Biofrontera AG | Half-yearly financial report as at 30 June 2015

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#### Financial developments in the first half of 2015

- Significant growth in sales revenue of 29% compared to the same period in the previous year
- Good sales performance in other European countries

### Financial developments in the first half of 2015

- Consolidated profit/loss before tax: EUR -7.3 million.
- Cash and cash equivalents of EUR 4.1 million as at 30 June 2015
- Capital increase for financing the submission fee in the USA has been successfully completed

# Further significant progress in operational business in the first half of the 2015 financial year

- Approval application for Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> submitted to the FDA in the USA.
- Patient recruitment for the phase III trial on basal cell carcinoma has been completed.
- Successful takeover of the sales and distribution in Spain from Allergan
- Preparations for marketing in the USA initiated, own US subsidiary founded, Monica L. Tamborini appointed CEO of US Operations
- Market launch carried out in Belgium

## **Key indicators**

Key consolidated figures for the first half of the 2015 financial year in accordance with IFRS

In EUR thousands	6 M 2015	6 M 2014
Describe of a condition (consists)		
Results of operations (earnings) Sales revenue	1,568.1	1,216.5
of which sales in Germany	1,186.1	915.1
of which downpayments	0.0	70,0
Sales and distribution and general administration costs	-3,385.3	-3,748.0
Research and development costs	-4,497.9	-2,063.0
Operating result	-6,848.9	-4,942.7
Profit/loss before tax	-7,322.9	-5,412.6
Profit/loss after tax	-7,322.9	-5,418.7
Cash flow statement		
Cash flow from aparating activities	-6,535.8	-4,256.4
Cash flow from operating activities		
Cash flow from investment activities	-6.9	-37.1
	-6.9 2,159.9	-37.1 13,379.1
Cash flow from investment activities		
Cash flow from investment activities  Cash flow from financing activities	2,159.9	13,379.1
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands		
Cash flow from investment activities  Cash flow from financing activities	2,159.9	13,379.1
Cash flow from investment activities Cash flow from financing activities  In EUR thousands Key balance sheet figures	2,159.9 6 M 2015	13,379.1 6 M 2014
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total	2,159.9 6 M 2015 9,551.2	13,379.1 6 M 2014 18.174,6
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)	2,159.9 6 M 2015 9,551.2 1,357.3	13,379.1 6 M 2014 18.174,6 1,055.0
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities	2,159.9 6 M 2015 9,551.2 1,357.3 11,321.2	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)	2,159.9 6 M 2015 9,551.2 1,357.3 11,321.2 101,644.2	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)  Equity ratio	2,159.9 6 M 2015 9,551.2 1,357.3 11,321.2 101,644.2 -45.01%	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1 28.74%
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)  Equity ratio  Cash and cash equivalents	2,159.9 6 M 2015 9,551.2 1,357.3 11,321.2 101,644.2 -45.01% 4,126.6	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1 28.74% 12,019.3
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)  Equity ratio  Cash and cash equivalents  Employees as at 30 June (average)	2,159.9  6 M 2015  9,551.2 1,357.3 11,321.2 101,644.2 -45.01% 4,126.6  49  30 June	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1 28.74% 12,019.3
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)  Equity ratio  Cash and cash equivalents  Employees as at 30 June (average)  Biofrontera share	2,159.9  6 M 2015  9,551.2 1,357.3 11,321.2 101,644.2 -45.01% 4,126.6  49  30 June 2015	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1 28.74% 12,019.3 39 30 June 2014
Cash flow from investment activities  Cash flow from financing activities  In EUR thousands  Key balance sheet figures  Balance sheet total  Current liabilities (excluding provisions)  Long-term liabilities  Equity (subscribed capital & capital reserve)  Equity ratio  Cash and cash equivalents  Employees as at 30 June (average)  Biofrontera share  Outstanding shares	2,159.9  6 M 2015  9,551.2 1,357.3 11,321.2 101,644.2 -45.01% 4,126.6  49  30 June 2015 23,573,842	13,379.1 6 M 2014 18.174,6 1,055.0 10,889.4 98,541.1 28.74% 12,019.3 39 30 June 2014 22,196,570

## Biofrontera's financial instruments

Key details of the Biofrontera share	
Stock exchanges	Düsseldorf, Frankfurt, Berlin, Munich, Stuttgart, Xetra, Tradegate, London, UK (AIM)
WKN (German securities ID number)	604611
ISIN	DE0006046113
Outstanding shares as at 30 June 2015	23,573,842
6-month high (24 March 2015)*	EUR 2.999
6-month low (26 February 2015)*	EUR 1.800
Closing price 30 June 2015*	EUR 2.11
Marked capitalisation as at 30 June 2015	EUR 49.74 million
*(Price data from Xetra)	

Key details for warrant bond I with warrar	ıt*
Stock exchanges	Düsseldorf
WKN (German securities ID number)	A0Z169
ISIN	DE000A0Z1690
Term, final maturity	8 years, 31 December 2017
Stepped coupon	4% (2010), 6% (2011), 8% (2012)
6-month high (1HY2015)	EUR 93.50
6-month low (1HY2015)	EUR 84.12
Closing price 30 June 2015	EUR 85.00
*(Price data from the Düsseldorf Exchange)	

Key details for warrant bond II with warrar	nt*
Stock exchanges	Düsseldorf
WKN (German securities ID number)	A1KQ9Q
ISIN	DE000A1KQ9Q9
Term, final maturity	5 years, 31 December 2016
Coupon	5%
6-month high (1HY2015)	EUR 90.00
6-month low (1HY2015)	_ EUR 84.12
Closing price 30 June 2015	EUR 86.50

<sup>\*(</sup>Price data from the Düsseldorf Exchange)

## Consolidated interim management report for the first half of the 2015 financial year

#### Fundamentals of the group

#### 1 Group structure

This report describes the business performance of the group (also referred to in the following as "Biofrontera" or the "Biofrontera Group") for the first half of 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 head office in Wilmington, Delaware, USA. All other companies are based at Hemmelrather Weg 201 in 51377 Leverkusen.

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 has responsibility for research and development tasks for the group and is the holder of patents and the approval for Ameluz<sup>®</sup>. Based on a licence agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also owner of the approval for BF-RhodoLED<sup>®</sup>, 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 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.

Biofrontera Inc. was founded in March 2015 and it is intended that this company will handle the group's business operations in the USA in the future.

#### 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 Germany, the main priorities are to increase the range of indications for existing products and to expand international sales activities.

