

Biofrontera AG | Quarterly financial report as at 30 September 2015

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Development of sales revenue in the third quarter of 2015

- Growth in sales revenue of 38% compared to the same period in the previous year
- Significant growth in sales revenue of 87% in Germany compared to the same period in the previous year

Financial developments in the first nine months of the 2015 financial year

- Growth in sales revenue of 32% compared to the previous year
- Consolidated profit/loss: EUR -9.3 million
- Cash and cash equivalents of EUR 2.4 million as at 30 September 2015
- At the 2015 Annual General Meeting, all resolutions were approved with a large majority

Further significant progress in operational business in the first nine months of the 2015 financial year

- Approval application for Ameluz[®] and BF-RhodoLED[®] accepted for detailed examination by the FDA in the USA; after preliminary examination, FDA has identified no significant criticisms and holds out the prospect of an interim report in March 2016 and approval in May 2016; marketing preparations have begun
- Last patient included in the phase III trial on the treatment of basal cell carcinoma in May; preliminary results of the trial expected around the end of the year
- Strengthening of the management team with the appointment of Christoph Dünwald as Chief Commercial Officer
- Addition of Belixos[®] Protect, a daily skincare product for sun-damaged skin, to the dermo-cosmetic line
- Long-term results of the field therapy of actinic keratosis with Ameluz[®] prove a long-term increase in the anti-ageing effect of PDT

Key indicators

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

In EUR thousands	9M 2015	9M 2014	Q3 2015	Q3 2014
	unaudited	unaudited	unaudited	unaudited
Results of operations (earnings)				
Sales revenue	2,635.0	1,991.8	1,066.9	775.3
of which sales in Germany	2,091.2	1,399.1	905.1	483.8
of which downpayments	0.0	70.0	0.0	0.0
Sales and distribution costs and general administration costs	-4,989.0	-5,231.0	-1,603.8	-1,483.0
Research & development costs	-5,364.8	-3,146.0	-866.9	-1,083.0
Operating profit/loss	-8,578.9	-7,260.0	-1,730.0	-2,317.2
Profit/loss before tax	-9,285.8	-7,955.4	-1,962.9	-2,542.8
Profit/loss after tax	-9,285.8	-7,964.6	-1,962.9	-2,545.9

Cash flow statement

Cash flow from operating activities	-8,199.8	-6,321.8	-1,664.1	-2,065.4
Cash flow from investment activities	-19.4	-29.1	-12.5	7.9
Cash flow from financing activities	2,159.4	13,379.1	-0.5	0.0

In EUR thousands	9M 2015	9M 2014
	unaudited	unaudited
Key balance sheet figures		
Balance sheet total	7,454.8	15,868.1
Current liabilities (excluding provisions)	1,196.2	1,194.9
Long-term liabilities	11,408.8	10,965.3
Equity (subscribed capital & capital reserve)	101,671.1	98,571.4
Equity ratio	-83.64%	17.06%
Cash and cash equivalents	2,449.6	9,961.8
Employees as at 30 September	55	41
Biofrontera share		
Outstanding shares	30.09.2015 23,573,842	30.09.2014 22,196,570
Share price (Xetra closing price)	2.13	2.20
Dividend in euros	0	0

Biofrontera's financial instruments

Key details of the Biofrontera share

Stock exchanges	Frankfurt, Xetra, Tradegate, Düsseldorf, Berlin, Munich, Stuttgart, London (AIM)
WKN (German securities ID number)	604611
ISIN	DE0006046113
Shares outstanding as at 30 September 2015	23,573,842
9-month high (24 March 2015)*	EUR 2.999
9-month low (24 August 2015)*	EUR 1.66
Closing price 30 September 2015*	EUR 2.13
Market capitalisation as at 30 September 2015	EUR 62.765 million

*(Price data from Xetra)

Key details for warrant bond I with warrant*

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)
9-month high (9M 2015)	EUR 94.00
9-month low (9M 2015)	EUR 84.12
Closing price 30 September 2015	EUR 84.401

*(Price data from the Düsseldorf Exchange)

Key details for warrant bond II with warrant*

Stock exchanges	Düsseldorf
WKN (German securities ID number)	A1KQ9Q
ISIN	DE000A1KQ9Q9
Term, final maturity	5 years, 31 December 2016
Coupon	5%
9-month high (9M 2015)	EUR 90.10
9-month low (9M2015)	EUR 81.00
Closing price 30 September 2015	EUR 82.00

