employee  | 1 July 2014                                  | 1 February 2015                            |
| Annual Improvements Project   | 1 July 2014                                  | 1 February 2015                            |
| Amendments to IAS 1 "Presentation of  | 1 January 2016                               | 1 January 2016                             |
| Amendments to IAS 16 "Property, Plant and Equipment" and IAS 38   | 1 January 2016                               | 1 January 2016                             |
| Amendments to IAS 16 "Property, Plant and Equipment" and IAS 41   | 1 January 2016                               | 1 January 2016                             |
| Amendments to IAS 27 "Separate Financial Statements": Equity  | 1 January 2016                               | 1 January 2016                             |
| Amendments to IFRS 10 "Consolidated Financial Statements", IFRS 12 "Disclosure of Interests in Other Entities" and IAS 28 "Interests in Associates and Joint Ventures": Investment Entities: Applying the Consolidation Exception | 1 January 2016                               | 1 January 2016                             |
| Amendments to IFRS 11 "Joint Arrangements": Acquisitions of Interests in Joint Operations   | 1 January 2016                               | 1 January 2016                             |
| Annual Improvements Project Cycle 2012-2014   | 1 January 2016                               | 1 January 2016                             |

With the exception of minor changes due to IAS 1, no changes have arisen for the consolidated financial statements of Biofrontera AG.

Standards and interpretations applied early voluntarily

(No mandatory application, although EU endorsement has already occurred)

| Standard / Interpretation   | First-time mandatory application as per IASB | First-time mandatory application in the EU |
|---|--|--|
| IFRS 15 "Revenue from Contracts with Customers" (including supplements) | 1 January 2018                               | 1 January 2018                             |
| IFRS 9 "Financial Instruments"  | 1 January 2018                               | 1 January 2018                             |

Standards and interpretations not (yet) applicable in the EU

(EU endorsement has not yet occurred)

| Standard / Interpretation  | First-time mandatory application as per IASB | First-time mandatory application in the EU |
|--|--|--|
| Amendments to IAS 7 "Statements of Cash Flows": Disclosure Initiative  | 1 January 2017                               | Not yet known                              |
| Amendments to IAS 12 "Income Taxes": Recognition of Deferred Tax Assets for Unrealised Losses  | 1 January 2017                               | Not yet known                              |
| Amendments to IAS 28 "Interest in Associates and Joint Ventures" and IFRS 10 "Consolidated Financial Statements": Sale or Contribution of Assets | Postponed for an indefinite period           | Not yet known                              |
| Amendments to IAS 40 "Investment Property": Transfers of Investment Property   | 1 January 2018                               | Not yet known                              |
| Amendments IFRS 2 "Share-based Payment": Classification and Measurement of   | 1 January 2018                               | Not yet known                              |
| Amendments to IFRS 4 "Insurance Contracts": Applying IFRS 9 Financial Instruments  | 1 January 2018                               | Not yet known                              |
| IFRS 14 "Regulatory Deferral Accounts"   | 1 January 2016                               | Not recognised                             |
| IFRS 16 "Leases"   | 1 January 2019                               | Not yet known                              |
| IFRIC 22 "Foreign Currency Transactions and Advance Consideration"   | 1 January 2018                               | Not yet known                              |
| Annual Improvements Project Cycle 2014-2016  | 01.01.2017/01.01.2018                        | Not yet known                              |
| Clarification of IFRS 15 "Revenue from Contracts with Customers"   | 01 January 2018                              | Not yet known                              |

It is expected that unless details of their effects are given below, the listed standards and interpretations that are not yet applied will have no effect on the Biofrontera Group, in the absence of relevant facts and circumstances.

As part of its disclosure initiative, the IASB has published amendments to IAS 7 – Statements of Cash Flows. The core changes are requirements for additional disclosures in the notes, which should enable the readers of financial statements to assess the changes in liabilities arising from the company's

financing activities. The amendments are to be applied the first time in the first reporting period of a financial year beginning on or after 1 January 2017. Earlier application is also permitted. When first applied, there is no comparative information from the same period in the previous year to report. Adoption of the amendments by the EU is still pending. Apart from the requirement for additional notes, the Group expects no effects on its consolidated financial statements.

In May 2014, the IASB issued the new standard IFRS 15. The aim of this new standard concerning revenue recognition is to amalgamate the various rules previously contained in different standards and interpretations. At the same time, uniform principles are defined that are applicable for all sectors and for all types of revenue transactions. The questions regarding what amount, at what time and for which time period revenue is to be realised are to be answered with the help of the 5-stage model. In addition, the standard includes a number of other regulations covering detailed issues and an expansion of the disclosures required. The new standard is to be applied to annual periods beginning on or after 1 January 2018. The first application must in principle be carried out retrospectively, but various simplification options are available; earlier application is permitted.

The Group pursues instalment sales over several years which include a financing element. Furthermore, the adoption of the new standard IFRS 15 may lead in individual cases to a different approach in revenue recognition of licences. The evaluation of individual license agreements is not yet completed. Requirements to make expanded disclosures will also arise.

In January 2016, the IASB issued the new standard IFRS 16 – Leases. IFRS 16 establishes principles for the recognition, measurement, presentation and disclosure of leases, and notes regarding leases, with the aim of ensuring that lessees and lessors provide relevant information regarding the impact of leases. At the same time, the previous accounting model applied in accordance with IAS 17, involving the classification into operating and finance leases, is abandoned in favour of a uniform accounting model for leasing agreements with a mandatory control concept. For the lessee, the standard provides a single accounting model. This model leads in the case of the lessee to all the assets and liabilities from leases being recognised on the balance sheet, provided that their term does not exceed 12 months or if they are minor assets (option). The lessor continues to differentiate, for accounting purposes, between finance and operating leases. The mandatory first-time application date of IFRS 16 – Leases is for financial years beginning on or after 1 January 2019. Early application is permitted, in principle, if IFRS 15 – Revenue from Contracts with Customers is already applied (early) in full. The lessee either has to fully apply IFRS 16 retrospectively, with the inclusion of prior reporting periods, or has to recognise the cumulative adjustment effect at the point in time of initial application as an entry in

equity at the beginning of the financial year of initial application. Adoption of the standard by the EU is still pending. The Group is currently evaluating the possible impact of the initial application of IFRS 16 on its consolidated financial statements, and will define an adoption date and transitional method, provided that the standard is adopted by the EU in this form.

In July 2014, the IASB approved the final version of IFRS 9 "Financial Instruments". The new standard includes revised regulations for the classification and measurement of financial assets, including impairment regulations, and supplements the new hedge accounting regulations published in 2013. Furthermore, more extensive disclosure obligations pursuant to IFRS 9 are to be complied with. The Group anticipates effects on the classification of financial instruments as well as expanded disclosures in the notes to the financial statements. The more precise effects, including as a result of the modified impairment model, are currently being examined.

The accounting policies applied are consistent with those applied on 31 December 2015, with the exception of the new and revised standards and interpretations described above that were applied from the 2016 financial year for the first time.

The consolidated financial statements as at 31 December 2016 are presented in euros (EUR) or thousands of euros.

The Biofrontera Group presents current and non-current assets and current and non-current liabilities as separate categories in the balance sheet, in accordance with IAS 1.60, with these categories also being subdivided to some extent according to their respective terms in the notes to the consolidated financial statement for 31 December 2016. The income statement is prepared applying the cost of sales method. In this reporting format, the net sales revenue is set against the expenses incurred in achieving it, subdivided into cost of sales, research and development costs, sales costs and general administration costs.

The consolidated financial statements for 31 December 2016 contain no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz<sup>®</sup>, including the supplementary products BF-RhodoLED<sup>®</sup> (PDT lamp) and Belixos<sup>®</sup>, and are internally monitored and managed accordingly.



On 05 April 2017, the Management Board approved the consolidated financial statements for the financial year ending 31 December 2016 for publication and forwarding to the Supervisory Board.

### ***Basis of consolidation***

The consolidated financial statements for the financial year ending 31 December 2016 include the financial statements of the parent company, Biofrontera AG, and the subsidiary companies in which the parent has a direct majority of the voting rights or another means of exercising control. The following companies have been included in the consolidated financial statements:

1. Biofrontera Bioscience GmbH, Leverkusen, Germany, with a direct interest of 100%
2. Biofrontera Pharma GmbH, Leverkusen, Germany, with a direct interest of 100%
3. Biofrontera Development GmbH, Leverkusen, Germany, with a direct interest of 100%
4. Biofrontera Neuroscience GmbH, Leverkusen, Germany, with a direct interest of 100%.
5. Biofrontera Inc., Wilmington, Delaware, USA with a direct interest of 100% since March 2015.

The basis for the consolidation of the companies included in the consolidated financial statements are the financial statements (or HBII pursuant to IFRS) of these companies prepared for 31 December 2016 pursuant to uniform principles. The consolidated financial statements for 31 December 2016 have been prepared on the basis of uniform accounting policies (IFRS).

The subsidiaries have been fully consolidated from the date of acquisition. The date of acquisition is the date when the parent company obtained control of these subsidiaries. The subsidiaries are included in the consolidated financial statements until control over these companies no longer exists.

All inter-company balances and income and expenses have been eliminated on consolidation. Results of intra-group transactions have been eliminated.

### ***Translation of amounts in foreign currencies***

The consolidated financial statements for 31 December 2016 have been prepared in EUR (or thousands of EUR), which is the functional currency of all the German companies included in the consolidated financial statements, and of the Group, and is the Group's reporting currency.

For subsidiaries with a functional currency that is the local currency of the country in which they have their registered office, the assets and liabilities that are recognised in the foreign currency on the balance sheets of the foreign, economically independent subsidiaries, are converted to euros applying the relevant period-end exchange rate (2016: 1,052 USD/EUR, previous year: 1,091 USD/EUR). Income and expense items are translated applying the average exchange rates (2016: 1,107 USD/EUR, previous year: 1,102 USD/EUR) applicable to the relevant period. The differences resulting from the valuation of equity at historical rates and applying the period-end exchange rates are reported as a change not affecting profit or loss and carried directly to equity within the other equity components.

Transactions realised in currencies other than EUR are reported using the exchange rate on the date of the transaction. Assets and liabilities are translated applying the closing exchange rate for each balance sheet date. Gains and losses arising from such currency translations are recognised in income.

### ***Application of estimates***

The preparation of the consolidated financial statements for 31 December 2016 in accordance with IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities – as well as contingent assets and liabilities – as reported on the balance sheet date, and revenues and expenses arising during the financial year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lives of non-current assets and the formation of provisions, as well as income taxes. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary from the actual values.

The carrying amounts of items affected by estimates are presented in the respective explanatory remarks concerning the items in the notes to the consolidated financial statements.

### ***Transactions with related parties***

With regard to transactions with shareholders, particularly in connection with capital increases and the issue of Biofrontera AG bonds, please see our comments in the appendix note "Equity".

With respect to the issue of share options to employees of the Biofrontera Group, please see our comments on the "Share Option Plan" in the appendix note "Equity".

With regard to the remuneration of Management Board members, please see our comments in the appendix note "Members of the Management Board".

With regard to the remuneration of Supervisory Board members, please see our comments in the appendix note "Members of the Supervisory Board".

***Fixtures and equipment***

Pursuant to IAS 16, the value of fixtures and equipment is recognised on the balance sheet at historical acquisition and production cost less scheduled depreciation.

Depreciation of fixtures and equipment is generally applied straight-line over the estimated useful life of assets (generally three to thirteen years). The main useful lives are unchanged:

- IT equipment 3 years, straight-line
- Fixtures and equipment 4 years, straight-line
- Office and laboratory facilities 10 years, straight-line
- Laboratory devices 13 years, straight-line

Since 1 January 2008, low value assets with purchase costs of between EUR 150 and EUR 1,000 have been booked to the year of acquisition as a single item for the relevant year, and are fully depreciated over five years.

***Intangible assets***

Purchased software is recognised at cost less amortisation applied straight-line over a three-year useful life.

Purchased intangible assets consist of licenses and other rights. They are recognised at cost less accumulated amortisation. Only intangible assets purchased from third parties are capitalised as assets, as the requirements for the recognition of internally generated intangible assets are not met. These

intangible assets are capitalised as assets and generally amortised straight-line over an estimated useful life of between 4 and 20 years.

No intangible assets exist with indefinite useful lives.

Borrowing costs are not recognised as part of the purchase cost of the acquired assets but are instead expensed in the period in which they arrived, because the Group has no qualifying assets in the meaning of IAS 23.5.

### ***Impairment of assets***

The company tests assets for impairment when indications exist that the carrying amount of an asset exceeds its recoverable amount. A possible impairment requirement of assets held for use is evaluated by comparing the carrying amount of an asset with the cash flows that the asset is expected to generate in the future. When such an asset is considered to be impaired, the impairment loss is measured at the amount by which the carrying amount of the asset exceeds its recoverable amount. Assets that are to be sold are reported at the lower of the carrying amount or fair value less costs to sell.

### ***Financial instruments***

The financial instruments held by the Biofrontera Group on the balance sheet date primarily consist of cash and cash equivalents, current (short-term) investments, trade payables and receivables as well as financial debt. Biofrontera does not currently deploy derivative financial instruments. Due to the short terms of the current financial investments, trade payables and trade receivables, the carrying amounts of these items correspond to their fair values. The current financial investments are assigned to the "financial investments held to maturity" category, and other receivables and liabilities are assigned to the "loans and receivables" category. The financial liabilities are measured applying the effective interest method, less treasury stock.

The Biofrontera Group was not exposed to significant foreign currency risk on the balance sheet date. Financial investments have been transacted in euros. Trade payables denominated in foreign currency are of minor importance. Trade receivables are regularly reviewed with respect to potential default risk.

Various safeguarding criteria are applied when selecting of current capital investments (for example, ratings, capital guarantee, safeguarding by the deposit protection fund). Based on the selection criteria

and the ongoing monitoring of capital investments, Biofrontera does not consider any default risks to exist in this area that have not been taken into account. The amounts reported in the balance sheet generally represent the maximum default risk.

The monitoring and management of liquidity is based on short-term and long-term corporate planning. Liquidity risks are identified at an early stage, using simulations of various scenarios. Current liquidity is reported and monitored on a daily basis.

To date, Biofrontera has always succeeded in providing the necessary financing for its business operations through injections of equity.

As a result of the capital increases implemented in February, April and November 2016, and another capital increase implemented in January 2017, the company currently has sufficient liquidity at its disposal. Especially as a result of independent marketing in the USA, however, further capital measures will be required until breakeven is reached.

As of 31 December 2016, Biofrontera held no financial positions that were exposed to interest rate risks.

### ***Financial investments held to maturity***

The company classifies the securities held as current financial investments as "financial investments held to maturity", in accordance with IAS 39.9. As of the 31 December 2016 reporting date, Biofrontera had in its portfolio holdings of its own Warrant Bond I 2009/2017 with a nominal value of EUR 1,500 thousand. The warrant bonds held by Biofrontera were written up by a further EUR 267 thousand (depreciation previous year: EUR 100 thousand), to EUR 1,500 thousand, as of 31 December 2016, due to an increase in the market price. In accordance with IAS 32, the bonds are reported on a net basis with the corresponding bond debt.

### ***Inventories***

Raw materials and supplies, as well as finished and unfinished goods, are recognised at the lower of cost or net realisable value. Borrowing costs are not capitalised. Cost is calculated applying the first-

in-first-out method (FIFO). A value adjustment is made to the inventories on the balance sheet date if the net realisable value is lower than the carrying amount.

### ***Trade receivables***

Trade receivables are reported at their nominal value. Any value adjustments are booked directly against the relevant receivable. Receivables denominated in foreign currencies have been translated into euros applying the exchange rates on the balance sheet date, with any translation differences being recognised in profit or loss.

### ***Cash and cash equivalents***

Cash and cash equivalents include cash in hand, cheques and bank deposits with a term of up to three months at the time of acquisition, as well as current financial assets. These are measured at amortised cost.

### ***Trade payables, overdrafts***

Trade payables, as well as liabilities from current accounts and other liabilities are recognised at their redemption amount. Due to their short-term nature, the reported carrying amount reflects the fair value. Foreign currency liabilities are translated applying the period-end exchange rate. Exchange rate losses and gains are reported in the income statement.

### ***Provisions***

Provisions are formed if an obligation to third parties resulting from a past event exists, and is likely to result in an outflow of assets in the future, and if the effect on assets can be reliably estimated.

### ***Share options***

Share options (equity-settled share-based payments) are valued at the fair value on the date of granting. The fair value of the obligation is capitalised as a personnel expense over the retention period. Obligations relating to cash-settled share-based payment transactions are recognised as liabilities and are measured at the fair value on the balance sheet date. In the event that Biofrontera AG has the right to choose between payment in cash or payment using shares when a right is exercised, an increase in the capital reserve is initially performed pursuant to IFRS 2.41 and IFRS 2.43. The costs

are recognised over the vesting period. The fair value of both cash-settled and equity-settled share-based payment transactions is generally determined applying internationally recognised methods.

### ***Warrant bonds***

In accordance with IAS 32, warrant bonds are classified as hybrid financial instruments that represent a debt security with an embedded conversion or subscription option. The issuer of such a financial instrument, which contains both a liability and an equity component, is required to present the liability component and the equity component separately from the financial instrument originally reported on the balance sheet. At the start, the market value of the liability component corresponds to the present value of the contractually fixed future cash flows discounted at the prevailing market interest rate valid for financial instruments as of this date, which have a comparable credit status and lead essentially to the same cash flows given the same conditions, but where no exchange or subscription option exists. Subsequent measurement is performed applying the effective interest method. The liability is derecognised to the extent that the obligation underlying the liability is fulfilled, terminated or expires. The equity instrument consists of the embedded option to convert the liability into issuer's equity. The market value of the option comprises its present value and, where relevant, its intrinsic value. The intrinsic value of an option or of another derivative financial instrument is, if any, the difference between the market value of the underlying instrument and the contract price at which the underlying instrument is to be purchased, issued, sold or exchanged. The fair value of a derivative financial instrument consists of its market value less its intrinsic value. The present value is determined by the length of the remaining period up until maturity or until the expiration of the derivative financial instrument.

If the warrant bonds are redeemed before maturity through early redemption or early repurchase, with the original conversion rights remaining unchanged, the fee paid and all transactions relating to the repurchase or redemption are allocated to the liability and equity components of the instrument at the time of the transaction. The method for the allocation of the fees and transaction costs to the two components is identical to that utilised in the original allocation applied to the revenue received when issuing the bond.

### ***Income tax***

In accordance with IAS 12, Biofrontera recognises deferred taxes for valuation differences between IFRS valuation and tax law valuation. Deferred tax liabilities are generally recognised for all taxable temporary differences – claims from deferred taxes are only recognised to the extent that it is probable

that taxable profits will be available to utilise the claims. The carrying amount of deferred income tax assets is reviewed on each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available against which the deferred tax claim can be at least partially utilised. Previously unrecognised deferred income tax assets are reassessed on each balance sheet date and are recognised to the extent that it is probable from a current perspective that sufficient future taxable profit will be available to realise the deferred tax asset.

Deferred tax liabilities and deferred tax assets are offset if a right to offset exists, and if they are levied by the same tax authority.

Current taxes are calculated on the basis of the company's taxable earnings for the period. The tax rates applicable to the respective companies on the balance sheet date are used for this purpose.

### ***Earnings per share***

Earnings per share are calculated by dividing net consolidated income by the weighted average number of outstanding shares during the year in accordance with IAS 33 ("Earnings per Share").

### ***Leasing***

The leases that have been agreed are classified as either finance leases or operating leases. If the lessor has passed all significant opportunities and risks onto the Group as a lessee, the Group is assigned beneficial ownership. The companies included in the consolidated financial statements have usually concluded contracts that are classified as operating leases. In this case, ongoing lease payments are expensed as they are incurred. Agreed leases that are classified as finance leases are recognised as assets at the lower of the present value of the minimum lease payments or the fair value of the leased asset at the beginning of the lease, and depreciated over the shorter of the lease duration or useful life, if the transfer of ownership to the lessee at the end of the contract term is insufficiently certain.

### ***Revenue recognition***

The company recognises revenue in accordance with IAS 18 if the risks and opportunities connected with ownership have transferred to the customer. The company realises its revenue primarily through the sale of its products. Income from milestone and licensing agreements with third parties are recognised once the underlying contractual conditions come into force. The receipt of revenue can



always be fully and immediately recognised as revenue if the conditions of IAS 18 IE 20 are met in the form of a one-off contract start payment.

Revenue and other income are recognised if the amount can be measured reliably and payment is sufficiently probable as well as other conditions mentioned below are met. All income in connection with the sale of products and licence income is recognised as revenue. Revenue is deemed to be realised when the deliveries and services owed have been provided and substantial risk and chances have been passed to the acquirer.

Most of the revenues are generated by product sales. The sale of Ameluz® almost exclusively occurs through pharmaceutical wholesalers or in Europe also directly to pharmacies or hospitals. Above and beyond this, in 2016 a considerable portion of sales revenue was achieved through passing costs on to Maruho Co. Ltd as part of the development partnership that has been agreed.

In the case of direct sales of the BF-RhodoLED® lamps, the delivered products and services on which amounts are owed are settled only after complete installation, since the installation services requires specialised knowledge, is not just an ancillary service and, for legal reasons, the lamp may only be used by the customer after successful installation. In the case of lamps on loan, in other words, in the case of lamps already installed for testing by buyers before a purchase, the preconditions are met through the origination of a valid purchase agreement and the generation of an outgoing invoice.

Belixos® is predominantly sold through Amazon. Revenue is recognised after delivery and payment by the customer. Based on experience, return rights granted with the sale through Amazon are exercised by customers only in very few cases.

Revenues are recognised less revenue based trade taxes and sales deductions. Expected sales deductions, for instance rebates, discounts or returns, are recognised based on estimated values at revenue recognition. Payment terms for Ameluz® include short-term payment terms with a possibility for sales rebates. Instalment payments over 48 months, which include a financing component, are sometimes agreed upon with the sale of BF-RhodoLED®.

Licence income as well as milestone-based payments are recognised when the contractual obligation has been fulfilled.

### ***Research and development expenses***

Pursuant to IAS 38, development costs are recognised as "intangible assets" under certain conditions. Research costs are recognised as costs as they are incurred. Development costs are capitalised if certain conditions are fulfilled depending on the possible outcome of development activities.

Estimates of such possible outcomes involve management making significant assumptions. In the management's opinion, due to uncertainties related to the development of new products, the criteria prescribed under IAS 38.57 "Intangible Assets" for capitalising development costs as assets are only fulfilled by the Biofrontera Group if the prerequisites for the expansion of the European approval and the approval in the USA are met, and if it is likely a future economic benefit will accrue to the company.

The research and development costs relating to the medication Ameluz®, which has been approved in Europe, and to the company's other research and development projects, are consequently expensed in the period in which they are incurred.

### ***Notes to the consolidated balance sheet***

#### ***1. Intangible assets and property, plant and equipment***

Changes in non-current assets in the 2016 financial year, as well as accumulated depreciation, amortisation and impairment losses, are presented in the statement of changes in non-current assets. Property, plant and equipment consist mainly of office and business equipment and laboratory and production facilities.

The additions to intangible assets and to property, plant and equipment in the reporting period arise mainly from the purchase of software to compare important documents (EUR 20 thousand; previous year: EUR 0), right-of-use assets connected with the prototype of the PDT lamp (EUR 36 thousand; previous year: EUR 26 thousand), as well as further laboratory devices (EUR 290 thousand; previous year: EUR 35 thousand) and other fixtures and equipment (EUR 117 thousand; previous year: EUR 42 thousand). The asset disposals with costs totalling EUR 66 thousand (previous year: EUR 20 thousand) resulted primarily from sales of the rental lamps in an amount of EUR 52 thousand (previous year: EUR 20 thousand).

The right-of-use assets reported with a net carrying amount totalling EUR 1,112 thousand relate mainly to rights totalling EUR 1,079 thousand to use technology developed by the company ASAT Applied Science and Technology AG, Zug, Switzerland, in terms of the active ingredient ALA (aminolevulinic acid), including all related patents and know how. The right-of-use assets that are acquired are amortised over their estimated remaining useful life, from their date of acquisition, due to their direct usability. This useful life is derived from the term of the patents issued and acquired by Biofrontera AG and is reviewed annually pursuant to IAS 38.104. The remaining amortisation period amounts to 2 years (previous year: 3 years). No indications of impairment exist.

Consolidated statement of changes in non-current assets in 2016

|                                  | Cost         |             |            |           |               | Accumulated depreciation, amortisation and impairment losses |             |            |           |              | Carrying amounts |              |
|----------------------------------|--------------|-------------|------------|-----------|---------------|--|-------------|------------|-----------|--------------|------------------|--------------|
|                                  | 1 Jan. 16    | Currency    | Additions  | Disposals | 31 Dec. 16    | 1 Jan. 16  | Currency    | Additions  | Disposals | 31 Dec. 16   | 31 Dec. 16       | 31 Dec. 15   |
|                                  | EUR          | translation | EUR        | EUR       | EUR           | EUR  | translation | EUR        | EUR       | EUR          | EUR              | EUR          |
| I. Property, plant and equipment |              |             |            |           |               |  |             |            |           |              |                  |              |
| Operating and business equipment | 3,476,916.05 | 1,986.27    | 420,685.67 | 65,683.04 | 3,833,904.96  | 3,104,081.82   | 294.68      | 119,827.70 | 35,010.0  | 3,189,194.20 | 644,710.75       | 372,834.23   |
|                                  |              |             |            |           |               |  |             |            |           |              | 0                |              |
| II. Intangible assets            |              |             |            |           |               |  |             |            |           |              |                  |              |
| 1. Software and licences         | 418,895.51   | 274.59      | 25,136.08  | 0.00      | 444,306.18    | 295,052.08   | 30.51       | 9,250.46   | 0.00      | 304,333.05   | 139,973.13       | 123,843.43   |
| 2. Right-of-use assets           | 6,053,339.09 | 0.00        | 35,526.00  | 0.00      | 6,088,865.09  | 4,275,254.59   | 0.00        | 701,700.88 | 0.00      | 4,976,955.47 | 1,111,909.62     | 1,778,084.50 |
|                                  | 6,472,234.60 | 274.59      | 60,662.08  | 0.00      | 6,533,171.27  | 4,570,306.67   | 30.51       | 710,951.34 | 0.00      | 5,281,288.52 | 1,251,882.75     | 1,901,927.93 |
|                                  | 9,949,150.65 | 2,260.86    | 481,347.75 | 65,683.04 | 10,367,076.23 | 7,674,388.49   | 325.19      | 830,779.04 | 35,010.0  | 8,470,482.72 | 1,896,593.50     | 2,274,762.16 |

Consolidated statement of changes in non-current assets in 2015

|                                  | Cost        |             |           |           |             | Accumulated depreciation, amortisation and impairment |             |           |           |             | Carrying amounts |             |
|----------------------------------|-------------|-------------|-----------|-----------|-------------|---|-------------|-----------|-----------|-------------|------------------|-------------|
|                                  | 1 Jan. 15   | Currency    | Additions | Disposals | 31 Dec. 15  | 1 Jan. 15   | Currency    | Additions | Disposals | 31 Dec. 15  | 31 Dec. 15       | 31 Dec. 14  |
|                                  | EUR         | translation | EUR       | EUR       | EUR         | EUR   | translation | EUR       | EUR       | EUR         | EUR              | EUR         |
| I. Property, plant and equipment |             |             |           |           |             |   |             |           |           |             |                  |             |
| Operating and business equipment | 3,342,769.0 | 0.00        | 154,418.7 | 20,271.7  | 3,476,916.0 | 3,003,237.00  | 0.00        | 107,647.8 | 6,803.00  | 3,104,081.8 | 372,834.23       | 339,532.00  |
|                                  | 0           |             | 6         | 1         | 5           |   |             | 2         |           | 2           |                  |             |
| II. Intangible assets            |             |             |           |           |             |   |             |           |           |             |                  |             |
| 1 Software and licences          | 418,895.51  | 0.00        | 0.00      | 0.00      | 418,895.51  | 281,912.08  | 0.00        | 13,140.00 | 0.00      | 295,052.08  | 123,843.43       | 136,983.43  |
| 2 Right-of-use assets            | 6,027,454.3 | 0.00        | 25,884.78 | 0.00      | 6,053,339.0 | 3,584,360.57  | 0.00        | 690,894.0 | 0.00      | 4,275,254.5 | 1,778,084.5      | 2,443,093.7 |
|                                  | 6,446,349.8 | 0.00        | 25,884.78 | 0.00      | 6,472,234.6 | 3,866,272.65  | 0.00        | 704,034.0 | 0.00      | 4,570,306.6 | 1,901,927.9      | 2,580,077.1 |
|                                  | 9,789,118.8 | 0.00        | 180,303.5 | 20,271.7  | 9,949,150.6 | 6,869,509.65  | 0.00        | 811,681.8 | 6,803.00  | 7,674,388.4 | 2,274,762.1      | 2,919,609.1 |

## **2. Inventories**

Inventories comprise finished products, work in progress, and raw materials and supplies at the sales companies.

Inventories amount to EUR 3,646 thousand (previous year: EUR 1,534 thousand). In assessing the consumption of inventories, the sequence of consumption is assumed to be based on the first-in-first-out (FIFO) method.

## **3. Trade receivables**

The trade receivables are mainly attributable to the sale of Ameluz<sup>®</sup>, the BF-RhodoLED<sup>®</sup> PDT lamp and the medical cosmetic product Belixos<sup>®</sup>, as well as receivables due from Maruho arising from revenues from development projects. It is expected that all trade receivables will be settled within twelve months of the balance sheet date. Value adjustments for doubtful receivables have not been applied. As of the reporting date, no receivables existed that were overdue but not value-adjusted (previous year: EUR 20 thousand).

## **4. Other financial and miscellaneous assets**

The other assets comprise mainly prepayments and accrued income (EUR 707 thousand; previous year: EUR 116 thousand), prepayments rendered for studies (EUR 570 thousand; previous year: EUR 585 thousand) and VAT reimbursement claims (EUR 174 thousand; previous year: EUR 57 thousand). No individual value adjustments were applied during the reporting year (previous year: EUR 0 thousand).

## **5. Income tax reimbursement claims**

These consist of claims for tax refunds relating to withheld capital gains tax, plus the Solidarity Surcharge (EUR 33 thousand; previous year: EUR 32 thousand).

## **6. Securities**

The valuation of securities classified as financial investments held to maturity is based on amortized costs. On 31 December 2016, the company's holdings in its own Warrant Bond I 2009/2017 had a nominal value of EUR 1,500 thousand (previous year: EUR 1,500 thousand). The warrant bonds held

by Biofrontera were written up in fiscal year 2016 by EUR 267 thousand (previous year: write-down of EUR 100 thousand), to EUR 1,500 thousand (previous year: EUR 1,233 thousand) due to an increase in the market price. In accordance with IAS 32, the bonds are offset against the bond debt.

## 7. *Cash and cash equivalents*

Cash and cash equivalents relate to cash in hand, cheques, bank deposits and money deposits with a term of up to three months at the time of acquisition amounting to EUR 15,126 thousand (previous year: EUR 3,959 thousand). The carrying amounts of the cash and cash equivalents correspond to their fair value, due to the short-term nature of these investments.

## 8. *Deferred income tax claims*

The Biofrontera Group reported a net loss before tax on 31 December 2016 and on 31 December 2015. Deferred tax assets are generally determined on the basis of the existing income tax rates in Germany. The corporate tax rate is 15% as a result of the 2008 German Corporation Tax Reform Act (UStRG 2008). Including the 5.5% Solidarity Surcharge, this results in a combined tax rate of 15.8% (previous year: 15.8%). Due to the basic federal rate of 3.5% on businesses and the fact that it is no longer possible to deduct business tax as an operating expense, the resulting tax rate, taking into account the local business tax rate, is 16.6% (previous year: 16.6%).

The following table shows changes in the Group's existing deferred tax claims deriving, as a matter of principle, from tax loss carryforwards (the previous year's figures have been adjusted to the amounts determined for tax purposes):

|  | 31 December 2016     |                     | 31 December 2015  |                     |
|--|----------------------|---------------------|-------------------|---------------------|
|  | Loss carried forward | Deferred tax assets | Loss carryforward | Deferred tax assets |
|  | kEUR                 | kEUR                | kEUR              | kEUR                |
| Corporation tax including Solidarity Surcharge | 111,742              | 17,683              | 104,757           | 16,583              |
| Business tax                                   | 100,716              | 16,744              | 94,915            | 15,784              |
| <b>Total</b>                                   |                      | <b>34,427</b>       |                   | <b>32,367</b>       |

These loss carryforwards have an unlimited carryforward period under current German law.

Due to the lack of predictability regarding future taxable profits, the existing deferred tax claims deriving, as a matter of principle, from loss carryforwards (EUR 34,427 thousand; previous year: EUR

32,367 thousand) and tax deductible differences of EUR 3 thousand (previous year: EUR 33 thousand) were not recognised on the balance sheet, in accordance with IAS 12.34.

The following provides a reconciliation between expected and actual reported income tax expense, with the output value being based on the rounded income tax rate of 32.5% currently applicable to the Biofrontera Group:

|   | 31.12.2016 | 31.12.2015 |
|---|------------|------------|
|   | kEUR       | kEUR       |
| Consolidated earnings before tax  | (10,579)   | (11,203)   |
| Expected income tax reimbursement at the tax rate of the parent company | 3,433      | 3,635      |
| Differences arising from different tax rates                            | (14)       | 0          |
| Tax reductions due to changes in permanent differences                  | 10         | 161        |
| Tax increases due to non-deductible expenses                            | (222)      | (187)      |
| Changes in unrecognised deferred tax assets                             |            |            |
| - from active temporary differences                                     | 3          | 33         |
| - from loss carryforwards   | (2,060)    | (3,602)    |
| Other effects   | (1,140)    | (40)       |
| Income taxes as per statement of comprehensive income                   | 0          | 0          |

## 9. Equity

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 37,722,433.00 on 31 December 2016. It was divided into 37,722,433 registered shares with a nominal value of EUR 1.00 each. On 31 December 2015, the share capital amounted to EUR 25,490,430.00 and was increased by a total of EUR 9,870,333.00, divided into 9,870,333 registered shares, during the course of the 2016 financial year as a result of three capital increases.

As part of the capital increase implemented in February 2016, the company's share capital was increased against cash capital contributions by EUR 2,357,384.00 through issuing 2,357,384 new ordinary registered shares from approved capital. Shareholders' subscription rights were excluded for this capital increase. The new shares were offered to selected institutional investors at an issue price of EUR 1.90 per new share, consequently for a total issue amount of EUR 4,479,029.60. These shares were fully placed and the implementation of the capital increase was entered in the commercial register on 26 February 2016. The net proceeds amounted to EUR 4.4 million.

As part of the capital increase implemented in April 2016, the company's share capital was increased against cash capital contributions by EUR 2,499,999.00 through issuing 2,499,999 new ordinary registered shares from approved capital. Statutory subscription rights were granted to the shareholders.

An "additional subscription" was also offered. In other words, shareholders exercising subscription rights could apply to subscribe for unsubscribed shares at the subscription price. The subscription price per share amounted to EUR 2.00. The capital increase was fully placed. The implementation of the capital increase was entered in the commercial register on 26 April 2016. The net issue proceeds amounted to EUR 4.9 million.

As part of the capital increase implemented in November 2016, the company's share capital was increased against cash capital contributions by EUR 5,012,950.00 through issuing 5,012,950 new ordinary registered shares from approved capital. The implementation of the capital increase was entered in the commercial register on 21 November 2016. Statutory subscription rights were granted to the shareholders in a 6:1 ratio. The subscription price per share amounted to EUR 3.00. The net issue proceeds amounted to EUR 14.7 million.

Also in November 2016, 49,990 subordinated convertible 2016/2021 bonds were issued in a total nominal amount of EUR 4,999,000 ("convertible bond"). The bonds were offered at a subscription price of 100% of the nominal value per bond in a denomination of EUR 100.00 per bond, and were fully placed. Shareholders were granted indirect subscription rights to the bonds. The conversion price amounted initially to EUR 3.00 per share, EUR 4.00 per share from 1 January 2017 and EUR 5.00 per share from 1 January 2018. Shareholders were granted statutory subscription rights in a 607:1 ratio at an issue price of EUR 100.00 per bond. The total issue volume amounted to EUR 5.0 million.

The exercising of warrant rights from the 2011/2016 warrant bond generated issue proceeds of EUR 2.2 million in the 2016 financial year.

The Biofrontera AG shares were listed on the Regulated Market of the Düsseldorf Stock Exchange in 2006. In August 2012, the company's shares were also admitted to trading on the Regulated Market of the Frankfurt Stock Exchange in response to an application by the company. The company's shares are also traded on the Xetra computer trading system and all other German stock exchanges. On 3 June 2014, the share was admitted to the Prime Standard of the Frankfurt Stock Exchange and the AIM Market of the London Stock Exchange. The listing on the AIM Market was discontinued as of 18 February 2016.

The numbers of shares held by the shareholders on 31 December 2016, based on the most recent compulsory disclosures of the shareholders, are as follows:

31.12.2016  
EUR

31.12.2015  
EUR



|  |                   |                   |
|--|-------------------|-------------------|
| Maruho Deutschland Co., Ltd., Osaka Japan<br>The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former. | 7,631,586         | 4,467,143         |
| Wilhelm Konrad Thomas Zours<br>The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours:   |                   |                   |
| • DELPHI Unternehmensberatung AG   | 3,400,907         | 1,053,154         |
| • VV Beteiligungen AG  |                   |                   |
| • Deutsche Balaton AG  |                   |                   |
| • ABC Beteiligungen AG   |                   |                   |
| • Heidelberger Beteiligungsholding AG  |                   |                   |
| Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany<br>The share of voting rights is attributed to Universal-Investment GmbH through the company FEHO Vermögensverwaltungsgesellschaft.            | 799,463           | 799,463           |
| Free float   | 25,890,477        | 19,170,670        |
| <b>Total</b>   | <b>37,722,433</b> | <b>25,490,430</b> |

Consolidated equity determined in accordance with IFRS is managed as capital. The company's capital management body regularly reviews the equity facilities available to the Group. The management's objective is to ensure an appropriate equity base, within the framework of the expectations of the capital market, and creditworthiness with respect to national and international business partners. The company's Management Board ensures that all Group companies have sufficient capital at their disposal in the form of equity and debt funding. Financing measures occurred in February 2016, April 2016 and November 2016.

The statement of changes in equity provides further information about the development of equity.

The following items are reported as of 31 December 2016 in connection with the 2009/2017 bond with warrants that was issued, the 2011/2016 bond with warrants that was issued in July 2011 (Tranche 1) and December 2011 (Tranche 2), and the 2016/2021 convertible bond:

|   | 31.12.2016<br>EUR | 31.12.2015<br>EUR |
|---|-------------------|-------------------|
| Non-current financial liabilities<br>(measured at amortised cost)       | 3,596,896.89      | 11,229,946.00     |
| Current financial debt<br>(accrued interest from nominal interest rate) | 273,424.06        | 830,174.00        |
| Capital reserve<br>(equity component: 2009/2017 warrant bond)           | 1,485,294.99      | 1,485,294.99      |
| Capital reserve<br>(equity component: 2011/2016 warrant bond)           | 1,226,747.16      | 1,226,747.16      |
| Capital reserve<br>(equity component: 2016/2021 convertible bond)       | 323,155.01        | 0.00              |

The interest effects of the warrant bonds on the non-current borrowings were initially calculated applying an effective annual interest rate of 14.35% p.a. for the 2009/2017 warrant bond, 9.8% p.a. for the first tranche of the 2011/2016 warrant bond and 5.8% p.a. for the second tranche of the 2011/2016 warrant bond as well as 7.9% p.a. for the convertible bond 2016/2021.

In accordance with IAS 32.37, equity procurement costs less any related income tax benefits are to be deducted from equity. In the 2016 financial year, costs of raising equity totalling EUR 321 thousand (previous year: EUR 496 thousand) were recognised in connection with the capital increases that were implemented.

In the event of the company achieving an annual surplus, the Management and Supervisory boards are authorised to transfer all or part of the annual surplus that remains, after deduction of the sums to be placed in the legal reserves and of a loss carried forward, to retained earnings. It is not permissible to transfer more than half of the annual surplus to retained earnings if, after such a transfer, the other retained earnings would exceed half of the share capital. The shareholders' dividends are calculated based on the size of their holding of the share capital.

### **2010 share option programme**

At the Annual General Meeting on 2 July 2010, the Management and Supervisory boards proposed a share option programme for employees to the Annual General Meeting, which approved the initiative. Accordingly, the Management Board, or the Supervisory Board if the beneficiaries are Management Board members, are entitled to issue up to 839,500 share options, the exercising of which is linked to specific targets.