Biofrontera was the first small German company to receive a centralised European drug approval for a complete-ly independently developed drug, Ameluz<sup>®</sup>. In the months prior to the market launch of Ameluz<sup>®</sup>, the company's own sales division was gradually developed, and Biofrontera has been selling Ameluz<sup>®</sup> via its own field sales team to dermatologists in Germany since the product was launched in February 2012 and in Spain since March 2015. The drug is distributed in other European Union member states, 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 indication to include basal cell carcinoma, first in the EU and in a further step in the USA.

Preparatory work for the approval of Ameluz<sup>®</sup> in the USA for submission continued in the reporting period. In early July 2015, the application for regulatory approval (NDA = New Drug Application) was submitted to the FDA (Food and Drug Administration). Since Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> must be approved in the USA as a combination of a drug product and a medical device, the approval application is unusually complex. According to the guidelines, the FDA will make a decision within a period of 60 days regarding the formal acceptance to file. We expect an interim report six months later, in which the additional requirements in the approval process are described. The approval could be granted to a large extent following this report. Once the approval has been issued, which is expected approximately 12 months after submission of the application, Biofrontera will have access to the largest healthcare market in the world.

The extension of the indication of Ameluz® to basal cell carcinoma was also initiated in 2014. The patient recruitment for the phase III clinical testing in direct comparison to the competitive product Metvix® was concluded in May 2015. Thus the last patient will complete the study in November 2015 and the results could therefore be available by the end of the year. To date, Metvix® has had a competitive advantage over Ameluz® due to its approval for the treatment of basal cell carcinoma, despite its proven inferiority with regard to the treatment of actinic keratosis. In particular in other European countries, in which PDT is carried out mainly in hospitals and less in the registered doctors sector, the market opportunities for Ameluz® are significantly reduced as a result. An extension of the indication would therefore put Biofrontera in a significantly improved market position. The submission of the application for the extended indication of Ameluz® to include basal cell carcinoma is to be carried out in early 2016, following completion of the phase III clinical trial and creation of the trial report; approval by the European authorities is expected towards the end of the first half of 2016.

#### 3. Products

#### Ameluz®

Ameluz<sup>®</sup> 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. As part of the Phase III development, the superiority compared to the direct competitor product Metvix<sup>®</sup> was proven with 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<sup>®</sup> with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European approval authority, the EMA, explicitly mentions the significant superiority of Ameluz<sup>®</sup> to its direct competitor product in terms of removing all of a patient's keratoses.

In the phase III trials relevant to approval, Ameluz<sup>®</sup> showed excellent healing rates and demonstrated significant superiority to the approved comparison preparation, which was tested in parallel to it. In the first phase III trial, which involved the drug being combined with an LED lamp, all keratoses were completely removed for 87% of patients treated with Ameluz<sup>®</sup>. When counting individual keratoses, no fewer than 96% were completely healed

(all of the values specified here are ITT *Intent to Treat* values). In the second phase III trial required for approval, the effectiveness of Ameluz<sup>®</sup> in comparison to the approved standard medication was tested. The results of the trial provided evidence that Ameluz<sup>®</sup> was clearly superior to the competitor drug available in Europe. Based on the average for all lamps used in the treatment, Ameluz<sup>®</sup> resulted in complete healing of actinic keratoses in 78% of patients, whereas the rival product approved at that time achieved a healing rate of only 64%. With LED lamps, the healing rates increased to 85% for Ameluz<sup>®</sup> and 68% for the competitor product. The side effect profile was comparable for both preparations.

As approval in the USA requires a combination of medication and lamp therapy, Biofrontera has developed its own PDT lamp, BF-RhodoLED<sup>®</sup>, 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<sup>®</sup> and BF-RhodoLED<sup>®</sup>, and this was completed in the reporting period. With this combination, keratoses was completely eradicated from 91% of patients. When counting individual lesions, 94% were completely removed after treatment (99.1% of which were mild and 91.7% of which were moderate lesions). As it has been reported a lot in the literature that PDT has pronounced skin rejuvenating properties, in particular with regard to sun-damaged skin, this phase III trial of PDT, which was the first of its kind in the world, involved applying the medication over large surface areas and determining the cosmetic result, 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 by 14.8% after treatment with Ameluz<sup>®</sup>, to 63.0%. The group of patients without hyperpigmentation or hypopigmentation increased from 40.7% to 57.4% and 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 declined 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.

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 supplement the European approval package for Ameluz<sup>®</sup> with the safety data required for registration in the USA. Specifically, one of the trials is a sensitisation study, which determines the potential of Ameluz<sup>®</sup> to trigger allergies, and the other is a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz<sup>®</sup>, 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 to 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 8 million people affected in Germany alone, and that there is a marked upward trend in cases. 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 taking actinic keratosis more and more seriously is illustrated by the fact that actinic keratosis has been recognised as an occupational illness 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 period and who fulfil certain criteria, for the duration of these pa-

tients' lives. However, to date, the remuneration process has not yet been defined, but this is expected to happen in 2015.

At present, actinic keratoses are treated using a wide range of methods. Lesions may be treated for weeks or months with topical creams, which are often ineffective, or the degenerated 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 the use of medicinally and legally questionable PDT formulations remains at a high level. Because Ameluz<sup>®</sup> is the market leader in the PDT proprietary medicinal product market for practising dermatologists, with over 70% of the market, a significant increase in sales can and must result from taking market share from the above-mentioned sectors.

The overall advantages of Ameluz<sup>®</sup> in terms of effectiveness, handling, user friendliness and cosmetic results, as well as the clear superiority of PDT in the treatment of actinic keratoses, will encourage dermatologists to focus on this treatment option in the future. This will be helped by the expansion of the range of indications to include basal cell carcinoma, which the company is currently striving to achieve, as the vast majority of PDT treatments are for this indication, particularly in Great Britain and Spain.

Biofrontera is currently carrying 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. About 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. The EMA approval for approval extension is expected by the middle of 2016.

#### 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 is ideally suited for PDT illumination with drugs containing ALA or methyl ALA. It is red but is still outside 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 intensity and fan power settings can be adjusted during a PDT treatment session in order to reduce any discomfort experienced during 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<sup>®</sup>

Belixos<sup>®</sup> is a medical skin care product with herbal ingredients for the regeneration of damaged skin. The Belixos<sup>®</sup> skin cosmetics range combines selected extracts of traditional medicinal plants with a modern formulation technology.

Belixos® cream was launched on the market in October 2009. It was initially available via the company's own online shop and then also via pharmacies. The Belixos range was extended in February 2014 with the addition of Belixos® liquid and in December 2014 with the addition of Belixos® gel. Belixos® Protect has been added to the range since July 2015. The products are now available for sale at pharmacists and via the online retailer Amazon.