*(Price data from the Düsseldorf Exchange)

Consolidated interim management report for the first nine months 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 nine months 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, 51377 Leverkusen in 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 has responsibility for 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 owner 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 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 established 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 completely independently developed drug, Ameluz[®]. In the months prior to the market launch of Ameluz[®],

the company's own sales division 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. 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[®] 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[®] and BF-RhodoLED[®] must be approved in the USA as a combination of a drug product and a medical device, the approval application is unusually complex. In accordance with the guidelines, 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 priority testing areas. In this letter, FDA also set the date for the detailed interim report as 30 March 2016, provided that no significant problems arise, and held out the prospect of the issuing of final approval (PDUFA date) on 10 May 2016, two months earlier than originally expected. Biofrontera will then 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 phase III clinical testing in direct comparison to the competitive product Metvix[®] was completed in May 2015. The last patient will thus complete the study in November 2015 and the results may 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. Particularly 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 substantially reduced as a result. An extension of the indication would therefore put Biofrontera in a significantly improved market position. The extension of the indication of Ameluz[®] to include basal cell carcinoma is to be applied for towards the end of the first quarter of 2016, following completion of the phase III clinical trial and creation of the trial report; approval by the European agency is expected in the summer of 2016.

2016 will therefore be a very decisive year for Biofrontera, with Ameluz[®] approvals expected for basal cell carcinoma in Europe and for actinic keratosis in the USA, Switzerland and Israel. In light of this and the related challenges for Biofrontera, the Management Board was expanded to include a sales director. Christoph Dünwald was appointed as Chief Commercial Officer, bringing with him extensive international experience and all the necessary skills to 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. In the phase III development, its superiority compared to the 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 approval authority, the EMA, explicitly mentions the significant superiority of Ameluz[®] to its direct competitor product in terms of removing all of a patient's keratoses.

In the phase III trials relevant to approval, Ameluz[®] 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[®]. When counting individual keratoses, no fewer than 96% were completely eradicated (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[®] was tested in comparison with the approved standard medication. The results of the trial provided evidence that Ameluz[®] was clearly superior to the competitor drug available in Europe. Based on the average for all lamps used in the treatment, Ameluz[®] resulted in complete healing of actinic keratoses in 78% of patients, whereas the rival 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 preparations.

The phase III trial on the photodynamic field therapy of actinic keratosis in combination with Biofrontera's PDT lamp, BF-RhodoLED[®], demonstrated excellent preliminary long-term results. 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 efficacy, safety and the cosmetic result.

The new trial data demonstrates that 63.3% of the initially completely asymptomatic patients were still asymptomatic one year later. The long-term efficacy achieved with field therapy is thus in the same region as that already observed in previous long-term studies on lesion-directed PDT with Ameluz[®].

The progressive improvement in the skin appearance of patients treated with Ameluz[®] is excellent. The analysis of the cosmetic quality of the surface of the skin, as measured by the parameters of roughness, dryness and flakiness of the skin, showed a continuous improvement in the surface of the skin, which was even more pronounced one year after the last treatment than it was 3 or 6 months after the last treatment. Before PDT, only 14.8% of patients showed no impairments to the surface of the skin. But twelve weeks after the last PDT, 63% of patients were already free of such cosmetic damage, and 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, and 48.1% exhibited 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 enduring and the repair processes triggered by the therapy remain active for at least 12 months.

Patients may therefore benefit over a long period both from the sustained healing of the actinic keratosis and from the accompanying skin rejuvenation.

It is the first time that data on the aesthetic effect of PDT has been collected within the scope of an approval-related phase III 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.

As approval in the USA requires a combination of medication and lamp therapy, 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 this was completed in the reporting period. With this combination, keratoses were 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[®], 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 fell 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, 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[®] with 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 is 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 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 obliged 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 patients' lives. However, to date, the remuneration process has not yet been defined, but this is expected to happen in 2016.

At present, actinic keratoses are treated using a wide range of methods. Lesions may be treated with topical creams, which are often ineffective, sometimes for weeks, or the degenerated skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often lead 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. As Ameluz® is the market leader in the PDT proprietary medicinal product sector among practising dermatologists in Germany, with a market share of over 70%, a significant increase in sales can and must result from taking market share from the above-mentioned sectors.