The programme has a total nominal volume of EUR 839,500 and a term of six years from the issue date, in other words, until 24 November 2016. For this, conditional capital amounting to EUR 839,500 was approved by means of the issuing of up to 839,500 registered no par value unit shares with a proportional amount of the share capital of EUR 1.00 per share, in accordance with Section 192 (1) No. 3 of the German Stock Corporation Act (AktG). The conditional capital was registered on 30 July 2010 in the commercial register of the Cologne District Court, under commercial register sheet number 49717. Eligibility for the 2010 share option programme was granted to members of the Management Board and employees of the company as well as to members of management bodies and employees of affiliates of Biofrontera AG.

The issue date was 24 November 2010. The granting of options is made without any consideration being rendered in return. On 24 November 2010, 106,400 options (first tranche) were issued with an exercise price per share of EUR 1.91. On 30 September and 7 October 2011 (second tranche) a further 96,400 options were issued with an exercise price of EUR 2.48 each. On 23 March 2012 and 11 May 2012 (third tranche), 65,000 options were issued with an exercise price of EUR 3.30 each, and 51,500 options were issued with an exercise price of EUR 4.09 each. On 2 September 2013, 179,500 options were issued (fourth tranche) with an exercise price of EUR 3.373 each. On 2 April 2014, 159,350 options were issued with an exercise price of EUR 3.43 each (fifth tranche).

In accordance with the associated conditions, each subscription right that is granted entitles the beneficiary to acquire one new registered no par value unit share in the company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices on the Frankfurt Stock Exchange in floor trading and in Xetra trading for the company's shares on the ten trading days prior to the issuing of the share. However, the minimum exercise price amounts to the proportionate share of the company's share capital allocated to each individual no par value unit share, pursuant to Section 9 (1) of the German Stock Corporation Act (AktG).

The options granted can only be exercised after expiry of a blocking period. The blocking period is four years from the respective date of issue. A prerequisite for the whole or partial exercising of the options is that the following performance target is achieved:

Exercising the options from a tranche is possible if at the beginning of the respective exercise period, the price (hereinafter referred to as the "reference price") of a share in Biofrontera Aktiengesellschaft exceeds the exercise price by at least 20%, and a minimum reference price of at least EUR 5.00 is reached (hereinafter referred to as the "minimum reference price"). The reference price is equal to the arithmetical average (unweighted) of the closing prices on the Frankfurt Stock Exchange in floor trading and Xetra trading for the company's shares between the 15th and the 5th stock market day (in each case inclusive) before the start of the respective exercise window. The minimum reference price is adjusted in the following cases to align the specified performance target with changed circumstances:

- In the event of a capital increase from company funds being implemented by issuing shares, the minimum reference price is reduced by the same ratio as new shares issued compared to existing shares. If the capital increase is implemented from company funds without issuing

new shares (Section 207 (2) Clause 2 of the German Stock Corporation Act (AktG)), the minimum reference price is not changed.

- In the case of a capital reduction, no adjustment of the minimum reference price is implemented, provided that the total number of shares is not changed by the capital reduction, or if the capital reduction is connected to a capital repayment or purchase of treasury shares. In the case of a capital reduction performed by consolidating shares without capital repayment and in the case of increasing the number of shares with no associated change in capital (share split), the minimum reference rate increases proportionally with the capital reduction or share split.

Other adjustments to the minimum reference price are not implemented.

The exercising of options is limited to the following time periods (hereinafter "exercise windows"), in other words, only declarations of exercising of rights submitted to the company within an exercise window will be considered:

- a) on the 6th and subsequent 14 banking days after the date of the Annual General Meeting (exclusive),
- b) on the 6th and subsequent 14 banking days after the date of submission of the semi-annual or quarterly report or an interim statement by Biofrontera AG (exclusive)
- c) in the period between the 15th and the 5th banking day before expiration of the options for each respective expiry date (exclusive).

After expiry of the relevant blocking period, the options can be exercised up until the expiry of six years from the date of issue (exclusive).

The right to exercise the options ends at the latest six years after the first day of issue. The right to exercise the first options that were issued thus ends on 24 November 2016. If the options have not been exercised by this time, they expire without provision of compensation. In the valuation of the employee share options, we have assumed an average holding period of 5 years.

Any claim by the beneficiaries to receive a cash settlement in the event of non-exercise of the options is invalid even in the event of the existence of the above exercise prerequisites. An option may only be exercised if the holder has a current service or employment contract with the company or another company affiliated with the company or if the holder is a member of the Management Board or the management team of another company affiliated with the company.

In the event of the exercising of a subscription right, the company is generally and in specific cases permitted to choose between granting the registered share in exchange for payment of the exercise price, or fulfilling its debt by paying a cash settlement to the holder of the subscription right. The cash settlement per subscription right is equal to the difference between the exercise price per share and the share price on the exercise date, minus due taxes and fees.

As this share option scheme entails share-based payment transactions in which the terms of the arrangement provide the company with a choice of settlement, the company has decided, in accordance with IFRS 2.41 and IFRS 2.43, to recognise the transactions pursuant to the provisions for equity-settled share-based payments (IFRS 2.10-29). For this reason, the fair value of a share from this share option programme with a grant date of 24 November 2010 was determined, on the basis of a binomial model, to have a fair value of EUR 0.57 / share option. For the share options issued on 31 December 2010, this resulted in a total value of options of EUR 60,648.00. For the additional share options granted in 2011, a fair value of EUR 119,536.00 was calculated. For the two tranches of options granted in 2012, fair values of EUR 104,000.00 and EUR 106,090.00 were calculated, respectively. For the share options granted in 2013, a fair value of EUR 192,065 was calculated. For the share options granted in 2014, a fair value of EUR 132,260.50 was determined. The pro rata amounts are recognised in instalments over the vesting period until the end of the blocking period as personnel expenses and as an increase in the capital reserve. Share price volatilities of 45.78% and 51.3% were applied in calculating the fair value of the options granted in 2010 and 2011, volatilities of 53.5% and 65% were applied for the options granted in 2012, volatility of 39.2% was applied for the options granted in 2013, and volatility of 32.3% for the options granted in 2014 (based on the reporting date volatility). A dividend yield of 0% was applied in all cases, as well as risk-free rates of respectively 1.75% and 1.21%, and 0.9% and 0.82% in 2012 as well as 0.71% in 2013 and 0.68% in 2014, and a standard 20% annual beneficiary turnover rate. No share options were issued in financial year 2015. The authorisation to issue options under the 2010 share option programme ended on 1 July 2015.

The blocking period for the first tranche ran until 30 November 2014, and the blocking period for the second tranche ran until 30 September 2015. The option rights from the first tranche expired on 24 November 2016, as the exercise conditions were not met. No options from the second tranche had been exercised as of the reporting date.

The blocking period for the third tranche ran until 30 March 2016, and the blocking period for the fourth tranche ended on 11 May 2016. No options had been exercised from these tranches up to the reporting date.

No options from the fifth tranche could be exercised due to the blocking period.

A total of 137,250 options were forfeited by employees leaving the company.

By resolution of the Annual General Meeting on 28 August 2015, the Conditional Capital III planned for the servicing of options under this programme was reduced to EUR 542,400.00.

The cost expended in the reporting period amounted to EUR 62 thousand (previous year: EUR 103 thousand).

### **2015 share option programme**

At the Annual General Meeting on 28 August 2015, the Management Board and Supervisory Board proposed a new share option programme for employees to the Annual General Meeting, which approved the initiative. Accordingly, the Management Board or, to the extent that the beneficiaries are Management Board members, the Supervisory Board, are entitled until 27 August 2020 to issue up to 1,814,984 subscription rights to up to EUR 1,814,984 of the company's ordinary registered shares, whose exercise is tied to certain targets.

The programme has a total nominal volume of EUR 1,814,984 and a term of five years from the issue date, in other words, until 27 August 2020. For this, conditional capital amounting to EUR 1,814,984 was approved by means of the issuing of up to 1,814,984 registered no par value unit shares with a proportional amount of the share capital of EUR 1.00 per share, in accordance with Section 192 (1) No. 3 of the German Stock Corporation Act (AktG). The conditional capital was registered on 18

September 2015 in the commercial register of the Cologne District Court, under commercial register sheet number 49717. Eligibility for the 2015 share option programme was granted to members of the Management Board and employees of the company as well as to members of management bodies and employees of affiliates of Biofrontera AG. The granting of options is made without any payment being provided in return.

The conditions of the 2015 share option programme are to a large extent identical to those of the 2010 share option programme, therefore, with respect to the 2015 share option programme, we refer to the explanations of the conditions of the share option programme 2010 provided above, however 20 banking days are being used instead of 14 banking days.

The inclusion of a “comparison with a reference index” as performance target instead of “achievement of a minimum reference price of EUR 5.00” as performance target is deemed to be a major difference in the conditions of the 2015 share option programme compared to the 2010 share option programme. The fair value of each option of this share option programme was calculated on the grant date of the first tranche on 18 April 2016 based on a Monte Carlo risk simulation at a fair value of EUR 1.00/option. The fair value of each option of this share option programme was calculated on the grant date 01 December 2016 based on a Monte Carlo risk simulation at a fair value of EUR 1.30/option. A volatility of the share price of approximately 50.6% was used to calculate the fair value of the options granted in the first tranche and a volatility of approximately 49.0% for the second tranche (based on daily rates, annualised assuming 250 trading days per annum), an earning yield of 2.31% for the first tranche (based on daily rates, annualised assuming 250 trading days per annum) and 7.00% for the second tranche respectively (based on a Capital Asset Pricing Model (CAPM)) and a total risk adjusted interest rate of 5.92% for the first tranche and 13.26% for the second tranche respectively as well as a standard annual beneficiary turnover rate of 12% for both tranches.

On 18 April 2016, 425,000 options (first tranche) were issued with an exercise price per share of EUR 2.49. On 1 December 2016 (second tranche) a further 130,500 options were issued with an exercise price of EUR 3.28 each.

A total of 7,500 options were forfeited by employees leaving the company.

The total option value for options issued as at 31 December 2016 was therefore EUR 1,462,875. The pro rata amounts are recognised in instalments over the vesting period until the end of the blocking

period as personnel expenses and as an increase in the capital reserve. The expenditure recognised in the reporting period was EUR 49 thousand (previous year: EUR 0).

## **10. Financial liabilities**

On 26 June 2009, Biofrontera announced the placement of a warrant bond with a term ending on 1 January 2018. As part of this financing measure on the part of the company, a warrant bond was placed in 2009 ("**Warrant Bond I**"). The warrant bond has a total nominal value of EUR 10,000,000.00, divided into up to 100,000 bonds with a nominal value of EUR 100.00. The redemption at the end of the term is at 106% of par. The warrant bonds bear **interest** on the following scale:

- from 01.09.2009 to 30.12.2010 at an annual rate of 4%;
- from 31.12.2010 to 30.12.2011 at an annual rate of 6%;
- from 31.12.2011 to 31.12.2017 at an annual rate of 8%.

The accrual of interest on each warrant bond ends on the day before it is due for redemption. The interest payment is made on the last business day of the calendar year, but not until 31 December 2010, in other words, the interest for 2009 does not become due until then. An ordinary call on the bond by the bondholders is not permitted. Biofrontera has the right, upon issuing of written notice to the bondholders of Warrant Bond I, to repay 106% of the nominal amount (plus any accrued interest) at any time. Each holder of a partial bond is, in accordance with the bond and option terms, entitled to five detachable option rights per bond, with each of these providing the irrevocable right to acquire a registered voting-entitled no par value ordinary share in Biofrontera AG with a notional proportion of the share capital of EUR 1.00, at a warrant price of EUR 5.00 each. The warrant right expires on 30 December 2017. The share resulting from the exercising of a warrant right is dividend-entitled from the beginning of the financial year in which it originated from the exercising of the option right and payment of the capital contribution. To provide financing for the warrant rights, conditional capital of the company amounting to up to EUR 500,000.00 was approved at the Extraordinary General Meeting held on 17 March 2009.

Of these warrant bonds, partial bonds were issued with a total nominal value of EUR 4,930,300.00.

The liability from this warrant bond was measured at its present value of EUR 3,238,744.00 on the issue date, and the carrying amount of the non-current financial liability amounts to a total of EUR



3,419 thousand applying the effective interest method as of 31 December 2016 (31 December 2015: EUR 2,836 thousand). The current (due within one year) portion of this financial liability amounts to EUR 274 thousand (31 December 2015: EUR 394 thousand). The nominal interest for 2015 was paid in the subsequent financial year at the start of January 2016, and for the year 2016 on 31 December 2016. See section 6 for details of the warrant bonds held by Biofrontera.

On 7 June 2011, the Management Board resolved, with Supervisory Board approval and based on the authorisation granted by the Annual General Meeting, to issue a warrant bond 2011/2016 (hereinafter "Warrant Bond II").

Warrant Bond II has a total nominal value of up to EUR 25,000,000.00 and is divided into up to 250,000 individual warrant bonds with a nominal value of EUR 100.00 each. Each individual warrant bond is connected with ten detachable warrants issued by the company; each warrant entitles the holder to buy one registered voting-entitled no par value ordinary share in the company with an interest in the share capital of EUR 1.00 each at an option price of EUR 3.00. If all the warrant rights were to be issued and exercised, this would result in a calculated total exercise price of EUR 7,500,000.00. The issue price of each warrant bond is EUR 100.00.

The term of the warrant bonds begins on 20 July 2011 and ends on 31 December 2016. To provide financing for the option rights, conditional capital of up to EUR 2,500,000.00 was approved at the company's General Meeting on 10 May 2011 and entered in the commercial register on 18 May 2011. Warrant Bond II carries a coupon of 5% p.a. The accrual of interest on each warrant bond ended on 31 December 2016. Interest was paid annually on 1 January for the previous year, commencing on 1 January 2012 with a payment of EUR 195 thousand for the period 20 July 2011 until 31 December 2011. A nominal total of EUR 8,715 thousand of individual warrant bonds of Warrant Bond II was issued as a result of two transactions that exchanged the convertible bonds for Warrant Bond II in July and December 2011 and the direct subscription from the initial issue. With the early call of this warrant bond, the principal repayment of EUR 8,715 thousand and resultant interest owing for the 1 January 2016 to 5 December 2016 period of EUR 405 thousand was disbursed on 6 December 2016 (previous year: EUR 436 thousand).

The term of the 2016/2021 convertible bond begins on the date of its initial issue ("issue date") and ends on 31 December 2020.

The individual bonds carry 6% annual interest on their par value from 1 January 2017 (inclusive). The interest payments are payable annually subsequently on 1 January of each year, commencing on 1 January 2018.

The bonds can be converted into the company's ordinary no par value registered shares, each of which has a nominal share of EUR 1.00 in the share capital. The shares are dividend-entitled from the year when the conversion right is exercised.

During the term, the holders of the bonds are entitled to convert all bonds into the company's shares. The initial conversion price is staggered. From the start of the term until 31 December 2016, the initial conversion price amounts to EUR 3.00 per share. From 1 January 2017 until 31 December 2017, the conversion price amounts to EUR 4.00 per share. From 1 January 2018, the conversion price amounts to EUR 5.00 per share.

At the end of the term of the convertible bond, the company is entitled to deliver shares instead of repaying the bonds. Moreover, the company is entitled to convert the bonds into shares at any time if the average price of the company shares exceeds EUR 5.00 on one occasion. In both cases, the initial conversion price amounts to EUR 5.00.

The contractual interest and repayment obligations relating to warrant bonds are broken down on the balance sheet date as follows:

| kEUR                               | 31.12.2016 |       |      |      |      | Total |
|------------------------------------|------------|-------|------|------|------|-------|
|                                    | 2017       | 2018  | 2019 | 2020 | 2021 |       |
| <u>Warrant bond 2009/2017:</u>     |            |       |      |      |      |       |
| Principal repayment                |            | 5,226 |      |      |      | 5,226 |
| Interest payment                   | 394        |       |      |      |      | 394   |
| <u>Warrant bond 2011/2016:</u>     |            |       |      |      |      |       |
| Principal repayment                | 0          |       |      |      |      | 0     |
| Interest payment                   |            |       |      |      |      | 0     |
| <u>Convertible bond 2011/2021:</u> |            |       |      |      |      |       |
| Principal repayment                |            |       |      |      | 190  | 190   |
| Interest payment                   | 11         | 11    | 11   | 11   | 11   | 55    |

The position was as follows in the previous year:

| kEUR                           | 31.12.2015 |      |      |      |      | Total |
|--------------------------------|------------|------|------|------|------|-------|
|                                | 2016       | 2017 | 2018 | 2019 | 2020 |       |
| <u>Warrant bond 2009/2017:</u> |            |      |      |      |      |       |

|                                |     |       |       |       |
|--------------------------------|-----|-------|-------|-------|
| Principal repayment            |     |       | 5,226 | 5,226 |
| Interest payment               | 394 | 394   |       | 788   |
| <b>Warrant bond 2011/2016:</b> |     |       |       |       |
| Principal repayment            |     | 8,715 |       | 8,715 |
| Interest payment               | 436 | 436   |       | 872   |

### 11. Trade payables

The trade payables (EUR 2,093 thousand; previous year: EUR 1,043 thousand) increased by EUR 1,050 thousand from the previous year.

### 12. Other provisions

Other provisions report the following changes:

| Biofrontera Group                           | EUR                 |                   |                 |                     | EUR                 |
|---|---------------------|-------------------|-----------------|---------------------|---------------------|
|   | 01.01.2016          | Utilised          | Released        | Added               | 31.12.2016          |
| Bonuses for employees                       | 142,741.00          | 142,741.00        | 0.00            | 505,517.10          | 505,517.10          |
| Outstanding vacation                        | 82,015.08           | 82,015.08         | 0.00            | 197,597.55          | 197,597.55          |
| Outstanding invoices                        | 659,674.96          | 398,510.46        | 6,402.00        | 681,331.38          | 936,093.88          |
| Costs for financial statements and auditing | 109,200.00          | 108,940.00        | 260.00          | 154,000.00          | 154,000.00          |
| Miscellaneous other provisions              | 48,229.76           | 22,178.64         | 1,728.16        | 6,142.33            | 30,465.29           |
| <b>Total provisions</b>                     | <b>1,041,860.80</b> | <b>754,385.18</b> | <b>8,390.16</b> | <b>1,544,588.36</b> | <b>1,823,673.82</b> |

Other provisions concern various individually identifiable risks and contingent liabilities. Provisions classified as current are expected to be utilised prospectively within the subsequent financial year.

### 13. Other financial and other current liabilities

|                      | 31 December 2016 | 31 December 2015 |
|----------------------|------------------|------------------|
|                      | kEUR             | kEUR             |
| Payroll tax          | 114              | 97               |
| Financial leasing    | 4                | 12               |
| Credit card payments | 28               | 16               |
| Wages and salaries   | 57               | 10               |
| Other                | 45               | 26               |
|                      | <b>248</b>       | <b>161</b>       |

### 14. Reporting on financial instruments

During the course of its operating activities, the Group is exposed to market price and credit risk, as well as liquidity risk, which could have an effect on its financial position and performance.

**Market price risk:** Interest-rate risk is deemed minor as existing interest-rate modalities for the Biofrontera Group's relevant financing facilities can generally be adapted to market conditions short-term to medium-term. No cash flow risk exists in relation to fixed interest warrant bonds. Due to the fixing of interest, no disadvantageous changes can occur to the interest payments. As the liabilities are not recognised at fair value but instead at amortised cost, there is also no fair value risk.

**Credit risk:** A credit risk arises for the Group if transaction partners cannot meet their obligations within the normal payment deadlines. On the balance sheet, the maximum non-payment risk is represented by the carrying amount of the relevant financial asset. The situation regarding receivables is monitored so that any possible non-payment risks can be identified at an early stage and appropriate steps taken. In the reporting year, no individual value adjustments were made for other financial assets (previous year: EUR 0 thousand); in addition, no individual value adjustments were applied to trade receivables in the reporting year (previous year: EUR 0).

Based on the input factors used at the valuation methods fair values are divided into different steps of the fair value hierarchy:

**Level 1:** Fair value valuations using prices listed on active markets (not adjusted) for identical assets or liabilities.

**Level 2:** Fair value valuations using inputs for the asset or liability that are either directly observable (as prices) or indirectly observable (derived from prices), but which do not constitute listed prices pursuant to Level 1.

**Level 3:** Fair value valuations using inputs for the asset or liability that are not based on observable market data (unobservable input data).

Biofrontera only has financial instruments at levels 1 and 2. No reclassifications between level 1 and level 2 were performed during the 2016 financial year. With regard to financial liabilities, the full amount of non-current and current financial liabilities (EUR 3,871 thousand; previous year: EUR 12,060 thousand) is allocated to Level 1. This involves financial debt arising from the two warrant bonds.

Biofrontera reports under other operating expenses value adjustments to trade receivables and miscellaneous financial obligations allocable to the "loans and receivables" category. The currency translation losses arise mainly from trade payables. The net gains and losses generally include specific value adjustments and currency conversion effects.

The financial assets and liabilities can be subdivided into measurement categories with the following carrying amounts, and net gains and losses:

| Financial assets on 31.12.2016 (EUR)           | Fair value       | Carrying amounts |                       |   |                                     | TOTAL CARRYING AMOUNTS | Net gains (+) or losses (-) |
|--|------------------|------------------|-----------------------|---|-------------------------------------|------------------------|-----------------------------|
|  |                  |                  | Loans and receivables | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") | Financial assets available-for-sale |                        |                             |
| Financial assets                               |                  |                  |                       |   |                                     | 0                      | 0                           |
| Liquid assets                                  | 15,126,09        |                  | 15,126,096            |   |                                     | 15,126,096             | 79                          |
| Trade receivables                              | 1,624,067        |                  | 1,624,067             |   |                                     | 1,624,067              | 0                           |
| Other current financial receivables and assets | 1,376,870        |                  | 1,376,870             |   |                                     | 1,376,870              | 0                           |
| <b>TOTAL</b>                                   | <b>18,127,03</b> |                  | <b>18,127,033</b>     | <b>0</b>  | <b>0</b>                            | <b>18,127,033</b>      | <b>79</b>                   |

| Financial liabilities on 31.12.2016 (EUR) | Fair value | Carrying amounts  |   |  |  | TOTAL CARRYING AMOUNTS | Net gains (+) or losses (-) |
|---|------------|-------------------|---|--|--|------------------------|-----------------------------|
|   |            | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") |  |  |                        |                             |
| Financial liabilities current             | 274,424    | 274,424           |   |  |  | 274,424                | 0                           |
| Trade payables                            | 2,093,154  | 2,093,154         |   |  |  | 2,093,154              | (72,546)                    |
| Other financial liabilities current       | 58,458     | 58,458            |   |  |  | 58,458                 | 0                           |

|                                      |                  |                  |          |          |          |                  |                 |
|--------------------------------------|------------------|------------------|----------|----------|----------|------------------|-----------------|
| Other                                | 3,596,897        | 3,596,897        |          |          |          | 3,596,897        | 0               |
| financial liabilities<br>non-current |                  |                  |          |          |          |                  |                 |
| <b>TOTAL</b>                         | <b>6,022,933</b> | <b>6,022,933</b> | <b>0</b> | <b>0</b> | <b>0</b> | <b>6,022,933</b> | <b>(72,546)</b> |

| Financial assets on 31.12.2015 (EUR)                   | Fair value       | Carrying amounts      |   |                                     |          | TOTAL CARRYING AMOUNTS | Net gains (+) or losses (-) |
|--|------------------|-----------------------|---|-------------------------------------|----------|------------------------|-----------------------------|
|  |                  | Loans and receivables | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") | Financial assets available-for-sale |          |                        |                             |
| Financial assets                                       |                  |                       |   |                                     |          | 0                      | 0                           |
| Liquid assets  | 3,959,207        | 3,959,207             |   |                                     |          | 3,959,207              | 104                         |
| Trade accounts receivable                              | 894,559          | 894,559               |   |                                     |          | 894,559                | 0                           |
| Miscellaneous current financial receivables and assets | 730,440          | 730,440               |   |                                     |          | 730,440                | 0                           |
| <b>TOTAL</b>   | <b>5,584,206</b> | <b>5,584,206</b>      | <b>0</b>  | <b>0</b>                            | <b>0</b> | <b>5,584,206</b>       | <b>104</b>                  |

| Financial liabilities on 31.12.2015 (EUR) | Fair value | Carrying amounts  |   |  |  | TOTAL CARRYING AMOUNTS | Net gains (+) or losses (-) |
|---|------------|-------------------|---|--|--|------------------------|-----------------------------|
|   |            | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") |  |  |                        |                             |
| Financial liabilities current             | 830,174    | 830,174           |   |  |  | 830,174                | 0                           |
| Trade accounts payable                    | 1,043,426  | 1,043,426         |   |  |  | 1,043,426              | (21,594)                    |
| Other financial liabilities current       | 37,622     | 37,622            |   |  |  | 37,622                 | 0                           |
| Other                                     | 11,229,94  | 11,229,946        |   |  |  | 11,229,946             | 0                           |

financial liabilities

non-current

|              |                  |                   |          |          |          |                   |                 |
|--------------|------------------|-------------------|----------|----------|----------|-------------------|-----------------|
| <b>TOTAL</b> | <b>13,141,16</b> | <b>13,141,168</b> | <b>0</b> | <b>0</b> | <b>0</b> | <b>13,141,168</b> | <b>(21,594)</b> |
|--------------|------------------|-------------------|----------|----------|----------|-------------------|-----------------|

**Liquidity risk:** The refinancing of the Biofrontera Group companies is generally performed centrally by Biofrontera AG. A risk exists in this regard that the liquidity reserves may be insufficient to fulfil the financial obligations on the due date. In order to cover the liquidity requirements at 31 December 2016, cash and cash equivalents totalling EUR 15,126 thousand (31 December 2015: EUR 3,959 thousand) are available. See the relevant balance sheet notes on (undiscounted) payments from financial debt due in the next years.

***Notes to the consolidated statement of comprehensive income as of 31 December 2016***

**15. Sales revenue**

The Biofrontera Group recognised sales of EUR 6,130 thousand in the 2016 financial year (previous year: EUR 4,138 thousand), representing an increase of 48% compared with the previous year. This includes downpayments of EUR 40 thousand (previous year: EUR 70 thousand). Revenues from selling products in Germany reduced by 17% to EUR 2,515 thousand (previous year: EUR 3,028 thousand), while revenues generated in European countries outside Germany grew by 20% to EUR 1,247 thousand (previous year: EUR 1,040 thousand). For the first time, revenues were also generated from the sale of products in the USA in an amount of EUR 1,153 thousand. Revenues in the USA were achieved using a title model with one wholesaler. Revenues of EUR 1,177 thousand were generated in the financial year from the development partnership with Maruho.

**16. Cost of sales, gross profit**

The gross profit on sales improved from EUR 2,902 thousand to EUR 4,478 thousand. The gross margin increased to 73%, compared to 70% in the same period in the previous year.

The cost of sales amounted to EUR 1,652 thousand, equivalent to 27% of sales revenue (previous year: EUR 1,236 thousand, or 30%).

**17. Development costs**

Research and development costs amounted to EUR 4,640 thousand in the 2016 financial year, a reduction of EUR 1,564 thousand, or 25%, year-on-year. The decrease mainly reflects the EUR 2,072

thousand submission fee (PDUFA fee) paid at submission of the application for approval to the FDA during the first half of 2015. The FDA reimbursed this fee in March 2016, with the credit being reported under the other income item.

### **18 Sales and marketing costs**

Sales and marketing costs of EUR 8,763 thousand reflect an approximately 110% increase compared with the previous year's period (EUR 4,170 thousand). The sales and marketing costs include the costs of our own field sales team in Germany, Spain and in the US, as well as marketing expenses. The increase is mainly attributable to expenses for the start-up of sales activities and to establish sales structures in the USA.

### **19. Administrative costs**

Administrative costs increased by EUR 94 thousand year-on-year to EUR 2,853 thousand in the 2016 financial year (previous year: EUR 2,759 thousand). Financing costs shown under administrative costs include primarily consultancy and placement fees in connection with support for the search of investors.

### **20 Financial result**

The financial result consists primarily of the interest payable for the 2009/2017 warrant bond (EUR 463 thousand, previous year: EUR 439 thousand) and for the 2011/2016 warrant bond placed in 2011 (EUR 727 thousand, previous year: EUR 727 thousand), calculated using the effective interest method. The aforementioned interest expenses on the warrant bond 2009/2017 of EUR 463 thousand (previous year: EUR 439 thousand) include the opposite effect of EUR 204 thousand (previous year: EUR 193 thousand) from the repurchase of part of the warrant bond on 28 February 2014. The interest on Warrant Bond I for the 2015 financial year was paid at the end of December 2015, and the interest on Warrant Bond II was paid at the beginning of January 2016. The interest for the 2016 financial year for Warrant Bond I was paid at the start of January 2017. In December 2016, Warrant Bond II was repaid early at par plus accrued interest.

### **21. Other income (expenses), net**

The submission fee paid to the FDA in 2015 (PDUFA fee) was reimbursed in an amount of EUR 2,140 thousand in March 2016 after a "small business waiver" was granted. This fee was reported



under research and development costs in the income statement for 2015. The reimbursement is reported under other income. The difference to the amount originally paid results from currency translation differences

### Earnings per Share (EPS)

Earnings per share are calculated on the basis of the net loss for the year of the Biofrontera Group and the average ordinary shares in circulation in the financial year, in accordance with IAS 33.

|  | 31.12.2016 | 31.12.2015    |
|--|------------|---------------|
| Number of weighted ordinary shares in circulation (on average) | 29,742,634 | 23,156,343.32 |
| Net loss for the year in EUR                                   | (10,579)   | (11,203)      |
| Undiluted earnings per share in EUR                            | (0.36)     | (0.48)        |

When calculating diluted earnings per share for the 2015 and 2016 financial years, the warrant bond issued in 2009 (2009/2017), with a total nominal value of EUR 4,930 thousand and giving bondholders the right to acquire 246,515 shares at a price of EUR 5.00 each, as well as the warrant bond issued in 2011 (2011/2016), with a total nominal value of EUR 8,715 thousand and giving bondholders the right to acquire 871,500 shares at a price of EUR 3.00 each, have been taken into account as a matter of principle. As the Group achieved negative results for the year in the 2015 and 2016 financial years, no diluted earnings per share were reported, as the conversion or subscription rights for the periods shown counteracted any dilution.

### 23. Additional information about the consolidated statement of comprehensive income

The other income only includes conversion adjustments from the conversion of the foreign business entity into the Group's currency.

### Cost of materials

The cost of materials included in the cost of sales amounted to EUR 1,245 thousand for the 2016 financial year (previous year: EUR 947 thousand).

### Depreciation, amortisation and impairment losses

Depreciation and amortisation on tangible and intangible assets of EUR 831 thousand in the 2016 financial year and of EUR 812 thousand in the previous year is included in the following items in the statement of comprehensive income:

|  | 31.12.2016<br>kEUR | 31.12.2015<br>kEUR |
|--|--------------------|--------------------|
| Research and development costs                   | 689                | 691                |
| General administrative costs                     | 127                | 113                |
| Cost of sales                                    | 9                  | 8                  |
| Sales  | 6                  | 0                  |
| Depreciation, amortisation and impairment losses | 831                | 812                |

### Personnel costs

|                           | 31.12.2016<br>kEUR | 31.12.2015<br>kEUR |
|---------------------------|--------------------|--------------------|
| Wages and salaries        | 5,753              | 3,557              |
| Social security charges   | 908                | 482                |
| Costs for pension schemes | 33                 | 34                 |
| Total                     | 6,694              | 4,073              |

### 24. Staff

On average, the Biofrontera Group employed 64 people in the 2016 financial year (previous year: 46 employees).

### 25. Other information

#### Operating and finance leases

The Group companies lease administrative and research facilities, as well as vehicles and equipment, under operating lease contracts. The future minimum commitments from leases are as follows:

|                                  | 2016     | 2015    | 2016              | 2015      | 2016      | 2015      |
|----------------------------------|----------|---------|-------------------|-----------|-----------|-----------|
|                                  | ≤ 1 year |         | 1 year to 5 years |           | > 5 years |           |
| Operating leases                 |          |         |                   |           |           |           |
| Leases for business premises     | 519,725  | 424,277 | 1,870,316         | 2,156,013 | 1,619,895 | 1,619,895 |
| Leases for cars                  | 274,219  | 144,693 | 375,067           | 177,517   | 0         | 0         |
| Operating and business equipment | 23,375   | 17,789  | 36,833            | 35,267    | 0         | 0         |

Lease-related expenses for the reporting period amounted to EUR 237 thousand (previous year: EUR 176 thousand).

On the balance sheet date, a finance lease existed for a server leased by Biofrontera AG with a carrying amount of EUR 4 thousand (previous year: EUR 12 thousand). The contract has a minimum term of 60 months to 31 July 2017. Biofrontera AG is obliged to purchase the leased asset from the

lessor for a fixed residual value of EUR 2 thousand if the lessor exercises its option to sell. In the reporting year, minimum lease payments of EUR 11 thousand were expensed (previous year: EUR 11 thousand).

On the balance sheet date of 31 December 2016, the present value of the sum of future minimum lease payments is reconciled to their present values as follows:

| All amounts in kEUR   | Minimum lease payments | Discounting | Present value |
|-----------------------|------------------------|-------------|---------------|
| Up to 1 year:         | 7                      | 2           | 4             |
| Between 2 and 5 years | 0                      | 0           | 0             |
| More than 5 years     | 0                      | 0           | 0             |

## **26. Notes to the cash flow statement**

The cash flow statement is presented in accordance IAS 7. The net loss for the year is adjusted for effects of non-cash transactions, deferrals or accruals of past or future operational deposits or disbursements, and income and expense items attributable to investment or financing activities.

In the consolidated cash flow statement, cash and cash equivalents include cash in hand, cheques, bank deposits and money deposits with a maturity of up to three months. Current account liabilities are incorporated into the cash fund where applicable.

Interest paid out amounted to EUR 842 thousand (previous year: EUR 1,225 thousand). The change resulted from the two interest payments for Warrant Bond I made in the 2015 financial year: firstly, on 1 January 2015 for the 2014 financial year, and, secondly, on 31 December 2015 interest for the 2015 financial year. Interest received amounted to EUR 3 thousand (previous year: EUR 184 thousand), consisting of interest received for deposits. In the previous year, the interest received from Warrant Bond I held by the company itself already accrued to the company as of 30 December 2015.

## **27. Members of the Management Board**

Prof. Hermann Lübbert was the Management Board Chairman (Chief Executive Officer/CEO) in the reporting period. The CEO also holds a professorial chair at Bochum University in Germany. Prof. Lübbert was appointed to the Management Board from 27 March 2015 until 31 October 2020 by way of Supervisory Board resolution.

Mr. Thomas Schaffer is the Chief Financial Officer. Mr. Schaffer was appointed to the Management Board from 9 April 2015 until 30 November 2020 by way of Supervisory Board resolution.

Mr. Christoph Dünwald is the Management Board member responsible for the Sales and Marketing areas. With a Supervisory Board resolution of 9 July 2015, Mr. Dünwald was appointed to the Management Board until 15 November 2017.

The remuneration of the Management Board members consists of a fixed salary that is paid in twelve equal monthly instalments. In addition, an annual, performance-based bonus exists for the Management board members, as well as a long-term remuneration component consisting of participation in the company's share option programme. Company cars are also available to the directors for business and private use.

The remuneration for members of the Management Board in the 1 January until 31 December 2016 period consisted of a salary and a bonus as well as share options. The total remuneration for Management Board members in the reporting period, including the value of share options at the time they were granted, amounted to EUR 1,402 thousand (previous year: EUR 866 thousand). This was allocated as follows

|                           |   |   |
|---------------------------|---|---|
| Prof. Dr. Hermann Lübbert | – Non-performance based salary component: | EUR 363 thousand (31 December 2015: EUR 370 thousand)   |
|                           | - Performance based salary component:     | EUR 72 thousand (31 December 2015: EUR 35 thousand)   |
|                           | - stock options                           | 231,850 (fair value when granted: EUR 366,435.50) (previous year: 151,850, fair value when granted: EUR |

167,236); of which granted in 2016: 80,000 (2015: 0).

|                 |   |   |
|-----------------|---|---|
| Thomas Schaffer | – Non-performance based salary component: | EUR 213 thousand (31 December 2015: EUR 203 thousand)   |
|                 | - Performance based salary component:     | EUR 63 thousand (31 December 2015: EUR 28 thousand)   |
|                 | - stock options                           | 85,000 (fair value when granted: EUR 157,150) (previous year: 35,000, fair value when granted: EUR 32,650); of which granted in 2016: 50,000 (2015: 0). |

|                   |   |   |
|-------------------|---|---|
| Christoph Dünwald | – Non-performance based salary component: | EUR 236 thousand (31 December 2015: EUR 29 thousand)  |
|                   | - Performance based salary component:     | EUR 6 thousand (31 December 2015: EUR 0 thousand)   |
|                   | - stock options                           | 50,000 (fair value when granted: EUR 124,500) (previous year: 0, fair value when granted: EUR 0); of which granted in 2016: 50,000 (2015: 0). |

All salaries/bonuses are classified as short-term employee benefits as defined in IAS 24.17 (a).

## **28. Members of the Supervisory Board**

As a result of the resolution passed by the Annual General Meeting held on 31 May 2016, the Supervisory Board has consisted of the following members since 31 May 2016:

Dr. Ulrich Granzer      Chairman of the Supervisory Board, Owner and Managing Director of Ulrich Granzer Regulatory Consulting & Services, resident in Munich, Germany

Jürgen Baumann Deputy Chairman of the Supervisory Board, management consultant, resident in Monheim

John Borer Head of Investment Banking at The Benchmark Company LLC, New York, USA, resident in Jersey City, NJ, USA

Hansjörg Plaggemars Management Board member of Deutsche Balaton Aktiengesellschaft, Heidelberg, resident in Stuttgart

Mark Reeth attorney, resident in Frederick, MD, USA

Kevin Weber Principal of Skysis, LLC., Scottsdale, AZ, USA, resident in Scottsdale, AZ, USA

The Supervisory Board members held the following other supervisory board positions and positions on comparable domestic and foreign boards during the reporting period:

Hansjörg Plaggemars OOC CTV Verwaltungs GmbH, Managing Director  
Stellar Diamonds plc, Non-Executive Board Member  
Carus Grundstücksgesellschaft am Taubenfeld AG, Supervisory Board Chairman  
Eurohaus Frankfurt AG, Supervisory Board Chairman  
Youbisheng Greenpaper AG i.I., Supervisory Board Chairman  
Ming Le Sports AG, Supervisory Board Chairman  
Nordic SSW 1000 Verwaltungs AG, Supervisory Board Chairman  
Balaton Agro Invest AG, Deputy Supervisory Board Chairman  
Carus AG, Deputy Supervisory Board Chairman  
Deutsche Balaton Immobilien I AG, Supervisory Board member  
Ultrasonic AG i.I., Supervisory Board member

In the 2016 financial year, compensation paid to Supervisory Board members amounted to EUR 113 thousand (previous year: EUR 113 thousand). The compensation transactions are classified as short-term employee benefits as per IAS 24.17(a).

During the reporting period, the company availed itself of additional advisory services from Supervisory Board member Dr. Ulrich Granzer. These services went beyond the scope of normal Supervisory Board activities. Dr. Granzer assisted the company with key issues relating to the preparation of the applications for approval submitted to the supervisory authorities in Europe and the USA. During the course of the 2016 financial year, advisory services amounting to EUR 10 thousand (previous year: EUR 62 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 7 thousand on 31 December 2016 (31 December 2015: EUR 0 thousand). The amounts stated here do not include statutory VAT at the current rate of 19%. The underlying consultancy contract was approved in consideration of the statutory provisions.

## **29. Related party disclosures**

In July 2016, Biofrontera AG signed a research cooperation partnership (a collaboration and partnership agreement) with Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. According to this agreement's provisions, Biofrontera, as part of research services, will conduct the requisite work for the exploratory research of these product candidates. Maruho is bearing the related costs. It is planned that Maruho will be the owner of the new products and that Biofrontera will receive the licence to market in Europe.

This development partnership generated revenue of EUR 1,177 thousand in the financial year under review (previous year: EUR 0 thousand). Receivables due from Maruho amounted to EUR 472 thousand as of 31 December 2016 (31 December 2015: 0).

In the 2016 financial year, no further reportable transactions or relationships with related parties existed beyond the aforementioned facts and circumstances stated in subsections 27 and 28. The Group of related persons and entities is limited to those referred to therein.

In the context of the underlying holding structure, Biofrontera AG is responsible for the administrative and management tasks. Biofrontera AG is also responsible for the financing of the currently still loss-making business areas, as it is a listed company and consequently enjoys optimal access to the capital market.

The funds made available to the subsidiaries as loans bear interest at market rates and are, where necessary, furnished with a subordination agreement.

In light of the close cooperation between the subsidiaries, internal offsetting is applied, which is reviewed and adjusted to requirements on an annual basis.