The innovative biocolloid technology and specific combination of high-quality herbal ingredients should set new standards in the bitterly-contested medicinal cosmetics market. The combination of caring and regenerative effects should reduce the need for medical treatment and its side effects in people who suffer from itchiness or chronic ailments, such as atopic dermatitis or psoriasis. Belixos® Protect protects photodamaged skin from further damage.

Belixos<sup>®</sup> Cream rapidly and reliably soothes itching and is the ideal basic treatment for itchy, reddened and flaky skin. As well as mahonia, Belixos<sup>®</sup> Cream contains chamomile extract, which has soothing and healing properties, and tea plant extract, which is antipruritic and anti-oxidative.

Belixos<sup>®</sup> Liquid treats the problems of itchy and flaky scalp with a combination of anti-inflammatory mahonia, moisturising oats and a zinc PCA complex, which effectively fights the causes of itching and flaky scalp. Zinc PCA also helps to regulate sebaceous buildup on the scalp, which is highly susceptible to greasiness. Urea moisturises the skin, and panthenol has soothing and regenerative properties.

The Belixos<sup>®</sup> gel with mahonia and cinnamon was developed for the care of skin that is vulnerable and prone to redness and skin blemishes. In the case of rosacea and acne, it cools the skin and reduces redness. The cinnamon extract in the Sepicontrol A5 complex opens closed pores and thereby prevents new skin impurities.

The new Belixos<sup>®</sup> Protect combines the benefits of an anti-ageing day cream with those of a pleasantly light sun protection and is particularly suitable for the prevention of damage caused by the sun. In addition, Belixos<sup>®</sup> Protect also contains organic UV filters and concentrated niacinamide, which can demonstrably reduce signs of skin ageing, in a rich formulation with vitamin E and high-quality lipids identical to those found in the body.

The development pipeline for further expansion of the Belixos® range currently includes Belixos® to go, a roll-on pen for people on the move that is thus available at any time for treating insect bites or incipient Herpes cold sores.

## 4. Sales and marketing

With its central European approval, Ameluz<sup>®</sup> 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 reimbursement status for the drug has to be defined prior to market launch, which can in some cases be a very lengthy process. To date, the company has commenced sales and distribution in Germany, UK, Spain, Austria, Holland, Belgium, Denmark, Sweden, Norway and Slovenia. The new drug is available in these countries at a pharmacy retail price of between just under EUR 200 and approx. EUR 280 per 2g tube.

Ameluz<sup>®</sup> is marketed by Biofrontera's own sales force in Germany and, since March 2015, in Spain, while in other European countries it is promoted with the help of marketing partners. Biofrontera is also taking over the distribution activities in Great Britain and Slovenia, but will be supported in local marketing by companies based there.

Distribution to public pharmacies takes place via pharmaceutical wholesalers, whereas hospital pharmacies are supplied directly. In addition to regular sales force visits to dermatologists, Biofrontera has presented Ameluz® at major dermatological conferences in Germany and internationally since it was launched, as well as recently in Spain. The response from dermatologists has been extraordinarily positive. In comparison to 2013 and 2014, Biofrontera achieved a significant increase in sales of more than 27%, and growth during the first half of 2015 amounted to 30% in Germany. The Ameluz® market share in the PDT medication segment is consistently at approx. 70%, with the remaining approx. 30% going to the competing products Metvix® and Alacare®. In spite of this, Ameluz<sup>®</sup> still only has a small share of the actinic keratosis market as a whole, because only approximately 5% of patients are treated with proprietary medicinal products for photodynamic therapy (PDT). However, 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 public health insurance industry, as doctors do not receive any compensation for performing PDT in this industry. In order to provide more information for patients, a video on PDT has been uploaded to YouTube in German at (http://www.youtube.com/watch?v=aK4a3R5kgMA, and in English at http://www.youtube.com/watch?v=2xE08DWC08o).

Approval for basal cell carcinoma is a pre-requisite for the distribution of Ameluz® to hospitals, as basal cell carcinoma is mainly treated there, whereas this is less the case for actinic keratosis. This indication plays an essential role for the breakthrough of Ameluz®, in particular in European countries. Basal cell carcinoma is the most common infiltrating tumour in humans: in the USA alone, approx. 2.8 million such treatments are carried out annually, and European figures are comparable. As basal cell carcinoma is also triggered by lifelong UV exposure, this number is rapidly rising. Compared with the surgical procedures that are still most commonly used today, photodynamic therapy offers significant advantages, particularly for thin tumours. According to a market study published last year by Technavio, the international market for actinic keratosis medications is expected to grow by approx. 8% annually, from its current level of approximately 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 medications (Ameluz® is mentioned in this context) will mean that fewer and fewer patients undergo operations.

Ameluz<sup>®</sup> is marketed by Desitin Arzneimittel GmbH in Denmark, Sweden and Norway, by BiPharma N.V. in Benelux and by Pelpharma Handels GmbH in Austria. Biofrontera carries out sales and distribution activities itself in Great Britain and Slovenia and is supported with regard to marketing aspects by PHA Farmed in Slovenia. Biofrontera terminated the cooperation with Spirit Healthcare in Great Britain as at July 2015. Sales and distribution in Spain were initially handled by Allergan, but since March 2015 Biofrontera has carried out market activities in Spain itself via its own branch, Biofrontera Pharma GmbH sucursal en España. Louis Widmer SA has been granted the Ameluz<sup>®</sup> distribution licence for Switzerland and Liechtenstein, and the Ameluz<sup>®</sup> distribution licence for Israel has been allocated to Perrigo Israel Agencies LTD. In these countries, it is necessary to obtain an independent approval, which the above-mentioned distribution partners are currently carrying out in cooperation with Biofrontera.

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<sup>®</sup> from Biofrontera at a price that is coupled to their own sales price. Depending on the market conditions, Biofrontera's share of the sales price varies considerably from country to country, ranging from 35% to 65% of net sales.

For France, Biofrontera has submitted its application to make Ameluz® reimbursable, with the assistance of a consultancy that specialises in this field.

Biofrontera has already initiated preparations for sales and distribution activities in USA. With the help of a consulting company specialising in market access and a team of consultants specialising in medical issues, Biofrontera has started to analyse the market for actinic keratosis medications and the reimbursement systems in the American health care system. In this regard, Biofrontera can make use of the experience of a competitor product already sold and distributed in the USA, Levulan Kerastick®, from the company DUS Pharmaceuticals Inc. A dedicated local subsidiary, Biofrontera Inc., was established in March 2015 and a very experienced CEO was appointed in the form of Monica L. Tamborini.