**30. Corporate governance statement pursuant to Section 289a HGB including the statement on the German Corporate Governance Code required by Section 161 AktG**

The Management and Supervisory boards of Biofrontera AG have issued the corporate governance statement as required pursuant to Section 289a of the German Commercial Code (HGB), including the statement required pursuant to Section 161 of the German Stock Corporation Act (AktG), and have made these available to shareholders on the Biofrontera AG website ([www.biofrontera.com](http://www.biofrontera.com)).

**31. Auditor's fees and services**

The total fee invoiced by the auditor Warth & Klein Grant Thornton AG for the 2016 financial year consists of the following:

|                                  | 2016 | 2015 |
|----------------------------------|------|------|
|                                  | kEUR | kEUR |
| Auditing services                | 184  | 122  |
| (of which for the previous year) | (50) | (16) |
| Other certification services     | 55   | 43   |
|                                  | 239  | 165  |

**32. Events after the reporting date**

On 24 January 2017, the company announced that the issue of up to 49,990 subordinated convertible bonds that had been approved in December 2016 had been placed in full in a total nominal amount of up to EUR 4,999,000 ("convertible bond").

On 30 January 2017, the European Commission followed the positive vote by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and issued the expansion of the approval of Ameluz® to treat basal cell carcinoma. The extended approval comprises the treatment of superficial and/or nodular basal cell carcinoma in adults where surgical removal is ruled out due to potential morbidity or due to an undesirable cosmetic result.

On 6 February 2017, the company announced positive preliminary results for the primary endpoint of the clinical Phase III trial to investigate the efficacy and safety of the prescription medication



Ameluz® in combination with daylight photodynamic therapy (PDT). The trial reached its primary regulatory endpoint and proved the non-inferiority ( $p < 0.001$ ) of Ameluz® in daylight-PDT in relation to the comparator product Metvix® in treating mild or moderate actinic keratosis, a superficial skin cancer. After just one PDT, the trial reached its primary endpoint at 78.7% complete lesion clearance in a half side comparison per patient in treatment with Ameluz® and daylight-PDT, in comparison with 75.0% lesion clearance in treatment with Metvix® and daylight-PDT. The company published detailed results of this trial on 13 March 2017. Ameluz® has also reported higher results in all relevant secondary endpoints than the competitor product, with the greatest differences between Ameluz® and the competitor product arising for patients under 65 years of age and for patients treated under cloudy weather.

On 9 March 2017, the lawsuit of a shareholder of 30 June 2016 was withdrawn by the plaintiff. The lawsuit brought charges for nullity, alternatively rescission, of some of the resolutions passed at the company's Ordinary Annual Shareholder Meeting on 31 May 2016. In particular, the election of Mr. John Borer, Mr. Jürgen Baumann and Mr. Kevin Weber to the company's Supervisory Board was contested.

No further events subject to mandatory reporting occurred after the balance sheet date.

Leverkusen, Germany, 05 April 2016

|                           |                         |                                   |
|---------------------------|-------------------------|-----------------------------------|
| Prof. Dr. Hermann Lübbert | Thomas Schaffer         | Christoph Dünwald                 |
| Chief Executive Officer   | Chief Financial Officer | Chief Sales and Marketing Officer |

### **F.1.7) Auditor's Report**

The following is a translation of the German language original auditors' report:

We have audited the consolidated financial statements prepared by Biofrontera AG, Leverkusen/Germany – comprising a consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income for the period, consolidated statement of changes in equity, consolidated statement of cash flows and notes to the consolidated financial statements – and the combined management report of Biofrontera AG and the group for the financial year from 1 January 2016 to 31 December 2016. The preparation of the consolidated financial statements and the combined management report in accordance with IFRS, as adopted by the EU, and with the additional requirements of the German commercial law pursuant to section 315a paragraph 1 HGB are the responsibility of the parent company's management. Our responsibility is to express an opinion on the consolidated financial statements and the combined management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with paragraph 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer (Institute of Public Auditors in Germany) (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the combined management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the combined management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the combined management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements of Biofrontera AG for the financial year from 1 January 2016 to 31 December 2016 comply with IFRS, as adopted by the EU, and the additional requirements of the German commercial law pursuant to § 315a Abs. 1 HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The combined management report of Biofrontera AG and the group is consistent with the consolidated financial statements, complies with the legal

requirements, as a whole provides a suitable view of the Group's position and suitable presents the opportunities and risks of future development.

Without modifying our opinion, we would like to point out the statements made in the combined management report. As mentioned in the section " Risk, opportunity and forecast report " under "Liquidity risk", during the financial year 2017 additional capital measures will be needed until the break-even is reached, for the planned investments into marketing in the USA and to meet obligations from the issued option bond. On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realized, this could constitute a threat to the company's continued existence.

Düsseldorf, 5 April 2017

Warth & Klein Grant Thornton AG  
Wirtschaftsprüfungsgesellschaft

Kai-Niclas Rauscher  
Wirtschaftsprüfer  
(German Public Auditor)

Ralf Clemens  
Wirtschaftsprüfer  
(German Public Auditor)

## **F.2 Audited IFRS group report 2015**

## **F.2.1) Combined Company and Group Management Report as of 31 December 2015**

### ***Fundamentals of the Group***

#### ***1. Group structure***

This report describes the business performance of the Group (hereafter also referred to as "Biofrontera" or the "Biofrontera Group") for the 2015 financial year. The Group consists of the parent company Biofrontera AG and five wholly owned direct subsidiaries - Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc. Biofrontera Inc. has its registered office in Wilmington, Delaware, USA. All the other companies are based at Hemmelrather Weg 201 in 51377 Leverkusen, Germany.

The listed public limited company (AG in German) has a holding function in the group of companies and ensures the necessary financing for the Group. Biofrontera Bioscience GmbH undertakes the research and development tasks for the Group and is the holder of patents and the approval for Ameluz®. Based on a licence agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also the holder of the approval for BF-RhodoLED®, is responsible for the manufacturing and also the further licensing and marketing of the Biofrontera Group's approved products.

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH were established as additional wholly owned subsidiaries of Biofrontera AG in December 2012. The purpose of both companies is to pursue the further development of pipeline products that are not part of Biofrontera's core business and therefore cannot be sufficiently financed within the framework of normal business development. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. By outsourcing the development projects, a structure has been created through which the financing of the further development of these two products can be separated from the normal Group financing.

Biofrontera Inc. was established in March 2015 and will be used in future to conduct business in the USA.

#### ***2. Group strategy***

The strategic objective of the Biofrontera Group is to establish the company as a pharmaceutical company specialising in the dermatological sector. In addition to further expansion of business in Europe, the main priorities are to increase the range of indications for existing products and to develop the independent marketing operation in the USA.

Biofrontera was the first small German company to receive centralised European drug approval for a completely independently developed drug, Ameluz®. In the months prior to the market launch of Ameluz®, the company's own sales operation was gradually developed, and Biofrontera has been selling Ameluz® via its own field sales team to dermatologists in Germany since the product was launched in February 2012 and in Spain since March 2015. In the UK, the contract with the local marketing partner was terminated on 31 July 2015. Biofrontera will take over distribution in the UK itself once indications have been extended to include basal cell carcinoma. The drug is distributed in other countries of the European Union, as well as in Israel and Switzerland, by licensing partners.

Biofrontera has thus established itself as a specialist pharmaceutical company with an unusually high level of research and development expertise in comparison to other companies in this sector. The focus of the Group's strategy is to further expand its business in Europe, achieve market entry of Ameluz® in the USA and extend the indications to include basal cell carcinoma, first in the EU and at a later stage in the USA.

Further preparatory work was carried out for the approval of Ameluz® in the USA in the reporting period. In early July 2015, the approval application (NDA = New Drug Application) was submitted to the FDA (Food and Drug Administration). Ameluz® and BF-RhodoLED® have to be approved as a combination of a drug and a medical device in the USA, and therefore the approval application is unusually complex. In accordance with the guidelines, the FDA made a decision on the formal "acceptance to file" after a period of 60 days, and this was granted on 11 September 2015. In the subsequent "74-day letter", the company was informed on 2 October 2015 that no significant verification issues had been identified in the preliminary review process. In this letter, the FDA also gave the date for the detailed interim report including the proposed labelling as 30 March 2016, and gave an estimated date for issuing the final approval (PDUFA date) of 10 May 2016, provided that no significant problems arise. In a further communication on 20 January 2016, the FDA informed the company that the midcycle review had been completed and the FDA had no further questions arising from this regarding the approval application. The proposed labelling was provided to the company by the FDA at the end of March 2016. Once the approval process has been completed, Biofrontera will have access to the largest healthcare market in the world.

The extension of the indications for Ameluz® to include the treatment of basal cell carcinoma (BCC) was initiated in 2014. The phase III clinical testing was carried out in direct comparison with the competitor product Metvix®. Patient recruitment was completed in May 2015 and the last patient completed the clinical part of the trial in November 2015. There is then a 5-year follow-up period for all the patients. The results of the trial have been available since January 2016 and prove that Ameluz® is highly clinically effective for the indication of BCC. In comparison with the competitor product Metvix®, it demonstrated higher healing rates, especially with thicker and nodular carcinomas. Metvix® has had a major competitive advantage over Ameluz® up to now due to its

approval for the treatment of basal cell carcinoma, despite its statistically significant inferiority for the treatment of actinic keratosis (in the case of AK, Ameluz® is approved for mild and moderate AK on the face and scalp as the first choice therapy, while Metvix® is only approved for mild AK on the face and scalp as a second choice therapy). Particularly in other European countries, where dermatologists are mainly based in hospitals and there are fewer independent practices, the market opportunities of Ameluz® are significantly reduced by the lack of approval for BCC. The extension of the indications currently being sought is therefore expected to put Biofrontera in a significantly improved market position. The application to extend the indications of Ameluz® to include basal cell carcinoma is due to be made once the trial report has been completed in the 2nd quarter of 2016, and the approval of the European Medicines Agency is then expected in the 4th quarter of 2016.

2016 will therefore be a very decisive year for Biofrontera, with new Ameluz® approvals expected for actinic keratosis in the USA, Switzerland and Israel and an approval extension expected for basal cell carcinoma in Europe. In light of this and the related challenges facing Biofrontera, the Management Board was expanded to include a Chief Commercial Officer. Christoph Dünwald was appointed as Chief Commercial Officer, bringing with him extensive international experience and all the necessary skills to successfully manage the internationalisation of sales and in particular the marketing of Ameluz® in the USA and Europe. Mr. Dünwald has 24 years of experience in sales and marketing in the healthcare sector in Europe, the USA and Asia. He joined Biofrontera on 16 November.

### **3. Products**

#### **Ameluz®**

Ameluz® 78 mg/g Gel ("for people who love the light", development name: BF-200 ALA) received a first centralised European approval for the treatment of mild and moderate actinic keratoses on the face and scalp in December 2011. During the phase III development, its superiority compared to its direct competitor product Metvix® was proven for this indication. Actinic keratoses are superficial forms of skin cancer, and there is a risk that they can spread to deeper layers of skin. The combination of Ameluz® with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European Medicines Agency (EMA) explicitly mentions the significant superiority of Ameluz® for removing all of a patient's keratoses compared to its direct competitor product.

In the phase III approval trials, Ameluz® showed excellent healing rates and demonstrated significant superiority compared to the approved comparator product, which was tested in parallel. In the first phase III trial in which the drug was combined with an LED lamp, in 87% of patients treated with

Ameluz®, all keratoses were completely removed, and in terms of the number of individual keratosis lesions, as many as 96% were completely eradicated (all the values stated are ITT (intent to treat) values). In the second phase III approval trial, the effectiveness of Ameluz® was tested in comparison with the approved standard medication. The results of the trial provided evidence that Ameluz® was clearly superior to the competitor product already available in Europe at the time. Based on the average for all lamps used in the treatment, Ameluz® resulted in the complete healing of actinic keratoses in 78% of patients, whereas the competitor product already approved at the time achieved a healing rate of only 64%. With LED lamps, the healing rates increased to 85% for Ameluz® and 68% for the competitor product. The side effect profile was comparable for both products.

As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which requires the company to be certified pursuant to the ISO 9001 and ISO 13485 standards. In preparation for the approval in the USA, a phase III trial was carried out with a combination of Ameluz® and BF-RhodoLED®, and was completed in the reporting period. With this combination, keratoses were completely eradicated from 91% of patients, and in terms of the number of individual lesions, 94% were completely removed after treatment (99.1% of mild and 91.7% of moderate lesions). As it has been widely reported in the literature that PDT has pronounced skin-rejuvenating properties, particularly in the case of sun-damaged skin, in this trial, for the first time in a phase III trial of PDT anywhere in the world, the drug was applied over large surface areas (field therapy) and the cosmetic result was established, without taking into account the disappearance or not of the keratotic lesions. All the parameters that were tested improved significantly as a result of the treatment. The proportion of patients without rough, dry and scaly skin increased from 14.8% to 63.0% after treatment with Ameluz®. The group of patients without hyperpigmentation or hypopigmentation increased from 40.7% to 57.4% and from 53.7% to 70.4%, respectively. The proportion of patients with mottled pigmentation who had both hyperpigmentation and hypopigmentation in the treated area decreased from 48.1% to 29.6%. Before treatment, 22.2% of the patients had mild scarring, which dropped to 14.8% of patients after treatment. Atrophic skin was diagnosed in 31.5% of patients before treatment but in only 16.7% of patients after the treatment.

The patients treated in the field therapy trial were observed by the trial doctors over the course of a year after the final treatment. Here, the long-term nature of the pharmaceutical effect of Ameluz® was analysed in terms of effectiveness, safety and the cosmetic result. 63.3% of the patients who were initially completely asymptomatic were still asymptomatic one year later. The long-term effectiveness achieved using field therapy is thus in the region of that already observed in previous long-term studies on lesion-directed PDT with Ameluz®. The improvement in the skin appearance of patients treated with Ameluz® that was observed immediately after PDT continued to develop during the follow-up period. Before PDT, only 14.8% of patients had no impairments to the surface of the skin. Whereas twelve weeks after the last PDT, 63% of patients were already free of such cosmetic damage,



this percentage rose after a year to 72.2%. Similar results were also observed for pigment disorders. Before PDT, hyperpigmentation occurred in 59.3% and hypopigmentation in 46.3% of patients, with 48.1% exhibiting irregular pigmentation. Twelve weeks after Ameluz® PDT, these percentages initially fell to 42.6%, 29.6% and 29.6% and decreased over the course of a year to 24.1%, 11.1% and 18.5%. These results clearly show that the skin rejuvenation effect achieved using photodynamic therapy with Ameluz® is long-lasting and the repair processes triggered by the therapy remain active for at least 12 months.

It is the first time that data on the aesthetic effect of PDT has been collected within the scope of a phase III approval trial. The results underline the significance of PDT with Ameluz® and BF-RhodoLED® and show that the therapy stands out clearly from many other treatment options.

Both the phase I trials required by the American approval authority, the FDA, were also completed in the reporting period. These clinical trials were initiated with a total of approximately 240 patients or subjects in order to add to the European approval package for Ameluz® the safety data required for registration in the USA. Specifically, one of the trials was a sensitisation study, which determines the potential of Ameluz® to trigger allergies, and the other was a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz®, aminolevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, i.e. the application of a complete tube onto the defective skin. No safety concerns were identified in either of the studies.

Actinic keratosis is classified as a tumour that requires treatment, and the international treatment guidelines list photodynamic therapy as the gold standard for the removal of actinic keratoses, particularly for patients with large keratotic areas. The latest statistics show that actinic keratosis is becoming a widespread disease, with up to 8 million people affected in Germany alone, and that there is a marked upward trend in cases. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this happens to the relevant lesions within two years on average. The fact that doctors are therefore taking actinic keratosis increasingly seriously is illustrated by the fact that actinic keratosis has been recognised as an occupational disease since summer 2013. Since then, occupational insurance associations have been obligated to cover the treatment costs of patients who have mainly worked outdoors for a long time and who fulfil certain criteria, for the duration of these patients' lives. Reimbursement will be determined shortly.

At present, actinic keratoses are treated using a wide range of methods. Lesions are treated, sometimes for weeks, with topical creams, which are often ineffective, or the diseased skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often leads to scar formation or permanent pigment disorders.

The market for topical creams continues to show constant growth, and medicinally and legally questionable PDT formulations continue to be used in Germany. Because Ameluz® is the market

leader among independent dermatologists in Germany in the PDT proprietary medicinal product market, with a market share of over 70%, a significant increase in sales can and must result from the above-mentioned sectors.

The overall advantages of Ameluz® in terms of effectiveness, handling, user-friendliness and cosmetic results, as well as the high healing rates of PDT in the treatment of actinic keratoses, will increasingly bring this treatment option to the attention of dermatologists over the next few years. This will be helped by the expansion of the range of indications to include basal cell carcinoma, which the company is currently working on, as the vast majority of PDT treatments are carried out for this indication, particularly in the UK and Spain.

Biofrontera has carried out a phase III trial for the extension of the European approval to include the indication basal cell carcinoma (BCC). BCCs are the most common invasive tumours that affect humans and account for approximately 80% of all invasive white skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in Germany but this can lead to clearly visible scarring, whereas treatment with photodynamic therapy (PDT), which is an alternative particularly in the treatment of thin BCCs, gives rise to excellent cosmetic results. In the pivotal phase III trial, a total of 278 patients were treated. The trial was conducted under the clinical supervision of Prof. Dr. Colin Morton (UK) and Prof. Dr. Markus Szeimies (Germany) and was carried out at 27 clinical trial centres in the UK and Germany. Patient recruitment for the trial, which was carried out in direct comparison with the competitor product Metvix®, was completed in May 2015 and the last patient completed the trial in November 2015. The results of the trial have been available since January 2016. The results confirm the company's positive expectations. In the clinical trial, the effectiveness and safety of Ameluz® were compared with that of Metvix®, a drug already approved in the EU for the treatment of BCC. Non-aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved the complete elimination of all BCCs from the patient in 93.4% of cases compared to 91.8% with Metvix®. There were greater differences in the case of thicker BCCs. With Ameluz®, 89.3% of the tumours were completely removed, compared to only 78.6% with Metvix®.

Based on the results of this phase III trial, Biofrontera will shortly apply to the European Medicines Agency for approval for the treatment of BCC with Ameluz®. As the existing Ameluz® approval only has to be extended for this, the extended approval should be issued as early as this year.

## **BF-RhodoLED®**

BF-RhodoLED® is a lamp designed for photodynamic therapy (PDT), and uses LEDs emitting red light at a wavelength of approx. 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. The light energy and fan power settings can be adjusted during a PDT treatment session in order to reduce any discomfort caused by the treatment. No other lamp on the market offers comparable power and flexibility. BF-RhodoLED® has been CE-certified since November 2012 and is distributed throughout the EU.

## **Belixos®**

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated skin. The biocolloid technology patented by Biofrontera, which optimises epidermal penetration, makes the products unique: pure plant biocolloids are combined with medicinal plant extracts to form an extraordinary combination of active substances with proven depth penetration, bringing together the best of nature and science.

Belixos® Cream rapidly and reliably soothes itching and is the ideal basic treatment for inflamed, reddened and flaky skin. It soothes the skin, reduces scratching and allows the skin to regenerate naturally. Belixos® Cream, which has been available since 2009, has thus proved particularly useful as an effective basic treatment for atopic dermatitis and psoriasis.

Over the past two years, other specialist regenerative cosmetic products for skin problems have been developed. The typical deep yellow colour is the unmistakeable mark of quality. This is derived from the traditional medicinal plant extract obtained from the roots of Mahonia aquifolium. Belixos® products use only natural active substance extracts with clinically proven effects.

Belixos® Liquid is an innovative scalp tonic with a practical pipette for dosing, which soothes scalps irritated by psoriasis or eczema, for example, and restores their balance. For itchy and flaky scalps, a combination of anti-inflammatory mahonia, moisturising oats, irritation-relieving panthenol and a special zinc PCA complex is used.

Belixos® Gel is specially formulated for skin that is inflamed, reddened and prone to skin blemishes, providing an effective treatment for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin and regulates sebum.

In summer 2015, a modern daily skincare product for sun-damaged skin with exceptional lipid matrix formulation and skin-regenerating properties was added to the Belixos® range: Belixos® Protect. Highly concentrated niacinamide smooths the skin and helps repair skin damage. It also contains UVA and UVB broad spectrum protection with SPF15 to protect against further light-induced skin ageing and hyperpigmentation.

Irritated skin requires the highest level of care. Belixos® products are manufactured in accordance with strict quality and environmental requirements. They are free of paraffins, parabens, ethyl alcohol, animal products, dyes and fragrances that may have negative dermatological effects. Their skin-compatibility was dermatologically tested without the use of animal testing and was assessed as "very good" by the independent institute 'Dermatest'. Belixos® is available at selected pharmacies, dermatological institutes and on Amazon.

A further product launch is planned for 2016.

#### ***4. Sales and markets***

With its central European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland and Liechtenstein. However, in many European countries, the price and the reimbursement status have to be defined prior to market launch, which can be a very lengthy process. To date, the company has commenced sales and distribution in Germany, the UK, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway and Slovenia. The drug is available in these countries at a pharmacy retail price of between just under EUR 200 and approx. EUR 270 per 2g tube.

Ameluz® is marketed in Germany and, since March 2015, also in Spain by Biofrontera's own field sales force, and in other European countries using marketing partners. In the UK, Biofrontera is currently preparing its own sales operation, and the contract with a local marketing company was terminated on 31 July 2015. Biofrontera also carries out its own sales and distribution in Slovenia, but its local marketing there is supported by a local company.

Distribution to public pharmacies generally takes place via pharmaceutical wholesalers, whereas hospital pharmacies are supplied directly. In addition to regular visits by the field sales force to dermatologists, Biofrontera has presented Ameluz® at the major dermatological conferences both in Germany and in other European countries since it was introduced onto the market. The response from dermatologists has been extraordinarily positive. In 2015, Biofrontera again recorded a significant increase in sales of 34% compared to the previous year. The market share of Ameluz® in the segment of PDT drugs dispensed by German public pharmacies is consistently over 70%. In spite of this, Ameluz® still only has a small share of the overall market for preparations used to treat actinic keratosis, because only approximately 5% of patients are treated with proprietary medicinal products

for photodynamic therapy (PDT). Although PDT achieves by far the highest healing rates, the complexity of the treatment and the time required by medical practices to administer it have so far prevented significant market penetration in the statutory health insurance sector. In this sector in Germany, doctors do not usually receive any compensation from statutory health insurance for performing PDT. A film about PDT is available to view on YouTube (<http://www.youtube.com/watch?v=aK4a3R5kqMA>, and in English <http://www.youtube.com/watch?v=2xE08DWCO8o>).

Approval for basal cell carcinoma is a prerequisite for the widespread use of Ameluz® in hospitals, as basal cell carcinoma is mainly treated there, whereas this is only very rarely the case for actinic keratosis. This indication plays an essential role for the breakthrough of Ameluz®, particularly in European countries. BCCs are the most common invasive tumours that affect humans and account for 50-80% of all invasive white skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and this is a rapidly growing trend worldwide due to increased exposure to UV light. BCCs are normally removed surgically, often resulting in scarring. Treatment with photodynamic therapy (PDT) is a highly effective alternative which also leads to excellent cosmetic results. According to a market study published in 2014 by Technavio, the international market for actinic keratosis medications is expected to grow by approx. 8% annually, from approx. USD 546 million to USD 942 million in 2020. However, during the same period, the market for basal cell carcinoma medications is expected to grow at a phenomenal rate, from approx. USD 236 million today to nearly USD 5 billion, because the availability of new drugs (Ameluz® is mentioned in this context) will mean that fewer and fewer patients undergo operations.

In Denmark, Sweden and Norway, Ameluz® is marketed by Desitin Arzneimittel GmbH, in Benelux by Bipharma N.V. and in Austria, by Pelpharma Handels GmbH. Biofrontera carries out its own sales and distribution activities in Slovenia and is supported in its marketing activities by PHA Farmed. The cooperation with Spirit Healthcare in the UK was terminated by Biofrontera as of 31 July 2015, and Biofrontera is currently preparing to set up its own sales operation in the UK. Sales in Spain were initially handled by Allergan SA, but since March 2015 Biofrontera has marketed its products itself in Spain via its own branch, Biofrontera Pharma GmbH sucursal en España. Louis Widmer SA has been granted the Ameluz® distribution licence for Switzerland and Liechtenstein, and the Ameluz® distribution licence for Israel has been allocated to Perrigo Israel Agencies LTD. In these countries, it is necessary to undergo an independent approval process, which is currently being carried out by the above-mentioned distribution partners in collaboration with Biofrontera. In Switzerland, both the approval and the reimbursement approval were issued in December 2015. The market launch will take place during 2016. In Israel, Ameluz® has been included in the National Health Basket and thus accepted for reimbursement. Approval is now also expected in the next few months.

The contracts with the respective sales partners have been concluded in such a way that Biofrontera has received no down payment, or only a modest down payment, and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their own sales price. Biofrontera's share of the sales price varies considerably depending on the market conditions in each country, ranging from 35% to 60% of net sales.

For France, Biofrontera has submitted its application to make Ameluz® reimbursable and to establish the pricing with the assistance of a consultancy that specialises in this field. The processing of the application has not yet been completed.

Biofrontera has already started preparations for its sales operation in the USA. With the help of a consulting firm specialising in market access and a team of medical advisors, Biofrontera has started to analyse the actinic keratosis drug market and the reimbursement systems in the American healthcare system. For this, Biofrontera can draw on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick®. A local subsidiary, Biofrontera Inc., was established in March 2015 and a very experienced CEO was appointed in the form of Monica L. Tamborini, who has already started setting up the necessary infrastructure for a pharmaceutical company in the USA and developing detailed plans to prepare for marketing. If approval is granted by the FDA as planned on 10 May 2016, the plan is to launch Ameluz® on the US market on 1 September 2016. As the drug and lamp are approved as a combined product in the USA, the speed of market penetration in the USA will depend in particular on Biofrontera's ability to position the BF-RhodoLED® PDT lamp.

## ***5. Other development projects***

### **BF-derm1**

BF-derm1 is a tablet for the treatment of severe chronic urticaria (hives). In its severe form, this illness cannot be treated adequately using currently available drugs. The tablet contains an active ingredient with a completely new action profile, and it can be used to soothe chronic urticaria that cannot currently be adequately treated. A phase IIa trial has already been completed that has demonstrated the product's efficacy and also its limited side effects. As Biofrontera will be concentrating on further developing Ameluz® over the next few years, it intends to look for a partner for the further development and funding of the phase III costs and the approval expenses. However, no work has yet been carried out on this for reasons of capacity.

## **BF-1**

BF-1 is an active agent candidate from the Biofrontera drug portfolio. It is intended to be used for the prophylactic treatment of patients who frequently suffer from migraines. As this product candidate no longer fits Biofrontera's dermatological product focus, the intention is to license it out after the initial development stages.

After the first results in humans, which proved the excellent bioavailability and pharmacokinetics of the active agent, further preclinical investigations were carried out concerning the tissue distribution, metabolism and toxicology of the substance. These trials did not yield any critical findings, so there is no reason why further tests on humans should not be carried out. The chemical manufacturing process has been optimised and the active ingredient required for clinical development has been synthesised in accordance with the Good Manufacturing Practice (GMP) quality standards.

### ***Patent and trademark developments since 31 December 2014***

#### **Nanoemulsion**

Regarding the "Nanoemulsion" patent (PCT/EP2007/011404), further official communications were issued in Canada, India, Israel, Chile, Europe, the United Arab Emirates and the USA, and responses were sent by the relevant deadlines.

In Europe, the patent is expected to be issued shortly, so patent protection is likely soon.

The patent was issued in Canada on 24 November 2015 and in India on 26 June 2015.

#### **Belixos®**

Regarding the patent "Pharmaceutical and/or cosmetic composition for treating the skin" (US Patent Application No. 13/081,737), a pending official communication was answered by the deadline and an application was made for continued testing.

#### **Migraines**

Regarding the migraine patent EP 1 438 307, this was not renewed in Belgium, Bulgaria, Estonia, Finland, Greece, Ireland, Luxembourg, Monaco, Portugal, Slovakia, the Czech Republic and Cyprus, and therefore this patent will expire in these countries due to non-payment of renewal fees.

The same applies to the corresponding patent in Hong Kong (HK1073311).

## **Brand development**

Protection was granted in full for Russia, Singapore, Japan and the USA for two different versions of the international trademark "Natural Heritage with Herbal Biocolloids".

Protection for international trademark No. 1113422 (BF-RhodoLED) and No. 1031222 (Ameluz) was granted in Liechtenstein.

An application was made for a new European Community Trademark, "Daylight-PDT" (No. 014943518).

## ***Economic report***

For the 2015 financial year for the Biofrontera Group:

- 34% overall sales growth compared to the previous year, including significant growth of 27% in Germany and strong sales growth of 61% in the other European countries
- Operating profit/loss: EUR -10.2 million (previous year: EUR -9.6 million)
- Consolidated profit/loss before tax: EUR – 11.2 million (previous year: EUR -10.7 million)
- Liquid assets as of 31 December: EUR 4.0 million (previous year: EUR 8.5 million)
- Undiluted earnings per share amounted to EUR -0.48 (previous year: EUR -0.49)

Sales revenue: Sales revenue in Germany increased by 27% compared to the same period in the previous year. This almost corresponds to the desired increase for the whole year of 30%. In the third quarter in particular, an unusually large increase in sales was achieved, boosted by high levels of stocking by wholesalers. Moreover, significantly higher orders were recorded in other European countries than in the previous year, which led to a sharp increase of 61% in international sales. Down-payments remained unchanged compared to the previous year, at EUR 70 thousand.

Operating profit/loss: In the 2015 financial year, Biofrontera again invested substantial amounts to further develop its products and to establish sales and marketing structures. Overall, the costs exceeded the sales revenue achieved, leading to an operating loss of EUR 10.2 million.

## ***Financial position, cash flows and results of operations of the Biofrontera Group***

### **Sales revenue**

The Biofrontera Group recorded sales of EUR 4,138 thousand during the 2015 financial year (2014: EUR 3,096 thousand), corresponding to an increase of 34% compared to the same period in the



previous year. Revenue from sales of our products in Germany increased by 27% to EUR 3,028 thousand (2014: EUR 2,379 thousand), and in other countries, sales rose significantly, by 61% to EUR 1,040 thousand (2014: EUR 647 thousand). In the 2015 financial year, EUR 70 thousand of down-payments were received (2014: EUR 70 thousand).

### **Cost of sales, gross profit from sales**

The gross profit from sales improved from EUR 1,979 thousand in the 2014 financial year to EUR 2,902 thousand in the 2015 financial year. The gross margin increased to 70%, compared to 64% in the same period in the previous year.

The cost of sales amounted to EUR 1,236 thousand, or 30% of the sales revenue, improving slightly relative to sales revenue compared with the previous year (EUR 1,117 thousand, or 36%).

### **Development costs**

The research and development costs increased by 37%, from EUR 4,534 thousand in the previous year to EUR 6,204 thousand in the 2015 financial year. The investment in research and development to extend the range of indications and obtain approval for Ameluz® in the USA remained almost constant. In addition, a submission fee ("PDUFA fee") of EUR 2,072 thousand was paid for the submission of the approval application to the FDA. This fee is usually waived for small companies for their initial submission. In consultation with the FDA, Biofrontera lodged an application for a waiver of this fee, but this could not be processed on the filing date as the American approval authority, the FDA, did not have a process for handling such applications. This fee was refunded by the FDA in March 2016.

### **Sales costs**

The sales costs increased only slightly by 8% to EUR 4,170 thousand compared to the previous year (EUR 3,847 thousand), despite the build up of a sales structure in Spain. The sales costs include the costs of our own field sales team in Germany and Spain, as well as marketing expenses. They also include expenses for marketing preparations in the USA.

### **Administrative costs**

The administrative costs decreased compared to the same period in the previous year by EUR 485 thousand to EUR 2,759 thousand, primarily due to lower financing costs. Financing costs shown under administrative costs include primarily consultancy and placement fees in connection with support for the search of investors.

## **Financial result**

The financial result consists primarily of the interest payable for the 2009/2017 warrant bond (EUR 439 thousand, previous year: EUR 447 thousand) and for the 2011/2016 warrant bond placed in 2011 (EUR 727 thousand, previous year: EUR 702 thousand), calculated using the effective interest method. The aforementioned interest expenses of EUR 439 thousand (previous year: EUR 447 thousand) for the 2009/2017 warrant bond include the opposite effect amounting to EUR 193 thousand (previous year: EUR 156 thousand) resulting from the repurchase of part of the warrant bond on 28 February 2014. The interest payment for the 2014 calendar year from warrant bond I and II occurred in January 2015. The interest payment for warrant bond I for the 2015 financial year was made at the end of December 2015, and for warrant bond II, the interest payment was made beginning of January 2016.

## **Investments**

The increases in intangible assets and property and equipment in the reporting period resulted primarily from the acquisition of further rights of use in connection with the prototype of the PDT lamp (EUR 26 thousand, previous year: EUR 77 thousand) as well as the capitalisation of production facility expenses (EUR 45 thousand; previous year: EUR 0) and office and business equipment (EUR 42 thousand; previous year: EUR 29 thousand). The asset disposals with acquisition and production cost of a total of EUR 20 thousand (previous year EUR 128 thousand) primarily resulted from sales of rental lamps.

## **Inventories**

Inventories amounted to EUR 1,534 thousand (31 December 2014: EUR 1,394 thousand). These included: finished products (Ameluz®) amounting to EUR 400 thousand, BF-RhodoLED® lamps recorded in the inventories amounting to EUR 435 thousand and Belixos® products amounting to EUR 46 thousand as well as unfinished products, raw materials and supplies amounting to EUR 633 thousand.

## **Receivables**

The receivables from goods and services increased by EUR 586 thousand due to the higher sales in the 4th quarter of 2015, from EUR 309 thousand as of 31 December 2014 to EUR 895 thousand.

## **Share capital**

The fully paid share capital of the parent company, Biofrontera AG, as of 31 December 2015 amounted to EUR 25,490,430.00. It was divided into 25,490,430 registered shares with a nominal value of EUR 1.00 each. On 31 December 2014, the share capital amounted to EUR 22,196,570.00 and was increased by a total of EUR 3,293,860.00, divided into 3,293,860 registered shares, during the course of the 2015 financial year by means of two capital increases.

In the first capital increase carried out in 2015, new shares were offered to all shareholders for subscription or additional subscription. The new shares that were not acquired as part of the subscription right or the additional subscription were offered to selected investors for acquisition in a private placement. EUR 1,377,272.00, divided into 1,377,272 registered shares, was placed and the execution was entered in the commercial register on 1 June 2015. The issue proceeds amounted to EUR 3.1 million.

In addition, in a further capital increase, a total of EUR 1,916,588.00, divided into 1,916,588 registered shares, was placed and this was entered in the commercial register on 3 December 2015. This capital increase was also initially offered to all shareholders for subscription or additional subscription. Shares that were not acquired as part of the subscription or additional subscription were offered to institutional investors for subscription. The issue proceeds amounted to EUR 3.5 million.

Biofrontera AG shares were listed on the regulated market of the Düsseldorf Stock Exchange in 2006. Approval was granted for trading on the regulated market of the Frankfurt Stock Exchange in August 2012. The company's shares are also traded on the Xetra computer trading system and all other German stock exchanges. On 3 June 2014, the shares were admitted to the Prime Standard of the Frankfurt Stock Exchange and to the AIM Market of the London Stock Exchange. The listing on the AIM Market was rescinded effective from 18 February 2016.

### **Group equity and company equity**

According to IFRS, the Group has negative equity amounting to EUR -4,809 thousand. As of 31 December 2015, Biofrontera AG has positive shareholders' equity of EUR 65,496 thousand (previous year: EUR 65,847 thousand). There is no over-indebtedness in the legal sense at the two subsidiaries Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH as their balance sheet insolvency is remedied by qualified letters of subordination from Biofrontera AG. On the level of Biofrontera AG extraordinary depreciation on the investment book values of Biofrontera Neuroscience GmbH and Biofrontera Development GmbH were recorded in a total amount of EUR 6,561 thousand, since the group will focus on the development and approvals of Ameluz® and BF-RhodoLED® in the US as well as indication expansion in Europe and therefore no intensive efforts were made in the fiscal year 2015 which would lead to positive cash flows from the products BF-derm1 and BF-1 in the near future.

The net loss of Biofrontera AG is thus EUR -7,263 thousand (previous year: EUR -1,409 thousand).

## Financial position

The company's capital management body regularly reviews the equity ratio of the Group and of the Group subsidiaries. The management's objective is to ensure an appropriate equity base, within the framework of the expectations of the capital market, and creditworthiness with respect to national and international business partners. The Management Board of the company ensures that all Group companies have sufficient capital at their disposal in the form of equity and debt capital. The equity reconciliation statement provides further information about the development of equity.

The cash flow from operating activities fell compared to the previous year, from EUR -7,928 thousand to EUR -9,717 thousand on 31 December 2015.

Sales of rental lamps held in inventory decreased compared to the previous year from EUR 117 thousand to EUR 20 thousand. At the same time, cash flows from interest revenue increased by EUR 41 thousand to EUR 184 thousand. Investments into fixed assets increased slightly by EUR 16 thousand. These factors led to a decrease in the cash flow from investment activities of EUR 62 thousand from EUR 79 thousand to EUR 17 thousand.

The cash flow from financing activities decreased by EUR 8,275 thousand compared to the same period in the previous year, from EUR 13,425 thousand to EUR 5,150 thousand. This change results primarily from proceeds from the issuance of shares, a capital increase with issuance proceeds of EUR 15.3 million was performed in the previous year.

The company was able to meet its payment obligations at all times, but it will also be dependent on further financing in future. (compare notes to liquidity risk).

### Achievement of objectives in 2015:

|                                | Outlook for 2015      | Achievement of objectives as of 31 December 2015 |
|--------------------------------|-----------------------|--|
| Group sales revenue            | EUR 4 to 5 million    | EUR 4.1 million                                  |
| Research and development costs | EUR 4 to 5 million    | EUR 6.2 million                                  |
| Net profit/loss before tax     | EUR -9 to -10 million | EUR -11.2 million                                |

Biofrontera achieved all of its financial objectives in 2015, when considering the one time payment of the submission fee to the FDA ("PDUFA-fee") in an amount of EUR 2.1 million. In the forecast, sales revenue of EUR 4 to 5 million was expected. In Germany, revenues from product sales increased by more than 27% compared with the previous year and were thus close to the target. Furthermore, sales in other European countries and with foreign sales partners were increased by 61%. Despite this, market penetration in other European countries continues to be difficult, particularly due to the fact that basal cell carcinoma is not yet included as an indication.

Biofrontera also continued to invest heavily in research and development and regulatory affairs in 2015, in order to expand the indications for Ameluz® - to include basal cell carcinoma in particular - and to obtain approval in the USA. The R&D costs of EUR 6.2 million were on target considering the PDUFA fee paid in May 2015.

Our net loss before taxes of EUR -11.2 million also lay within the predicted range, also considering the PDUFA-fee.

## ***Personnel details***

### **Management Board**

The Management Board comprises Prof. Dr. Hermann Lübbert (Chief Executive Officer), Mr. Thomas Schaffer (Chief Financial Officer) and Mr. Christoph Dünwald (Chief Commercial Officer).

The remuneration of the Management Board members consists of a fixed salary that is paid in twelve equal monthly instalments. In addition, there is an annual, performance-based bonus for the directors, as well as a long-term remuneration component consisting of participation in the company's stock option programme. Company cars are also available to the directors for business and private use.

### **Staff**

As of 31 December 2015, 58 employees worked for the Biofrontera Group (31 December 2014: 46). Of these, 17 were employed at Biofrontera AG (31 December 2014: 16), 6 at Biofrontera Bioscience GmbH (31 December 2014: 6) and 34 at Biofrontera Pharma GmbH, including the Spanish office (31 December 2014: 24). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. As of 31 December 2015, one member of staff was employed by Biofrontera Inc.

### **Employee stock option programme 2010**

In order not to be at a disadvantage in the future regarding staff recruitment and retention, the company must continue to be able to offer share and/or securities-based remuneration. Moreover, in accordance with the German Act regarding the Appropriateness of Management Board Remuneration, such schemes must be linked to the long-term success of the company. As the stock option programme approved by the Annual General Meeting of the company on 24 May 2007 could not be used, the Annual General Meeting held on 2 July 2010 granted the Management Board and the Supervisory Board the authorisation to issue, within the next 5 years, up to 839,500 options to

directors and employees. Further provisions governing this action were specified in the invitation to the Annual General Meeting and are available on the company's website.

On 24 November 2010, 106,400 options (first tranche) were issued with an exercise price per share of EUR 1.91. On 30 September and on 7 October 2011 (second tranche) a further 96,400 options were issued with an exercise price of EUR 2.48 each. On 23 March 2012 and 11 May 2012 (third tranche), 65,000 options were issued with an exercise price of EUR 3.30 each, and 51,500 options were issued with an exercise price of EUR 4.09 each. On 2 September 2013, 179,500 options were issued (fourth tranche) with an exercise price of EUR 3.373 each. On 2 April 2014, 159,350 options were issued with an exercise price of EUR 3.43 each. A total of 123,750 options were forfeited by employees leaving the company. No options were issued in the 2015 financial year.

The authorisation to issue options under the 2010 stock option programme ended on 1 July 2015. By resolution of the Annual General Meeting on 28 August 2015, the conditional capital III provided to service options under this programme was reduced to EUR 542,400.00.

### ***Supervisory Board***

By resolution of the Annual General Meeting of 10 May 2011, the following were appointed as Supervisory Board members for five years:

|                               |  |
|-------------------------------|--|
| <b>Jürgen Baumann</b>         | Chairman of the Supervisory Board, expert in the field of sales and marketing of pharmaceuticals, resident in Monheim, Germany   |
| <b>Prof. Dr. Bernd Wetzel</b> | Deputy chair of the Supervisory Board, advisor, resident in Biberach/Riss, Germany   |
| <b>Dr. Ulrich Granzer</b>     | Owner and Managing Director of Granzer Regulatory Consulting & Services, resident in Munich, Germany   |
| <b>Ulrike Kluge</b>           | Managing Partner of klugeconcepts GmbH in Cologne, resident in Cologne, Germany  |
| <b>Andreas Fritsch</b>        | Member of the management board, Xolaris Service Kapitalverwaltungs AG, Munich; Managing Director of Unternehmensberatung Fritsch, Seefeld, resident in Seefeld, near Munich, Germany |
| <b>Alfred Neimke</b>          | Managing director of Kopernikus AG in Zurich, Switzerland; CFO of MAN Oil in Zug, Switzerland; resident in Zurich, Switzerland   |

The members of the Supervisory Board had the following other supervisory board positions and positions on other comparable domestic and foreign boards during the reporting period:

Alfred Neimke

Board of directors at DERPHARM AG in Zurich, Switzerland  
Director Prudent Investment Fund, Luxembourg

### ***Supplementary report***

#### **Events of special significance occurring since 31 December 2015**

In January 2016, the FDA informed the company that the midcycle review as part of the approval process in the US had been completed, and that the FDA did not have any further questions for the company in this regard.

A submission fee (PDUFA fee) of EUR 2,072 thousand was paid during the 2015 financial year for the submission of the ap-proval application for Biofrontera's drug Ameluz® to the FDA. This fee is usually waived for small companies for their initial submission. In consultation with the FDA, Biofrontera lodged an application for a waiver of this fee, but this could not be processed on the filing date as the American approval authority, the FDA, did not have a process for handling such applications. Biofrontera subsequently requested a refund of the fee from the FDA. The FDA approved the request in a letter dated 14 January 2016 and the fee was refunded in March 2016.

On 28 January 2016, the company announced that the preliminary results of the phase III trial for the treatment of basal cell carcinoma (BCC) were available. In the clinical trial, the effectiveness and safety of Ameluz® were compared with that of Metvix®. Non-aggressive superficial and nodular BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved the complete elimination of all BCCs from the patient more often, with a rate of 93.4%, compared to Metvix® with 91.8%. On 4 March 2016, detailed results from the trial were published and these fully confirm the initial positive impression.

On 16 February 2016, the company announced that a capital increase had been carried out in order to secure further corporate financing by issuing 2,357,384 shares to selected institutional investors, with the exclusion of subscription rights. The issue price for the new shares was EUR 1.90, and the capital increase was entered in the commercial register on 26 February 2016. Net proceeds were EUR 4.4 million.

On 24 March 2016 the company announced an agreement with an institutional investor that has agreed to acquire up to 2.0 million New Shares at an issue price of EUR 2.00 in a yet to be performed capital increase. The capital increase will have a maximum volume of EUR 5.0 million.

On 29 March 2016 the company announced that the Management Board, with the approval of the Supervisory Board, has decided to increase the share capital by up to 2,499,999 New Shares by way of a rights issue. Shareholders shall be granted their statutory subscriptions rights such that up to

2,421,549 New Shares will be offered at a ratio of 23:2 within a subscription period of two weeks according to the execution of subscription rights at an issue price of EUR 2.00. The statutory subscription right was excluded regarding 78,450 supernumerary New Shares. The shareholders are furthermore offered an “Additional Subscription” right. I.e. all shareholders executing subscription rights may apply to subscribe to unsubscribed shares plus the supernumerary shares at the Subscription Price.

No further events subject to mandatory reporting occurred after the balance sheet date.

### ***Risk, opportunity and forecast report***

#### **Risk management system**

Biofrontera's management has a comprehensive risk management system to deal with the risks existing in the Group. For a description of this system, please refer to the combined company and Group management report most recently published.

#### **Risk management system**

The risk and opportunity management system for the Biofrontera Group applies equally to Biofrontera AG. By virtue of its holding function, Biofrontera AG controls all the legally independent entities within the Biofrontera Group. Therefore, it is necessary to assess the risks and opportunities on a uniform basis throughout the entire Group.

The primary objective of the Biofrontera Group is to achieve long-term growth and thus to increase the company's value on a consistent basis. Risk management plays a major role in achieving this objective. At Biofrontera, risk management involves the identification of risks that could do lasting or significant harm to the company's financial position, cash flows and results of operations, as well as the responsible analysis and monitoring of these risks, and the adoption of suitable countermeasures. To this end, it is necessary to establish guidelines, organisational structures and measuring and monitoring processes that are specifically geared to the Biofrontera Group's activities.

Correspondingly detailed risk prevention measures are essential in order to fully exploit the opportunities that arise from Biofrontera's business activities. In the 2015 financial year, Biofrontera's existing risk management structures were enhanced within the scope of the quality management system required for pharmaceutical manufacturers and entrepreneurs and medical device manufacturers. This system incorporates sales and marketing activities, as well as the international responsibilities of licence holders with regard to the manufacture and sale of drugs, medical devices and cosmetics.



## **The management of opportunities and risks at Biofrontera**

The Biofrontera Group's risk management system is incorporated into the Group's corporate processes and decisions, so it is an integral part of the entire Group's planning and controlling processes. Risk management and control mechanisms are coordinated with each other. They ensure that risks relevant to the company are identified and assessed at an early stage, while at the same time enabling the company to respond rapidly to potential opportunities.

Risk management at Biofrontera is organised both locally and centrally. Opportunities and risks are regularly identified, evaluated and analysed at all hierarchical levels. All management staff in the Group are involved in the Group-wide risk policy and associated reporting. This includes the Management Board, the managing directors of the Group companies, and the process and project managers.

The Risk Management Team, under the leadership of the Chief Executive Officer, is responsible for the centrally organised risk management system. It coordinates the individual governing bodies, and it ensures that they continually receive the information that they need in a timely manner. The Risk Management Team is also responsible for the continuous monitoring of risk profiles, for initiating risk prevention measures, and for the corresponding monitoring instruments. The Biofrontera Group management holds regular meetings in which the Group's central and operational departments can exchange information relevant to risk management at all levels.

The Group-wide point of contact is the Risk Management Officer, who is also a member of the Risk Management Team. If unexpected risks arise, he/she immediately initiates the necessary steps to counteract them.

He/she is responsible for developing the risk management system, and for ensuring that it is properly documented in the risk manual. Furthermore, the Risk Manager sets uniform standards and ensures that similar types of risk management processes are implemented throughout the Biofrontera Group. Regular analysis of key business performance figures helps to ensure that any possible discrepancies from expected performance levels can be identified and assessed at an early stage, and that necessary countermeasures can be adopted in good time. Overall monitoring is carried out on the sales activities relating to Ameluz®, including the PDT lamp, and Belixos®. Risk planning and identification in this area are carried out in collaboration with the relevant unit managers. The structure and function of the early risk detection system are assessed by the auditor.

## **Risks and opportunities for future business development**

The Biofrontera Group strives to achieve its strategic objectives, in particular the establishment of its own sales operation in some countries, the identification of sales partners, and the approval of development projects. It has already obtained Euro-pean approval for Ameluz®, giving it the opportunity to grow rapidly and become highly profitable.

In addition to general risks, such as market developments and the competitive situation, the company is also exposed to specific risks associated with the pharmaceutical and biotechnology sectors.

It is possible that the product Ameluz® will not be successful in competition with other treatment options for actinic keratosis. Despite the greater effectiveness of Ameluz®, doctors may resort to other products more often than expected because of the higher treatment costs associated with PDT, for which they frequently do not obtain any or sufficient remuneration from the healthcare systems.

There is no guarantee that a product will be launched on the market at the end of a project's development period – which is 6 to 10 years on average. A lack of success in the individual development steps could incur additional costs, cause project delays or even bring project development to a complete halt. It is possible that none, or only some, of the funds invested will be recouped in sales revenue.

The company tries to counterbalance these risks, to some extent, by selecting projects with relatively attractive risk profiles, by setting up a project control and reporting system, and by drawing on the outstanding professional expertise of the Su-pervisory Board members. The project control system represents the entire development process in detail right up to ap-proval, and it makes it possible to analyse the effects that even small changes or delays, e.g. with clinical trials, can have on the development process and on its costs. Thus it is possible to observe the development risk associated with individual projects precisely, and to take the steps necessary to minimise the development risk.

Because of the existing loss situation and uncertainties relating to future business expansion, it is possible that the com-pany's survival will depend substantially on further cash injections from shareholders or other capital investors.

In this context, investors' acceptance of this industry and the associated risks as well as the special balance-sheet charac-teristics and fiscal framework conditions is of great importance. The company cannot influence such circumstances, although they are of crucial importance for the company as long as it is in the development phase and reliant on the allocation of the necessary equity from the financial markets.

### **Patent protection**

Patents guarantee the protection of our intellectual property. If our products are marketed successfully, the resulting profits can be used for sustainable ongoing investment in research and development activities. Because of the long intervening period between the patent application and the launch of a product, Biofrontera generally has only a few years to earn reasona-ble income from its intellectual input. This makes it all the more important for the Group to obtain effective and secure patent

protection. The majority of our products are subject to patent protection. If a patent expires, or we cannot successfully defend it, we generally face the prospect of increased competition and price pressure resulting from the market entry of generic drug suppliers. Moreover, third-party claims regarding Biofrontera's potential infringement of patents or other protective rights may hinder or completely prevent the development or manufacturing of certain products, and may obligate us to pay damages or royalties to third parties. Our patent department regularly reviews the current patent situation, in cooperation with the relevant operational departments, and monitors possible patent infringement attempts, so that it can take suitable legal steps if necessary. We consider it unlikely that patent risks will arise. Biofrontera is not aware of any patent infringement claims lodged by third parties.

### **Products and product stewardship**

Biofrontera assesses potential environmental and health risks associated with a product along the entire value creation chain. This includes every stage from research and development to disposal, including production, marketing and customer use. Although comprehensive trials are carried out prior to approval/registration, it is possible that some or all of our products will subsequently be withdrawn from the market for various reasons, including the occurrence of unexpected side effects. Sales may be stopped voluntarily or as a consequence of legal or official measures. Possible payments of damages associated with the risks described above could have a considerable negative effect on the company's result. Because no previously unknown drug side effects have appeared, we consider it highly improbable that risks of this kind will arise.

### **Procurement**

Purchase prices for raw materials may vary considerably, and they cannot always be passed on to our customers through price adjustments due to regulated drug prices. The safety and tolerance of our products, and the protection of our employees and of the environment, are key priorities. Risks associated with the manufacturing, bottling, storage and transport of products may result in personal injury or material or environmental damage, and may give rise to an obligation to pay damages. In this regard, Biofrontera is dependent to some extent on individual suppliers. Using our own audit and monitoring system, we regularly ensure that the manufacturing conditions at our most important suppliers meet the required standard. This enables us to avoid such risks and damages. We have already found two new suppliers of the agent aminolevulinic acid, whose manufacturing processes have been approved by the EMA. Biofrontera is the owner of the Drug Master Files for one of the two manufacturers. This will ensure the long-term security of supply of aminolevulinic acid. We are currently setting up our own production facilities for the final assembly and final quality control of the BF-RhodoLED® lamp in order to reduce our dependence on suppliers in this area as well.

## **Staff**

Qualified and dedicated staff are a key prerequisite for the company's success. To this end, competitive remuneration and extensive training and development opportunities are essential. Furthermore, we have adopted a diversity-orientated HR policy in order to exploit the full potential of the labour market. To date, Biofrontera has always succeeded in acquiring the qualified staff necessary for the company, so the company also regards this area as having a low risk.

## **Information technology**

The Group's business processes and internal and external communication are increasingly based on global IT systems. A significant technical malfunction or total failure of IT systems could result in the severe impairment of our business processes. It is of fundamental importance to us that both internal and external data must be confidential. If the confidentiality, integrity or authenticity of data or information is lost, this could result in the manipulation and/or uncontrolled outflow of data and know-how. We have adopted appropriate measures to counteract this risk, e.g. a comprehensive authorisation concept. The measures adopted by the company have always proven to be adequate to date, so this risk must also be regarded as low.

## **Law and compliance**

The Group may be subjected to legal disputes or proceedings in the future. In particular, this includes risks arising from product liability, antitrust law, competition law, patent law, tax law or environmental protection. Inquiries and investigations on grounds of possible infringements of statutory or regulatory provisions may result in criminal and civil sanctions, including considerable fines or other financial disadvantages, and these may damage the company's reputation and ultimately have a negative effect on the company's success.

## **Liquidity risk**

Liquidity risks arise from the possibility that the Group will be unable to fulfil existing or future payment obligations on account of insufficient funds. We calculate and manage the liquidity risk in our weekly and medium-term liquidity planning sessions. Payment obligations arising from financial instruments are defined separately in the consolidated financial statement, based on their due dates.

In order to ensure the ability to make payments at all times, liquid funds are kept available so that all the Group's scheduled payment obligations can be fulfilled on their respective due dates. The size of this liquidity reserve is regularly reviewed and, if necessary, adjusted in line with current circumstances.

The company was able to meet its payment obligations at any time, but will depend on additional financing measures also in the future. To date, Biofrontera has always succeeded in providing the necessary financing for business operations through injections of equity. Due to the capital increases in 2015 and a further capital increase in February 2016, the company currently has sufficient liquidity at its disposal. However, further capital measures will be needed until break-even is reached, particularly to obtain approval in the USA, the planned investments into marketing in the US and to meet obligations from the issued option bond however constitute a necessity for further capital measures during the fiscal year 2016.

On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realised, this could constitute a threat to the company's continued existence.

### **Legal disputes**

Biofrontera is not currently involved in any legal disputes.

### ***Forecast report (outlook)***

In order to support the further expansion of sales of Ameluz® in the European Union, Biofrontera is currently working towards the objective of extending European approval to include field therapy for the treatment of actinic keratosis, and the indication basal cell carcinoma (BCC). The required phase III trials for both approval extensions have been completed with very good results, and the results of both trials have been available since January 2016. According to current plans, it is expected that approval extensions will be granted both for field therapy and for BCC during 2016. The approval extension for field therapy has already been submitted to the EMA.

Furthermore, significant milestones have been reached towards approval in the USA. An initial consultation session with the American approval authority, the FDA, took place in 2012, and in October 2014 we had the final discussion before the submission of the approval application, known as the pre-NDA meeting. In early July 2015, the approval application (NDA = New Drug Application) was then submitted to the FDA (Food and Drug Administration). Ameluz® and BF-RhodoLED® have to be approved as a combination of a drug and a medical device in the USA, and therefore the approval application was unusually complex. In accordance with the guidelines, the FDA made a decision on the formal "acceptance to file" after a period of 60 days, and this was granted on 11 September 2015. In the subsequent "74-day letter", the company was informed on 2 October 2015 that there were no significant verification issues. In this letter, the FDA also announced the date of the

detailed report and their proposed labelling as 30 March 2016. Proposed labelling was provided to the company by the FDA at the end of March 2016. An expected approval date of 10 May 2016 was given, provided that no significant problems arise. Biofrontera will then have access to the largest healthcare market in the world.

Biofrontera has decided to operate on the American market using its own sales and marketing organisation. Initial preparations have already been made for this. A wholly owned subsidiary, Biofrontera Inc., was established in the USA for this purpose, and a very experienced CEO was appointed in April 2015 in the form of Ms. Monica Tamborini, who has initially set up the company structures necessary for the pharmaceutical business. In the 2nd and 3rd quarter of 2016, the plan is to appoint more employees and make preparations for the market launch.

### ***Forecast of key financial figures***

For the 2016 financial year, Biofrontera expects to achieve sales revenue of approximately EUR 6 to 7 million. In Germany, as in recent years, we envisage an increase in sales revenue of approximately 30% compared with the previous year. It is still very difficult to predict the increase in sales in other European countries, which means that the achievable revenue could be anywhere within a wide margin. In addition, we are also expecting the first sales in the USA towards the end of the year, although the extent of the sales achievable initially is difficult to plan in advance and is heavily dependent on the exact timing of the launch, which is planned for autumn, the availability of suitable staff and the speed with which the BF-RhodoLED® lamps can be placed.

In order to extend the range of indications, and to obtain approval for the USA, Biofrontera will continue to invest heavily in research and development and regulatory affairs in 2016. The development and approval costs will be approx. EUR 4 to 5 million. In 2016, Biofrontera will invest particularly in setting up its sales and marketing organisation in the USA, and therefore the sales costs will rise significantly compared to 2015, amounting to approx. EUR 10 to 11 million in total.

No significant investments in tangible assets are planned in 2016.

The financial result reflects the interest payments and compounding of interest using the effective interest method for the two warrant bonds. Therefore, this will not significantly change in 2016 compared with 2015.

The reimbursement of the PDUFA fee by the FDA will be shown under "Other Income".

With the above-mentioned conditions and forecasts, the company will achieve a net result of EUR -11 to -12 million in 2016. The achievement of this result depends heavily on progress in terms of sales revenue.

### **Remuneration report**

The total remuneration paid to members of the Management Board in the 2015 financial year and the total accumulated number of stock options issued to the Management Board were as follows as of 31 December 2015:

|   |                 |   |
|---|-----------------|---|
| <b>Prof. Dr. Hermann Lübbert</b> - Salary/bonus |                 | EUR 405 thousand (31 December 2014: EUR 405 thousand)   |
|   | - Stock options | 151,850 (fair value when granted: EUR 167,236) previous year 151,850, (fair value when granted: EUR 167,236), of which 0 were granted in 2015 (2014: 16,850). |
| <b>Thomas Schaffer</b>                          | - Salary/bonus  | EUR 231 thousand (31 December 2014: EUR 202 thousand)   |
|   | - Stock options | 35,000 (fair value when granted EUR 32,650) previous year 35,000, (fair value when granted EUR 32,650), of which 0 were granted in 2015 (2014: 20,000).       |
| <b>Christoph Dünwald</b>                        | - Salary/bonus  | EUR 29 thousand (31 December 2014: EUR 0)   |

The salaries/bonuses are classified as short-term employee benefits as defined in IAS 24.17 (a).

Company cars are also available to the directors for business and private use. The existing employment contracts stipulate that – depending on the achievement of targets to be mutually agreed – an annual bonus is payable. If the targets are exceeded, the maximum annual bonus payable is capped. If the targets are missed by a margin no greater than 30% (i.e. a level of at least 70% is achieved), the bonus payment is reduced linearly. If the targets are missed by a greater margin than this, no bonus is payable. The calculation factors are set at the end of each financial year for the following financial year in a mutually agreed target agreement.

Severance pay in the case of premature termination of Management Board duties without good reason is capped at twice the specified annual salary, and amounts to no more than the total remuneration due for the remaining period of the contract (severance cap).

In order to further increase the long-term incentive effect of variable remuneration, and thus to gear it even more effectively to long-term business development, the Management Board members have

pledged to match the stock options granted as part of the 2010 stock option programme by holding ordinary shares of the company as private investors, thereby under-taking a personal commitment for a period of three years, starting one month after the date of issue of the options (restricted shares). The level of personal commitment is specified differently in detail for each member of the Management Board. If such restricted ordinary shares are sold prematurely, this must be reported to the Chairperson of the Supervisory Board without delay, and the company can request a return transfer of an equivalent number of stock options free of charge within a month of receiving such notification, with the most recently granted options being those that must be returned first (last in, first out). A return transfer is not required if the Management Board member can demonstrate that the sale of the restricted shares was necessary in order to meet urgent financial obligations. In 2010, the Chief Executive Officer was granted 35,000 options, and the other Management Board member was granted 20,000 options, and in 2011, the Chief Executive Officer was granted 30,000 options and the other Management Board member was granted 20,000 options on this basis. In 2012, a further 40,000 options were granted to the Chief Executive Officer, and an additional 25,000 options were granted to the other Management Board member. In the 2013 financial year, the Chief Executive Officer was granted 30,000 options, and the other Management Board member was granted 15,000 options, and in the 2014 financial year, 16,850 options were granted to the Chief Executive Officer, and 20,000 options were granted to the other Management Board member. No further options were granted to the Management Board members in 2015.

All the Supervisory Board members held their positions throughout the entire 2015 financial year. In the financial year, the remuneration of the Supervisory Board members amounted to EUR 113 thousand (2014: EUR 113 thousand).

***Other information pursuant to §§ 289 paragraph 4 and 315 paragraph 4 of the German Commercial Code (HGB)***

Management Board members are appointed and removed pursuant to §§ 84 and 85 of the German Stock Corporation Act (AktG). The composition of the Management Board is specified in more detail in § 9 paragraph 3 of the Articles of Association. Pursuant to this, the Management Board must consist of one or more members. Since the addition of Mr. Dünwald to the Management Board in mid-November 2015, it has consisted of three people. The Supervisory Board appoints Management Board members and determines their number. The Supervisory Board may appoint a Chief Executive Officer.

The employment contract of the Chief Executive Officer and that of the Chief Financial Officer include a compensation agreement in the form of a special right of termination, for example in the case of a takeover bid as defined in the Securities Acquisition and Takeover Act (WpÜG).



Pursuant to §119 paragraph 1 number 5, §179 and §133 of the German Stock Corporation Act (AktG), amendments to the Articles of Association must be made by a resolution of the General Meeting. Where legally permissible, a simple majority of the share capital represented at the vote is sufficient for such a resolution, in accordance with § 179 paragraph 2 sentence 2 AktG in conjunction with § 22 paragraph 2 of the Articles of Association, instead of the majority of three-quarters of the represented share capital stipulated in § 179 paragraph 2 sentence 1 AktG. Pursuant to § 179 paragraph 1 sentence 2 AktG in conjunction with § 22 paragraph 2 of the Articles of Association, the Supervisory Board is authorised to make changes that affect only the wording of the Articles of Association.

With regard to the repurchasing of shares, the Management Board is not subject to any restrictions beyond those specified in the German Stock Corporation Act.

### ***Accounting risk management system and internal control system***

Below, in addition to the risk management system already explained under subsection 4.1, the significant aspects of the internal control and risk management system relating to accounting processes for separate and consolidated financial statements, pursuant to § 289 paragraph 5 of the German Commercial Code (HGB), as amended by the German Accounting Law Modernisation Act (BilMoG), are described.

The Biofrontera AG accounting process aims to ensure that the figures and information provided in external accounting instruments (bookkeeping, components of the annual and consolidated financial statements, and the combined company and Group management report) are accurate and complete, and to ensure compliance with the relevant legal requirements and provisions of the Articles of Association. The existing structures and processes for this also include the risk management system and the internal control measures relating to the accounting processes. In line with the increasing sales activities, the internal accounting control system was extended to include processes that had been newly established from the 2012 financial year onwards, and it is subject to a permanent monitoring and improvement process.

The risk management system aims to identify, assess and manage all the risks that could prevent the regular preparation of the annual and consolidated financial statements. Any risks identified must be assessed with regard to their influence on the annual and consolidated financial statements. The purpose of the internal accounting control system is to ensure that the process of compiling financial statements complies with all the relevant laws and regulations, by implementing appropriate guidelines, processes and controls to this end.

The risk management system and the internal control system cover all the areas that are essential for the annual and consolidated financial statements and all the processes relevant to the preparation of the financial statements.

Significant aspects of accounting risk management and control include the clear assignment of responsibilities and controls for the compilation of financial statements, as well as transparent accounting standards. The two-person rule and the separation of roles are also important control principles in accounting processes.

The Management Board assumes overall responsibility with regard to the organisation of the internal control system. The coordinated subsystems of the internal control system are the responsibility of the quality management/controlling/risk management and accounting departments.

## ***Takeover information***

### **Trading venue**

Biofrontera shares are traded under stock abbreviation B8F and ISIN DE0006046113 in the Prime Standard segment of the Frankfurt Stock Exchange and on all other German stock exchanges. In addition, the shares were admitted for trading with the same stock ID number in the form of depositary interests (DI) on the Alternative Investment Market (AIM) of the London Stock Exchange up to 18 February 2016.

### **Shareholders**

The numbers of shares held by the shareholders on 31 December 2015, based on the most recent compulsory disclosures of the shareholders, are as follows:

|   | 31 December 2015  |             |
|---|-------------------|-------------|
|   | EUR               | %           |
| <b>Maruho Deutschland Co., Ltd., Osaka Japan</b><br>The total share of voting rights is assigned to Maruho Co., Ltd. via the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.  | 4,467,143         | 17.52       |
| <b>Prof. Dr. Ulrich Abshagen, Germany</b><br>Professor Abshagen has a direct holding of 62,850 voting rights, and he is indirectly assigned 976,056 voting rights by Heidelberg Innovation BioScience Venture II GmbH & Co.KG (in liquidation) via Heidelberg Innovation Asset Management GmbH & Co. KG, of which he is a managing partner. | 1,038,906         | 4.08        |
| <b>Wilhelm Konrad Thomas Zours</b><br>Of this, the 3.48% share of voting rights is assigned via the company Deutsche Balaton Aktiengesellschaft.  | 1,053,154         | 4.13        |
| <b>Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany</b><br>The share of voting rights is assigned to Universal-Investment GmbH via the company FEHO Vermögensverwaltungsgesellschaft.  | 799,463           | 3.14        |
| <b>Prof. Dr. Hermann Lübbert, Leverkusen, Germany</b>   | 720,512           | 2.83        |
| <b>Free float</b>   | 17,411,252        | 68.30       |
|   | <b>25,490,430</b> | <b>100%</b> |

## Share capital

On 31 December 2015, the fully paid-up share capital of the parent company, Biofrontera AG, amounted to EUR 25,490,430.00. It was divided into 25,490,430 registered shares, each with a nominal value of EUR 1.00.

Two capital increases were carried out against cash contributions in the reporting period. In the first capital increase, new shares were offered to all shareholders for subscription or additional subscription. The new shares that were not acquired as part of the subscription right or the additional subscription were offered to selected investors for acquisition in a private placement. EUR 1,377,272.00, divided into 1,377,272 registered shares, was placed and the execution was entered in the commercial register on 1 June 2015. The issue proceeds amounted to EUR 3.1 million.

In a further capital increase, the company's share capital was increased by EUR 1,916,588.00, divided into 1,916,588 registered shares, and entered in the commercial register on 3 December 2015. This capital increase was also initially offered to all shareholders for subscription or additional subscription. Shares that were not acquired as part of the subscription or additional subscription were offered to institutional investors for subscription. The issue proceeds amounted to EUR 3.5 million.

## Existing capital

The company's share capital was conditionally increased by up to EUR 6,434,646.00 by the issuing of up to 6,434,646 new registered ordinary shares with no par value (no-par-value shares) (Conditional Capital I). The purpose of the conditional capital increase is (i) to ensure the granting of option rights and the agreement of option obligations in accordance with the bond conditions and (ii) to ensure the fulfilment of conversion rights and the fulfilment of conversion obligations in accordance with the bond conditions, which are issued, agreed and guaranteed by the company or its direct or indirect majority-owned subsidiaries (affiliated companies) in the period up to 27 August 2020, based on the authorisation of the Annual General Meeting of 28 August 2015. The conditional capital increase is to be implemented only in the event that financial instruments are issued based on the authorisation of the Annual General Meeting of 28 August 2015, and only insofar as the holders or creditors of financial instruments issued by the company exercise their option or conversion rights or fulfil their option or conversion obligations. The new shares carry dividend rights from the start of the financial year in which they are issued. The Management Board is authorised to determine the other details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board. The Supervisory Board is authorised to amend § 7 of the Articles of Association in accordance with the use of conditional capital and after the expiry of all option and conversion periods.

The share capital was conditionally increased by up to EUR 500,000.00 by the issuing of up to 500,000 new registered ordinary shares, each of which constitutes a share of EUR 1.00 of the share

capital (no-par-value shares) (Conditional Capital II). The purpose of the conditional capital increase is to redeem option rights, pursuant to the option conditions, to the benefit of the holders of warrants from warrant bonds issued on the basis of the authorisation resolution of the Annual General Meeting of 17 March 2009. The new shares are issued at the option price set pursuant to the aforementioned authorisation resolutions (issue amount pursuant to § 193 paragraph 2 No. 3 AktG). The conditional capital increase is to be implemented only in the event that warrant bonds are issued, and only insofar as that the holders of the warrants exercise their option rights, and the company does not use other sources for the required shares or replace them with a cash payment. The new shares issued by the exercise of the option right carry dividend rights from the start of the financial year in which they are issued. The Management Board is authorised to determine the other details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board. The company's share capital was conditionally increased by EUR 542,400 by the issuing of up to 542,400 no-par-value registered shares (no-par-value shares) (Conditional Capital III). The purpose of the conditional capital increase is solely to fulfil the options granted up to 1 July 2015 on the basis of the authorisation of the Annual General Meeting of 2 July 2010. The conditional capital increase is implemented only insofar as holders of the issued options exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay cash settlement in order to fulfil the options. The new shares carry dividend rights from the start of the financial year in which they are issued by the exercise of options.

The company's share capital was conditionally increased by up to EUR 2,494,890.00 by the issuing of up to 2,494,890 new ordinary registered no-par-value shares (no-par-value shares) (Conditional Capital IV). The purpose of the conditional capital increase is to ensure the granting of option rights and the agreement of option obligations in accordance with the warrant bond conditions on holders or creditors of warrants from warrant bonds, or to ensure the fulfilment of conversion rights and the fulfilment of conversion obligations in accordance with the convertible bond conditions on holders or creditors of convertible bonds issued by the company in the period up to 9 May 2016 on the basis of the authorisation of the Annual General Meeting of 10 May 2011. The conditional capital increase is to be implemented only in the event that warrant or convertible bonds are issued, and only insofar as the holders or creditors of warrants or convertible bonds issued by the company on the basis of the authorisation of the Annual General Meeting of 10 May 2011 exercise their option or conversion rights or fulfil their option or conversion obligations (also in the event that a corresponding company voting right is exercised). The new shares carry dividend rights from the start of the financial year in which they are issued. The Management Board is authorised to determine the other details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board.

The company's share capital was conditionally increased by EUR 1,814,984.00 by the issuing of up to 1,814,984 no-par-value registered shares (no-par-value shares) (Conditional Capital IV). The purpose of the conditional capital increase is solely to fulfil the option rights granted up to 27 August 2020 on

the basis of the authorisation of the Annual General Meeting of 28 August 2015. The conditional capital increase is implemented only insofar as holders of the issued options exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay a cash settlement in order to fulfil the options. The new shares carry dividend rights from the start of the financial year in which they are issued by the exercise of options. The Supervisory Board is authorised to amend § 7 of the Articles of Association in accordance with the use of conditional capital and after the expiry of all option and conversion periods.

The Management Board is authorised, subject to the approval of the Supervisory Board, to increase the company's share capital by up to EUR 9,870,333.00 up to 27 August 2020 by issuing up to 9,870,333 no-par-value registered shares in exchange for cash contributions and/or assets in kind in one or more share issues (Authorised Capital I). The Management Board is authorised, subject to the approval of the Supervisory Board, to define the further content of the share rights and the conditions of the share issue. The new shares are to be offered to the shareholders for subscription. Subscription rights can also be granted to shareholders indirectly pursuant to § 186 paragraph 5 AktG.

The capital measure carried out in February 2016 has resulted in changes with regard to Authorised Capital I and the authorisation of the Management Board. Further information on this can be found in the supplementary report.

Declaration on Corporate Governance pursuant to § 289a of the German Commercial Code (HGB), including the statement required by § 161 of the German Stock Corporation Act (AktG) on the German Corporate Governance Code

Pursuant to § 289a HGB, listed stock corporations are required to issue a Declaration on Corporate Governance. This must either be included in the management report, or it must be published on the company's website. The current Declaration on Corporate Governance by Biofrontera AG and the Corporate Governance Report are available on the company's website at [www.biofrontera.com](http://www.biofrontera.com) in the section "Investors", subsection "Corporate Governance".

Leverkusen, 07 April 2016

Biofrontera AG

|                           |                          |                         |
|---------------------------|--------------------------|-------------------------|
| Prof. Dr. Hermann Lübbert | Christoph Dünwald        | Thomas Schaffer         |
| Chief Executive Officer   | Chief Commercial Officer | Chief Financial Officer |

***Responsibility Statement***

Affirmation of the legal representatives pursuant to § 37y of the German Securities Trading Act (WpHG) in conjunction with § 37w para. 2 no.3 WpHG

We affirm that, to the best of our knowledge and in accordance with the applicable accounting principles, the consolidated financial statement gives a true and fair view of the financial position, cash flows and results from operations of the Group, and that the combined company and Group management report presents the business performance, including the business results and the position of the Biofrontera Group and of Biofrontera AG, in such a way that a true and fair view is conveyed, and that the main opportunities and risks relating to the anticipated performance of the Biofrontera Group and Biofrontera AG are described.

Leverkusen, 07 April 2016

Biofrontera AG

|                           |                 |                   |
|---------------------------|-----------------|-------------------|
| Prof. Dr. Hermann Lübbert | Thomas Schaffer | Christoph Dünwald |
|---------------------------|-----------------|-------------------|

## F.2.2) Consolidated balance sheet as of 31 December 2015

Annex 1

Assets

| in EUR                             | Note | 31 December 2015    | 31 December 2014     |
|------------------------------------|------|---------------------|----------------------|
| <b>Non-current assets</b>          |      |                     |                      |
| Tangible assets                    | (1)  | 372,834.23          | 339,532.00           |
| Intangible assets                  | (1)  | 1,901,927.93        | 2,580,077.17         |
|                                    |      | <b>2,274,762.16</b> | <b>2,919,609.17</b>  |
| <b>Current assets</b>              |      |                     |                      |
| <b>Current financial assets</b>    |      |                     |                      |
| Trade receivables                  | (3)  | 894,558.96          | 308,984.35           |
| Other financial assets             | (4)  | 730,440.34          | 726,790.94           |
| Cash and cash equivalents          | (7)  | 3,959,207.16        | 8,509,398.16         |
|                                    |      | <b>5,584,206.46</b> | <b>9,545,173.45</b>  |
| <b>Other current assets</b>        |      |                     |                      |
| Inventories                        | (2)  |                     |                      |
| Raw materials and supplies         |      | 590,420.47          | 684,455.83           |
| Unfinished products                |      | 42,723.50           | 107,784.39           |
| <b>Finished products and goods</b> |      | <b>900,505.05</b>   | <b>601,281.83</b>    |
| Income tax reimbursement claims    | (5)  | 32,220.80           | 62,072.99            |
| Other assets                       | (4)  | 72,879.33           | 90,118.27            |
|                                    |      | <b>1,638,749.15</b> | <b>1,545,713.31</b>  |
|                                    |      | <b>7,222,955.61</b> | <b>11,090,886.76</b> |
| <b>Total assets</b>                |      | <b>9,497,717.77</b> | <b>14,010,495.93</b> |

## Liabilities

| in EUR   | Note | 31 December 2015      | 31 December 2014     |
|--|------|-----------------------|----------------------|
| <b>Equity</b>  |      |                       |                      |
|  | (9)  |                       |                      |
| Subscribed capital   |      | 25,490,430.00         | 22,196,570.00        |
| Capital reserve from foreign currency conversion adjustments |      | (1,188.65)            | 0.00                 |
| Capital reserve  |      | 79,525,292.28         | 76,402,715.36        |
| Loss carried forward   |      | (98,620,285.49)       | (87,899,306.51)      |
| Net loss for the year  |      | (11,203,410.20)       | (10,720,978.98)      |
|  |      | <b>(4,809,162.06)</b> | <b>(21,000.13)</b>   |
| <b>Long-term liabilities</b>                                 |      |                       |                      |
| Long-term financial liabilities                              | (10) | 11,229,946.00         | 10,774,298.38        |
| <b>Current liabilities</b>                                   |      |                       |                      |
| <b>Current financial liabilities</b>                         |      |                       |                      |
| Trade payables   | (11) | 1,043,425.65          | 967,437.66           |
| Short-term financial debt                                    | (9)  | 830,174.00            | 1,224,598.00         |
| Other financial liabilities                                  | (13) | 37,622.28             | 27,012.10            |
|  |      | <b>1,911,221.93</b>   | <b>2,219,047.76</b>  |
| <b>Other current liabilities</b>                             |      |                       |                      |
| Other provisions   | (12) | 1,041,860.80          | 951,944.41           |
| Other current liabilities                                    | (13) | 123,851.10            | 86,205.51            |
|  |      | <b>1,165,711.90</b>   | <b>1,038,149.92</b>  |
|  |      | <b>3,076,933.83</b>   | <b>3,257,197.68</b>  |
| <b>Total liabilities</b>                                     |      | <b>9,497,717.77</b>   | <b>14,010,495.93</b> |



### F.2.3) Consolidated statement of comprehensive income

Annex 2

| in EUR  | Note        | 01.01.-<br>31.12.2015 | 01.01.-<br>31.12.2014 |
|---|-------------|-----------------------|-----------------------|
| Sales revenue   | (15)        | 4,137,917.39          | 3,095,555.98          |
| Cost of sales   | (16)        | -1,235,504.25         | -1,116,686.16         |
| Gross profit from sales                                     |             | 2,902,413.14          | 1,978,869.82          |
| <b>Operating expenses:</b>                                  |             |                       |                       |
| Research and development costs                              | (17)        | -6,203,986.93         | -4,534,181.97         |
| General administrative costs                                | (19)        | -2,759,334.78         | -3,244,158.24         |
| of which financing costs                                    |             | -264,924.08           | -869,733.43           |
| Sales costs   | (18)        | -4,170,044.72         | -3,847,487.94         |
| <b>Loss from operations</b>                                 |             | <b>-10,230,953.29</b> | <b>-9,646,958.33</b>  |
| <b>Financial result</b>                                     |             |                       |                       |
| Interest expenses and the like                              | (20)        | -1,168,551.42         | -1,169,613.16         |
| Interest income and the like                                | (20)        | 9,225.68              | 190,294.10            |
| <b>Other income and expenses</b>                            |             |                       |                       |
| Other expenses  | (21)        | -32,046.20            | -280,282.13           |
| Other income  | (21)        | 218,915.03            | 185,580.54            |
| <b>Profit/loss before income tax</b>                        | <b>(23)</b> | <b>-11,203,410.20</b> | <b>-10,720,978.98</b> |
| Income tax  |             | 0.00                  | 0.00                  |
| <b>Profit or loss for the period</b>                        | <b>(23)</b> | <b>-11,203,410.20</b> | <b>-10,720,978.98</b> |
| <b>Expenses and income not included in profit/loss</b>      |             |                       |                       |
| Subsequent valuation of financial assets available for sale |             | 0.00                  | 0.00                  |
| Other expenses and income not included in profit/loss       |             | 0.00                  | 0.00                  |
| <b>Total profit/loss for the period</b>                     | <b>(23)</b> | <b>-11,203,410.20</b> | <b>-10,720,978.98</b> |
| Undiluted (= diluted) earnings per share                    | (22)        | -0.48                 | -0.49                 |

## F.2.4) Statement of changes in equity for 2015

### Annex 3

See Note 9

|  | Ordinary shares   | Subscribed capital   | Capital reserve      | Capital reserve from<br>foreign currency<br>conversion<br>adjustments | Accumulated loss        | Total                 |
|--|-------------------|----------------------|----------------------|---|-------------------------|-----------------------|
|  | Number            | EUR                  | EUR                  | EUR   | EUR                     | EUR                   |
| <b>Balance as of 01 January 2014</b>   | <b>17,753,168</b> | <b>17,753,168.00</b> | <b>65,598,778.57</b> | <b>0.00</b>   | <b>(87,899,306.51)</b>  | <b>(4,547,359.94)</b> |
| Capital increase   | 4,443,402         | 4,443,402.00         | 11,105,950.00        | 0.00  | 0.00                    | 15,549,352.00         |
| Cost of equity procurement   | 0                 | 0.00                 | (215,725.71)         | 0.00  | 0.00                    | (215,725.71)          |
| Changes in the capital reserve associated with the repurchase of own Warrant Bonds I                                     | 0                 | 0.00                 | (198,939.00)         | 0.00  | 0.00                    | (198,939.00)          |
| Changes in the capital reserve resulting from transaction costs in connection with the repurchase of own Warrant Bonds I | 0                 | 0.00                 | (99.00)              | 0.00  | 0.00                    | (99.00)               |
| Increase in capital reserves from the stock option programme   | 0                 | 0.00                 | 112,750.50           | 0.00  | 0.00                    | 112,750.50            |
| Net loss for the year  | 0                 | 0.00                 | 0.00                 | 0.00  | (10,720,978.98)         | (10,720,978.98)       |
| <b>Balance as of 31 December 2014</b>  | <b>22,196,570</b> | <b>22,196,570.00</b> | <b>76,402,715.36</b> | <b>0.00</b>   | <b>(98,620,285.49)</b>  | <b>(21,000.13)</b>    |
| Capital increase   | 3,293,860         | 3,293,860.00         | 3,515,382.80         | 0.00  | 0.00                    | 6,809,242.80          |
| Cost of equity procurement   | 0                 | 0.00                 | (495,769.88)         | 0.00  | 0.00                    | (495,769.88)          |
| Foreign currency conversion adjustments  | 0                 | 0.00                 | 0.00                 | (1,188.65)  | 0.00                    | (1,188.65)            |
| Increase in capital reserves from the stock option programme   | 0                 | 0.00                 | 102,964.00           | 0.00  | 0.00                    | 102,964.00            |
| Net loss for the year  | 0                 | 0.00                 | 0.00                 | 0.00  | (11,203,410.20)         | (11,203,410.20)       |
| <b>Balance as of 31 December 2015</b>  | <b>25,490,430</b> | <b>25,490,430.00</b> | <b>79,525,292.28</b> | <b>(1,188.65)</b>   | <b>(109,823,695.69)</b> | <b>(4,809,162.06)</b> |

## F.2.5) Consolidated cash flow statement for the 2015 and 2014 financial year

Annex 4

| In EUR (see Note 26)   | 01.01.-31.12.15      | 01.01.-31.12.14      |
|--|----------------------|----------------------|
| <b>Cash flows from operations:</b>   |                      |                      |
| <b>Total profit/loss for the period</b>  | -11,203,410.20       | -10,720,978.98       |
| <b>Adjustments to reconcile profit/loss for the period to cash flow into operations:</b> |                      |                      |
| Financial result   | 1,159,325.74         | 1,099,319.06         |
| Depreciation   | 811,681.84           | 811,005.00           |
| (Gains)/losses from disposal of assets   | 115.00               | 2,632.00             |
| Non-cash expenses and income   | -22,203.75           | 302,084.17           |
| <b>Changes in operating assets and liabilities:</b>                                      |                      |                      |
| Trade receivables  | -585,574.61          | 269,426.25           |
| Other assets and income tax assets   | -11,314.11           | -269,667.37          |
| Inventories  | -140,126.97          | 191,674.09           |
| Trade payables   | 75,987.99            | 254,339.49           |
| Provisions   | 149,945.42           | 132,619.86           |
| Other liabilities  | 48,255.77            | -385.69              |
| <b>Net cash flow into operations:</b>  | <b>-9,717,317.88</b> | <b>-7,927,932.12</b> |
| <b>Cash flows from investment activities:</b>  |                      |                      |
| Purchase of intangible and tangible assets   | -180,303.54          | -164,082.80          |
| Interest received  | 183,978.17           | 142,588.26           |
| Revenue from the sale of intangible and tangible assets                                  | 13,353.71            | 100,368.88           |
| <b>Net cash flow from (into) investment activities</b>                                   | <b>17,028.34</b>     | <b>78,874.34</b>     |
| <b>Cash flows from financing activities:</b>   |                      |                      |
| Proceeds from the issue of shares  | 6,313,472.92         | 15,333,626.29        |
| Payouts from the repurchase of own warrant bonds   | 0.00                 | -1,500,750.00        |
| Interest paid  | -1,224,598.00        | -454,489.62          |
| Increase/(decrease) in long-term financial debt  | 455,647.62           | -742,357.20          |
| Increase/(decrease) in short-term financial debt   | -394,424.00          | 788,848.00           |
| <b>Net cash flow from financing activities</b>   | <b>5,150,098.54</b>  | <b>13,424,877.47</b> |
| <b>Net increase (decrease) in cash and cash equivalents</b>                              | <b>-4,550,191.00</b> | <b>5,575,819.69</b>  |
| Cash and cash equivalents at beginning of period   | 8,509,398.16         | 2,933,578.47         |
| <b>Cash and cash equivalents at end of period</b>  | <b>3,959,207.16</b>  | <b>8,509,398.16</b>  |
| <b>Composition of financial resources at end of period:</b>                              |                      |                      |
| <b>Cash and bank balances and cheques</b>  | <b>3,959,207.16</b>  | <b>8,509,398.16</b>  |

## **F.2.6) Notes to the Consolidated Financial Statement as of 31 December 2015**

### ***Information about the company***

Biofrontera AG ([www.biofrontera.com](http://www.biofrontera.com)), with its head office at Hemmelrather Weg 201, 51377 Leverkusen, Germany, registered in the Commercial Register of Cologne District Court, Department B under no. 49717, and its wholly-owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc., which is based in Wilmington, Delaware, USA, research, develop and market dermatological products. The main focus is on the discovery, development and distribution of dermatological drugs and dermatologically-tested cosmetics for the treatment and care of diseased skin. Biofrontera AG (hereinafter also the "company") pursues this goal along with its subsidiaries. All the companies together form the "Biofrontera Group".