#### 5. Further 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 focus on further developing Ameluz® in the coming 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 to this end has yet been undertaken, 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. Because this product candidate no longer fits Biofrontera's dermatological product focus, the intention is to licence it out after the initial development stages.

After the first results involving 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

Further official communications regarding the "Nanoemulsion" patent (PCT/EP2007/011404) were issued in Canada, Chile and the USA, and responses were sent by the relevant deadlines.

In Europe and Canada, the issuing of the patent grant is imminent, so patent protection is expected soon.

### **Brand development**

Protection was granted in full for Singapore and Japan for two different forms of the international "Natural Heritage with Herbal Biocolloids" trademark.

## **Economic report**

## For the first half of the 2015 financial year for the Biofrontera Group:

- 29% overall revenue growth compared to the first half of the previous year, including 30% growth in Germany as well as significant sales growth in other European countries
- EBIT: EUR -6.8 million (first half previous year: EUR -4.9 million)
- Consolidated profit/loss before tax: EUR -7.3 million (first half previous year: EUR -5.4 million)
- Cash and cash equivalents as at 30 June: EUR 4.1 million
- Undiluted earnings per share amounted to EUR -0.33 Euro (first half previous year: EUR -0.25)

#### Achievement of objectives as at 30 June 2015:

<u>Sales revenue</u>: Sales revenue in Germany increased by 30% compared to the same period in the previous year. The target of 30% revenue growth in Germany has thus been reached; the forecast of 30% growth in Germany for the whole of 2015 remains unchanged. Significantly higher orders were recorded in other European countries, which led to a sharp increase in international sales.

Preparation of the approval application for Ameluz® in the USA: All preparations for submission of the approval application file to the FDA (Food and Drug Administration) were completed in the reporting period. In addition to the implementation of the three clinical trials already completed in 2014, the reformatting of the study results into the data format of the FDA and a joint evaluation of all the clinical results (integrated analysis) was required. The submission of the NDA (New Drug Application) to the FDA took place in early July 2015. Approval is expected to be issued about one year later.

<u>Clinical studies:</u> patient recruitment for the Phase III clinical trial on basal cell carcinoma was completed in May 2015. It is planned that the last recruited patient will have gone through the course of treatment after 6 months, and results could therefore be available by the end of the year.

## Financial position, cash flows and results of operations of the Biofrontera Group

## Biofrontera Group profit/loss account (summary)

	6 M 2015 6 M 2014		Change
	in thousand EUR	in thousand EUR	in %
Sales revenue	1,568	1,217	+29
Cost of sales	534	348	+53
Research and development costs	4,498	2,063	+118
Cost of sales	2,038	2,008	+2
General administration costs	1,348	1,740	-23
Other operating income and expenses	86	91	-6
EBIT	-6,763	-4,852	-39
Financial result	-560	-561	0
Profit/loss before income tax	-7,323	-5,413	-35
Income tax	0	-6	-100
Profit/loss after tax	-7,323	-5,419	-35

#### Sales revenue

The Biofrontera Group recorded sales of EUR 1,568 thousand in the first half of the 2015 financial year (same period in the previous year: EUR 1,217 thousand), corresponding to an increase of 29% compared to the same period in the previous year. Turnover from sales of our products in Germany increased by 30% to EUR 1,186 thousand (same period in the previous year: EUR 915 thousand), sales in other countries rose by 65% to EUR 382 thousand (same period in the previous year: EUR 231 thousand). No down payments were collected during the first half of the 2015 financial year (same period in previous year: EUR 70 thousand).

#### Cost of sales

In line with this increase in sales, the cost of sales also increased by 53%, from EUR 348 thousand to EUR 534 thousand, which resulted in the gross profit from sales improving from EUR 868 thousand in the first half of the 2014 financial year to EUR 1,034 thousand in the first half of the 2015 financial year.

The gross margin fell to 66% as compared to 71% in the same period in the previous year, due to the higher proportion of foreign sales.

#### Research and development costs, distribution and administration costs

The research and development costs, which amounted to EUR 2,063 thousand in the first half of the 2014 financial year, rose to EUR 4,498 thousand in the first half of the 2015 financial year. This is in line with Biofrontera's strat-

egy, which provides for investment in research and development for extending the range of indications and the approval for Ameluz<sup>®</sup> in the USA. A submission fee ("PDUFA fee") of EUR 2,072 thousand was paid for the submission of the approval application for Biofrontera's drug Ameluz<sup>®</sup> to the FDA. This fee is usually waived for small companies for their initial submission. Biofrontera had already made an application for the waiver of the fee in consultation with the FDA, which, however, could not yet be processed as the US approval authority FDA has not yet put a process in place to handle such applications.

Sales costs (at EUR 2,038 thousand) remained virtually constant compared to the same period in the previous year (EUR 2,008 thousand). The administrative costs decreased compared to the same period in the previous year, primarily due to lower financing costs. These costs fell by EUR 392 thousand, to EUR 1,348 thousand.

#### Financial result

The interest expenses included in the financial result, which amount to EUR 569 thousand, are almost entirely the result of the interest payments for the two warrant bonds and the compounding of interest on them using the effective interest method. The interest payment for the 2014 calendar year from the warrant bond I and II was made in January 2015.

#### Share capital

On 30 June 2015, the fully paid-up share capital of the parent company, Biofrontera AG, amounted to EUR 23,573,842.00. It was divided into 23,573,842 registered shares, each with a nominal value of EUR 1.00. On 31 December 2014, the share capital amounted to EUR 22,196,570.00, and it was increased in the course of the first half of the 2015 financial year by EUR 1,377,272.00, divided into 1,377,272 registered shares.

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 to the AIM market of the London Stock Exchange.

The shares held by the shareholders as at 30 June 2015, based on the most recent compulsory disclosures of the shareholders, are as follows:

	30 June 2015 EUR
Maruho Deutschland Co., Ltd., Osaka Japan The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, via the company Maruho Deutschland GmbH, Düsseldorf, Germany which is controlled by the former.	4,467,143
Professor Ulrich Abshagen, Germany Professor Abshagen has a direct holding of 59,793 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.	1,035,849
Universal-Investment-Gesellschaft mbH, Frankfurt *Most recent notification of voting rights on 10 February 2011. Since then, no threshold transgressions have been reported, so the actual shareholdings as at 30 June 2015 may deviate significantly from this information.	981,438*
Professor Dr Hermann Lübbert, Leverkusen	695,512
Free float	16,393,900
	23.573.842

## Financial position and cash flows

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. For more details concerning the development of the company's equity capital, please see the equity reconciliation statement.