The Biofrontera Group was the first small German pharmaceutical company to receive centralised European drug approval for an independently developed drug, Ameluz®. Ameluz® was approved for the treatment of mild and moderate actinic keratoses in December 2011. Two further clinical development projects, one a dermatological project and one for the prevention of migraines, have been hived off into dedicated subsidiaries and are not being actively pursued at the present time. In addition, a range of cosmetic products is to be expanded; the first product in this range, Belixos®, was launched in the autumn of 2009. A hair tonic, Belixos® LIQUID, was introduced in the spring of 2014 and a Belixos® gel skin care for rosacea and acne was launched at the beginning of December 2014. Belixos® Protect, a day cream with protective anti-aging properties designed especially for photodamaged skin, followed in July 2015.

The product Ameluz® (development name BF-200 ALA), which was approved at the end of 2011, has been tested for the Europe-an approval in one phase II and two phase III clinical trials for the treatment of actinic keratosis. In preparation for approval in the USA, two further phase I trials and a phase III trial have been conducted. Ameluz® is a combination of the drug aminolevulinic acid (ALA) and a nanoemulsion (BF-200), with the latter providing chemical stabilisation of the ALA and enhancing its skin penetration. The clinical results regarding the treatment of actinic keratosis have shown its clear superiority to the competitor product against which it was compared in the phase III trials. An application for centralised European approval was submitted on 1 September 2010, and this approval was granted by the European Commission on 16 December 2011. Ameluz® has been sold in Germany since February 2012 and in several other European countries since autumn 2012. For the approval in the USA, an application for approval of the drug was submitted to the FDA in early July 2015 and this was accepted for intensive examination ("acceptance to file") by the FDA in September 2015. Since then, the approval application has been examined by the FDA and inspections have been carried out at study centres and manufacturers as part of a structured process. Subject to the successful completion of the examination, the FDA has announced that the approval date in the USA will be 10

May 2016. In addition, Biofrontera has carried out another phase III trial for the treatment of basal cell carcinoma. This trial is to form the basis for the application for an extension of the existing European approval to include this indication.

In November 2012, Biofrontera's BF-RhodoLED® PDT lamp received pan-European approval for use as a medical device and has since been sold together with Ameluz®. In Europe, doctors can choose to use any of the lamps approved for PDT, whereas in the USA the approval of Ameluz® will be linked to that of the lamp. This will therefore be approved as a combination product, along with the drug.

The BF-derm1 project, which is currently not being actively pursued, was tested in a three-part phase II trial for the treatment of chronic, antihistamine-resistant urticaria. The trial demonstrated the good effect of the drug, which reduced the intensity of urticaria rashes and itching, as well as reducing the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is an innovative substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007. They show that the substance is almost completely absorbed in the gut, and that it takes around two days for 50% of the substance to be broken down or excreted. These results are an excellent starting point for developing the substance for administration in tablet form.

The intention is to finance the development of both BF-derm1 and BF-1 independently of Biofrontera's normal budget, using funds that are specifically sought for and directly allocated to the development of these products. For this reason, the two projects were acquired by Biofrontera AG and introduced as shareholder contributions to the two subsidiaries Biofrontera Development GmbH and Biofrontera Neuroscience GmbH, which were formed in December 2012. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is now the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products can be uncoupled from the normal group financing. As a result, the company's short-term financial plans can focus on the market launch of Ameluz® in North America and the extension of its range of indications, as well as the establishment of the group as a specialist pharmaceutical company.

### ***Summary of significant accounting and valuation methods***

#### **Basis for preparation of the consolidated financial statement**

The consolidated financial statement for Biofrontera AG for the financial year from 1 January 2015 to 31 December 2015 has been prepared in accordance with the International Financial Reporting

Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC), which are endorsed by the European Union (EU) and applicable on the balance sheet date. In addition, the law pursuant to § 315a paragraph 1 of the German Commercial Code (HGB) has been observed.

The assets and liabilities are defined and valued in accordance with the IFRS that were mandatory on 31 December 2015.

**Standards, amendments to standards and interpretations used for the first time in the consolidated financial statement for 31 December 2015.**

| Standard / Interpretation                   | First mandatory use according to IASB | First mandatory use in the EU |
|---|---------------------------------------|-------------------------------|
| IFRIC 21 "Levies"                           | 1 January 2014                        | 17 June 2014                  |
| Annual improvement project: cycle 2011-2013 | 1 July 2014                           | 1 January 2015                |

Unless described below, the standards and interpretations listed above that have to be applied for the first time have no effect on the Biofrontera Group.

In May 2013 the IASB published IFRIC 21, an interpretation of IAS 37 regarding provisions, contingent liabilities and contingent receivables. This interpretation guides the accounting of public charges, which do not constitute income taxes according to IAS 12, and clarifies in particular, at which point in time such charges have to be accounted for as liabilities. The interpretation has to be applied on financial years beginning on or after 17 June 2014. The new interpretation did not result in any changes of the accounting in the reporting year for the Group. Following the approval in the USA however public fees for the commencement of the trade business will become due on a yearly basis.

The IASB has published the standards and interpretations listed below, which have already been adopted in EU law through the endorsement process but which were not yet mandatory in the 2015 financial year. The group will not apply these standards and interpretations prematurely. We do not expect any of the optional standards and interpretations listed to have any effect on the Biofrontera Group, as the relevant circumstances do not apply.

| Standard / Interpretation   | First mandatory use according to IASB | First mandatory use in the EU |
|---|---------------------------------------|-------------------------------|
| Amendments to IAS 19 "Employee Benefits": Defined Benefit Plans: Employee contributions | 1 July 2014                           | 1 February 2015               |
| Annual improvement project: cycle 2010-2012   | 1 July 2014                           | 1 February 2015               |
| Amendments to IAS 1 "Presentation of Financial Statements": Disclosure initiative       | 1 January 2016                        | 1 January 2016                |

|  |                |                |
|--|----------------|----------------|
| Amendments to IAS 16 "Property, plant and equipment" and IAS 38 "Intangible Assets":<br>Clarification of acceptable methods of depreciation and amortisation | 1 January 2016 | 1 January 2016 |
| Amendments to IAS 16 "Property, plant and equipment" and IAS 41 "Agriculture": Bearer plants   | 1 January 2016 | 1 January 2016 |
| Amendments to IAS 27 "Separate Financial Statements":<br>Equity method in separate financial statements  | 1 January 2016 | 1 January 2016 |
| Amendments to IFRS 11 "Joint Arrangements":<br>Accounting for acquisitions of interests in joint operations  | 1 January 2016 | 1 January 2016 |
| Annual improvement project<br>cycle 2012-2014  | 1 January 2016 | 1 January 2016 |

The IASB has published the standards and interpretations listed below, which were not yet mandatory in the 2015 financial year. These standards and interpretations have not previously been endorsed by the EU and are not applied by the group. The group currently assumes that no effects will arise from the not yet applicable standards and interpretations.

| Standard / Interpretation   | First mandatory use according to IASB | First mandatory use in the EU |
|---|---------------------------------------|-------------------------------|
| Amendments to IAS 7 "Statement of cash flows": Disclosure initiative  | 1 January 2017                        | Not yet known                 |
| Amendments to IAS 12 "Income Taxes": Recognition of deferred tax assets for unrealised losses   | 1 January 2017                        | Not yet known                 |
| Amendments to IAS 28 "Investments in Associates and Joint Ventures" and IFRS 10 "Consolidated Financial Statements":<br>Sale or contribution of assets between an investor and its associate or joint venture                         | suspended indefinitely                | Not yet known                 |
| IFRS 9 "Financial Instruments"  | 1 January 2018                        | Not yet known                 |
| Amendments to IFRS 10 "Consolidated Financial Statements", IFRS 12 "Disclosure of Interests in Other Entities" and IAS 28 "Investments in Associates and Joint Ventures": Investment Entities: Application of Consolidation Exception | 1 January 2016                        | Not yet known                 |
| IFRS 14 "Regulatory Deferral Accounts"  | 1 January 2016                        | No recognition by EU          |
| IFRS 15 "Revenue from Contracts with Customers"   | 1 January 2018                        | Not yet known                 |
| IFRS 16 "Leases"  | 1 January 2019                        | Not yet known                 |

It is expected that unless details of their effects are given below, the listed standards and interpretations that are not yet applied will have no effect on the Biofrontera Group, in the absence of relevant facts and circumstances.

As part of its disclosure initiative, the IASB has published amendments to IAS 7 - Statements of cash flows. The core changes are requirements for additional disclosures via notes, which should enable the readers of financial statements to assess the changes in liabilities arising from financing activities of the company. The amendments are to be applied for the first time in the first reporting period of a financial year beginning on 1 January 2017 or thereafter. Earlier application is also permitted. When first applied, there is no comparative information from the same period in the previous year to report. Adoption of the amendments by the EU is still pending. Apart from the requirement for additional notes, the group expects no impact on its consolidated financial statement.

In May 2014, the IASB issued the new standard IFRS 15. The aim of this new standard about revenue recognition is to bring together the variety of rules previously contained in various standards and interpretations. At the same time, uniform principles are defined that are applicable for all sectors and for all types of revenue transactions. The questions regarding what amount, at what time and for which time period revenue is to be realised are answered with the help of the 5-stage model. In addition, the standard includes a number of other regulations covering detailed issues and an expansion of the disclosures required. The new standard is to be applied to annual periods beginning on or after 1 January 2017. The first application must in principle be carried out retrospectively, but various simplification options are available; earlier application is permitted. Adoption of the amendments by the EU is still pending. The group pursues instalment purchases over several years which include a financing element. Effects by the initial application are expected insofar the standard will be endorsed by the EU in this form. No effect is expected from the first application insofar this standard will be adopted by the EU.

In January 2016, the IASB issued the new standard IFRS 16 - Leases. IFRS 16 establishes principles for the recognition, measurement, presentation and disclosure of leases, and notes regarding leases, with the aim of ensuring that lessees and lessors provide relevant information regarding the impact of leases. At the same time, the previous accounting model applied in accordance with IAS 17, involving the classification into operating and finance leases, is abandoned in favour of a uniform accounting model for leasing agreements with a mandatory control concept. For the lessee, the standard provides a single accounting model. This model leads in the case of the lessee to all the assets and liabilities from leases being recognised in the balance sheet, provided that their term does not exceed 12 months or if they are minor assets (option). The lessor continues to differentiate, for accounting purposes, between finance and operating leases. The mandatory first application of IFRS 16 - Leases is for financial years beginning on or after 1 January 2019. Early application is permitted in principle, if IFRS 15 - Revenue from Contracts with Customers is already applied (early) in full. The lessee either has to fully apply IFRS 16 retrospectively, with the inclusion of prior reporting periods, or has to recognise the cumulative adjustment effect at the point in time of initial application as an entry in equity at the beginning of the financial year of initial application. Adoption of the standard by the EU is still pending. The group is currently evaluating the possible impact of the initial application of IFRS 16 on its consolidated financial statement, and will define an adoption date and transitional method, provided that the standard is adopted by the EU in this form.

The accounting and valuation principles applied are consistent with those applied on 31.12.2014, with the exception of the new and revised standards and interpretations described above that were applied from the 2015 financial year for the first time.



The consolidated financial statements as at 31 December 2015 are presented in EUR or thousands of EUR.

The Biofrontera Group presents current and non-current assets and current and non-current liabilities as separate categories in the balance sheet, in accordance with IAS 1.60, with these categories also being broken down to some extent according to their respective terms in the notes to the consolidated financial statement for 31 December 2015. The statement of profit/loss is prepared using the cost of sales method. In this reporting format, the net turnover is set against the expenses incurred in achieving it, broken down into cost of sales, research and development costs, distribution costs and general administration costs.

The consolidated financial statement for 31 December 2015 contains no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz®, including the supplementary products BF-RhodoLED® (PDT lamp) and Belixos®, and are internally monitored and managed accordingly.

### ***Basis for consolidation***

The consolidated financial statement for 31 December 2015 includes the financial statements of the parent company, Biofrontera AG, and the subsidiary companies in which the parent has a direct majority of the voting rights or another means of exerting control. The following companies have been included in the consolidated financial statement:

1. Biofrontera Bioscience GmbH, Leverkusen, Germany, with a direct shareholding of 100%
2. Biofrontera Pharma GmbH, Leverkusen, Germany, with a direct shareholding of 100%
3. Biofrontera Development GmbH, Leverkusen, Germany, with a direct shareholding of 100%
4. Biofrontera Neuroscience GmbH, Leverkusen, Germany, with a direct shareholding of 100%.
5. Biofrontera Inc., Wilmington, Delaware, USA with a direct shareholding of 100% since March 2015.

Biofrontera Inc. was founded on 3 March 2015, with its registered head office at 1209 Orange Street, Wilmington, Delaware, 19801, County of New Castle, USA. The share capital of Biofrontera Inc. is USD 1.00. It is divided into 1000 shares with a nominal par value of USD 0.001 each.

The basis for the consolidation of the companies included in the consolidated financial statements is the financial statements (or HBII pursuant to IFRS) of these companies prepared for 31 December 2015 pursuant to uniform principles. The consolidated financial statement for 31 December 2015 has been prepared on the basis of uniform accounting and valuation principles (IFRS).

The subsidiaries have been fully consolidated from the date of acquisition. The date of acquisition is the point in time at which the parent company obtained control of these subsidiaries. The subsidiaries are included in the consolidated financial statements until the state of control over these companies no longer exists.

All inter-company balances and income and expenses have been eliminated on consolidation. Interim results have not been realised.

### ***Conversion of amounts in foreign currencies***

The consolidated financial statements for 31 December 2015 have been drawn up in EUR (or thousands of EUR), which is the operational currency of all the German companies included in the consolidated financial statement and of the group, and is the group's reporting currency.

For subsidiaries with a functional currency that is the local currency of the country in which they have their registered office, the assets and liabilities that are accounted for in the foreign currency in the balance sheets of the foreign, economically independent subsidiaries, are converted to euros using the relevant period-end exchange rate. Income and expense items are converted using the average exchange rates applicable to the relevant period. The differences resulting from the valuation of equity at historic rates and using the period-end exchange rates are reported as a change not affecting net income recognised in equity within the other equity components.

Transactions made in currencies other than EUR are recorded using the exchange rate on the date of the transaction. Assets and liabilities are revalued using the closing exchange rate for each balance sheet date. Gains and losses arising from such conversions are recognised in income.

### ***Use of estimates***

The preparation of the consolidated financial statement for 31 December 2015 pursuant to IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities - as well as contingent assets and liabilities - reported on the balance sheet date, and revenues and expenses occurring during the financial year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lifespans of long-term assets and the establishment of provisions, for example employee pensions and other benefits, as well as income taxes. Estimates are based on historical experience and other assumptions that are considered to be appropriate in the circumstances. They are continually reviewed but may vary from the actual values.

### ***Transactions with related parties***

With regard to transactions with shareholders, particularly in connection with capital increases and the issue of Biofrontera AG bonds, please see our comments in the appendix note "Equity".

With respect to the issue of share options to employees of the Biofrontera Group, please see our comments on the "Share Option Plan" in the appendix note "Equity".

With regard to the remuneration of Management Board members, please see our comments in the appendix note "Members of the Management Board".

With regard to the remuneration of Supervisory Board members, please see our comments in the appendix note "Members of the Supervisory Board".

### ***Fixtures and equipment***

Pursuant to IAS 16, the value of fixtures and equipment is recorded in the balance sheet based on the historical purchase or production costs minus the scheduled depreciation.

Depreciation of fixtures and equipment is generally linear over the estimated useful lifespan of assets (generally 3 to 13 years). The main useful lifespans are unchanged:

|                          |                                  |                  |
|--------------------------|----------------------------------|------------------|
| <input type="checkbox"/> | IT devices                       | 3 years, linear  |
| <input type="checkbox"/> | Office furniture and equipment   | 4 years, linear  |
| <input type="checkbox"/> | Office and laboratory facilities | 10 years, linear |
| <input type="checkbox"/> | Laboratory devices               | 13 years, linear |

Since 01 January 2008, low value assets with acquisition costs of between EUR 150 and EUR 1,000 have been booked to the year of acquisition as a single item for the relevant year, and are fully written off over five years.

### ***Intangible assets***

Software that is purchased is valued at cost and depreciated linearly over a useful lifespan of three years.

Intangible assets that are acquired consist of licenses and other rights. They are accounted for at cost less accumulated de-preciation. Only intangible assets acquired from third parties are entered on the assets side, as the requirements for the recognition of internally generated intangible assets are not

met. Intangible assets are entered on the assets side and written off over the estimated useful life of between 4 and 10 years.

Borrowing costs are not included as part of the procurement cost of the acquired assets but rather as an expense for the period in which they arise, because the group has no qualified assets in terms of the definition in IAS 23.5.

### ***Impairment of assets***

The company reviews assets for impairment when there are indications that the book value of an asset exceeds its recoverable amount. The recoverability of assets held for use is evaluated by carrying out a comparison of the book value of an asset with the future, expected cash flows generated from the asset. When such an asset is considered to be impaired, the impairment loss is valued at the amount by which the book value of the asset exceeds its fair value. Assets that are to be sold are reported as the lower of the book value or the fair value less costs to sell.

### ***Financial instruments***

The financial instruments held by the Biofrontera Group on the balance sheet date primarily consist of cash and cash equivalents, short-term investments, trade payables and receivables and financial debt. Biofrontera does not currently use derivative financial instruments. Due to the short maturities of short-term financial investments and trade payables and receivables, the book values of these items correspond to their fair values. The short-term financial investments are assigned to the 'available for sale' category, and other receivables and liabilities are assigned to the 'loans and receivables' category. The financial liabilities are measured using the effective interest method, minus treasury stock.

The Biofrontera Group was not exposed to significant foreign currency risk on the balance sheet date. Financial investments have been transacted in euros. Trade payables denominated in foreign currency are of secondary importance. Trade receivables are regularly checked with respect to a potential default risk.

Regarding the selection of short-term capital investments, various security criteria are applied (for example, ratings, capital guarantee, safeguarding by the deposit protection fund). Based on the selection criteria and the ongoing monitoring of capital investments, Biofrontera does not consider there to be any default risks in this area that have not been taken into account. The amounts reported in the balance sheet generally represent the maximum default risk.

The monitoring and management of liquidity is based on short-term and long-term corporate planning. Liquidity risks are detected at an early stage, using simulations of various scenarios. Current liquidity is recorded and monitored on a daily basis.

To date, Biofrontera has always succeeded in providing the necessary financing for its business operations through injections of equity.

As a result of the capital increases carried out in June and December 2015 and another capital increase implemented in February 2016, the company currently has sufficient liquidity at its disposal. However, further capital measures will be needed until break even is reached, in particular in order to carry out marketing activities in the USA. On 31 December 2015, Biofrontera held no financial positions that were exposed to interest rate risks.

### ***Financial assets available for sale***

The company classifies the securities held as short-term financial investments as financial assets available for sale, in accordance with IAS 39.9. On the reporting date of 31.12.2015, Biofrontera had in its portfolio holdings of its own Warrant Bond I 2009/2017 with a nominal value of EUR 1,500 thousand. The warrant bonds held by Biofrontera were depreciated by a further EUR 100 thousand (previous year: EUR 167 thousand), to EUR 1,233 thousand, as of 31 December 2015, due to a fall in the market price. In accordance with IAS 32, the bonds are reported as balanced against the corresponding bonded debt.

### ***Inventories***

Raw materials and supplies, as well as finished and unfinished goods, are valued at the lower of acquisition/manufacturing cost or market price. Borrowing costs are not capitalised. The acquisition/manufacturing costs are calculated in accordance with a first-in-first-out method (FIFO). A value adjustment is made to the inventories on the balance sheet date if the fair value is lower than the book value.

### ***Trade receivables***

Trade receivables are shown with their nominal value. In the case of value adjustments, these are booked directly against the relevant receivable. Receivables denominated in foreign currencies have been converted to euros using the exchange rates applicable on the balance sheet date, with any conversion differences being recorded in the statement of income.

### ***Cash and cash equivalents***

Cash and cash equivalents include cash-in-hand, cheques and bank deposits with a maturity of up to three months at the time of acquisition, as well as short-term financial assets. These are valued at amortised acquisition cost.

### ***Trade payables, overdrafts***

Trade payables, as well as liabilities from current accounts and other liabilities, are stated at their redemption amount. Due to their short-term nature, the reported book value reflects the fair value. Foreign currency liabilities are converted using the period-end exchange rate. Exchange rate losses and gains are shown in the statement of income.

### ***Provisions***

Provisions are formed if an obligation to third parties resulting from a past event exists and is likely to result in an outflow of assets in the future, and if the effect on assets can be reliably estimated.

### ***Share options***

Share options (share-based remuneration transactions settled via equity instruments) are valued at the market value on the date of granting. The market value of the obligation is capitalised as a personnel expense over the retention period. Obligations relating to share-based payment transactions with cash settlement are recognised as liabilities and are valued at the market value on the balance sheet date. In the event that Biofrontera AG has the right to choose between payment in cash or payment using shares when a right is exercised, an increase in the capital reserve is initially carried out pursuant to IFRS 2.41 and IFRS 2.43. The costs are compiled over the retention period. The market value of share-based payment transactions with cash settlement and equity instrument settlement are generally determined using internationally accepted methods, if the fair value of these share-based payments can be reliably determined.

### ***Warrant bonds***

In accordance with IAS 32, warrant options are classified as compound financial instruments that represent a debt security with an embedded conversion or purchase option. The issuer of such a financial instrument, which contains both a liabilities and an equity component, is obligated to portray the liabilities component and the equity component separately from the originally recorded financial instrument in the balance sheet. Initially, the market value of the liabilities component equates to the present value of the contractually defined future cash flows, discounted at the market interest rate valid at that time for financial instruments that have a comparable credit status and give rise under the same conditions to effectively the same cash flows, but which do not contain a conversion or purchase option. The subsequent valuation is carried out using the effective interest method. The liability is derecognised when the obligation underlying the liability is fulfilled, terminated or expires. The equity instrument consists of the embedded option to convert the liability into equity of the issuer. The market value of the option comprises its current value and, where relevant, its intrinsic value. The intrinsic value of an option or of another derivative financial instrument is, if any, the difference between the market value of the underlying instrument and the contract price at which the underlying instrument is to be purchased, issued, sold or exchanged. The fair value of a derivative financial instrument consists of its market value less its intrinsic value. The current value is determined by the length of the remaining period up until maturity or until the expiration of the derivative financial instrument.

If the warrant bonds are redeemed before maturity via early redemption or early repurchase, with the original conversion rights remaining unchanged, the fee paid and all transactions relating to the

repurchase or redemption are allocated to the liability and equity components of the instrument at the time of the transaction. The method for the allocation of the fees and transaction costs to the two components is identical to that used in the original allocation applied to the revenue received when issuing the bond.

### ***Income tax***

In accordance with IAS 12, Biofrontera recognises deferred taxes for valuation differences between commercial law and tax law valuation. Deferred tax liabilities are generally recorded for all taxable temporary differences - claims from deferred taxes are only recorded to the extent that it is probable that taxable profits will be available in order to be able to utilise the claims. The book value of deferred income tax claims is reviewed on each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available against which the deferred tax claim can be at least partially utilised. Previously unrecognised deferred income tax claims are reassessed on each balance sheet date and are recognised to the extent that it is probable from a current perspective that sufficient future taxable profit will be available in order to realise the deferred tax claim.

Deferred tax liabilities and deferred tax assets are offset if there is a right to offset and if they are being collected by the same tax authority.

Current taxes are calculated on the basis of the company's taxable earnings for the period. The tax rates applicable to the respective companies on the balance sheet date are used for this purpose.

### ***Earnings per share***

Earnings per share are calculated by dividing net consolidated income by the weighted average number of outstanding shares during the year in accordance with IAS 33 ("earnings per share").

### ***Leasing***

The leasing contracts that are signed are classified either as finance leases or operating leases. If as the lessor has passed all significant opportunities and risks onto the group as a lessee, the group is assigned beneficial ownership. The companies included in the consolidated financial statement have usually concluded contracts that are classified as operating leases. In this case, ongoing lease payments are recorded as expenses when they are incurred. Concluded leasing contracts that are classified as finance leases are entered on the assets side with the lower value of the present value of the minimum lease payments or the fair value of the leased asset at the beginning of the lease and depreciated over the shorter of the two periods duration of the lease and useful life, provided that the transfer of ownership to the lessee at the end of the contractual period is not sufficiently certain.

Revenue recognition

The company states earnings in accordance with IAS 18 if the earnings process is complete and if the property-related risks and opportunities have been transferred to the customer. The company realises its turnover primarily through the sale of its products. Income from milestone and licensing agreements with third parties is realised once the underlying contractual conditions come into force. It is always possible for turnover to be received immediately and in full and to be recorded as income if the conditions of IAS 18 IE 20 are met in the version of a one-off contract start payment.

Revenue and other income are realised when the amount can be measured reliably and payment is sufficiently probable as well as other conditions mentioned below are met.

All income in connection with the sale of products and licence income are recorded as revenue. Other operating incomes are shown as other operating income.

Revenue is determined to be realised when the deliveries and services owed have been provided and substantial risk and chances have been passed to the acquirer.

The majority share of revenues is achieved by product sales. The sale of Ameluz® is frequently pursued through pharma wholesalers or directly to pharmacies or hospitals.

Upon direct sales of the BF-RhodoLED® those conditions are only met after complete installation, since the installation services requires specialised knowledge, is not just an ancillary service and the lamp may only be used by the customer after successful installation. Those conditions are met with rental lamps once a binding sales contract has come into effect and the outgoing invoice has been generated.

Belixos® is predominantly sold through Amazon. Revenue is recognised after delivery and payment by the customer. Based on experience, return rights granted with the sale through Amazon are exercised by customers only in very few cases.

Revenues are recognised less revenue based trade taxes and sales deductions. Expected sales deductions, for instance rebates, discounts or returns, are recognised based on estimated values at revenue recognition. Payment terms for Ameluz® include short term payment terms with a possibility for sales rebates. Instalment payments which include a financing component are sometimes agreed upon with the sale of BF-RhodoLED®.

Licence income as well as milestone based payments are recognised when the contractual obligation has been fulfilled.

### ***Research and development expenses***

The costs relating to development are recognised, in accordance with IAS 38, as intangible assets, if certain conditions are fulfilled. Research costs are entered as costs as they are incurred. Development



costs are capitalised, if certain conditions are fulfilled, depending on the possible outcome of development activities.

Estimates of such possible outcomes involve the making of significant assumptions by the management. In the management's opinion, due to uncertainties related to the development of new products, the criteria prescribed under IAS 38.57 "Intangible Assets" for capitalising development costs as assets are only fulfilled by the Biofrontera Group if the prerequisites for the expansion of the European approval and the approval in the USA are met, and if it is likely that the company will accrue a future economic benefit.

The research and development costs relating to the medication Ameluz®, which has been approved in Europe, and to the company's other research and development projects, are therefore recorded as expenses in the period in which they are incurred.

## ***Balance sheet notes***

### ***1 Tangible and intangible assets***

The development of fixed asset items in the 2015 financial year is shown in the statement of assets, together with an indication of the accumulated depreciation. Tangible fixed assets consist mainly of office and business equipment and laboratory and production facilities.

Inflows to intangible assets and fixed assets in the reporting period resulted mainly from the acquisition of additional usage rights associated with the prototype of the PDT lamp (EUR 26 thousand, previous year: EUR 77 thousand) as well as the capitalisation of production facility expenses (EUR 45 thousand; previous year: EUR 0) and office and business equipment (EUR 42 thousand; previous year: EUR 29 thousand). The asset outflows with total acquisition and manufacturing costs of EUR 20 thousand (previous year: EUR 128 thousand) resulted primarily from sales of the rental lamps, which accounted for EUR 20 thousand (previous year: EUR 117 thousand).

The reported use rights, with a net book value totalling EUR 1,778 thousand, relate mainly to rights totalling EUR 1,642 thousand to use technology developed by the company ASAT Applied Science and Technology AG, Zug, Switzerland, in terms of the active ingredient ALA (aminolevulinic acid), including all patents and expertise associated with this. The rights of use that are acquired are depreciated over their estimated remaining useful lifespan of 20 years, from their date of acquisition, due to their direct usability. This useful lifespan is derived from the term of the patents issued and acquired by Biofrontera AG and is reviewed annually pursuant to IAS 38.104. There are no indications for an impairment loss. The development costs for the prototypes of the BF-RhodoLED® have also been capitalised in this item.

Consolidated statement of changes in fixed assets in 2015

|                                  | Acquisition and production costs |                   |                  |                     | Accumulated depreciation |                   |                 |                     | Book values         |                     |
|----------------------------------|----------------------------------|-------------------|------------------|---------------------|--------------------------|-------------------|-----------------|---------------------|---------------------|---------------------|
|                                  | 01 Jan.<br>2015                  | Inflows           | Outflows         | 31 Dec.<br>2015     | 01 Jan.<br>2015          | Inflows           | Outflows        | 31 Dec.<br>2015     | 31 Dec.<br>2015     | 31 Dec.<br>2014     |
|                                  | EUR                              | EUR               | EUR              | EUR                 | EUR                      | EUR               | EUR             | EUR                 | EUR                 | EUR                 |
| <b>I. Tangible assets</b>        |                                  |                   |                  |                     |                          |                   |                 |                     |                     |                     |
| Operating and business equipment | 3,342,769.00                     | 154,418.76        | 20,271.71        | 3,476,916.05        | 3,003,237.00             | 107,647.82        | 6,803.00        | 3,104,081.82        | 372,834.23          | 339,532.00          |
| <b>II. Intangible assets</b>     |                                  |                   |                  |                     |                          |                   |                 |                     |                     |                     |
| 1 Software and licences          | 418,895.51                       | 0.00              | 0.00             | 418,895.51          | 281,912.08               | 13,140.00         | 0.00            | 295,052.08          | 123,843.43          | 136,983.43          |
| 2 Usage rights                   | 6,027,454.31                     | 25,884.78         | 0.00             | 6,053,339.09        | 3,584,360.57             | 690,894.02        | 0.00            | 4,275,254.59        | 1,778,084.50        | 2,443,093.74        |
|                                  | 6,446,349.82                     | 25,884.78         | 0.00             | 6,472,234.60        | 3,866,272.65             | 704,034.02        | 0.00            | 4,570,306.67        | 1,901,927.93        | 2,580,077.17        |
|                                  | <b>9,789,118.82</b>              | <b>180,303.54</b> | <b>20,271.71</b> | <b>9,949,150.65</b> | <b>6,869,509.65</b>      | <b>811,681.84</b> | <b>6,803.00</b> | <b>7,674,388.49</b> | <b>2,274,762.16</b> | <b>2,919,609.17</b> |

Consolidated statement of changes in fixed assets in 2014

|                                  | Acquisition and production costs |            |            |                 | Accumulated depreciation |            |           |                 | Book values     |                 |     |
|----------------------------------|----------------------------------|------------|------------|-----------------|--------------------------|------------|-----------|-----------------|-----------------|-----------------|-----|
|                                  | 01 Jan.<br>2014                  | Inflows    | Outflows   | 31 Dec.<br>2014 | 01 Jan.<br>2014          | Inflows    | Outflows  | 31 Dec.<br>2014 | 31 Dec.<br>2014 | 31 Dec.<br>2013 |     |
|                                  | EUR                              | EUR        | EUR        | EUR             | EUR                      | EUR        | EUR       | EUR             | EUR             | EUR             | EUR |
| <b>I. Tangible assets</b>        |                                  |            |            |                 |                          |            |           |                 |                 |                 |     |
| Operating and business equipment | 3,395,985.95                     | 74,917.75  | 128,134.70 | 3,342,769.00    | 2,928,662.32             | 99,708.50  | 25,133.82 | 3,003,237.00    | 339,532.00      | 467,323.63      |     |
| <b>II. Intangible assets</b>     |                                  |            |            |                 |                          |            |           |                 |                 |                 |     |
| 1 Software and licences          | 410,461.51                       | 8,434.00   | 0.00       | 418,895.51      | 267,487.08               | 14,425.00  | 0.00      | 281,912.08      | 136,983.43      | 142,974.43      |     |
| 2 Usage rights                   | 5,937,723.26                     | 89,731.05  | 0.00       | 6,027,454.31    | 2,887,489.07             | 696,871.50 | 0.00      | 3,584,360.57    | 2,443,093.74    | 3,050,234.19    |     |
| 3 Prepayments made               | 9,000.00                         | 0.00       | 9,000.00   | 0.00            | 0.00                     | 0.00       | 0.00      | 0.00            | 0.00            | 9,000.00        |     |
|                                  | 6,357,184.77                     | 98,165.05  | 9,000.00   | 6,446,349.82    | 3,154,976.15             | 711,296.50 | 0.00      | 3,866,272.65    | 2,580,077.17    | 3,202,208.62    |     |
|                                  | 9,753,170.72                     | 173,082.80 | 137,134.70 | 9,789,118.82    | 6,083,638.47             | 811,005.00 | 25,133.82 | 6,869,509.65    | 2,919,609.17    | 3,669,532.25    |     |

## **2 Inventories**

Inventories encompass finished products, unfinished products, and raw materials and supplies.

Inventories amount to EUR 1,534 thousand (31.12.2014: EUR 1,394 thousand). In assessing the consumption of inventories, the sequence of consumption is assumed to be based on the first-in-first-out (FIFO) method.

## **3 Trade receivables**

Trade receivables relate mainly to the sale of Ameluz®, the BF-RhodoLED® PDT lamp and the medical cosmetic product Belixos®. It is expected that all trade receivables will be settled within twelve months of the balance sheet date. Provisions for doubtful receivables have not been made. There were overdue receivables for which no value adjustment was made amounting to EUR 20 thousand (31.12.2014: EUR 30 thousand) on the balance sheet date. Of these, EUR 15 thousand were 15 to 30 days overdue, and EUR 5 thousand were more than 30 days overdue. At the time of preparation of the consolidated financial statement, no overdue receivables were still unpaid.

## **4 Other financial and miscellaneous assets**

Miscellaneous assets primarily include prepayments for medical trials (EUR 585 thousand; 31.12.2014: EUR 586 thousand) and VAT reimbursement claims (EUR 57 thousand; 31.12.2014: EUR 87 thousand). No individual value adjustments were carried out during the reporting year (31.12.2014: EUR 261 thousand)

## **5 Income tax reimbursement claims**

These consist of claims for tax refunds relating to withheld capital gains tax, plus the solidarity surcharge (EUR 32 thousand; 31.12.2014: EUR 38 thousand).

## **6 Securities**

The valuation of securities is based on the prices quoted in an active market. On 31 December 2015, the company's holdings in its own Warrant Bond I 2009/2017 had a nominal value of EUR 1,500 thousand (31.12.2014: EUR 1,500 thousand). The warrant bonds held by Biofrontera were depreciated by a further EUR 100 thousand (depreciation 31.12.2014: EUR 167 thousand), to EUR 1,233 thousand (31.12.2014: EUR 1,333 thousand) due to a fall in the market price. In accordance with IAS 32, the bonds are offset against the bonded debt.

## 7 *Cash and cash equivalents*

Cash and cash equivalents relate to cash-in-hand, cheques, bank deposits and money deposits with a maturity of up to three months at the time of acquisition amounting to EUR 3,959 thousand (31.12.2014: EUR 8,509 thousand). The book values of the cash and cash equivalents correspond to their fair value, due to the short-term nature of these investments.

## 8 *Deferred income tax claims*

The Biofrontera Group recorded a net loss before tax on 31 December 2015 and on 31 December 2014. Deferred tax assets are generally determined on the basis of the existing income tax rates in Germany. The corporate tax rate is 15% as a result of the 2008 Company Tax Reform Act. When a solidarity surcharge of 5.5% is included, this results in a combined tax rate of 15.8% (previous year: 15.8%). Because of the basic rate of tax of 3.5% for businesses and the lack of deductibility of business tax as a business expense, the resulting tax rate, taking into account the local business tax rate, is 16.6% (previous year 16.6%).

The following table provides details of the basic current deferred tax claims arising from tax loss carryforwards as they have developed within the group (the previous year's figures have been adjusted to the amounts determined for tax purposes):

|  | 31 December 2015            |                            | 31 December 2014            |                            |
|--|-----------------------------|----------------------------|-----------------------------|----------------------------|
|  | Loss carried forward<br>EUR | Deferred tax claims<br>EUR | Loss carried forward<br>EUR | Deferred tax claims<br>EUR |
| Corporation tax including solidarity surcharge | 104,757                     | 16,583                     | 93,151                      | 14,746                     |
| Business tax                                   | 94,915                      | 15,784                     | 84,306                      | 14,020                     |
| <b>Total</b>                                   |                             | <b>32,367</b>              |                             | <b>28,766</b>              |

These losses carried forward have an unlimited carry forward period under current German law.

Due to the lack of predictability regarding future taxable profits, the fundamentally existing deferred tax claims from loss carryforwards (EUR 32,367 thousand; 31.12.2014: EUR 28,766 thousand) and tax deductible differences of EUR 33 thousand (31.12.2014 EUR 55 thousand) were not entered in the balance sheet, in accordance with IAS 12.34.

The following provides a reconciliation between expected and actual reported income tax expense, with the output value being based on the rounded income tax rate of 32.5% currently applicable to the Biofrontera Group:

|  | 31.12.2015<br>kEUR | 31.12.2014<br>kEUR |
|--|--------------------|--------------------|
| Group income before income taxes   | (11,203)           | (10,721)           |
| <b>Expected income tax reimbursement at the tax rate of the parent company</b> | <b>3,635</b>       | <b>3,479</b>       |
| Differences arising from different tax rates                                   | 0                  | 0                  |
| Tax reductions due to changes in permanent differences                         | 161                | 70                 |
| Tax increases due to non-deductible expenses                                   | (187)              | (150)              |
| Changes in unrecognised deferred tax assets                                    |                    |                    |
| - from active temporary differences  | 33                 | 55                 |
| - from losses carried forward  | (3,602)            | (3,456)            |
| Other effects  | 40                 | 2                  |
| <b>Income taxes according to statement of overall profit/loss</b>              | <b>0</b>           | <b>0</b>           |

## 9 *Equity*

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 25,490,430.00 on 31 December 2015. It was divided into 25,490,430 registered shares with a nominal value of EUR 1.00 each. On 31 December 2014, the share capital amounted to EUR 22,196,570.00 and was increased by a total of EUR 3,293,860.00, divided into 3,293,860 registered shares, during the course of the 2015 financial year, as a result of two capital increases.

In the first capital increase carried out in 2015, subscription of new shares was offered to all shareholders for allocation and additional subscription. The new shares that were not acquired as part of the subscription right or the additional subscription were offered to selected investors for acquisition in a private placement. EUR 1,377,272.00, divided into 1,377,272 registered shares, was placed and the implementation was entered in the trade register on 1 June 2015. The proceeds amounted to EUR 3.1 million

In addition, in a further capital increase, a total of EUR 1,916,588, divided into 1,916,588 registered shares, was placed and this was registered in the trade register on 3 December 2015. This capital increase was also initially offered to all shareholders for subscription and additional subscription. Shares that were not acquired in the allocation and additional subscription were offered to institutional investors for subscription. The proceeds amounted to EUR 3.5 million.

The Biofrontera AG shares were listed on the regulated market of the Düsseldorf Stock Exchange in 2006. Likewise, approval was granted for trading on the regulated market of the Frankfurt Stock Exchange in August 2012. The company's shares are also traded on the Xetra computer trading system

and all other German stock exchanges. On 3 June 2014, the share was admitted to the Prime Standard of the Frankfurt Stock Exchange and the AIM market of the London Stock Exchange. The listing on the AIM Market was rescinded on 18 February 2016.

The numbers of shares held by the shareholders on 31 December 2015, based on the most recent compulsory disclosures of the shareholders, are as follows:

|   | 31 December 2015<br>EUR | 31 December 2014<br>EUR |
|---|-------------------------|-------------------------|
| <b>Maruho Deutschland Co., Ltd., Osaka Japan</b><br>The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, via the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.   | 4,467,143               | 4,467,143               |
| <b>Dr. Carsten Maschmeyer, Germany</b><br>Dr Maschmeyer is assigned all the voting rights of the company ALSTIN Family GmbH, Hanover, which he controls (formerly: Alternative Strategic Investments GmbH), and MM Familien KG, Hanover.  | 0                       | 2,282,177               |
| <b>Professor Ulrich Abshagen, Germany</b><br>Professor Abshagen has a direct holding of 62,850 voting rights, and he is indirectly assigned 976,056 voting rights by Heidelberg Innovation BioScience Venture II GmbH & Co.KG (in liquidation) via Heidelberg Innovation Asset Management GmbH & Co. KG, of which he is one of the managing partners. | 1,038,906               | 1,028,349               |
| <b>Wilhelm Konrad Thomas Zours</b><br>Of this, 3.48% of the voting rights are assigned via the company Deutsche Balaton Aktiengesellschaft  | 1,053,154               | 0                       |
| <b>Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany</b><br>The voting rights are assigned to Universal-Investment GmbH via the company FEHO Vermögensverwaltungsgesellschaft   | 799,463                 | 981,438                 |
| <b>Prof. Dr. Hermann Lübbert, Leverkusen, Germany</b>   | 720,512                 | 685,512                 |
| <b>Free float</b>   | 17,411,252              | 12,751,951              |
| <b>Total</b>  | <b>25,490,430</b>       | <b>22,196,570</b>       |

The company's capital management body regularly reviews the equity ratio of the group and the group subsidiaries. The management's objective is to ensure an appropriate equity base, within the framework of the expectations of the capital market, and creditworthiness with respect to national and international business partners. The Management Board of the company ensures that all group companies have sufficient capital at their disposal in the form of equity and debt capital. Two financings took place, in June 2015 and December 2015.

The statement of changes in equity provides further information about the development of equity.

In connection with the already issued 2009/2017 warrant bond and the 2011/2016 warrant bond issued in July 2011 (1st tranche) and December 2011 (2nd tranche), the following items were reported on 31 December 2015:

|   | 31.12.2015<br>EUR | 31.12.2014<br>EUR |
|---|-------------------|-------------------|
| <b>Long-term financial debt</b><br>(at amortised cost)                            | 11,229,946.00     | 10,744,299.63     |
| <b>Short-term financial debt</b><br>(accrued interest from nominal interest rate) | 830,174.00        | 1,224,598.00      |
| <b>Capital reserve</b><br>(equity component 2009/2017 warrant bond)               | 1,485,294.99      | 1,485,294.99      |

|  |              |              |
|--|--------------|--------------|
| Capital reserve<br>(equity component 2011/2016 warrant bond) | 1,226,747.16 | 1,226,747.16 |
|--|--------------|--------------|

The interest effects of the warrant bonds on the long-term borrowings were initially calculated using an effective annual interest rate of 14.35% for the 2009/2017 warrant bond, 9.8% for the first tranche of the 2011/2016 warrant bond and 5.8% for the second tranche of the 2011/2016 warrant bond.

In accordance with IAS 32.37, the equity procurement costs reduced by any related income tax benefits are accounted for as a deduction from equity. As, in the opinion of the company management, the realisation of the losses carried forward is associated with a high degree of uncertainty, the costs of raising equity have been deducted in full from equity. In the 2015 financial year, costs of raising equity totalling EUR 496 thousand (previous year: EUR 216 thousand) were recognised in connection with the capital increases that were carried out.

In the event of the company achieving an annual surplus, the Management Board and the Supervisory Board are authorised to place all or part of the annual surplus that remains, after deduction of the sums to be placed in the legal reserves and of a loss carryforward, in the surplus reserves. It is not permissible to place more than half of the annual surplus in the surplus reserves if, after such placement, the other surplus reserves would exceed half of the share capital. The shareholders' dividends are calculated based on the size of their holding of the share capital.

### ***2010 share option programme***

At the Annual General Meeting on 2 July 2010, the Management Board and Supervisory Board proposed a share option programme for employees to the Annual General Meeting, which approved the initiative. In accordance with this, the Management Board, or the Supervisory Board if the beneficiaries are Management Board members, are entitled to issue up to 839,500 share options, the exercising of which is linked to specific targets.

The programme has a total nominal volume of EUR 840,000 and a term of six years from the issue date, i.e. until 24.11.2016. For this, conditional capital amounting to EUR 839,500 was decided by means of the issuing of up to 839,500 registered no-par value unit shares with a proportional amount of the share capital of EUR 1.00 per share, in accordance with § 192 para. 1 no. 3 of the German Stock Corporation Act (AktG). The conditional capital was registered on 30 July 2010 in the trade register of the Cologne District Court, under HRB 49717. Eligibility for the 2010 share option programme was granted to members of the Management Board and employees of the company as well as to members of management bodies and employees of affiliates of Biofrontera AG.



The date of issue was 24 November 2010. The granting of options is made without any payment being provided in return. On 24 November 2010, 106,400 options (first tranche) were issued with an exercise price per share of EUR 1.91. On 30 September 2011 and 7 October 2011 (second tranche) a further 96,400 options were issued with an exercise price of EUR 2.48 each. On 23 March 2012 and 11 May 2012 (third tranche), 65,000 options were issued with an exercise price of EUR 3.30 each, and 51,500 options were issued with an exercise price of EUR 4.09 each. On 2 September 2013, 179,500 options were issued (fourth tranche) with an exercise price of EUR 3.373 each. On 2 April 2014, 159,350 options were issued with an exercise price of EUR 3.43 each.

In accordance with the associated conditions, each subscription right that is granted entitles the beneficiary to acquire one new registered no-par value unit share in the company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange via the trading floor and Xetra trading for the company's shares on the ten trading days prior to the issuing of the share. However, the minimum exercise price amounts to the proportionate share of the company's share capital allocated to each individual no-par value unit share, pursuant to § 9, paragraph 1 of the German Stock Corporation Act.

The options granted may only be exercised after expiry of a retention period. The retention period is four years from the re-spective date of issue. A prerequisite for the whole or partial exercising of the options is that the following performance target is achieved:

Exercising the options from a tranche is possible if at the beginning of the respective exercise period, the price (hereinafter referred to as the "reference price") of a share in Biofrontera Aktiengesellschaft exceeds the exercise price by at least 20%, and a minimum reference price of at least EUR 5.00 is achieved (hereinafter referred to as the "minimum reference price"). The reference price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange via the trading floor and Xetra trading for the Company's shares between the 15th and the 5th trading day (inclusive in each case) prior to the respective exercise window. The minimum reference price is adjusted in the following cases in order to bring the stated performance target into line with changed circumstances:

- In the event of a capital increase from company funds being carried out by issuing shares, the minimum reference price is reduced by the same ratio as new shares issued compared to existing shares. If the capital increase is carried out from company funds without the issuing of new shares (§ 207 paragraph 2 clause 2 German Stock Corporation Act (AktG)), the minimum reference price remains unchanged.

- In the case of a capital reduction, no adjustment of the minimum reference price is carried out, provided that the total number of shares is not changed by the capital reduction or if the capital reduction is connected to a return of capital or an acquisition of own shares against payment. In the case of a capital reduction performed by consolidating shares without capital repayment and in the

case of increasing the number of shares with no associated change in capital (share split), the minimum reference rate increases in line with the capital reduction or share split.

Other adjustments to the minimum reference price are not carried out.

The exercising of options is limited to the following time periods (hereinafter "exercise windows"), i.e. only declarations of exercising of rights submitted to the company within an exercise window will be considered:

- a) on the 6th and the next 14 banking days after the date of the Annual General Meeting (exclusive),
- b) on the 6th and the next 14 banking days after the date of submission of the semi-annual or quarterly report or an interim statement by Biofrontera AG (exclusive)
- c) in the period between the 15th and the 5th banking day before expiration of the options for each respective expiry date (exclusive).

After expiry of the relevant retention period, the options can be exercised up until the expiry of six years from the date of issue (exclusive).

The right to exercise the options ends at the latest six years after the first day of issue. The right to exercise the first options that were issued thus ends on 24.11.2016. If the options have not been exercised by this time, they expire without provision of compensation. In the valuation of the employee share options, we have assumed an average holding period of 5 years.

Any claim by the beneficiaries to receive a cash settlement in the event of non-exercise of the options is invalid even in the event of the existence of the above exercise prerequisites. An option may only be exercised if the holder has a current service or employment contract with the company or another company affiliated with the company or if the holder is a member of the Management Board or the management team of another company affiliated with the company.

In the event of the exercising of a subscription right, the company is generally and in specific cases permitted to choose between granting the registered share in exchange for payment of the exercise price, or fulfilling its debt by paying a cash settlement to the holder of the subscription right. The cash settlement per subscription right is equal to the difference between the exercise price per share and the share price on the exercise date, minus due taxes and fees.

As this share option scheme involves share-based remuneration with a choice of settlement at the discretion of the company, the company has decided, in accordance with IFRS 2.41 and IFRS 2.43, to book the transactions pursuant to the provisions for share-based remuneration settled with equity instruments (IFRS 2.10-29). Therefore, the fair value of a share from this share option programme with a granting date of 24 November 2010 was determined, on the basis of a binomial model, to have a value of EUR 0.57 / share option. For the share options issued on 31.12.2010, this resulted in a total value of options of EUR 60,648.00. For the additional share options granted in 2011, a fair value of

EUR 119,536.00 was calculated. For the two tranches of options granted in 2012, fair values of EUR 104,000.00 and EUR 106,090.00 were calculated, respectively. For the share options granted in 2013, a fair value of EUR 192,065 was calculated. For the share options granted in 2014, a fair value of EUR 132,260.50 was determined. The booking of the pro-rata amounts is carried out proportionately as personnel expenses and as increases in the capital reserves over the period of accumulation, until the end of the retention period. Share price volatility factors of 45.78% and 51.3% were used in assessing the fair value of the options granted in 2010 and 2011, factors of 53.5% and 65% were used for the options granted in 2012, a factor of 39.2% was used for the options granted in 2013 and a factor of 32.3% for the options granted in 2013 (based on valuation date volatility). A dividend yield of 0% was used in all cases, as well as respective risk-free interest rates of 1.75%, 1.21%, 0.9% and 0.82% in 2012 as well as 0.71% in 2013 and 0.68% in 2014, and a uniform annual fluctuation of beneficiaries of 20%. No share options were issued in financial year 2015.

The vesting period for the first tranche ran until 30 Nov 2014 and until 30 Sep 2015 for the second tranche, no options were exercised until the balance sheet date.

No options from the third, fourth and fifth tranche could be exercised due to the vesting period.

A total of 123,750 options were forfeited by employees leaving the company.

The authorisation to issue options under the 2010 share option programme ended on 1 July 2015. By resolution of the Annual General Meeting made on 28 August 2015, the conditional capital III foreseen for the servicing of options under this pro-gramme was reduced to EUR 542,400.00.

The expenditure booked in the reporting period was EUR 103 thousand (previous year: EUR 113 thousand).

## **10 Financial liabilities**

On 26 June 2009, Biofrontera announced the placement of a warrant bond with a term ending on 31 December 2017. As part of this financing measure on the part of the company, an option bond was placed in 2009 ("Warrant Bond I"). The warrant bond has a total nominal value of EUR 10,000,000.00, divided into up to 100,000 bonds with a nominal value of EUR 100.00. The redemption at the end of the term is at 106% of the nominal value of the bond. The warrant bonds bear interest on the following scale:

- from 1.9.2009 to 30.12.2010 annual rate 4%;
- from 31.12.2010 to 30.12.2011 annual rate 6%;
- from 31.12.2011 to 31.12.2017 annual rate 8%.

The accrual of interest on each warrant bond ends on the day before it is due for redemption. The interest payment is made on the last business day of the calendar year, but not until 31 December 2010, i.e. the interest for 2009 does not become due until then. Ordinary termination by the bondholders is not permitted. Biofrontera has the right, upon issuing of written notice to the bondholders of Warrant Bond I, to repay 106% of the nominal amount (plus any accrued interest) at any time. Each holder of a partial bond is, in accordance with the bond and option terms, entitled to five detachable option rights per partial bond, with each of these providing the irrevocable right to acquire a registered no-par value unit share with voting rights in Biofrontera AG with a notional proportion of the share capital of EUR 1.00, at an option price of EUR 5.00 each. The option right expires on 30 December 2017. The share resulting from the exercising of an option right is entitled to participate in the company's profits from the beginning of the financial year in which it arose from the exercising of the option right and payment of the capital contribution. In order to provide financing for the option rights, conditional capital of the company amounting to up to EUR 500,000.00 was approved at the Extraordinary General Meeting held on 17.03.2009.

Of these warrant bonds, partial bonds were issued with a total nominal value of EUR 4.930.300.00.

The liability from this warrant bond was valued at the time of issue and was attributed a cash value of EUR 3,238,744.00, and the book value of the long-term financial debt amounted to EUR 2,836 thousand on 31 December 2015 (31.12.2014: EUR 2,671 thousand), using the effective interest method. The short-term portion of this financial liability, i.e. debts payable within one year, amounts to EUR 394 thousand (31.12.2014: EUR 789 thousand). The nominal interest for 2014 was paid in the beginning of January of the following financial year and for 2015 on 31 December 2015. See section 6 for details of the warrant bonds held by Biofrontera.

On 7 June 2011, the Management Board decided, with the approval of the Supervisory Board and based on the authorisation granted by the Annual General Meeting, to issue a warrant bond 2011/2016 (hereinafter "Warrant Bond II").

Warrant Bond II has a total nominal value of up to EUR 25,000,000.00 and is divided into up to 250,000 individual warrant bonds with a nominal value of EUR 100.00 each. Each individual warrant bond is associated with ten detachable warrants issued by the company; each warrant entitles the holder to acquire a registered no par value unit share in the company, with associated voting rights and with a stake in the share capital of EUR 1.00 each, at an option price of EUR 3.00. If all the option rights were to be issued and exercised, this would result in a calculated total exercise price of EUR 7,500,000.00. The issue price of each warrant bond is EUR 100.00.

The term of the warrant bonds begins on 20 July 2011 and ends on 31 December 2016. The company will return the warrant bonds on 01 January 2017 at 100% of the nominal amount. The company has the right to repay 100% of the nominal amount of Warrant Bond II (plus any accrued interest) at any time. Bondholders may terminate Warrant Bond II for good reason in certain cases; normal

termination on the part of the bondholders is not possible. In order to provide financing for the option rights, conditional capital of up to EUR 2,500,000.00 was approved at the company's General Meeting on 10 May 2011 and entered in the trade register on 18.05.2011. Warrant Bond II accrues annual interest of 5%. The accrual of interest on each warrant bond ends on 31 December 2016. Interest is paid annually on 1 January for the previous year, commencing on 01 January 2012 with a payment of EUR 195 thousand for the period 20 July 2011 until 31 December 2011. A nominal total of EUR 8,715 thousand of individual warrant bonds of Warrant Bond II was issued as a result of two transactions that exchanged the convertible bonds for Warrant Bond II in July and December 2011 and the direct acquisition from the initial issue. The resulting interest payment owed for the period from 1 January 2015 until 31 December 2015 was paid out on the interest due date on 04 January 2016, and amounted to EUR 436 thousand (previous year: EUR 436 thousand). On 31 December 2015, the interest payable for the period from 1 January 2015 until 31 December 2015 of EUR 436 thousand was reported within short-term financial debt.

The contractual interest and repayment obligations relating to warrant bonds are broken down on the balance sheet date as follows:

| kEUR                           | 31.12.2015 |       |       |      |      |       |
|--------------------------------|------------|-------|-------|------|------|-------|
|                                | 2016       | 2017  | 2018  | 2019 | 2020 | Total |
| <u>Warrant bond 2009/2017:</u> |            |       |       |      |      |       |
| Repayment                      |            |       | 5,226 |      |      | 5,226 |
| Interest payment               | 394        | 394   |       |      |      | 788   |
| <u>Warrant bond 2011/2016:</u> |            |       |       |      |      |       |
| Repayment                      |            | 8,715 |       |      |      | 8,715 |
| Interest payment               | 436        | 436   |       |      |      | 872   |

The situation was as follows in the previous year:

| kEUR                           | 31.12.2014 |      |       |       |      |       |
|--------------------------------|------------|------|-------|-------|------|-------|
|                                | 2015       | 2016 | 2017  | 2018  | 2019 | Total |
| <u>Warrant bond 2009/2017:</u> |            |      |       |       |      |       |
| Repayment                      |            |      |       | 5,226 |      | 5,226 |
| Interest payment               | 788        | 394  | 394   |       |      | 1,576 |
| <u>Warrant bond 2011/2016:</u> |            |      |       |       |      |       |
| Repayment                      |            |      | 8,715 |       |      | 8,715 |
| Interest payment               | 436        | 436  | 436   |       |      | 1,308 |

## 11 Trade payables

The trade payables (EUR 1,043 thousand; 31.12.2014: EUR 967 thousand) increased by EUR 76 thousand from the previous year. The increase is due to trade payables invoiced at the end of the year and the underlying payment conditions.

## 12 Other provisions

Other provisions have developed as follows:

| Biofrontera Group                        | Euros<br>01.01.2015 | Utilised          | Liquidated       | Allocated         | Euros<br>31.12.2015 |
|--|---------------------|-------------------|------------------|-------------------|---------------------|
| - Bonuses for employees                  | 106,622.00          | 79,622.00         | 27,000.00        | 142,741.00        | 142,741.00          |
| - Outstanding holiday                    | 72,262.67           | 72,262.67         | 0.00             | 82,015.08         | 82,015.08           |
| - Outstanding invoices                   | 635,764.67          | 546,041.66        | 28,949.15        | 598,901.10        | 659,674.96          |
| - Financial statement and auditing costs | 93,884.00           | 87,134.32         | 6,749.68         | 109,200.00        | 109,200.00          |
| - Other provisions                       | 43,411.07           | 5,715.70          | 0.00             | 10,534.39         | 48,229.76           |
| <b>Total provisions</b>                  | <b>951,944.41</b>   | <b>790,776.35</b> | <b>62,698.83</b> | <b>943,391.57</b> | <b>1,041,860.80</b> |

The remaining provisions concern various individually identifiable risks and uncertain obligations. The use of provisions classified as current is anticipated within the subsequent financial year.

## 13 Other financial and non-financial liabilities

|                      | 31 December<br>2015<br>EUR | 31 December<br>2014<br>EUR |
|----------------------|----------------------------|----------------------------|
| Payroll tax          | 97                         | 66                         |
| Financial leasing    | 12                         | 20                         |
| Credit card payments | 16                         | 16                         |
| Other                | 36                         | 11                         |
|                      | <u>161</u>                 | <u>113</u>                 |

## **14 Reporting on financial instruments**

In the ordinary course of business, the group faces market price and credit risks as well as liquidity risks, which may have an effect on the financial position, cash flows and results of operations.

Market price risk: The risk associated with interest rate changes is considered insignificant because, as a rule, the existing interest modalities for the relevant financing of the Biofrontera Group can be adjusted to market conditions in the short to medium term. There is no cash flow risk for the fixed-rate warrant bonds. No adverse changes in interest payments can occur, as a result of the fixed interest rates. Since the liabilities are not accounted for at fair value, but at amortised cost, there is also no fair value risk.

Credit risk: A credit risk arises for the group if transaction partners cannot meet their obligations within the normal payment deadlines. On the balance sheet, the maximum non-payment risk is represented by the book value of the relevant financial asset. The situation regarding receivables is monitored so that any possible non-payment risks can be identified at an early stage and appropriate steps taken. In the reporting year, no individual value adjustments were made for other financial assets (31.12.2014: EUR 261 thousand); also no individual value adjustments were made to trade receivables in the reporting year (31.12.2014: EUR 0).

Financial instruments evaluated at fair value in the consolidated balance sheet can be classified according to the following valuation hierarchy, which reflects the extent to which the fair value is observable:

Level 1: Fair value valuations using prices listed on active markets (not adjusted) for identical assets or liabilities.

Level 2: Fair value valuations using input data for the asset or liability that are either directly observable (as prices) or indirectly observable (derived from prices), but which do not constitute listed prices pursuant to Level 1.

Level 3: Fair value valuations using input data for the asset or liability that are not based on observable market data (unobservable input data).

Biofrontera only has financial instruments at levels 1 and 2. No reclassifications between level 1 and level 2 were carried out during the 2015 financial year. All the financial assets measured at fair value and listed in the following are classified as level 1. With regard to financial liabilities, the full amount of long-term and short-term financial debt (EUR 12,060 thousand; 31.12.2014: EUR 11,999 thousand) is allocated to level 2. This involves financial debt arising from the two warrant bonds.

Biofrontera records individual valuation allowances as trade receivables and the remaining financial liabilities assigned to the "loans and receivables" category are classified as other operating expenses. The losses from currency conversions from the "loans and receivables" assessment category are

mainly attributable to liabilities from deliveries and services. The net gains and losses include specific value adjustments and currency conversion effects.

The financial assets and liabilities can be broken down into valuation categories with the following book values, and the net gains and losses:

| Financial assets on 31.12.2015 (EUR)                | Fair value       | Book values               |                       |   |                                     |                   | Net gains (+) or losses (-) |
|---|------------------|---------------------------|-----------------------|---|-------------------------------------|-------------------|-----------------------------|
|   |                  | Cash and cash equivalents | Loans and receivables | Financial instruments recognised at fair value in profit or loss (excluding "held for trading") | Financial assets available for sale | TOTAL BOOK VALUES |                             |
| - Financial assets                                  |                  |                           |                       |   |                                     | 0                 | 0                           |
| - Liquid assets                                     | 3,959,207        | 3,959,207                 |                       |   |                                     | 3,959,207         | 104                         |
| - Trade receivables                                 | 894,559          |                           | 894,559               |   |                                     | 894,559           | 0                           |
| - Other short-term financial receivables and assets | 730,440          |                           | 730,440               |   |                                     | 730,440           | 0                           |
| <b>TOTAL</b>  | <b>5,584,206</b> | <b>3,959,207</b>          | <b>1,624,999</b>      | <b>0</b>  | <b>0</b>                            | <b>5,584,206</b>  | <b>104</b>                  |

| Financial liabilities on 31.12.2015 (EUR) | Fair value        | Book values       |   |          |          |                   | Net gains (+) or losses (-) |
|---|-------------------|-------------------|---|----------|----------|-------------------|-----------------------------|
|   |                   | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held for trading") |          |          |                   |                             |
| - Short-term financial debt               | 830,174           | 830,174           |   |          |          | 830,174           | 0                           |
| - Trade payables                          | 1,043,426         | 1,043,426         |   |          |          | 1,043,426         | (21,594)                    |
| - Other short-term financial liabilities  | 37,622            | 37,622            |   |          |          | 37,622            | 0                           |
| - Other long-term financial debt          | 11,229,946        | 11,229,946        |   |          |          | 11,229,946        | 0                           |
| <b>TOTAL</b>                              | <b>13,141,168</b> | <b>13,141,168</b> | <b>0</b>  | <b>0</b> | <b>0</b> | <b>13,141,168</b> | <b>(21,594)</b>             |



| Financial assets on 31.12.2014 (EUR)                | Fair value       | Book values               |                       |   |                                     | TOTAL BOOK VALUES | Net gains (+) or losses (-) |
|---|------------------|---------------------------|-----------------------|---|-------------------------------------|-------------------|-----------------------------|
|   |                  | Cash and cash equivalents | Loans and receivables | Financial instruments recognised at fair value in profit or loss (excluding "held for trading") | Financial assets available for sale |                   |                             |
| - Financial assets                                  |                  |                           |                       |   |                                     | 0                 | 0                           |
| - Liquid assets                                     | 8,509,398        | 8,509,398                 |                       |   |                                     | 8,509,398         | 61                          |
| - Trade receivables                                 | 308,984          |                           | 308,984               |   |                                     | 308,984           | (38)                        |
| - Other short-term financial receivables and assets | 726,791          |                           | 726,791               |   |                                     | 726,791           | (261,099)                   |
| <b>TOTAL</b>  | <b>9,545,173</b> | <b>8,509,398</b>          | <b>1,035,775</b>      | <b>0</b>  | <b>0</b>                            | <b>9,545,173</b>  | <b>(261,076)</b>            |

| Financial liabilities on 31.12.2014 (EUR) | Fair value        | Book values       |   |          |          | TOTAL BOOK VALUES | Net gains (+) or losses (-) |
|---|-------------------|-------------------|---|----------|----------|-------------------|-----------------------------|
|   |                   | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held for trading") |          |          |                   |                             |
| - Short-term financial debt               | 1,224,598         | 1,224,598         |   |          |          | 1,224,598         | 0                           |
| - Trade payables                          | 967,438           | 967,438           |   |          |          | 967,438           | (9,600)                     |
| - Other short-term financial liabilities  | 27,012            | 27,012            |   |          |          | 27,012            | 0                           |
| - Other long-term financial debt          | 10,774,298        | 10,774,298        |   |          |          | 10,774,298        | 0                           |
| <b>TOTAL</b>                              | <b>12,993,346</b> | <b>12,993,346</b> | <b>0</b>  | <b>0</b> | <b>0</b> | <b>12,993,346</b> | <b>(9,600)</b>              |

Liquidity risk: The refinancing of the Biofrontera group companies is generally carried out on a central basis by Biofrontera AG. There is a risk in this regard that the liquidity reserves may be insufficient to fulfil the financial obligations on the due date. In order to cover the liquidity requirements at 31 December 2015, cash and cash equivalents totalling EUR 3,959 thousand (31.12.2014: EUR 8,509

thousand) are available. See the relevant balance sheet notes on (undiscounted) payments from financial debt due in the next years.

## ***Notes on the consolidated statement of comprehensive income of 31 December 2015***

### ***15 Sales revenue***

The Biofrontera Group recognised sales of EUR 4,138 thousand in the 2015 financial year (previous year: EUR 3,096 thousand), corresponding to an increase of 34% compared to the previous year. Down payments of EUR 70 thousand (previous year: 70 thousand) are included in this. Turnover from sales of products in Germany increased by 27% to EUR 3,028 thousand (previous year: EUR 2,379 thousand), sales in other countries rose by 61% to EUR 1,040 thousand (previous year: EUR 647 thousand).

### ***16 Cost of sales, gross profit from sales***

The gross profit from sales improved from EUR 1,979 thousand in the 2014 financial year to EUR 2,902 thousand in the 2015 financial year. The gross margin increased to 70%, compared to 64% in the same period in the previous year.

The cost of sales amounted to EUR 1,236 thousand, and thus 30% of sales (EUR 1,117 thousand and 36%), thus improving relative to the revenue.

The above-average sales development with the European licensing partners had a slightly negative impact on the gross result. Unlike with the margin achieved in Germany and the European countries with direct sales activities, in countries with licensing agreements part of the margin is kept by the licensing partners.

### ***17 Development costs***

The costs for research and development increased by 37%, from EUR 4,534 thousand in the previous year to EUR 6,204 thousand in the 2015 financial year. The investment in research and development to extend the range of indications and obtain approval for Ameluz® in the USA remained almost constant. In addition, a submission fee ("PDUFA fee") of EUR 2,072 thousand was paid for the submission of the approval application to the FDA. This fee is usually waived for small companies for their initial submission. In consultation with the FDA, Biofrontera lodged an application for a waiver of this fee, but this could not be processed on the filing date as the American approval authority, the

FDA, did not have a process for handling such applications. This fee was refunded by the FDA in March 2016.

### **18     *Marketing costs***

The sales costs increased only slightly by 8% to EUR 4,170 thousand compared to the previous year (EUR 3,847 thousand), despite the build-up of a sales structure in Spain. The sales costs include the costs of our own field sales team in Germany and Spain, as well as marketing expenses. They also include expenses for marketing preparations in the USA.

### **19     *Administrative costs***

The administrative costs decreased compared to the same period in the previous year by EUR 485 thousand to EUR 2,759 thousand, primarily due to lower financing costs. Financing costs shown under administrative costs include primarily consul-tancy and placement fees in connection with support for the search of investors.

### **20     *Financial result***

The financial result consists primarily of the interest payable for the 2009/2017 warrant bond (EUR 439 thousand, previous year: EUR 447 thousand) and for the 2011/2016 warrant bond placed in 2011 (EUR 727 thousand, previous year: EUR 702 thousand), calculated using the effective interest method. The above mentioned interest expenses of EUR 439 thousand (previous year: 447 thousand) for the warrant bond 2009/2017 includes the opposite effect of EUR 193 thousand (previous year: EUR 156 thousand) resulting from the repurchase on 28 February 2014. The interest payment for the 2014 calendar year for Warrant Bonds I and II was made in January 2015. The payment of interest on Warrant Bond I for the 2015 calendar year was made in the end of December 2015, and the payment of interest on Warrant Bond II for 2015 was made in the beginning of January 2016.

### **21     *Other income (expenses), net***

In the 2015 financial year, other operational income increased slightly, by EUR 33 thousand to EUR 219 thousand. This is largely attributable to the reversal of provisions amounting to EUR 63 thousand (31.12.2014: EUR 72 thousand). Other operating expenses decreased, compared to the previous year, from EUR 280 thousand to EUR 32 thousand. This involved in particular a specific value adjustment amounting to EUR 261 thousand made in the previous financial year, relating to a short-term loan made available to a development partner. No specific valuation allowances were made in the 2015 financial year.

## 22 Earnings per share (EPS)

Earnings per share are calculated on the basis of the net loss for the year of the Biofrontera Group and the average ordinary shares in circulation in the financial year, in accordance with IAS 33.

|  | 31.12.2015    | 31.12.2014    |
|--|---------------|---------------|
| Number of weighted ordinary shares in circulation (on average) | 23.156.343,32 | 21,757,826.65 |
| Net loss for the year in EUR                                   | (11,203)      | (10,721)      |
| Undiluted earnings per share in EUR                            | (0.48)        | (0.49)        |

When calculating diluted earnings per share for the 2014 and 2015 financial years, the warrant bond already issued in 2009 (2009/2017), with a total nominal value of EUR 4,930 thousand and giving bondholders the right to acquire 246,515 shares at a price of EUR 5.00 each, as well as the warrant bond issued in 2011 (2011/2016), with a total nominal value of EUR 8,715 thousand and giving bondholders the right to acquire 871,500 shares at a price of EUR 3.00 each, generally have been taken into account. As the group achieved negative annual results in the 2014 and 2015 financial years, no diluted earnings per share were reported, as the conversion or subscription rights for the periods shown counteracted any dilution.

## 23 Additional information regarding the consolidated statement of comprehensive income

In the income statement, there was no "other comprehensive income (OCI)" to report on 31 December 2014 and 31 December 2015, as there were no relevant facts or circumstances. Therefore, the net loss equates to the total profit or loss for the period.

### Material costs

The cost of materials included in the cost of sales amounted to EUR 947 thousand (previous year: EUR 841 thousand) for the 2015 financial year.

## Depreciation

The depreciation of tangible and amortization of intangible assets of EUR 812 thousand in the 2015 financial year and of EUR 811 thousand in the previous year is included in the following items in the statement of comprehensive income:

|   | 31.12.2015 | 31.12.2014 |
|---|------------|------------|
|   | kEUR       | kEUR       |
| Research and development costs                        | 691        | 702        |
| General administrative costs                          | 113        | 105        |
| Cost of sales   | 8          | 4          |
| <b>Depreciation of tangible and intangible assets</b> | <b>812</b> | <b>811</b> |

## Personnel costs

|                         | 31.12.2015   | 31.12.2014   |
|-------------------------|--------------|--------------|
|                         | kEUR         | kEUR         |
| Salaries and wages      | 3,591        | 3,024        |
| Social security charges | 482          | 401          |
| <b>Total</b>            | <b>4,073</b> | <b>3,425</b> |

The personnel costs include contribution-related expenses for pension schemes amounting to EUR 34 thousand (previous year: EUR 41 thousand).

Earnings before income taxes correspond to earnings for the entire period. There are no expenses and income not affecting net income.

## 24 Staff

On average, the Biofrontera Group employed 46 people in the 2015 financial year (previous year: 37 employees).

## 25 Other information

### Operating and finance leases

The group companies lease administrative and research facilities, as well as vehicles and equipment, under operating lease contracts. The future minimum commitments relating to leases are as follows:

|                                     | 2015     | 2014    | 2015              | 2014    | 2015      | 2014 |
|-------------------------------------|----------|---------|-------------------|---------|-----------|------|
|                                     | ≤ 1 year |         | 1 year to 5 years |         | > 5 years |      |
| <u>Operating leasing agreements</u> |          |         |                   |         |           |      |
| Leases for business premises        | 424,277  | 142,981 | 2,156,013         | 512,482 | 1,619,895 | 0    |
| Leases for cars                     | 144,693  | 147,703 | 177,518           | 150,317 | 0         | 0    |
| Operating and business equipment    | 17,789   | 16,019  | 35,267            | 46,775  | 0         | 0    |

Lease-related expenses for the reporting period amounted to EUR 176 thousand (previous year: EUR 191 thousand).

On the balance sheet date, there was a finance lease for a server leased by Biofrontera AG with a book value of EUR 12 thousand (31.12.2014: EUR 20 thousand). The contract has a minimum term of 60 months to 31 July 2017. Biofrontera AG is obliged to purchase the leased asset from the lessor for a fixed residual value of EUR 2 thousand if the lessor exercises its option to sell. In the reporting year, minimum lease payments of EUR 11 thousand were recorded as expenses (previous year: EUR 11 thousand).

On the balance sheet date of 31 December 2015, the present value of the sum of future minimum lease payments can be reconciled to their present values as follows:

| All figures in kEUR    | Minimum leasing payments | Discounting | Present value |
|------------------------|--------------------------|-------------|---------------|
| Up to 1 year:          | 11                       | 3           | 8             |
| Between 2 and 5 years: | 7                        | 2           | 4             |
| More than 5 years:     | 0                        | 0           | 0             |

## 26 Notes to the cash flow statement

The cash flow statement is presented pursuant to IAS 7. The net loss is adjusted for effects of non-cash transactions, deferrals or accruals of past or future operational deposits or disbursements, and income and expense items attributable to investment or financing activities.

In the consolidated cash flow statement, cash and cash equivalents include cash-in-hand, cheques, bank deposits and money deposits with a maturity of up to three months. Current account liabilities are incorporated into the cash fund where applicable.

The interest payments made amounted to EUR 1,225 thousand (2014: EUR 454 thousand). The change resulted from both interest payments made in the reporting year for Warrant Bond I being 1 January 2015 on the one hand, and interest payment for the reporting year made on 31 Dec 2015. The interest payments received amounted to EUR 184 thousand (2014: EUR 143 thousand) which comprised of interest payments received for the Option Bond I held on our own account and from interest pay-ments received from financial investments.

## **27 Members of the Management Board**

Professor Hermann Lübbert was Chairman of the Management Board in the reporting period. The Chairman of the Management Board holds a professorship at the University of Bochum in Germany. His management contract was extended by a further five years, to 31 October 2020, as a result of a decision made by the Supervisory Board on 27 March 2015.

Thomas Schaffer is the Chief Financial Officer. The management contract with Thomas Schaffer was extended by five years, to 30 November 2020, as a result of a decision made by the Supervisory Board on 9 April 2015.

As a result of a decision made by the Supervisory Board made on 9 July 2015, Christoph Dünwald was appointed as an additional member of the management of Biofrontera AG with effect from 16 November 2015. On the board he is responsible for the area of Sales and Marketing.

The remuneration of the Management Board members consists of a fixed salary that is paid in twelve equal monthly instalments. In addition, there is an annual, performance-based bonus for the directors, as well as a long-term remuneration component consisting of participation in the company's share option programme. Company cars are also available to the directors for business and private use.

The remuneration for members of the Management Board in the period 1 January until 31 December 2015 consisted of a salary and a bonus and share options. The total remuneration for Management Board members in the reporting period, including the value of share options at the time they were granted, amounted to EUR 866 thousand (previous year: EUR 807 thousand). This was divided as follows

|                           |                 |                          |  |
|---------------------------|-----------------|--------------------------|--|
| Prof. Dr. Hermann Lübbert | - Salary/bonus  |                          | EUR 405 thousand<br>(31.12.14: EUR 405 thousand) |
|                           | - Share options | 151,850 (fair value when |  |

|  |  |   |  |
|--|--|---|--|
|  |  | granted: EUR 167,236)<br>previous year 151,850,<br>(fair value when granted:<br>EUR 167,236), of which<br>granted in 2015: 0 (2014:<br>16,850). |  |
|--|--|---|--|

|                 |                 |  |
|-----------------|-----------------|--|
| Thomas Schaffer | - Salary/bonus  | EUR 231 thousand (31.12.14: EUR 202 thousand)  |
|                 | - Share options | 35,000 (fair value when granted EUR 32,650) previous year 35,000, (fair value when granted: EUR 32,650)), of which granted in 2015: 0 (2014: 20,000) |

|                   |                |                                   |
|-------------------|----------------|-----------------------------------|
| Christoph Dünwald | - Salary/bonus | EUR 29 thousand (31.12.14: EUR 0) |
|-------------------|----------------|-----------------------------------|

All salaries/bonuses are classified as short-term employee benefits as defined in IAS 24.17 (a).