The cash flow from operating activities decreased in comparison with the first half of 2014, from EUR -4,256 thousand to EUR -6,536 thousand.

Due to interest received on cash investments, cash flow from investment activities improved by EUR 30 thousand from EUR -37 thousand to EUR -7 thousand.

The cash flow from financing activities decreased by EUR 11,219 thousand compared to the same period in the previous year, from EUR 13,379 thousand to EUR 2,160 thousand, due to the proceeds received in the first half of the 2014 financial year from shares issued in a large capital increase being compared to a significantly smaller capital increase in the first half of the 2015 financial year.

The company was able to meet its payment obligations at all times, but will also be dependent on further financing measures in the future.

The Management Board assumes, on the basis of recent, successful experience with capital measures, that the liquidity required for business activities is guaranteed even beyond the forecast period. If these valid estimates are, contrary to expectations, not realised, this could constitute a threat to the company's continued existence.

Pursuant to IFRS, the group has negative equity amounting to EUR 4,299 thousand. Biofrontera AG has positive equity amounting to EUR 68,736 thousand as at 30 June 2015.

#### Personnel details

#### Staff

As at 30 June 2015, 54 (31 December 2014: 46) employees worked for the Biofrontera Group. This figure comprises 16 employees of Biofrontera AG (31 December 2014: 16), 6 employees of Biofrontera Bioscience GmbH (31 December 2014: 6), and 31 employees of Biofrontera Pharma GmbH (31 December 2014: 24). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. One member of staff is currently employed at the newly founded Biofrontera Inc.

#### Supplementary report

#### Events of special significance occurring since 30 June 2015

The approval application (New Drug Application) for Ameluz<sup>®</sup> and the BF-RhodoLED<sup>®</sup> lamp were submitted to the American Health Authority FDA.

Pursuant to a resolution passed by the Supervisory Board on 09 July 2015, Mr. Christoph Dünwald was appointed as a further Supervisory Board member of Biofrontera AG with effect from 16 November 2015. He will be responsible the areas of sales and distribution and also marketing within the Supervisory Board.

Biofrontera terminated the marketing contract with Spirit Healthcare Limited with effect from the 31 July 2015. In the future, Biofrontera will perform all local marketing and sales support activities in Great Britain itself.

## Risk, opportunity and forecast report

The risks existing in the group are described in detail in the risk report included in the published consolidated management report of 31 December 2014. No other significant changes in the risks described there have occurred as of 30 June 2015.

#### Risk management system

Biofrontera's management counters the risks existing in the group using a comprehensive risk management system. For a description of this system, please refer to the consolidated management report most recently published.

### Forecast regarding key tax figures

The current outlook for the 2015 financial year is unchanged from the forecast contained in the 2014 Annual Report.

For the 2015 financial year, Biofrontera expects to achieve turnover of approximately EUR 4 to 5 million, though this is still subject to significant planning uncertainties relating primarily to the speed of market penetration. In Germany, as in 2014, we envisage an increase in turnover 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 spread. Further licence agreements with possible one-off payments are not included in the above turnover forecast.

In order to extend the range of indications, and to receive approval for the USA, Biofrontera will continue to invest heavily in research and development and regulatory affairs in 2015. EUR 2.1 million were unexpectedly expended on the submission fee in the USA, since the FDA currently does not have a process for dealing with requests for the waiver of this fee. Although the possibility of a refund exists, we assume at the moment that the development costs for the entire year will increase by this amount, and will thus amount to EUR 6 - 7 million.

Biofrontera does not plan to make any significant investments in tangible assets in 2015.

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 2015 compared with 2014.

With the above-mentioned conditions and forecasts, the company will achieve a net result of EUR -11 to -12 million in 2015. The achievement of this result depends heavily on progress in terms of turnover.

Leverkusen, 14 August 2015

Biofrontera AG

Professor Hermann Lübbert

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Thomas Schaffer

Declaration pursuant to section 37y in conjunction with § 37w (2) no. 3 WpHG (German Securities Trading Act) – affidavit of the legal representatives

"We affirm that, to the best of our knowledge, in accordance with the applicable accounting principles for interim financial reporting and the principles of proper accounting, the consolidated interim financial statement gives a true and fair view of the financial position, cash flows and results from operations of the group, and that the consolidated interim management report presents the business performance, including the business results and position, of the group 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 group in the remainder of the financial year are described."

Leverkusen, 14 August 2015

Biofrontera AG

Professor Hermann Lübbert

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Thomas Schaffer

## Consolidated balance sheet as at 30 June 2015

## **Assets**

in EUR	30 June 2015	31 December 2014
Non-current assets		
Tangible assets	345,108.18	339,532.00
Intangible assets	2,240,059.50	2,580,077.17
	2,585,167.68	2,919,609.17
Current assets		
Current financial assets		
Trade receivables	287,769.24	308,984.35
Other financial assets	714,529.56	726,790.94
Cash and cash equivalents	4,126,619.22	8,509,398.16
	5,128,918.02	9,545,173.45
Other current assets		
Inventories		
Raw materials and supplies	630,557.34	684,455.83
Unfinished products	179,448.78	107,784.39
Finished products and goods	798,822.93	601,281.83
Income tax reimbursement claims	38,043.05	62,072.99
Other assets	190,193.49	90,118.27
	1,837,065.59	1,545,713.31
	6,965,983.61	11,090,886.76
Total assets	9,551,151.29	14,010,495.93

## Liabilities

in EUR	30 June 2015	31 December 2014
<u>Equity</u>		
Subscribed capital	23,573,842.00	22,196,570.00
Capital reserve	78,070,354.26	76,402,715.36
Loss carried forward	(98,620,285.49)	(87,899,306.51)
Net loss for the year	(7,322,880.44)	(10,720,978.98)
	(4,298,969.67)	(21,000.13)
Long-term liabilities		
Long-term financial liabilities	11,321,181.86	10,774,298.38
<u>Current liabilities</u>		
Current financial liabilities		
Trade payables	812,426.35	967,437.66
Short-term financial debt	415,087.14	1,224,598.00
Other financial liabilities	37,716.07	
	1,265,229.56	2,219,047.76
Other current liabilities		
Other provisions	1,171,652.44	951,944.41
Other current liabilities	92,057.10	86,205.51
	1,263,709.54	1,038,149.92
	2,528,939.10	3,257,197.68
Total liabilities	9,551,151.29	14,010,495.93