## **28 Members of the Supervisory Board**

As a result of the resolution passed by the Annual General Meeting held on 10 May 2011, the Supervisory Board has consisted of the following members since 10 May 2011, with these members acting as representatives of the shareholders:

Jürgen Baumann Chairperson of the Supervisory Board, expert in the field of sales and marketing of pharma-ceuticals, resident in Monheim, Germany

Prof. Bernd Wetzel Deputy chair of the Supervisory Board, advisor, resident in Biberach/Riss, Germany

Dr. Ulrich Granzer Owner and managing director of Ulrich Granzer Regulatory Consulting & Services, resident in Munich, Germany

Ulrike Kluge Managing partner of klugeconcepts GmbH, Cologne; resident in Cologne, Germany



Andreas Fritsch Member of the Management Board, Xolaris Service Kapitalverwaltungs AG, Munich; Managing Director, Unternehmensberatung Fritsch, Seefeld, resident in Seefeld near Munich, Germany

Alfred Neimke Managing Director of Kopernikus AG in Zurich, Switzerland; CFO of MAN Oil in Zug, Switzerland; resident in Zurich, Switzerland, Director Prudent Investment Fund, Luxembourg

The members of the Supervisory Board had the following other supervisory board positions and positions on comparable domestic and foreign boards during the reporting period:

Alfred Neimke Administrative Board of DERPHARM AG in Zurich, Switzerland

In the 2015 financial year, the remuneration of the Supervisory Board members amounted to EUR 113 thousand (previous year: EUR 113 thousand). The remuneration is classified as short-term employee benefits as defined in IAS 24.17(a).

During the reporting period, the company availed itself of additional advisory services from a member of the Supervisory Board, Dr Ulrich Granzer. These services went beyond the scope of normal Supervisory Board activities. Dr Granzer assisted the company with key issues relating to the preparation of the applications for approval submitted to the supervisory authorities in Europe and the USA. During the course of the 2015 financial year, advisory services amounting to EUR 62 thousand (previous year: EUR 98 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 0 thousand on 31.12.2015 (31.12.2014: EUR 6 thousand). The amounts stated here do not include statutory VAT at the current rate of 19%. The underlying consultancy contract was approved in consideration of the statutory provisions.

## **29 Related party disclosures**

In the 2015 financial year, there were no reportable transactions or relationships with related parties, beyond the facts and circumstances stated in subsections 27 and 28. The group of related persons and entities is limited to those referred to therein.

In the context of the underlying holding structure, Biofrontera AG is responsible for the administrative and management tasks. Biofrontera AG is also responsible for the financing of the currently still loss-making areas of business, as it is a listed company and therefore has the best access to the capital markets.

The funds made available to the subsidiaries as loans bear interest at market rates and are, if necessary, furnished with a subordination clause.

In light of the close cooperation between the subsidiaries, internal offsetting is applied, which is reviewed and adjusted to requirements on an annual basis.

### **30 Corporate governance statement pursuant to § 289a of the German Commercial Code (HGB), including the statement required by § 161 of the German Stock Corporation Act (AktG) on the German Corporate Governance Code**

The Management Board and Supervisory Board of Biofrontera AG have provided the corporate governance statement as required pursuant to § 289a HGB, including the statement required pursuant to § 161 AktG, and have made these available to shareholders on the Biofrontera AG website.

### **31 Fees and services of the auditor**

The total fee invoiced by the auditor Warth & Klein Grant Thornton AG for the 2015 financial year consists of the following:

|                                  | 2015       | 2014       |
|----------------------------------|------------|------------|
|                                  | kEUR       | kEUR       |
| Auditing services                | 122        | 105        |
| (of which for the previous year) | (16)       | (14)       |
| Other certification services     | 43         | 33         |
| Tax advisory services            | 0          | 0          |
| Other services                   | 0          | 7          |
|                                  | <b>165</b> | <b>145</b> |

### **32 Events occurring after the balance sheet date**

In January 2016, the FDA informed the company that the midcycle review as part of the approval process in the US had been completed; the FDA thus has no further questions for the company in this regard.

On 28 January 2016, the company announced that the preliminary results of the phase III trial for the treatment of basal cell carcinoma (BCC) were available. In the clinical study, the efficacy and safety of Ameluz® were compared with that of Metvix®. The study included non-aggressive superficial and nodular BCCs with a thickness of up to 2 mm. Ameluz® achieved complete destruction of all BCCs in 93.4% of patients, which compared well with the figure of 91.8% achieved with Metvix®.

On 16 February 2016, the company announced that a capital increase had been carried out, with exclusion of subscription rights, by issuing 2,357,384 shares to selected institutional investors in order to secure further corporate financing. The issue price for the new shares was EUR 1.90. The capital increase was registered in the trade register on 26.02.2016. Net proceeds were EUR 4.4 million.

A submission fee ("PDUFA fee") of EUR 2,072 thousand was paid to the FDA for the submission of the approval application for Biofrontera's drug Ameluz®. This fee is usually waived for small companies for their initial submission. In consultation with the FDA, an application for remission of the fee was lodged by Biofrontera, but this could not be processed on the filing date as the American approval authority FDA did not yet have a process for handling such applications. A letter issued by the FDA on 14.01.2016 stated that the request for reimbursement of the PDUFA had been granted. The repayment was made by cheque in March 2016 and was credited as EUR 2,140 thousand after being paid into the bank account.

On 24 March 2016 the company announced an agreement with an institutional investor that has agreed to acquire up to 2.0 million New Shares at an issue price of EUR 2.00 in a yet to be performed capital increase. The capital increase will have a maximum volume of EUR 5.0 million.

On 29 March 2016 the company announced that the Management Board, with the approval of the Supervisory Board, has decided to increase the share capital by up to 2,499,999 New Shares by way of a rights issue. Shareholders shall be granted their statutory subscriptions rights such that up to 2,421,549 New Shares will be offered at a ratio of 23:2 within a subscription period of two weeks according to the execution of subscription rights at an issue price of EUR 2.00. The statutory subscription right was excluded regarding 78,450 supernumerary New Shares. The shareholders are furthermore offered an "Additional Subscription" right. I.e. all shareholders executing subscription rights may apply to subscribe to unsubscribed shares plus the supernumerary shares at the Subscription Price.

No further events subject to mandatory reporting occurred after the balance sheet date.

Leverkusen, Germany, 07 April 2016

Prof. Dr. Hermann Lübbert

Thomas Schaffer

Christoph Dünwald

Chairman of the Management Board

Chief Financial Officer

Head of Sales and Marketing

## **F.2.7) Auditor's Report**

The following is a translation of the German language original auditors' report:

We have audited the consolidated financial statements prepared by Biofrontera AG – comprising a consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income for the period, consolidated statement of changes in equity, consolidated statement of cash flows and notes to the consolidated financial statements – and the combined management report of Biofrontera AG and the group for the financial year from January 1, 2015 to December 31, 2015. The preparation of the consolidated financial statements and the combined management report in accordance with IFRS, as adopted by the EU, and with the additional requirements of the German commercial law pursuant to section 315a paragraph 1 HGB are the responsibility of the parent company's management. Our responsibility is to express an opinion on the consolidated financial statements and the combined management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with paragraph 317 HGB and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer (Institute of Public Auditors in Germany) (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the combined management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the combined management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements and the combined management report. We believe that our audit provides a reasonable basis for our opinion. Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements of Biofrontera AG for the financial year from January 1, 2015 to December 31, 2015 comply with IFRS, as adopted by the EU, and the additional requirements of the German commercial law pursuant to § 315a Abs. 1 HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The combined management report of Biofrontera AG and the group is consistent with the consolidated financial statements and as a whole provides a

suitable view of the Group's position and suitable presents the opportunities and risks of future development.

Without qualifying this opinion we refer to the explanations in the combined management re-port. In particular the Management Board clarifies under section "Opportunities and risks relating to future business performance", "Liquidity risk" that further capital measures are necessary until break-even is reached. Particularly to obtain approval in the USA, the planned investments into marketing in the US and to meet obligations from the issued option bond further capital measures during the fiscal year 2016 will be necessary. On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realised, this could constitute a threat to the company's continued existence.

Düsseldorf, April 7, 2015

Warth & Klein Grant Thornton AG

Wirtschaftsprüfungsgesellschaft

Dr. Jens Brune

Wirtschaftsprüfer

(German Public Auditor)

Renate Hermsdorf

Wirtschaftsprüferin

(German Public Auditor)

## **F.3 Unaudited half-year IFRS group report H1 2017**

### **F.3.1) Consolidated interim management report**

#### ***Group strategy***

The strategic objective of the Biofrontera Group is its global positioning as a pharmaceuticals company specialising in der-matology. Focus areas of activity include further expanding our products' sales, especially in the USA, as well as extending the approvals of Ameluz® to include further indications to enhance its market potential. Biofrontera enjoys a worldwide positioning unlike any other company, and aims to leverage the potential of photodynamic therapy within dermatology.

Biofrontera is the first smaller German company to receive centralised approval for a completely independently developed medication, which was initially marketed under the Ameluz® brand to treat actinic keratosis (AK), and is meanwhile also marketed for field cancerisation and basal cell carcinoma (BCC). Since its launch in February 2012, Biofrontera has been deploying its own sales force to market Ameluz® among dermatologists in Germany, as well as in Spain since March 2015. Ameluz® is also available in the United Kingdom, although Biofrontera will not actively market it there until from the second half of 2017, as the expansion of the indication in January 2017 to include basal cell carcinoma (BCC) represents an important precondition for sales in the UK market. Licensing partners distribute the drug in other European Union countries, as well as in Israel and Switzerland. Ameluz® has been available in the US market since October 2016 after the FDA granted its approval in May 2016. The subsidiary Biofrontera Inc. is responsible for sales in the USA.

The European Commission's first approval of Ameluz® was issued in December 2011 for mild and moderate actinic keratosis on the face and scalp. Biofrontera has since been endeavouring to expand the range of indications. In September 2016, the European Commission expanded the approval of Ameluz® to the treatment of field cancerisation. As the skin-rejuvenating effects of Ameluz® were also measured in the specially conducted trial on field-directed treatment, these results have also been included in the approved new product information. In 2014, Biofrontera started with the expansion of the indication for Ameluz® for the treatment of basal cell carcinoma (BCC). The Phase III clinical trial was conducted in direct comparison with competitor product Metvix®. The trial's results show the very high clinical efficacy and low recurrence rates of Ameluz® in the BCC indication, too. The competitive position of Ameluz® has improved considerably thanks to EU approval in January 2017 for the treatment of superficial and modular BCCs. Until then, the competitor product of relevance for Europe, Metvix®, had enjoyed a major competitive advantage against Ameluz®, despite statistically significant inferiority in the treatment of mild and moderate actinic keratosis, as well as in the restriction of its approval to just mild keratosis, and as a second therapy choice with its approval to

treat BCCs. In 2016, Biofrontera conducted a Phase III clinical trial on so-called “daylight PDT”. With the results that were generated, approval for this treatment in the EU was applied for in June 2017. The direct comparison with the competitor product Metvix® that was also conducted in this trial further documented the outstanding efficacy of Ameluz®. Three major problem areas of PDT can be eliminated by harnessing daylight PDT, with patients spending two hours outdoors 30 minutes after applying Ameluz®, utilising daylight as a replacement for illumination with a special lamp. Firstly, the treatment is almost painless. Secondly, almost the full effort of the treatment is not incurred in the specific physician's practice. Thirdly, it thereby eliminates problems of reimbursement in Germany, as the medication no longer forms part of a procedure evaluated by the joint German government committee. For this reason, Biofrontera hopes that PDT will achieve a breakthrough with AK patients, who were previously treated with self-applied medications for reasons of cost reimbursement or to make work in physicians' practices easier.

In May 2016, the US Food and Drug Administration (FDA) issued unrestricted US approval for Ameluz® in combination with the BF-RhodoLED® lamp for the lesion-directed and field-directed PDT (photodynamic therapy) of actinic keratosis without any post-approval obligations. In early July 2015, the company had submitted a new drug application (NDA) to the FDA. The world's largest healthcare market was consequently open to Biofrontera. Biofrontera established a US subsidiary, Biofrontera Inc., based in Wakefield, Massachusetts, for marketing within the USA. All requisite structures were created for the market launch in the USA in October 2016. Ameluz® was produced for the US market in Switzerland, and imported into the USA. To avoid the Biofrontera Group's destiny being dependent on a PDT lamp manufacturer passing an FDA inspection, production of the lamp was transferred to the company's own management at Biofrontera's headquarters in Leverkusen. The company passed the FDA inspection that fell due during the approvals process without any problems. Biofrontera meanwhile employs around 50 staff in, and related to, sales in the USA. The issuing of an individual J-code for Ameluz®, which is expected for January 2018, will comprise an important milestone for sales in the USA. Invoicing for physicians' practices will become easier and more predictable with this specific J-code for Ameluz®.

For the USA, too, Biofrontera is aiming for the approval of Ameluz® for the treatment of basal cell carcinoma. This approval should open up a further market for Ameluz® and document its superiority compared to the competitor product Levulan Kerastick®, which was already approved in the USA before Ameluz®. Levulan® is only approved for the lesion-directed therapy of AK on the face and scalp. In July 2017, Biofrontera coordinated the approval path for Ameluz® with the FDA to treat basal cell carcinoma, for which it received written confirmation in August. The FDA is expecting only

a single pivotal trial where Ameluz® is compared with a placebo. Biofrontera is currently preparing the submission of the IND (Investigational New Drug).

Biofrontera has thereby established itself as an internationally operating specialist pharmaceutical company, and is in the process of optimising its market opportunities and sales revenues. The Group strategy focuses in the short term on further expanding business in Europe and the USA, as well as on the indication expansions for daylight PDT in Europe and for basal cell carcinoma in the USA.

For Biofrontera, the first half of 2017 was characterised by the establishment of sales structures in the USA. Initial difficulties in reimbursement were resolved, but reimbursement will remain time-consuming and costly for the physician, thereby negatively affecting sales until a specific J-code is allocated to Ameluz®, which will simplify billing. The J-code is expected to be allocated in early January 2018. In the USA, 2017 is a year of preparation overall, whose various issues should be resolved by early 2018 when sales conditions are optimised with the company's own billing code and other sales-promoting structures.

## ***Products***

### ***Ameluz®***

Ameluz® 78 mg/g Gel (“love the light” – development name: BF-200 ALA) received a first centralised European approval for the treatment of mild and moderate actinic keratoses on the face and scalp in December 2011. Its superiority compared to its direct competitor product Metvix® was demonstrated for this indication during Phase III development. Actinic keratoses are superficial forms of skin cancer, with the risk that they spread to deeper layers of the skin, consequently transitioning to potentially fatal squamous carcinoma. The combination of Ameluz® with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European Medicines Agency (EMA) explicitly mentions the significant superiority of Ameluz® compared with the parallel-tested comparator product Metvix® in the removal of all of a patient's keratoses.

In the Phase III approval trials, Ameluz® showed excellent healing rates and demonstrated marked and statistically significant superiority compared to the approved comparator product tested in parallel. In the first Phase III trial in which the drug was combined with an LED lamp, in 87 % of patients treated with Ameluz®, all keratoses were completely removed, and in terms of the number of individual keratosis lesions, as many as 96 % were completely eradicated (all the values stated are ITT



– intent to treat – values). In the second Phase III approval trial, the effectiveness of Ameluz® was tested in comparison with the approved standard medication. The results of the trial provided evidence that Ameluz® was clearly superior to the competitor product already available in Europe at the time. Based on the average for all lamps, Ameluz® resulted in the complete healing of actinic keratoses in 78 % of patients, whereas the approved competitor product achieved a healing rate of only 64 %. With LED lamps, the healing rates increased to 85 % for Ameluz® and 68 % for the competitor product. The side effect profile was comparable for both products.

As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which also required the entire company to be certified pursuant to the ISO 9001 and ISO 13485 standards. In preparation for the approval in the USA, a Phase III trial was performed with a combination of Ameluz® and BF-RhodoLED®. With this combination, 91 % of patients were cleared from all keratoses, and in terms of the number of individual lesions, 94 % were completely removed after treatment (99.1 % of mild and 91.7 % of moderate lesions).

The patients treated in the field therapy trial were observed by the trial doctors over the course of a year after the final treatment. Here, the long-term nature of the pharmaceutical effect of Ameluz® was analysed in terms of effectiveness, safety and cosmetic result. A total of 63.3 % of the patients who were initially completely asymptomatic were still asymptomatic a year later. The long-term effectiveness achieved applying field-directed therapy consequently lies in the data range already observed in previous long-term studies on lesion-directed PDT with Ameluz®, which is significantly higher than that of all alternative treatments.

As it has been widely reported in the specialist literature that PDT enjoys pronounced skin-rejuvenating properties, particularly in the case of sun-damaged skin, and in this trial – for the first time in a Phase III trial of PDT anywhere in the world – the drug was applied over large surface areas (field-directed therapy), the cosmetic result was measured without taking the disappearance of the keratotic lesions into account. All the parameters that were tested improved significantly as a result of the treatment. An improvement in the skin appearance of patients treated with Ameluz® observed immediately after PDT continued to develop during the follow-up period. Before PDT, only 14.8 % of patients had no impairments to the surface of the skin. Whereas twelve weeks after the last PDT, 63 % of patients were already free of such cosmetic damage, this percentage rose after a year to 72.2 %. Similar results were also observed for pigment disorders. Before PDT, hyperpigmentation occurred in 59.3 % and hypopigmentation in 46.3 % of patients, with 48.1 % exhibiting irregular pigmentation.

Twelve weeks after Ameluz® PDT, these rates initially fell to 42.6 %, 29.6 % and 29.6 %, and decreased over the course of a year to 24.1 %, 11.1 % and 18.5 %. These results clearly show that the skin rejuvenation effect achieved using photodynamic therapy with Ameluz® is long-lasting, and the repair processes triggered by the therapy remain active for at least 12 months.

The results on skin-appearance improvement have meanwhile been included in the official product information in the EU.

Both of the Phase I trials required by the American approval authority, the FDA, were also already completed in 2015. These clinical trials were initiated with a total of approximately 240 patients or test persons to add the safety data required for registration in the USA to the European approval package for Ameluz®. Specifically, one of the trials was a sensitisation study, which determines the potential of Ameluz® to trigger allergies, and the other was a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz®, aminolevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, in other words, the application of a complete tube onto the defective skin. No safety concerns were identified in either of the trials.

The overall advantages of Ameluz® in terms of effectiveness, handling, user-friendliness and skin rejuvenation effects, as well as the high healing rates of PDT in the treatment of actinic keratoses, will increasingly bring this treatment option to the attention of dermatologists over the next few years. This will be helped by the recent expansion of the range of indications to include basal cell carcinoma, as the vast majority of PDT treatments are conducted for this indication, particularly in the UK and Spain. Biofrontera has conducted a Phase III trial for the extension of the European approval to include the BCC indication. BCCs are the most common invasive tumours that affect humans and account for approximately 50 % to 80 % of all skin cancers. Around 30 % of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in the USA but this can lead to clearly visible scarring, whereas treatment with PDT, which is an alternative particularly in the treatment of thin BCCs, gives rise to excellent cosmetic results. In the pivotal Phase III trial, a total of 278 patients were treated. This trial was under the clinical management of Prof. Colin Morton (UK) and Prof. Markus Szeimies (Germany) and was conducted at 27 clinical trial centres in England and Germany. Patient recruitment for the trial, which was conducted in direct comparison with the competitor product Metvix®, was completed in May 2015 and the last patient completed the trial in November 2015. The trial's results have been available since January 2016. The results confirm the company's positive expectations. In the clinical trial, the effectiveness and safety of Ameluz® were

compared with that of Metvix®, a drug already approved in the EU for the treatment of BCC. Non-aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved the complete elimination of all BCCs from the patient in 93.4 % of cases compared to 91.8 % with Metvix®. Greater differences occurred with thicker BCCs. For example, 89.3 % of nodular carcinomas were removed entirely with Ameluz®, and just 78.6 % with Metvix®. Recurrence rates after 12 months were higher for Metvix® than for Ameluz®.

Based on the results of this Phase III trial, Biofrontera applied to the European regulator in July 2016 for approval to treat BCC with Ameluz®, which the European Commission issued in January 2017.

In July 2017, Biofrontera reached agreement with the US FDA on the approval procedure for BCC in the USA, for which it received written confirmation from the FDA in August. According to the agreed development plan, the approval expansion for superficial basal cell carcinoma can be applied for based on a single supplementary Phase III trial conducted in the USA, comparing Ameluz® with a placebo. The FDA expects a combined evaluation of the clinical and histological healing rates from Biofrontera. The clinical investigation of patients with different ethnic backgrounds or children is not required. Due to the high efficacy of Ameluz® (approximately 95 % healing rate in superficial basal cell carcinomas in the European trial) and the low recurrence rates (5.4 % after 12 months), the requisite placebo-controlled trial can be conducted with relatively few patients, thereby minimising the time required and costs incurred. As far as safety information and long-term data are concerned, the FDA has accepted the existing European trial for review. The application for an Investigational New Drug (IND) that is required for this purpose is to be submitted to the FDA by autumn 2017. After a special review of the trial memorandum to which the FDA has committed itself, we will be able to estimate the further costs and timing of the approval process.

Between June and September 2016, patients were treated as part of a Phase III clinical trial, in which the efficacy and safety of Ameluz® in combination with PDT in daylight were measured in comparison with Metvix® in treating mild and moderate actinic keratosis. This comparative, randomised, observer-blind multicentre trial was conducted at seven trial centres in Spain and Germany with a total of 52 patients. Each patient had between 3 and 9 mild to moderate actinic keratoses (Olsen grades 1 and 2) on each of two comparable treatment areas on the face and/or scalp. The selection medication for the respective treatment side was random. The last patient completed the clinical phase of the trial in December 2016. The trial's results prove the non-inferiority (relevant from a regulatory standpoint) of Ameluz® compared with Metvix®. All relevant secondary endpoints produced comparable or higher cure rates for Ameluz® in relation to Metvix®.

Daylight PDT comprises a favourable and pain-free alternative to PDT treatment with a special lamp. Here, the topically applied medication is activated by natural or artificial daylight. The clinical endpoint of the trial is the total cure rate for all lesions on each treatment side 12 weeks after treatment. The secondary clinical endpoint comprises determining medication safety and additional efficacy parameters. The trial was jointly directed by Dr. Susana Puig, Research Director at the Biomedical Research Institute August Pi i Sunyer and professor at the University of Barcelona as the main research director in Spain, and Prof. Thomas Dirschka, founder of the private dermatology practice CentroDerm as the main research director in Deutschland. As treatment in daylight PDT does not need to be administered at a physician's practice it competes directly with the self-applied topical medications that are much more widely disseminated in Europe, and is consequently also reimbursed by statutory healthcare funds in Germany.

Biofrontera applied for approval for daylight PDT in May 2017 and anticipates initial feedback from the European regulator by the end of 2017.

#### **BF-RhodoLED®**

BF-RhodoLED® is a lamp designed for PDT, and utilises LEDs emitting red light at a wavelength of approximately 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. In the European version, light energy and fan power settings can be adjusted during a PDT treatment session to reduce any pain caused by the treatment. No other lamp on the market offers comparable power and flexibility. BF-RhodoLED® has been CE-certified since November 2012 and is distributed throughout the EU. For marketing in the USA, the final assembly of the PDT lamp was relocated to Biofrontera's premises, and Biofrontera itself has been performing final assembly since July 2016. From the FDA's perspective, Biofrontera is consequently the manufacturer responsible for the product.

#### **Belixos®**

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated skin. The biocolloid technology patented by Biofrontera, which optimises epidermal penetration, makes the products unique: pure plant biocolloids are combined with medicinal plant extracts to form an extraordinary combination of active substances with proven depth penetration, drawing together the

best of nature and science. The typical deep yellow colour of some Belixos® products is an unmistakable quality characteristic deriving from the traditional medicinal plant extract from the roots of Mahonia aquifolium. Belixos® products use only natural active substance extracts with clinically proven effects.

Belixos® Creme rapidly and reliably soothes itching and is the ideal basic treatment for inflamed, reddened and flaky skin. It soothes the skin, reduces scratching and allows the skin to regenerate naturally. Belixos® Creme, which has been available since 2009, has consequently proved particularly useful as an effective basic treatment for atopic dermatitis and psoriasis.

Belixos® body cream has been created in response to significant demand for larger packaging of the Belixos® cream, and is ideal for application on larger body areas.

Belixos® Liquid is an innovative scalp tonic with a practical pipette for dosing, which soothes scalps irritated by psoriasis or eczema, for example, and restores their balance. For itchy and flaky scalps, a combination of anti-inflammatory mahonia, moisturising oats, irritation-relieving panthenol and a special zinc PCA complex is used.

Belixos® Gel is specially cosmetically formulated for skin that is inflamed, reddened and prone to skin blemishes, providing an effective treatment for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin and regulates sebum.

Belixos® to go is a roll-on acute care product available since July 2016, which utilises a highly precise stainless-steel ball to deliver care for itchy skin, insect bites and minor skin irritations. Anti-inflammatory mahonia, calming beach chamomile and the anti-irritative Sepicalm S Complex lead to faster relief for irritations and inflammation.

Belixos® Protect is ideal for individuals with skin suffering overexposure to UV radiation, and the only Belixos® product that does not include Mahonia extract and consequently does not have a yellow colour. It is a modern daily care product specially developed for sun-damaged skin. With its skin-regenerative properties deriving from highly concentrated niacinamide, it leaves skin smooth and helps repair damaged skin. It also contains UVA and UVB broad spectrum protection with SPF15 to

protect against further light-induced skin ageing and hyperpigmentation. This light protection factor is optimal for daily use, without being a specialised sunscreen for application on the beach or ski track.

Belixos® products are manufactured according to stringent quality and environmental regulations. They are free of paraffins, parabens, ethyl alcohol, animal products, dyes and fragrances that may have negative dermatological effects. Its skin compatibility was certified as “very good” by the independent Dermatest Institute. Belixos® is obtainable in selected pharmacies, dermatological institutes and from the online retailer Amazon.

### ***Sales and markets***

Actinic keratosis (AK) is a disease that is most frequent in the Caucasian, light-skin population. It has been estimated that AK affects up to 10 % of the entire Caucasian population worldwide. Only a fraction of these patients is currently being treated. Several drugs are available, but patients may also be treated with cryotherapy (freezing) or simple curettage. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this occurs to the relevant lesions within two years on average. Actinic keratosis is categorised as a tumour requiring mandatory treatment. At present, actinic keratoses are treated applying a wide range of methods. Lesions are treated, sometimes for weeks, with topical creams, which are often ineffective, or the diseased skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often leads to scar formation or permanent pigment disorders, besides offering little efficacy. The fact that doctors are taking actinic keratosis increasingly seriously is illustrated by the fact that actinic keratosis has been recognised in Germany as an occupational disease since summer 2013. Since then, occupational insurance associations have been obligated to cover the treatment costs of patients who have mainly worked outdoors for a long time and who fulfil certain criteria, for the duration of such patients' lives. The related payment modalities were set in March 2016, with PDT being included as a treatment method. PDT can be used to treat actinic keratosis in the context of an occupational disease, and can be billed accordingly.

In the EU, the number of destructive treatments (cryotherapy or curettage) is not available, since they are not covered in databases, but it is assumed that only a minor percentage of the patients are treated by physical manipulations. Most patients are treated with various available medications, which can be assessed through the number of prescriptions. All over Europe, there are more than 2 million prescriptions per year, and their number has been growing by about 10 % annually in recent years. The company estimates that about 33 % of all prescriptions for AK drugs occur in Germany, followed by

the UK (15 %), France (12 %), Italy (12 %), Spain (10 %) and Switzerland (3 %). The remaining European countries are responsible for 15 % of prescriptions.

The total AK drugs market in Europe is currently around EUR 120 million, with about EUR 22 million for PDT drugs. Most of the prescriptions in Europe are for self-applied topical drugs, for which the driver seems to be the minimal amount of time required by the doctor. Almost half of all prescriptions go to Solaraze (45 %), which according to a meta-analysis of clinical trials by Vector and Tolley (2014) has a comparably low efficacy. This reinforces the assumption that another driver, such as time spent in consultation, determines treatment selection besides efficacy. Solaraze prescriptions are followed by Aldara (18 %), Picato (16 %) and Actikerall (7 %).

Only a minor part of all prescriptions, about 120,000 prescriptions in 2016, representing sales of EUR 22 million, are for PDT drugs. Since PDT drugs generally have a higher price than the self-applied topical drugs, their percentage of revenues is higher than that of prescription numbers (18.3 % vs. 5.7 %, respectively). With the advent of daylight PDT, which eliminates the procedures in doctor's offices and allows easier reimbursement (Biofrontera has filed an approval application in the EU) we see the potential for PDT to significantly grow its share of the AK market. The PDT sector was growing slightly faster, by about 15 % per year, than the total AK market, but still represents below 6 % of all prescriptions in Europe. This market size may, however, be a slight underestimation since in many countries PDT drugs may be sold directly into hospitals and thereby are not tracked by regular market research sources. Available PDT drugs in Europe include Ameluz® gel, Metvix® cream, AlaCare® adhesive plaster and Luxerm® cream. Metvix® has been on the market since 2002, and is still the most frequently used PDT drug throughout the EU. In our phase III trial, we compared the efficacy of Ameluz® with that of Metvix® and showed significant superiority in the treatment of actinic keratosis. AlaCare is a 2x2 cm adhesive plaster that is commercially less relevant. Luxerm® is identical to Metvix®, but its use is restricted to daylight PDT. It is on the market in Germany only, and was launched in 2016. Throughout Europe, Metvix® had 74 % market share, followed by Ameluz® with 21 %, Luxerm® with 3 % and AlaCare® with 2 % in 2016. In Germany, where Biofrontera has been active with its own sales force, the market share of Ameluz® for conventional (with a lamp) PDT products rose to >70 %. It then declined with the Metvix® approval for daylight PDT in 2016 to about 50 %, but has increased again to 55 % in July 2017. Also in July 2017, for the first time more units of the specific daylight PDT product Luxerm® were sold than all conventional PDT products combined. In Spain, where Biofrontera markets Ameluz® on its own since 2015, its share of the PDT products market has been growing from <5 % in 2014 to 12 % in 2015 and 23 % in 2016.

The AK market in the US differs greatly from the European market, since the US reimbursement system favours procedures, for which physicians in Europe may not get paid. By quite some distance, the most frequently used treatment option is cryotherapy. In 2013, Medicare (the public insurance for the elderly) alone has paid for the cryotherapy of 5.977 million patients. This had been growing by 2-3 % per year from 2008. If the 2013 number is therefore extrapolated to 2016 with an assumed 2 % growth, we estimate that about 6.4 million Medicare patients were treated with cryotherapy in 2016. An analysis of “National Ambulatory Medical Care Survey” and “Medicare Current Beneficiary Survey” data with respect to the frequency and cost of actinic keratosis treatment concluded that about 60 % of AK patients were covered by Medicare, 40 % of treatments are reimbursed by private payers (Dermatology Surgery 2006 Aug;32(8):1045-9). Thus, we assume that the latter 40 % of cryotherapy treatments have to be added to the above number for cryotherapies of Medicare patients.

Sun Pharma has reported for 2016 annual Levulan® revenues of USD 106 million (Source: Sun Pharma, Annual Report). With an approximated annual average sales price of USD 309 per Levulan Kerastick®, this refers to 343,000 prescriptions. Ameluz® sales in 2016 can be disregarded here due to their still low numbers. We estimate that there were an additional 1.65 million prescriptions for self-applied topical drugs in the US. The latter are distributed over multiple products, the most frequently prescribed ones are drugs with the active ingredient 5-fluorouracil (44 % generic plus 4 % branded), followed by imiquimod (31 %), diclofenac (16 %) and ingenol mebutate drugs (5.5 %).

Altogether, based on the above assumptions the cryotherapy treatments and the topical products including PDT drugs add up to an estimated 12.6 million AK treatments in 2016. According to these numbers, PDT is only applied in about 3 % of all AK treatments, and there is substantial uncovered market potential and room for growth. Some of our conclusions, which are based on various sources potentially providing outdated or misleading information, may be not precise or incorrect, potentially rendering the market size less than we assume, which may reduce the revenue potential for Ameluz®. However, since PDT represents only a minor part of the AK market both in the EU and the US, there is ample room for growth.

BCCs are the most frequent infiltrating tumours in man, and responsible for 50-80 % of all skin cancers. About 30 % of all Caucasians develop at least one BCC in their lifetime, with strongly increasing incidence due to rising exposure to UV light. In the US, where more reliable numbers are available, there are >4 million BCC treatments annually, of which 1 million could potentially be treated with PDT as an alternative to surgery. In Europe, the approval for BCC was elementary for



increased use of Ameluz® in hospitals, where BCCs are treated more frequently than AKs. In particular in those European countries where dermatology is mostly a hospital discipline, this indication was elementary for the commercial success of Ameluz®.

Basal cell carcinoma treatment is mostly based on surgery or, for infiltrating forms, Mohs micrographic surgery. While this is clearly the gold standard, there are conditions where surgery is not appropriate due to patient morbidity or not desired for cosmetic reasons. Mohs surgery is cost-intensive and therefore contraindicated for non-aggressive, thin forms of BCC. For thin BCCs, PDT is an excellent alternative and listed as such in international treatment guidelines. The most relevant non-aggressive forms of BCC are superficial and nodular tumours, which together represent more than 25 % of all BCCs. The recently approved systemic hedgehog inhibitor drugs are directed to the upper end of the BCC severity scale, and therefore no competition to PDT.

According to a market trial published in 2014 by Technavio, the international market for actinic keratosis medications is expected to grow by approximately 8 % annually, from approximately USD 546 million to USD 942 million in 2020. However, the market for BCC medications is expected to grow to a multiple of its current size, from approximately USD 236 million today to nearly USD 5 billion over the same period, because the availability of new drugs (Ameluz® is also mentioned in this context) will mean that increasingly fewer patients undergo operations.

With its centralised European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland and Liechtenstein. In many European countries, however, price and reimbursement status have to be defined before market launch, which can entail a very protracted process. To date in Europe, the company has started sales and distribution in Germany, the UK, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway and Switzerland. The drug is available in these countries at a pharmacy retail price of between just under EUR 200 and approximately EUR 270 per 2g tube. With the coming into force of the new counterfeiting directive and related serialisation – in other words, the capability to track every tube – some small European markets are no longer profitable, and Biofrontera has consequently withdrawn Ameluz® from the market in Slovenia with effect as of 31 August 2017.

Ameluz® is marketed in Germany, Spain and the United Kingdom by Biofrontera's own field sales force, and in other European countries through marketing partners. In the German market, Biofrontera has been present in the market with its own field sales force since the outset, and still generates most of its European sales revenues there. Sales in Spain were initially handled by Allergan SA, but since

March 2015 Biofrontera has marketed its products itself in Spain through its own branch operation, Biofrontera Pharma GmbH sucursal en España. After the successful approval for BCC, Biofrontera will also be active in the UK from the second half of 2017, initially with one sales force staff member based in the London area.

In Denmark, Sweden and Norway, Ameluz® is marketed by Desitin Arzneimittel GmbH, in Benelux by Bipharma N.V., and in Austria by Pelpharma Handels GmbH. Louis Widmer SA has been granted the Ameluz® distribution licence for Switzerland and Liechtenstein, and the Ameluz® distribution licence for Israel has been allocated to Perrigo Israel Agencies Ltd. It was necessary to undergo an independent approval process in these countries, which was conducted by the aforementioned distribution partners in collaboration with Biofrontera. Market launch in Switzerland occurred at the start of 2016, and in Israel in July 2017.

The contracts with the respective sales partners have been concluded in such a way that Biofrontera has received no down-payment, or only a modest downpayment, and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their own sales price. Biofrontera's share of the sales price varies considerably depending on the market conditions in each country, ranging from 35 % to 60 % of net sales.

Biofrontera launched Ameluz® in the US market to treat actinic keratosis in October 2016. In advance, with the help of a consulting firm specialising in market access and a team of medical advisors, a start was made with analysing the actinic keratosis drug market and reimbursement systems in the American healthcare system. For this, Biofrontera also drew on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick®. Marketing in the USA is occurring through the company's own subsidiary, Biofrontera Inc., which was founded for this purpose in March 2015. Very qualified and experienced local staff were hired for important key positions in the USA. Some of the staff have switched from direct competitors to join Biofrontera. Until an individual reimbursement code is issued – which Biofrontera applied for in January 2017 and will prospectively come into force in January 2018 – Ameluz® is being reimbursed in the USA through a so-called “miscellaneous code”. Although this is a normal procedure for any newly launched medication due to the prescribed application periods, this still makes it difficult to process reimbursement in physicians' practices, and is consequently continuing to hamper sales revenue growth in 2017. This is particularly relevant in the case of Ameluz®, as Biofrontera is not dispensed in pharmacies like most other medications, but is instead

purchased directly by physicians, who pay the costs themselves and then become personally dependent on reimbursement.

For market access in the USA, Ameluz® must first assert itself against its direct competitor product Levulan Kerastick®. Along with better clinical data for AK and easier application, the planned expansion of approval for basal cell carcinoma, in particular, should also make Ameluz® the leading PDT medication in the USA. Ameluz® must subsequently increasingly gain further market shares at the cost of medications applied by patients themselves, and, in particular, cryotherapy. The US subsidiary is meanwhile organised so professionally that the collaboration with Biofrontera's warehousing was recently scaled down from a supply chain management function to a “3rd party logistics (3-PL)” connection. The precondition for this was registering and licensing Biofrontera Inc. as the distributor of medications in all the individual federal states of the USA. Along with lower costs long-term, the advantage for Biofrontera with this structure lies in direct contact with customers, whose orders can be processed directly and flexibly through Biofrontera. In particular, the appointment of Randall Wilhoite as Chief Operating Officer of Biofrontera Inc. has significantly strengthened the US team.

### ***Further development projects***

In July 2016, the company agreed a research partnership with Maruho Co., Ltd, (“Maruho”), a Japanese company specialising in dermatology, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. Ameluz® was developed with a similar strategy. The nanoemulsion technology stabilised the active substance and improved skin penetration, leading to greater clinical efficacy. According to the agreement, Maruho will bear all costs connected with the exploratory research of for new product candidates. It is planned that Maruho will be the owner of the new products and that Biofrontera will receive the licence to market in Europe. In some cases of a change of control Maruho has the right but not an obligation to terminate the cooperation agreement.

### ***Patent and trademark developments since 31 December 2016***

#### **Nanoemulsion**

The response to a further office decision for Argentina was ordered for the “Nanoemulsion” patent.

## **Migraine**

A “Notice to Allowance” has been submitted for the patent “Antimigraine compounds and their use” (US Patent Application No. 14/765,176), prompting the expectation that the patent for the USA will be awarded soon. The company has instigated the order for the issuance fee to be paid on the due date.

A further office decision has been awarded for the European part of the patent, which was responded to by the due date.

## ***Economic and business report***

For the first half of the 2017 financial year for the Biofrontera Group:

- Sales revenue: EUR 5.0 million (prior-year period: EUR 1.7 million), sales revenue growth of 193 % compared with the first half of the previous year.
- Operating result: EUR -7.8 million (previous-year period: EUR -5.1 million)
- Consolidated result before tax: EUR -8.7 million (prior-year period: EUR -3.5 million)
- Cash and cash equivalents as of 30 June: EUR 11.5 million (previous-year period: EUR 10.2 million)
- Undiluted earnings per share amounted to EUR -0.23 (prior-year period: EUR -0.12)

## ***Operative highlights in the first half of 2017***

### **Marketing Ameluz® in the USA:**

Ameluz® has been marketed in the USA in combination with BF-RhodoLED® since October 2016. This generated sales revenues of EUR 2.4 million during the first half of 2017.

### **Approval and clinical trials**

The approval of Ameluz® to treat basal cell carcinoma was issued by the European Commission in January 2017.

A clinical Phase III trial on daylight therapy was completed in the first quarter of 2017, and the application for an expanded approval was submitted to the European Medicines Agency in May 2017.

## Financing

In January 2017, a further convertible bond was placed successfully in a volume of EUR 5.0 million.

In May 2017, a loan agreement for up to EUR 20 million was arranged with the European Investment Bank.