## Consolidated statement of comprehensive income for the first half of 2015

in EUR	6 M 2015	6 M 2014
Sales revenue	1,568,102.67	1,216,529.60
Cost of sales	-533.797,53	-348,231.35
Gross profit from sales	1,034,305.14	868,298.25
Operating expenses:		
Research and development costs	-4,497,894.88	-2,063,034.48
General administrative costs	-1,347,526.21	-1,740,272.32
of which financing costs	-150,746.32	-231,028.52
Cost of sales	-2,037,748.00	-2,007,732.22
Loss from operations	-6,848,863.95	-4,942,740.77
Financial result		
Interest expenses and similar	-568,810.49	-594,062.91
Interest income and similar	8,822.28	32,992.60
Other income and expenses		
Other expenses	-19,929.14	-12,688.47
Other income	105,900.86	103,909.77
Profit/loss before income tax	-7,322,880.44	-5,412.589.78
Income tax	0.00	-6,124.00
Profit or loss for the period	-7,322,880.44	-5,418,713.78
Expenses and income not included in profit/loss		
Subsequent valuation of financial assets available for sale	0	0
Other expenses and income not included in profit/loss	0	0
Total result for the period	-7,322,880.44	-5,418,713.78
Undiluted (= diluted) earnings per share	-0.33	-0.25

## Consolidated cash flow statement for the first half of 2015 and 2014

	6 M 2015	6 M 2014
	EUR	EUR
Cash flows from operations	LUK	LUK
Total result for the period	-7,322,880.44	-5,418,713.78
Adjustments to reconcile net profit or loss for the period with	1,022,000.11	0/110/110.110
cash flow into operations:		
Financial result	559,988.21	561,070.31
Depreciation	404,814.52	409,484.90
(Gains)/losses from disposal of assets	115.00	2,632.00
Non-cash expenses and income	23,814.20	-5,922.12*
Changes in operating assets and liabilities:		
Trade receivables	21,215.11	408,699.85
Other assets and income tax assets	-118,539.74	-203,431.01
Inventories	-215,307.00	845.27
Trade payables	-155,011.31	-178,511.22
Provisions	249,467.31	175,774.91
Other liabilities	16,555.56	-8,296.96
Net cash flow into operations:	-6,535,768.58	-4,256,367.85
Cook flows from investment activities.		
Cash flows from investment activities:	70 000 74	05 524 50
Purchase of intangible and tangible assets Interest received	-79.808.74	-85,524.50
	63,574.77	3,326.11
Revenue from the sale of intangible and tangible assets	9,320.71	45,144.58
Net cash flow from (into) investment activities	-6,913.26	-37,053.81
Cash flows from financing activities:		
Proceeds from the issue of shares	2,990,076.90	15,333,626.29
Payouts from the repurchase of own warrant bonds	0.00	-199,038.00
Interest paid	-830,174.00	-454,416.67
Increase/(decrease) in long-term financial debt	-20,663.14	-1,716,163.14*
Increase/(decrease) in short-term financial debt	20,663.14	415,087.14*
Net cash flow from financing activities	2,159,902.90	13,379,095.62
Net increase (decrease) in cash and cash equivalents	-4,382,778.94	9,085,673.96
Cash and cash equivalents at beginning of period	8,509,398.16	2,933,578.47
Cash and cash equivalents at end of period	4,126,619.22	12,019,252.43
Composition of financial resources at end of period:	- 1/1E0/017.EE	12/017/232:13
Cash and bank balances and cheques	4,126,619.22	12,019,252.43
*Adjustment to the statement of the provious year's figures	1,1LU,017.LL	16,017,636.43

## Consolidated statement of changes in equity for the first halves of the 2015 and 2014 financial years

	Ordinary shares	Subscribed	Capital reserve	Accumulated loss	Total
	Number	capital EUR	EUR	EUR	EUR
Account balance on 1 January 2014	17,753,168	17,753,168.00	65,598,778.57	(87,899,306.51)	(4,547,359.94)
Capital increase	4,443,402	4,443,402.00	11,105,950.00	0.00	15,549,352.00
Costs of capital procurement	0	0.00	(215,725.71)	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	(198,939.00)
Change 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	(99.00)
Increase in capital reserves from the stock option programme	0	0.00	54,522.00	0.00	54,522.00
Net loss for the year	0	0.00	0.00	(5,418,713.78)	(5,418,713.78)
Account balance on 30 June 2014	22,196,570	22,196,570.00	76,344,486.86	(93,318,020.29)	5,223,036.57
Capital increase	0	0.00	0.00	0.00	0.00
Costs of capital procurement	0	0.00	0.00	0.00	0.00
Changes in the capital reserve associated with the repurchase of own Warrant					
Bonds I	0	0.00	0.00	0.00	0.00
Changes in the capital reserve resulting from transaction costs in connection					
with the sale/repurchase of own Warrant Bonds I and II	0	0.00	0.00	0.00	0.00
Increase in capital reserves from the stock option programme	0	0.00	58,228.50	0.00	58,228.50
Net loss for the year	0	0.00	0.00	(5,302,265.20)	(5,302,265.20)
Account balance on 31 December 2014	22,196,570	22,196,570.00	76,402,715.36	(98,620,285.49)	(21,000.13)
Capital increase	1,377,272	1,377,272.00	1,790,453.60	0.00	3,167,725.60
Costs of capital procurement	0	0.00	(177,648.70)	0.00	(177,648.70)
Changes in the capital reserve associated with the repurchase of own Warrant					
Bonds I	0	0.00	0.00	0.00	0.00
Changes in the capital reserve resulting from transaction costs in connection					
with the sale/repurchase of own Warrant Bonds I and II	0	0.00	0.00	0.00	0.00
Increase in capital reserves from the stock option programme	0	0.00	54,834.00	0.00	54,834.00
Net loss for the year	0	0.00	0.00	(7,322,880.44)	(7,322,880.44)
Account balance on 30 June 2015	23,573,842	23,573,842.00	78,070,354.26	(105,943,165.93)	(4,298,969.67)

#### Selected notes on the consolidated interim financial statement as at 30 June 2015

## 1 Information about the company

### Information about the company

Biofrontera AG (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 whollyowned 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 a centralised European drug approval for an independently developed drug, Ameluz<sup>®</sup>. Ameluz<sup>®</sup> was approved for the treatment of mild and moderate actinic keratoses in December 2011. Two further clinical development projects, one dermatological project and one for the prevention of migraines, are in the pipeline but 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<sup>®</sup>, was launched in the autumn of 2009. A hair tonic, Belixos<sup>®</sup> LIQUID, was introduced in the spring of 2014 and a Belixos<sup>®</sup> gel skin care for rosacea and acne was launched at the beginning of December 2014. The launch of Belixos<sup>®</sup> 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 in one phase II and two phase III clinical trials for the European approval to treat actinic keratosis. In preparation for approval in the USA, two further phase I trials and a phase III trial have been conducted. Ameluz® consists of a combination of the active agent aminolevulinic acid (ALA) and a nanoemulsion (BF-200), which gives the ALA chemical stability and enables it to penetrate the skin effectively. 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. The application for regulatory approval (NDA = New Drug Application) was submitted to the FDA (Food and Drug Administration) in early July 2015.

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 choose to use any of the lamps approved for PDT, whereas in the USA the approval of Ameluz® will be intrinsically linked to that of the lamp. This will therefore be approved as a combination product along with the drug.

The BF-derm1 project is not currently being actively developed, but it has been tested in a three-part phase II trial for the treatment of chronic, antihistamine-resistant urticaria (hives). 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, both projects were acquired from Biofrontera AG and allocated as partner's investments to the two newly-founded subsidiaries, Biofrontera Development GmbH and Biofrontera Neuroscience GmbH, 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.

## 2 Accounting and valuation principles

Pursuant to the provisions of section 37y of the German Securities Trading Act (Wertpapierhandelsgesetz - WphG) in conjunction with section 37w WphG, the half-yearly financial statement as at 30 June 2015 comprises an abridged consolidated interim financial statement, a consolidated interim management report, and an affidavit of the legal representatives that corresponds to the specifications of section 297(2) p.3 and section 315(1) p.6 of the German Commercial Code (HGB).

As at 30 June 2015, the half-yearly financial statement of Biofrontera AG from 1 January 2015 to 30 June 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) for "Interim Financial Reporting" pursuant to IAS 34, as applicable in the European Union. In the opinion of the Management Board, these half-yearly financial statements contain all the half-yearly business transactions that are necessary for presentation of the financial position, cash flows and results of operations for the periods ending on 30 June 2015 and 2014.

These interim financial statements do not include all the information and data required to prepare annual financial statements. The interim financial statements should therefore be read in conjunction with the consolidated financial statements for 2014.

In the context of the preparation of the consolidated interim financial statements, the Management Board has to make estimates and assumptions that influence the application of accounting principles in the group as well as the reported amounts of the assets and liabilities and the income and expenses. The actual amounts may deviate from these estimates. The results achieved in the first half of the 2015 financial year do not permit any forecasts to be made concerning the further progress of business performance.

With regard to the accounting, valuation and consolidation principles used in the preparation of the consolidated interim financial statement of Biofrontera AG, which are essentially unchanged, and the information on the companies included in the consolidated statement, please see the notes to the consolidated financial statement of 31 December 2014 Biofrontera AG founded the 100% subsidiary Biofrontera Inc. in the first half of 2015 in order to prepare for the starting of business operations in the USA. Costs of capital procurement offset against equity are presented in the consolidated statement of changes in equity.

The consolidated financial statement as at 31 December 2014 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<sup>®</sup>, including the supplementary products BF-RhodoLED<sup>®</sup> (PDT lamp), and Belixos<sup>®</sup>, and are internally monitored and managed accordingly.

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.

This half-yearly financial statement of Biofrontera AG was approved for publication by resolution of the Management Board in August 2015.

In 2014, the German Financial Reporting Enforcement Panel (Deutsche Prüfstelle für Rechnungslegung, DPR) audited the consolidated financial statement as at 31 December 2013 and the 2013 group management report (sample audit). The audit was concluded without any findings being issued. Notes and suggestions for improvement from the DPR in terms of formulations and representations and breakdowns of items were though implemented in the consolidated financial statement and the group management report as at 31 December 2014 and in the half-yearly financial report as at 30 June 2015, as well as correspondingly for the previous year.

#### 3 Deferred taxes

As at 30 June 2015, the company has a considerable amount of tax loss carryforwards.

In accordance with the tax regulations applicable in Germany, these tax loss carryforwards are non-forfeitable and can be offset against future taxable profits of the company.

The existing tax loss carryforwards were assessed as legally binding in the tax audit in the first half of 2008 and in the final assessment up to the 2003 assessment period. In addition, another audit was conducted for the years from 2003 to 2009 and the existing tax loss carryforwards were also assessed as legally binding.

Nevertheless, no deferred tax assets from temporary differences or from tax loss carryforwards have been recognised in the balance sheet. This decision has been taken against the background that, from the current perspective, the Management Board still does not regard it as certain that the deferred tax claims can be realised in the next few years.

In accordance with IAS 12.34, the recognition of the deferred tax claims has therefore been dispensed with.

## 4 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 concerning the appropriateness of management board remuneration, such schemes must be linked to the longterm 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. The issue of a first tranche of these options is described in the consolidated financial statements of 31 December 2010. The second tranche took place in the 2011 calendar year and is noted in the consolidated financial statements of 31 December 2011. A further 116,500 option rights (third tranche) were issued in the first half of 2012 at an exercise price of EUR 3.30 or EUR 4.09 each. On 2 September 2013, 179,500 options (fourth tranche) were issued with an exercise price of EUR 3.373. In a further tranche (fifth tranche), on 2 April 2014 159,350 option rights were issued with an exercise price of EUR 3.43 each. All in all, 115,750 option rights were forfeited by employees leaving the company. There were therefore still 181,350 options outstanding on 30 June 2015. In the period under review, the expenditure booked was EUR 55 thousand (30 June 2014: EUR 55 thousand).

## 5 Shares / earnings per share

The earnings per share are calculated in accordance with IAS 33 on the basis of the half-yearly results of the Biofrontera Group as well as on the basis of the ordinary shares in circulation during the relevant periods in 2015 and 2014.

	30 June 2015	30. June 2014
Number of weighted ordinary shares in circulation (on average)	22,424,847.13	21,311,811.31
Net loss for the year in EUR	(7,322,880.44)	(5,418,713.78)
Earnings per share in EUR, related to net loss for the year	(0.33)	(0.25)

The increase in the number of ordinary shares to 23,573,842 can be attributed to a capital increase from authorised capital. On 1 June 2015, the share capital was increased by 1,377,272 shares (see ad-hoc news from 27 May 2015).

## 6 Reporting on financial instruments

In the ordinary course of business, the group faces interest rate changes 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 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 and medium term. Cashflow risk does not exist for the fixed interest bearing warrant bonds. No adverse changes in interest payments can occur, as a result of 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 exists for the group if transaction partners cannot fulfil their obligations within 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. No individual value adjustments were made for other financial assets (31 December 2014: EUR 261 thousand) in the reporting year; No individual value adjustments were made on deliveries and services in the first half of 2015 (31 December 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 evaluations using prices listed on active markets (not adjusted) for identical assets or liabilities.