## *Biofrontera Group financial position and performance*

### Biofrontera Group profit & loss account (summary)

| In kEUR                        | 6M 2017   | 6M 2016   | Change in % |
|--------------------------------|-----------|-----------|-------------|
| Sales revenue                  | 5,006.4   | 1,708.6   | 193         |
| Cost of sales                  | 635.4     | 763.7     | (17)        |
| Research and development costs | 2,185.4   | 1,852.0   | 18          |
| Sales and marketing costs      | 8,275.3   | 2,832.3   | 192         |
| Administrative costs           | 1,695.5   | 1,372.4   | 24          |
| Other income and expenses      | (626.0)   | 2,232.2   | (128)       |
| EBIT                           | (8,411.2) | (2,879.5) | (192)       |
| Financial result               | (325.4)   | (592.8)   | (45)        |
| Earnings before income tax     | (8,736.6) | (3,472.3) | (152)       |
| Earnings after tax             | (8,736.6) | (3,472.3) | (152)       |

## Sales revenue

Revenue of EUR 5,006 thousand was generated overall during the first half of 2017, reflecting 193 % year-on-year growth. Sales revenues in Germany increased slightly compared with the prior-year period, by EUR 70 thousand, to reach EUR 1,103 thousand. Revenues from abroad performed particularly well during the first half of 2017, mainly driven by the new sales market, the USA, where sales revenue totalling EUR 2,386 thousand was achieved (previous year: 0). Sales revenues in Europe were up by 15 % to EUR 732 thousand. Revenue of EUR 785 thousand was achieved from development projects with Maruho during the first half of 2017 (previous-year period: 0).

## Cost of sales, gross profit

The gross profit on sales improved from EUR 945 thousand in the prior-year period to EUR 4,371 thousand in the first half of 2017. The gross margin increased to 87 %, compared to 55 % in the same period of the previous year.

The cost of sales amounted to EUR 635 thousand, or 13 % of the sales revenue, improving relative to sales revenue compared with the prior-year period (EUR 764 thousand, or 45 %). The improvement in the gross margin is a consequence of a higher level of propriety sales revenue compared to sales revenue generated through licence partners.

### **Development costs**

Research and development costs amounted to EUR 2,185 thousand in the first half of 2017, up 18 % compared with the previous year. This trend is chiefly attributable to costs incurred as part of the development partnership with Maruho.

### **Sales and marketing costs**

Sales and marketing costs totalled EUR 8,275 thousand in the first half of 2017, more than doubling compared with the prior-year period (EUR 2,832 thousand). Sales and marketing costs include the costs of our own field sales team in Germany, Spain and the USA, as well as marketing expenses. This increase mainly reflects our investments in marketing and sales activities in the USA.

### **Administrative costs**

Administrative costs rose by EUR 324 thousand year-on-year to EUR 1,696 thousand in the first half of 2017 (previous year: EUR 1,372 thousand). Financing costs shown under administrative costs include primarily consultancy and placement fees in connection with support in the search for investors.

### **Financial result**

The financing costs of EUR 330 thousand included in the financial result arise almost exclusively from interest payments for the bonds with warrants and the two convertible bonds, as well as the reversal of discounts applied to these bonds in accordance with the effective interest method.

The interest for the 2016 financial year for Warrant Bond I was paid at the start of January 2017.

## Other income and expenses

After other income of EUR 2,246 thousand was generated in the first half of 2016, mainly due to the repayment of the FDA submission fee of EUR 2,140 thousand, other income in the first half of 2017 stood at EUR 115 thousand. Other expenses rose by EUR 727 thousand in the first half of 2017 to reach EUR 741 thousand. This change mainly reflects currency differences.

## Share capital

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 38,416,428.00 on 30 June 2017. It was divided into 38,416,428 registered shares with a nominal value of EUR 1.00 each. The share capital amounted to EUR 37,722,433.00 on 31 December 2016, and was increased by EUR 693,995.00, divided into 693,995 registered shares, during the first half of the 2017 financial year through the exercise of conversion rights from the 2016/2021 convertible bond as well as from the 2017/2022 convertible bond.

The numbers of shares held by the shareholders on 30 June 2017 based on shareholders' most recent mandatory disclosures are as follows:

|   | 30.06.2017<br>EUR |
|---|-------------------|
| <b>Maruho Deutschland Co., Ltd., Osaka Japan</b><br>The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former. | 7,631,586         |
| <b>Wilhelm Konrad Thomas Zours</b><br>The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours:   |                   |
| • DELPHI Unternehmensberatung AG  | 3,400,907         |
| • VV Beteiligungen AG   |                   |
| • Deutsche Balaton AG   |                   |
| • ABC Beteiligungen AG  |                   |
| • Heidelberger Beteiligungsholding AG   |                   |
| <b>Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany</b><br>The share of voting rights is attributed to Universal-Investment GmbH through the company FEHO Vermögensverwaltungsgesellschaft.            | 799,463           |
| <b>Free float</b>   | <b>26,584,472</b> |
| <b>Total</b>  | <b>38,416,428</b> |

## Financial position

The company's capital management body regularly reviews the equity ratio of both the Group and the parent company. The management's objective is to ensure an appropriate equity base within the context of capital market expectations, and creditworthiness with respect to national and international

business partners. The company's Management Board ensures that all Group companies have sufficient equity and debt funding at their disposal.

Cash flow from operating activities reduced compared with the first half of the 2016 from EUR -2,511 thousand to EUR -8,087 thousand as of 30 June 2017.

Cash flow from investing activities decreased slightly, by EUR 49 thousand, to EUR -192 thousand.

Cash flow from financing activities diminished by EUR 4,262 thousand year-on-year, from EUR 8,867 thousand to EUR 4,605 thousand. This change arises especially from cash inflows from issuing new shares with total issue proceeds of EUR 9.3 million in the prior-year period, compared with cash flows from issuing the 2017/2022 convertible bond of EUR 5.0 million during the first half of 2017.

### **Liquidity**

The liquidity position in the first half of 2017 reduced by EUR 3,675 thousand compared with 31 December 2016. Cash and cash equivalents stood at EUR 11,451 thousand as of 30 June 2017.

The company was able to meet its payment obligations at all times, but will continue to depend on additional financing measures in the future. To date, Biofrontera has always succeeded in providing the necessary financing for its business operations through injections of equity. As a result of several capital measures in 2016 and 2017, the company currently has sufficient liquidity at its disposal. However, the planned investments in marketing in the USA will necessitate further capital measures.

Based on its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. Should – contrary to expectations – these valid estimates not be realised, a going concern risk would ensue.

### **Staff**

As of 30 June 2017, 124 employees worked for the Biofrontera Group (31 December 2016: 94). Of these, a total of 47 staff were employed by Biofrontera Inc. (31 December 2016: 24).



## ***Supplementary Report***

Significant events occurring since 30 June 2017

For related information, please refer to the section “Significant events after the interim reporting date” on page 30 of the notes to the consolidated financial statements.

## ***Risk, opportunity and forecast report***

### **Risk and opportunity report**

The risks existing within the Group are described in detail in the risk report in the Group management report published for the financial year ending 31 December 2016. Compared with the opportunities and risks that it describes, no further significant changes have arisen as of the 30 June 2017 reporting date, except for the litigation described below.

### **Litigation**

Deutsche Balaton AG brought a lawsuit for rescission and nullity against the resolutions passed by the company's Ordinary AGM on 24 May 2017 under agenda item 2 (resolution concerning the discharge of the Management Board members for the 2016 financial year) and agenda item 6 (resolution concerning adding a new section 7 (3b) to the company's bylaws (Approved Capital II with the possibility to exclude subscription rights for fractional amounts and pursuant to Section 186 (3) Clause 4 of the German Stock Corporation Act (AktG))). The lawsuit pending before the Cologne District Court is registered under file reference 82 O 66/17.

### **Forecast report (outlook)**

#### **Forecast of key financial figures**

The competitive situation has stabilised for Biofrontera in Germany as well as in other European countries. From today's perspective, sales revenues in these regions in the full 2017 year will lie within the range of expectations. In the USA, we anticipate continuous sales revenue growth during 2017, although initial system-related difficulties in the reimbursement of the medication through a so-called Miscellaneous Code prompt the expectation of somewhat slower sales revenue growth than previously anticipated. The receipt of an individual reimbursement code for the medication Ameluz® in January 2018 will significantly simplify and accelerate the acquisition of market shares and related sales revenue growth. Overall, however, sales growth remains very difficult to forecast, continuing to generate a considerable fluctuation range of achievable revenues. Total revenue are expected to be at

the lower end of the outlook range, depending on sales development in the US maybe even slightly below the range.

To extend the range of indications, Biofrontera will make further significant investments in research and development as well as in regulatory affairs in 2017. The forecast for development and approval costs remains at between approximately EUR 6 million and EUR 7 million. The establishment of the sales and marketing organisation in the USA is largely occurring to plan, so that sales and marketing costs remain largely unchanged compared with the last forecast report at between approximately EUR 18 million and EUR 21 million. Compared with the last forecast, administrative costs will rise slightly due to additional costs for financing measures, and amount to between around EUR 4 million and EUR 5 million.

The company continues to plan no significant investments in property, plant and equipment in 2017.

The financial result reflects the interest payments and compounding of interest applying the effective interest method for the still outstanding warrant bond on a proportional basis until the repayment date in August 2017. This item also shows the interest payments from the EIB loan from the date when the loan was granted. The 2011/16 bond with warrants was already repaid December 2016. Taking all the aforementioned effects into account, the financial result will lie approximately at the previous year's level. We also anticipate a non-cash burden on earnings of between EUR 0.5 million and EUR 1.0 million from translating balance-sheet items due to changes in the US dollar exchange rate to the euro.

With the aforementioned conditions and forecasts, the company will achieve a result in 2017 in the lower end of the outlook range. The achievement of this result depends significantly on sales revenue trends.

Leverkusen, 31 August 2017

Biofrontera AG

|                           |                         |                          |
|---------------------------|-------------------------|--------------------------|
| Prof. Dr. Hermann Lübbert | Thomas Schaffer         | Christoph Dünwald        |
| Chief Executive Officer   | Chief Financial Officer | Chief Commercial Officer |

### ***Responsibility Statement***

Affirmation of the legal representatives pursuant to Section 37y of the German Securities Trading Act (WpHG) in conjunction with Section 37w (2) No.3 WpHG

We affirm that, to the best of our knowledge and in accordance with the applicable accounting principles, the consolidated financial statement gives a true and fair view of the financial position, cash flows and results from operations of the Group, and that the combined company and Group management report presents the business performance, including the business results and the position of the Biofrontera Group and of Biofrontera AG, in such a way that a true and fair view is conveyed, and that the main opportunities and risks relating to the anticipated performance of the Biofrontera Group and Biofrontera AG are described.

Leverkusen, 31 August 2017

Biofrontera AG

|                           |                         |                          |
|---------------------------|-------------------------|--------------------------|
| Prof. Dr. Hermann Lübbert | Thomas Schaffer         | Christoph Dünwald        |
| Chief Executive Officer   | Chief Financial Officer | Chief Commercial Officer |

### F.3.2) Consolidated balance sheet

#### Assets

| in kEUR                                | 30 June 2017 | 31 December 2016 |
|--|--------------|------------------|
| <b>Non-current assets</b>              |              |                  |
| <b>Tangible assets</b>                 | 662.3        | 644.7            |
| <b>Intangible assets</b>               | 984.5        | 1,251.9          |
|  | 1,646.7      | 1,896.6          |
| <b>Current assets</b>                  |              |                  |
| <b>Current financial assets</b>        |              |                  |
| <b>Trade receivables</b>               | 1,202.0      | 1,624.1          |
| <b>Other financial assets</b>          | 1,135.8      | 1,376.9          |
| <b>Cash and cash equivalents</b>       | 11,451.5     | 15,126.1         |
|  | 13,789.3     | 18,127.0         |
| <b>Other current assets</b>            |              |                  |
| <b>Inventories</b>                     |              |                  |
| <b>Raw materials and supplies</b>      | 1,573.1      | 1,350.3          |
| <b>Unfinished products</b>             | 427.7        | 477.1            |
| <b>Finished products and goods</b>     | 1,833.7      | 1,818.9          |
| <b>Income tax reimbursement claims</b> | 32.9         | 33.0             |
| <b>Other assets</b>                    | 44.6         | 175.7            |
|  | 3,911.9      | 3,855.1          |
|  | 17,701.2     | 21,982.1         |
| <b>Total assets</b>                    | 19,347.9     | 23,878.7         |

#### Liabilities

| in kEUR   | 30 June 2017 | 31 December 2016 |
|---|--------------|------------------|
| <b>Equity</b>   |              |                  |
| <b>Subscribed capital</b>   | 38,416.4     | 37,722.4         |
| <b>Capital reserve</b>  | 100,670.1    | 98,676.8         |
| <b>Capital reserve from foreign currency conversion adjustments</b> | 441.8        | (154.2)          |
| <b>Loss carry forward</b>   | (120,402.9)  | (109,823.7)      |
| <b>Net loss of the year</b>   | (8,736.6)    | (10,579.2)       |
|   | 10,388.9     | 15,842.1         |
| <b>Long-term liabilities</b>  |              |                  |
| <b>Long-term financial liabilities</b>                              | 2,654.0      | 3,596.9          |
| <b>Current liabilities</b>  |              |                  |
| <b>Current financial liabilities</b>                                |              |                  |
| <b>Trade payables</b>   | 448.5        | 2,093.2          |
| <b>Short-term financial debt</b>                                    | 3,664.6      | 274.4            |
| <b>Other financial liabilities</b>                                  | 48.1         | 58.5             |
|   | 4,161.3      | 2,426.0          |
| <b>Other current liabilities</b>                                    |              |                  |
| <b>Other provisions</b>   | 1,880.0      | 1,823.7          |
| <b>Other current liabilities</b>                                    | 263.7        | 190.0            |
|   | 2,143.7      | 2,013.6          |
|   | 6,305.0      | 4,439.7          |
| <b>Total liabilities</b>  | 19,347.9     | 23,878.7         |



### F.3.3) Consolidated statement of comprehensive income

| <b>in kEUR</b>  | <b>6M 2017</b> | <b>6M 2016</b> |
|---|----------------|----------------|
| <b>Sales revenue</b>  | 5,006.4        | 1,708.6        |
| <b>Cost of sales</b>  | (635.4)        | (763.7)        |
| <b>Gross profit from sales</b>  | 4,371.1        | 945.0          |
| <b>Operating expenses</b>   |                |                |
| <b>Research and development costs</b>   | (2,185.4)      | (1,852.0)      |
| <b>General administrative costs</b>   | (1,695.5)      | (1,372.4)      |
| <i>thereof financing costs</i>  | (510.8)        | (372.4)        |
| <b>Sales costs</b>  | (8,275.3)      | (2,832.3)      |
| <b>Loss from operations</b>   | (7,785.2)      | (5,111.7)      |
| <b>Interest expenses</b>  | (329.6)        | (594.5)        |
| <b>Interest income</b>  | 4.2            | 1.7            |
| <b>Other expenses</b>   | (740.9)        | (14.0)         |
| <b>Other income</b>   | 114.9          | 2,246.3        |
| <b>Profit/loss before income tax</b>  | (8,736.6)      | (3,472.3)      |
| <b>Income tax</b>   | 0.0            | 0.0            |
| <b>Profit or loss for the period</b>  | (8,736.6)      | (3,472.3)      |
| <b>Expenses and income not included in profit/loss</b>  |                |                |
| <b>Items which may in future be regrouped into the profit and loss statement under certain conditions</b> | 596.0          | 0.6            |
| <b>Translation differences resulting from the conversion of foreign business operations</b>               |                |                |
| <b>Other income total</b>   | 596.0          | 0.6            |
| <b>Total profit/loss for the period</b>   | (8,140.6)      | (3,471.7)      |
| <b>Non-diluted (=diluted) earnings per share</b>  | (0.23)         | (0.12)         |

### F.3.4) Statement of changes in equity

|   | Ordinary shares<br>number | Subscribed<br>capital<br>kEUR | Capital reserve<br>kEUR | Capital reserve<br>from foreign<br>currency<br>conversion<br>kEUR | Accumulated loss<br>kEUR | Total<br>kEUR |
|---|---------------------------|-------------------------------|-------------------------|---|--------------------------|---------------|
| <b>Balance as at 01 January 2016</b>  | 25,490,430                | 25,490.4                      | 79,525.3                | (1.2)   | (109,823.7)              | (4,809.2)     |
| <b>Capital increase</b>   | 4,857,383                 | 4,857.4                       | 4,621.6                 | 0.0   | 0.0                      | 9,479.0       |
| <b>Costs of equity procurement</b>  | 0                         | 0.0                           | -175.9                  | 0.0   | 0.0                      | (175.9)       |
| <b>Foreign currency conversion adjustment</b>   | 0                         | 0.0                           | 0.0                     | 0.6   | 0.0                      | 0.6           |
| <b>Increase in capital reserve from the stock option programme</b>                            | 0                         | 0.0                           | 53.9                    | 0.0   | 0.0                      | 53.9          |
| <b>Net loss of the year</b>   | 0                         | 0.0                           | 0.0                     | 0.0   | (3,472.3)                | (3,472.3)     |
| <b>Balance as at 30 June 2016</b>   | 30,347,813                | 30,347.8                      | 84,025.0                | (0.6)   | (113,296.0)              | 1,076.3       |
| <b>Capital increase</b>   | 5,012,950                 | 5,013.0                       | 10,025.9                | 0.0   | 0.0                      | 15,038.9      |
| <b>Conversion from convertible bond 2016/2021</b>   | 1,603,050                 | 1,603.0                       | 3,231.3                 | 0.0   | 0.0                      | 4,834.4       |
| <b>Conversion from option bond 2011/2016</b>  | 758,620                   | 758.6                         | 1,486.9                 | 0.0   | 0.0                      | 2,245.5       |
| <b>Foreign currency conversion adjustment</b>   | 0                         | 0.0                           | 0.00                    | (153.6)   | 0.0                      | (153.6)       |
| <b>Costs of equity procurement</b>  | 0                         | 0.0                           | (145.5)                 | 0.0   | 0.0                      | (145.5)       |
| <b>Changes in capital reserves pursuant to the issuance of the convertible bond 2016/2021</b> | 0                         | 0.0                           | (4.2)                   | 0.0   | 0.0                      | (4.2)         |
| <b>Increase in capital reserve from the stock option programme</b>                            | 0                         | 0.0                           | 57.4                    | 0.0   | 0.0                      | 57.4          |
| <b>Net loss of the year</b>   | 0                         | 0.0                           | 0.0                     | 0.0   | (7,106.9)                | (7,106.9)     |
| <b>Balance as at 31 December 2016</b>   | 37,722,433                | 37,722.4                      | 98,676.8                | (154.2)   | (120,402.9)              | 15,842.1      |
| <b>Conversion from convertible bond 2016/2021</b>   | 26,700                    | 26.7                          | 74.5                    | 0.0   | 0.0                      | 101.2         |
| <b>Conversion from convertible bond 2017/2022</b>   | 667,295                   | 667.3                         | 1,836.0                 | 0.0   | 0.0                      | 2,503.3       |
| <b>Foreign currency conversion adjustment</b>   | 0                         | 0.0                           | 0.0                     | 596.0   | 0.0                      | 596.0         |

### F.3.5) Consolidated cash flow statement

| in kEUR   | 6M 2017          | 6M 2016          |
|---|------------------|------------------|
| <b>Cash flows from operations</b>   |                  |                  |
| Profit/loss for the period  | (8,736.6)        | (3,472.3)        |
| <b>Adjustments to reconcile profit/loss for the period to cash flow into operations</b> |                  |                  |
| Financial result  | 325.4            | 592.8            |
| Depreciation  | 443.8            | 404.3            |
| (Gains)/losses from disposal of assets  | 0.0              | 4.8              |
| Non-cash expenses and income  | 3,340.8          | 46.4             |
| <b>Changes in operating assets and liabilities</b>                                      |                  |                  |
| Trade receivables   | 422.0            | 382.1            |
| Other assets and Income tax assets  | 372.4            | (338.6)          |
| Inventories   | (188.1)          | (142.3)          |
| Trade payables  | (1,644.6)        | (45.3)           |
| Long-term and short-term financial debt   | (2,551.7)        | 0.0              |
| Provisions  | 66.1             | 83.1             |
| Other liabilities   | 63.4             | (25.7)           |
| <b>Net cash flow from operational activities</b>  | <b>(8,087.0)</b> | <b>(2,510.7)</b> |
| <b>Cash flows from investment activities</b>  |                  |                  |
| Purchase of intangible and tangible assets  | (203.7)          | (154.6)          |
| Interest received   | 1.8              | 1.7              |
| Revenue from sale of intangible and tangible assets                                     | 9.7              | 9.7              |
| <b>Net cash flow from (into) investment activities</b>                                  | <b>(192.2)</b>   | <b>(143.2)</b>   |
| <b>Cash flows from financing activities</b>   |                  |                  |
| Proceeds from the issue of shares   | 0.0              | 9,303.2          |
| Proceeds from conversions of convertible bonds 2017/2022                                | 4,999.0          | 0.0              |
| Interest paid   | (394.4)          | (435.8)          |
| <b>Net cash flows from financing activities</b>   | <b>4,604.6</b>   | <b>8,867.4</b>   |
| <b>Net increase (decrease) in cash and cash equivalents</b>                             | <b>(3,674.6)</b> | <b>6,213.4</b>   |
| <b>Cash and cash equivalents at the beginning of the period</b>                         | <b>15,126.1</b>  | <b>3,959.2</b>   |
| <b>Cash and cash equivalents at the end of the period</b>                               | <b>11,451.5</b>  | <b>10,172.6</b>  |
| <b>Composition of financial resources at the end of the period</b>                      |                  |                  |
| <b>Cash and cash balances and cheques</b>   | <b>11,451.5</b>  | <b>10,172.6</b>  |



### **F.3.6) Notes to the consolidated financial statements as of 30 June 2017**

#### Information about the company

Biofrontera AG ([www.biofrontera.com](http://www.biofrontera.com)), registered in the commercial register of Cologne District Court, Department B under No. 49717, and its wholly-owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, all with head office at Hemmelrather Weg 201, 51377 Leverkusen, Germany, and Biofrontera Inc., which is based in Wakefield, Massachusetts, USA, research, develop and market dermatological products. The main focus is on the discovery, development and distribution of dermatological drugs and dermatologically tested cosmetics for the treatment and care of diseased skin. Biofrontera AG (hereinafter also the “company” or “Biofrontera”) pursues this goal along with its subsidiaries. All the companies together form the “Biofrontera Group”.

The Biofrontera Group was the first small German pharmaceutical company to receive centralised European and US drug approval for an independently developed drug, Ameluz®. In December 2011, Ameluz® was approved in Europe to treat light and moderate actinic keratosis. In September 2016, European approval was expanded to treat field cancerisation, and in January 2017 to treat basal cell carcinoma. In May 2016, the FDA issued approval in the USA for lesion-directed and field-directed treatment of actinic keratosis in combination with the red-light lamp BF-RhodoLED®. In addition, a range of cosmetic products is to be expanded. The first product in this range, Belixos® Creme, was launched in the autumn of 2009. A hair tonic, Belixos® LIQUID, was introduced in the spring of 2014 and a Belixos® Gel skin care for rosacea and acne was launched at the beginning of December 2014. Belixos® Protect, a day cream with protective anti-aging properties designed especially for photodamaged skin, followed in July 2015, as well as in July 2016 Belixos® to go, a practical 5 ml roll-on applicator with a stainless-steel roller, with simple and hygienic application leading to an immediate cooling effect for the affected skin. Belixos® body cream has arisen due to significant demand for larger packaging of the Belixos® cream, and is ideal for application on larger body areas. Two further clinical development projects, one a dermatological project and one for the prevention of migraines, have been spun off into dedicated subsidiaries and are not being actively pursued at the present time.

The product Ameluz® (development name BF-200 ALA), which was approved in Europe at the end of 2011, has been tested for European approval in one Phase II and two Phase III clinical trials to treat actinic keratosis. In preparation for approval in the USA, two Phase I trials and a further Phase III trial were conducted. Ameluz® consists of a combination of the drug aminolevulinic acid (ALA) and a patent-protected nanoemulsion (BF-200), with the latter chemically stabilising the ALA and enhancing its skin penetration. The clinical results regarding the treatment of actinic keratosis have shown its

clear superiority to the competitor product against which it was compared in the Phase III trials. An application for centralised European approval was submitted on 1 September 2010, and this approval was granted by the European Commission on 16 December 2011. Ameluz® has been sold in Germany since February 2012 and in several other European countries since autumn 2012. In September 2016, approval was expanded to treat field cancerisation, in other words, larger related areas permeated by tumour cells. Approval in the USA occurred on 10 May 2016, which now opens up the world's largest healthcare market to Biofrontera. Market launch occurred in October 2016. A further Phase III trial to treat basal cell carcinoma formed the basis for the expansion of the existing EU approval for this indication, which was issued in January 2017. Furthermore, Ameluz® was tested in a Phase III trial for the application of daylight PDT in a direct comparison with the competitor product, and this trial formed the basis for filing for approval for this therapy type in June 2017. In August 2017, the FDA confirmed in writing the approval procedure that was agreed with Biofrontera at a formal meeting for the treatment of basal cell carcinoma with Ameluz®.

In November 2012, Biofrontera's BF-RhodoLED® PDT lamp received pan-European approval for use as a medical device and has since been sold in parallel with Ameluz®. In Europe, doctors can opt to use any of the lamps approved for PDT, whereas in the USA the approval of Ameluz® is combined with utilisation of the BF-RhodoLED® lamp. It is consequently approved as a combination product along with Ameluz®.

In July 2016, the company agreed a research partnership with Maruho Co., Ltd, ("Maruho"), a Japanese company specialising in dermatology, in which possibilities to jointly develop pharmaceutical products for the European market based on Biofrontera's proprietary nanoemulsion technology are to be researched. This corresponds to the same strategy with which Ameluz® was also developed. The nanoemulsion technology stabilised the active substance and improved skin penetration, leading to greater clinical efficacy. This principle is also to be applied to other substances as part of the partnership with Maruho. According to the agreement, Maruho will bear all costs connected with the exploratory research of four new product candidates. It is planned that Maruho will be the owner of the results, but that all new inventions are to belong to both companies jointly. As part of the agreement, Biofrontera does not issue to Maruho any licence for the utilisation of the nanoemulsion or other existing intellectual property. The licence to market the new products in Europe shall be allocated to Biofrontera. The agreement does not cover other markets.

The BF-derm1 project, which is currently not being actively pursued, was tested in a three-part Phase II trial for the treatment of chronic, antihistamine-resistant urticaria. The trial demonstrated the drug's

good efficacy, which reduced the intensity of urticaria rashes and itching as well as reducing the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is an innovative substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007. They show that the substance is almost completely absorbed in the intestine, and that it takes around two days for 50 % of the substance to be broken down or excreted. These results are an excellent starting point for developing the substance for administration in tablet form.

The intention is to finance the development of both BF-derm1 and BF-1 independently of Biofrontera's normal budget by seeking funding providers who will benefit directly from the development of these products. For this reason, the two projects were acquired by Biofrontera AG and transferred as shareholder contributions to the two subsidiaries Biofrontera Development GmbH and Biofrontera Neuroscience GmbH, which were formed in December 2012. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is now the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products was uncoupled from the normal Group financing. As a result, the company's short-term financial plans can focus on the market launch of Ameluz® in North America and the extension of its range of indications, as well as the establishment of the Group as a specialist pharmaceutical company.

#### Accounting policies

Pursuant to the regulations of Section 37y of the German Securities Trading Act (WpHG), in combination with Section 37w WpHG, this half-year financial report as of 30 June 2017 comprises condensed interim consolidated financial statements, an interim Group management report and a responsibility statement pursuant to the regulations of Section 297 (2) Clause 4, Section 315 (1) Clause 6 of the German Commercial Code (HGB).

The condensed interim consolidated financial statements as of 30 June 2017 of Biofrontera AG were prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) as well as the interpretations of the International

Financial Reporting Standards Interpretations Committee (IFRS IC) for “Interim Financial Reporting” in accordance with IAS 34, as applicable in the European Union. As a consequence, they do not include all information and disclosures required for consolidated financial statements, and for this reason should be read in connection with the consolidated financial statements for the financial year ending 31 December 2016.

As part of preparing the interim consolidated financial statements, the Management Board must make assumptions that affect the application of accounting policies within the Group, and the reporting of assets and liabilities as well as income and expenses. Actual amounts can differ from such estimates. The results achieved during the first half of the 2017 financial year do not allow any predictions to be made about trends during the further course of business.

The accounting policies applied to prepare the consolidated financial statements as of 31 December 2016 continued to be applied on an unmodified basis for the preparation of the condensed interim consolidated financial statements. In this connection, please also refer to the notes to the consolidated financial statements as of 31 December 2016.

The consolidated financial statements for 31 December 2016 contain no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz®, including the supplementary products BF-RhodoLED® (PDT lamp) and Belixos®, and are internally monitored and managed accordingly.

This half-year financial report of Biofrontera AG was approved for publication by a Management Board resolution on 31 August 2017.

Rounding differences can arise in the tables due to commercial rounding.

#### Convertible bond 2017/2022

The company's Management Board passed a resolution to issue a further convertible bond on 23 December 2016. This EUR 5.0 million bond was fully placed in January 2017. The initial conversion price for the bond amounts to EUR 3.50, to EUR 4.00 from 1 April 2017 and to EUR 5.00 from 1 January 2018. The bonds carry 6 % annual interest on their par value from 1 February 2017. The bond

will be redeemed in cash on 1 January 2022 unless it is converted previously. As of 30 June 2017, bonds with a nominal amount of EUR 2,335,600 had been converted into the company's shares.

#### Loan agreement with the European Investment Bank

In May 2017, a loan agreement for up to EUR 20 million was arranged with the European Investment Bank (EIB). The loan is unsecured and guaranteed by our main subsidiaries. It is available in tranches over a two-year period. In July 2017, the company drew down a first tranche of EUR 10 million. Two further tranches of EUR 5 million each can be drawn down after certain milestones have been achieved. Each tranche must be repaid five years after it was made available. The loan incurs standard market interest, whereby some of the interest payments must be paid in cash quarterly, some of the interest payments are initially deferred and are to be paid at the end of the term, and a further portion of the interest payments are also to be paid at the end of the term depending on the company's market capitalisation.

#### Employee stock option programme 2015

After the end of the 2010 employee share option programme, the company's Annual General Meeting on 28 August 2015 authorised the Management and Supervisory boards until 27 August 2020 to issue to Management Board members and employees up to 1,814,984 subscription rights to up to EUR 1,814,984 of the company's ordinary registered shares according to the more detailed specifics of the authorisation resolutions. Further related provisions were specified in the invitation to the Annual General Meeting and are available on the company's website (2015 option programme).

On 18 April 2016, a total of 425,000 options were issued for the first time from the potential 1,814,914 share options (exercise price: EUR 2.49 per option). On 1 December 2016, a further 130,500 options (second tranche) were issued with an exercise price of EUR 3.28 each. On 28 April 2017, a further 329,000 options (third tranche) were issued at an exercise price of EUR 4.02 each. A total of 38,500 options were forfeited by employees leaving the company. Due to the blocking period, no options have yet been exercised or forfeited. As a consequence, 891,983 options are still outstanding on 30 June 2017. The cost expensed in the reporting period amounted to EUR 56 thousand (prior-year period: EUR 16 thousand).

#### Shares / Earnings per share

Earnings per share are calculated by dividing net consolidated income by the weighted average number of outstanding shares during the year in accordance with IAS 33 ("Earnings per Share").

|  | 30 June 2017 | 30 June 2016 |
|--|--------------|--------------|
| Number of weighted ordinary shares in circulation (on average) | 37,730,066   | 29,194,771   |
| Net loss for the year in kEUR                                  | (8,736.6)    | (3,472.3)    |
| Earnings per share in EUR based on the net loss for the year   | (0.23)       | (0.12)       |

#### Reporting on financial instruments

In the course of its operating activities, the Group is exposed to market price and credit risk, as well as liquidity risk, which could have an effect on its financial position and performance.

Market price risk: Interest-rate risk is deemed minor as existing interest-rate modalities for the Biofrontera Group's relevant financing facilities can generally be adapted to market conditions short-term to medium-term. No cash flow risk exists in relation to fixed interest warrant bonds. Due to the fixing of interest, no disadvantageous changes can occur to the interest payments. As the liabilities are not recognised at fair value but instead at amortised cost, there is also no fair value risk.

Credit risk: A credit risk arises for the Group if transaction partners cannot meet their obligations within the normal payment deadlines. On the balance sheet, the maximum non-payment risk is represented by the carrying amount of the relevant financial asset. The situation regarding receivables is monitored so that any possible non-payment risks can be identified at an early stage and appropriate steps taken. In the first half of 2017, no individual value adjustments were made for other financial assets (prior-year period: EUR 0); in addition, no individual value adjustments were applied to trade receivables in the first half of 2017 (prior-year period: EUR 0).

Based on the input factors used at the valuation methods fair values are divided into different steps of the fair value hierarchy:

Level 1: Fair value valuations using prices listed on active markets (not adjusted) for identical assets or liabilities.

Level 2: Fair value valuations using inputs for the asset or liability that are either directly observable (as prices) or indirectly observable (derived from prices), but which do not constitute listed prices pursuant to Level 1.

Level 3: Fair value valuations using inputs for the asset or liability that are not based on observable market data (unobservable input data).

Biofrontera only has financial instruments at levels 1 and 2. During the first half of 2017, no reclassifications between the individual levels of the fair value hierarchy were implemented. With regard to financial liabilities, the full amount of non-current and current financial liabilities (EUR 6,319 thousand; 31 December 2016: EUR 3,871 thousand) is allocated, except for the residual value of warrant bond 2016 (EUR 81 thousand), to Level 1. This involves financial debt arising from warrant and convertible bonds.

The financial assets and liabilities can be subdivided into measurement categories with the following carrying amounts, and net gains and losses:

| Financial assets on<br>30.06.2017 (EUR)                 | Fair value       | Carrying amounts         |   |   |  | TOTAL<br>CARRYING<br>AMOUNTS |
|---|------------------|--------------------------|---|---|--|------------------------------|
|   |                  | Loans and<br>receivables | Financial<br>instruments<br>recognised at<br>fair value in<br>profit or loss<br>(excluding<br>"held-for-<br>trading") | Financial<br>assets<br>available-for-<br>sale |  |                              |
| Financial assets  |                  |                          |   |   |  | 0                            |
| Liquid assets   | 11,451,46        | 11,451,466               |   |   |  | 11,451,466                   |
| Trade   |                  |                          |   |   |  |                              |
| receivables   | 1,202,029        | 1,202,029                |   |   |  | 1,202,029                    |
| Other current<br>financial<br>receivables and<br>assets | 1,135,803        | 1,135,803                |   |   |  | 1,135,803                    |
| <b>TOTAL</b>  | <b>13,789,29</b> | <b>13,789,298</b>        |   |   |  | <b>13,789,298</b>            |

| Financial liabilities on 30.06.2017 (EUR) | Fair value       | Carrying amounts  |   |  |  | TOTAL CARRYING AMOUNTS |
|---|------------------|-------------------|---|--|--|------------------------|
|   |                  | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") |  |  |                        |
| Financial liabilities current             | 3,593,239        | 3,664,640         |   |  |  | 3,664,640              |
| Trade payables                            | 448,508          | 448,508           |   |  |  | 448,508                |
| Other financial liabilities current       | 48,142           | 48,142            |   |  |  | 48,142                 |
| Other financial liabilities non-current   | 2,927,910        | 2,654,018         |   |  |  | 2,654,018              |
| <b>TOTAL</b>                              | <b>7,017,799</b> | <b>6,815,308</b>  |   |  |  | <b>6,815,308</b>       |

| Financial assets on 31.12.2016 (EUR)                   | Fair value       | Carrying amounts      |   |                                     |  | TOTAL CARRYING AMOUNTS |
|--|------------------|-----------------------|---|-------------------------------------|--|------------------------|
|  |                  | Loans and receivables | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") | Financial assets available-for-sale |  |                        |
| Financial assets                                       |                  |                       |   |                                     |  | 0                      |
| Liquid assets  | 15,126,09        | 15,126,096            |   |                                     |  | 15,126,096             |
| Trade accounts receivable                              | 1,624,067        | 1,624,067             |   |                                     |  | 1,624,067              |
| Miscellaneous current financial receivables and assets | 1,376,870        | 1,376,870             |   |                                     |  | 1,376,870              |
| <b>TOTAL</b>   | <b>18,127,03</b> | <b>18,127,033</b>     |   |                                     |  | <b>18,127,033</b>      |



| Financial liabilities on 31.12.2016 (EUR) | Fair value       | Carrying amounts  |   |  |  | TOTAL CARRYING AMOUNTS |
|---|------------------|-------------------|---|--|--|------------------------|
|   |                  | Other liabilities | Financial instruments recognised at fair value in profit or loss (excluding "held-for-trading") |  |  |                        |
| Financial liabilities current             | 274,424          | 274,424           |   |  |  | 274,424                |
| Trade accounts payable                    | 2,093,154        | 2,093,154         |   |  |  | 2,093,154              |
| Other financial liabilities current       | 58,458           | 58,458            |   |  |  | 58,458                 |
| Other financial liabilities non-current   | 3,596,897        | 3,596,897         |   |  |  | 3,596,897              |
| <b>TOTAL</b>                              | <b>6,022,933</b> | <b>6,022,933</b>  |   |  |  | <b>6,022,933</b>       |

#### Members of the Supervisory Board

One change relating to the following Supervisory Board member occurred during the first half of 2017:

Hansjörg Plaggemars is a Supervisory Board member of Biofrontera AG and to date has been employed

as a member of the Management Board of Deutsche Balaton Aktiengesellschaft, Heidelberg, resident in Stuttgart,

and is now a member of the Management Board of Delphi Unternehmensberatung AG, Heidelberg, resident in Stuttgart.

#### Related party disclosures

In July 2016, Biofrontera AG signed a research cooperation partnership (a collaboration and partnership agreement) with Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. According to this agreement's provisions, Biofrontera, as part of research services, will

conduct the requisite work for the exploratory research of these product candidates. Maruho is bearing the related costs.

This development partnership generated revenue of EUR 785 thousand in the first half of 2017 (prior-year period: EUR 0 thousand). Receivables due from Maruho amounted to EUR 187 thousand as of 30 June 2017 (31 December 2016: EUR 472 thousand).

During the reporting period, the company availed itself of additional advisory services from Supervisory Board member Dr. Ulrich Granzer. Dr. Granzer assisted the company with key issues relating to the preparation of the applications for approval submitted to the supervisory authorities in Europe and the USA. During the first half of 2017, advisory services amounting to EUR 33 thousand (previous-year period: EUR 2 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 0 thousand on 30 June 2017 (31 December 2016: EUR 7 thousand). The amounts stated here do not include statutory VAT at the current rate of 19 %. The underlying consultancy contract was approved in consideration of the statutory provisions.

In the first half of 2017, no further significant reportable transactions or relationships with related parties existed beyond the aforementioned facts and circumstances.

#### Significant events after the interim reporting date

In July 2017, the Cologne District Court served a lawsuit on the company dated 23 June 2017 and brought by Deutsche Balaton AG for the rescission and nullity of two resolutions passed at the AGM on 24 May 2017.

In August 2017, the company received the written opinion of the American drugs regulator, the FDA, on the terms for the approval of Ameluz® for basal cell carcinoma in the USA, on which the company had reached agreement with the FDA at a formal meeting in July. According to the agreed development plan, the approval expansion for superficial basal cell carcinoma can be applied for based on a single supplementary Phase III trial conducted in the USA, comparing Ameluz® with a placebo. The FDA expects from Biofrontera a combined evaluation of the clinical and histological healing rates. The clinical investigation of patients with different ethnic backgrounds or children is not required. As far as safety information and long-term data are concerned, the FDA has accepted the existing European trial for review.

July 2017, a first tranche of EUR 10 million from the loan from the European Investment Bank was drawn down.

In July 2017 a further patent for the development project BF-1 was granted by the United States Patent and Trademark Office.

Following a resolution by the supervisory board on 19 July 2017 the service contract with Christoph Dünwald and his ap-ointment to the management board have been extended until 30 November 2020.

The 2009/2017 bond with warrants with stepped interest rates and with final maturity on 31 December 2017 was repaid early on 3 August 2017.

On 2 August 2017, the company announced the market launch of Ameluz® and BF-RhodoLED® in Israel by its partner Perrigo Israel Ltd.

Marketing activities in Slovenia were discontinued as of 31 August 2017 due to low market volume.

No further events subject to mandatory reporting occurred after the interim balance sheet date.

Leverkusen, Germany, 31 August 2017

Prof. Dr. Hermann Lübbert

Thomas Schaffer

Christoph Dünwald

Chief Executive Officer

Chief Financial Officer

Chief Commercial Officer