Level 2: fair value evaluations 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 evaluations 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 one and two. No reclassifications between level 1 and 2 were carried out during the first half of 2015. All the financial assets assessed at fair value and listed in the following are classified as level 1. With regard to financial liabilities, the full amount (EUR 11,736 thousand; 31 December 2014: EUR 11,999 thousand) is allocated to level 2. This involves financial debt arising from the two warrant bonds.

Biofrontera records individual value adjustments on the trade receivables from deliveries and services and on the remaining financial liabilities assigned to the "loans and receivables" category under other operating expenses. The losses from the currency conversion from the "loans and receivables" assessment category are mainly attributable to liabilities from deliveries and services. The net profits and losses contain individual value adjustments and currency conversion effects.

The financial assets and liabilities as well as the net profits and losses can be broken down into assessment categories with the following book values:

Financial	Fair value			Book values			Net profit
assets as at 30 June 2015 (EUR)		Cash and cash equiv- alents	Credits and receivables	Financial instruments recognised at fair value in profit or loss (excluding	Financial assets availa- ble for sale	TOTAL BOOK VALUES	(+) or losses (-)
				"held for trading")			
<ul> <li>Financial investments</li> </ul>							
- Liquid assets	4,126,619	4,126,619				4,126,619	113
- Trade receivables	287,769		287,769			287,769	
- Other short-term financial receivables and assets	714,530		714,530			714,530	
TOTAL	5,128,918	4,126,619	1,002,299	0	0	5,128,918	113

Financial liabilities	Fair value		Net profit (+)				
as at 30 June 2015 (EUR)		Other liabilities	Financial instruments recognised at fair value in profit or loss (excluding "held for trading")	Book values		TOTAL BOOK VALUES	or losses (-)
- Financial liabilities (short-term)	415,087	415,087				415,087	
- Trade payables	812,426	812,426				812,426	(16,753)
- Other financial liabilities (short- term)	37,716	37,716				37,716	
<ul> <li>Other Financial liabilities (long- term)</li> </ul>	11,321,182	11,321,182				11,321,182	
TOTAL	12,586,411	12,586,411	0	0	0	12,586,411	(16,753)

Financial assets as at 31	Fair value		Book values						
December 2014 (EUR)		Cash and cash equiva- lents	Credits and receivables	Financial instruments recognised at fair value in profit or loss (exclud- ing "held for trading")	Financial assets available for sale	TOTAL BOOK VALUES	Net profit (+) or losses (-)		
<ul><li>Financial investments</li><li>Liquid assets</li></ul>	8,509,398	8,509,398				8,509,398	61		
- Trade receivables	308,984	0,007,070	308,984			308,984	(38)		
- Other short-term Finan- cial receivables and assets	726,791		726,791			726,791	(261,099)		
TOTAL	9,545,173	8,509,398	1,035,775	0	0	9,545,173	(261,076)		

Financial liabilities as at 31	Fair value					Net profit	
December 2014 (EUR)		Other liabilities	Financial instruments recognised at fair value in profit or loss (exclud- ing "held for trading")	Book values		TOTAL BOOK VALUES	(+) or losses (-)
- Financial liabilities (short-term)	1,224,598	1,224,598				1,224,598	
- Trade payables	967,438	967,438				967,438	(9,600)
- Other financial liabilities (short-term)	27,012	27,012				27,012	
- Other financial liabilities (long-term)	10,774,298	10,774,298				10,774,298	
TOTAL	12,993,346	12,993,346	0	0	0	12,993,346	(9,600)

Liquidity risk: 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. As at 30 June 2015, liquid assets and cash equivalents of EUR 4,127 thousand (31 December 2014: EUR 8,509 thousand) were available to cover the liquidity requirements. See the relevant balance sheet notes on (undiscounted) payments from financial debts due in the next few years.

## 7 Members of the Management Board

The members of the Management Board are:

- **Prof. Hermann Lübbert**, chairman of the Management Board (Chief Executive Officer)
- Thomas Schaffer, member of the Management Board (Chief Financial Officer)
- Pursuant to a resolution passed by the Supervisory Board on 27 March 2015, the management contract with Professor Hermann Lübbert was extended for a further five years, until 31 October 2020.
- Pursuant to a resolution passed by the Supervisory Board on 9 April 2015, the management contract with Mr. Thomas Schaffer was extended for a further five years, until 30 November 2020.

In the first half of the 2015 financial year, the remuneration of the members of the Management Board amounted to EUR 343 thousand (during the same period in the previous year: EUR 324 thousand).

## 8 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:

Jurgen Baumann	Chairperson of the	Supervisory	Board, expe	t in the	field of	sales and	marketing of
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pharmaceuticals, 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 Granzer Regulatory Consulting & Services, resident in

Munich, Germany

Ulrike Kluge Managing partner of klugeconcepts GmbH, Cologne; resident in Cologne, Germany

Andreas Fritsch Managing Director of Unternehmensberatung Fritsch, Seefeld; resident in Seefeld,

near Munich, Germany

Alfred Neimke Managing Director of Kopernikus AG in Zurich, Switzerland, resident in Zurich, Switzer-

land

In the first half of the 2015 financial year, the remuneration of the members of the Supervisory Board amounted to EUR 56 thousand (during the same period in the previous year: EUR 56 thousand).

## 9 Transactions with related persons

During the period under review, the company availed itself of additional advisory services from one 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 application for approval submitted to the supervisory authorities. During the course of the first half of the 2015 financial year, advisory services amounting to EUR 56 thousand (during the first half of the previous year: EUR 63 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 6 thousand on 30 June 2015 (31 December 2014: EUR 6 thousand). The amounts stated here do not include statutory VAT at the current rate of 19%. The underlying consultancy contracts were approved in consideration of the statutory provisions.

## 10 Significant events occurring after the interim balance sheet date.

The approval application (New Drug Application) for  $Ameluz^{@}$  and the BF-RhodoLED $^{@}$  lamp was submitted to the American Health Authority FDA.

Pursuant to a resolution passed by the Supervisory Board on 9 July 2015, Mr. Christoph Dünwald was appointed as a further Supervisory Board member of Biofrontera AG with effect from 16 November 2015. He will be responsible the areas of sales and distribution and also marketing within the Supervisory Board.

Biofrontera terminated the marketing contract with Spirit Healthcare Limited with effect from the 31 July 2015. In the future, Biofrontera will perform all local marketing and sales support activities in Great Britain itself.

Leverkusen, 14 August 2015

Professor Hermann Lübbert

Chief Executive Officer

Thomas Schaffer

Chief Financial Officer

## Issuer

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