The overall advantages of Ameluz® 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 the UK 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 they 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 application for approval extension should be submitted towards the end of the first quarter of 2016 and approval by the EMA is expected in mid-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®

Belixos® is a medical skin care product with herbal ingredients designed to promote the regeneration of damaged skin. The Belixos® 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 was added to the range in July 2015. The products are now available for sale at pharmacists and via the online retailer Amazon.

The innovative biocolloid technology and the specific combination of high-quality herbal ingredients should set new standards in the very competitive 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 provides protection for photodamaged skin from incurring further damage.

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

Belixos® 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® 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® 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® Protect also contains organic UV filters and concentrated niacinamide, which demonstrably reduces 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[®] 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, the UK, Spain, Austria, the Netherlands, Luxembourg, 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 270 per 2g tube.

Ameluz[®] 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. In the UK, Biofrontera is currently making preparations for its own sales operation and the contract with a local marketing company was terminated as of 31 July 2015. Biofrontera is also taking over the sales operation in Slovenia, but its marketing there is supported by a local company. 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 the major dermatological conferences both in Germany and in other European countries since it was launched. The response from dermatologists has been extraordinarily positive. A comparison with 2013 and 2014 shows that Biofrontera has achieved a significant increase in sales of more than 27% and during the first nine months of 2015 growth in Germany amounted to an excellent 49%, boosted in part by unusually high levels of stocking by wholesalers. The Ameluz[®] market share in the PDT medication segment is consistently around 70%, with the remaining approx. 30% being taken by the competing products Metvix[®] and Alacare[®]. In spite of this, Ameluz[®] 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 sector, as doctors do not receive any compensation for performing PDT in this area. 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=aK4a3R5kqMA>, 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 actinic keratosis is only very rarely treated there. This indication has an essential role in Ameluz[®] achieving a market breakthrough, 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 figure is rising rapidly. Photodynamic therapy offers significant advantages, particularly for thin tumours, compared to the surgical procedures that are still most commonly used today. 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.

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 sales and distribution activities itself in Slovenia and is supported in its marketing activities there by PHA Farmed. The cooperation with Spirit Healthcare in the UK was terminated by Biofrontera as of 31 July 2015, and Biofrontera is currently making preparations to set up its own sales operations. Sales in Spain were initially handled by Allergan SA, but since March 2015 Biofrontera has carried out sales activities in Spain itself 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 procedure, which is currently being carried out by the above-mentioned distribution partners 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[®] from Biofrontera at a price that is linked 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 60% of net sales.

For France, Biofrontera has submitted its application to make Ameluz[®] reimbursable, with the assistance of a consulting company 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 Dusa 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, who has already started building 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 intention is to launch Ameluz[®] on the US market on 1 September 2016.

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 is imminent, so patent protection is expected soon.

The patent fee in Canada was paid by the deadline.

The patent was issued in India.

Brand development

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

Economic report

For the first nine months of the 2015 financial year for the Biofrontera Group:

- 32% overall revenue growth compared to the first nine months of the previous year, including significant growth in Germany of 49% and low sales growth in other European countries
- Operating profit/loss: EUR -8.6 million (same period in previous year: EUR -7.3 million)
- Consolidated profit/loss before tax: EUR -9.3 million (same period in previous year: EUR -8.0 million)
- Cash and cash equivalents as at 30 September: EUR 2.4 million
- Undiluted earnings per share amounted to EUR -0.41 (same period in previous year: EUR -0.37)

Achievement of objectives as at 30 September 2015:

Sales revenue: Sales revenue in Germany increased by 49% compared to the same period in the previous year. The target of 30% revenue growth in Germany has thus been significantly exceeded. However, revenues were boosted in particular in the third quarter by unusually high levels of stocking by wholesalers, and the forecast of 30% growth in Germany for the whole of 2015 remains unchanged. Slightly higher orders were recorded in other European countries in the reporting period than in the first nine months of 2014, which led to an increase in international sales of 4%.

Preparation of the approval application for Ameluz® in the USA: all preparations for submission of the approval application file to 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 FDA and a joint evaluation of all the clinical results (integrated analysis) was required. The submission of the NDA (New Drug Application) to FDA took place in early July 2015. The application was accepted by FDA for intensive examination on 11 September ("acceptance to file"). In the so-called "74-day letter", FDA informed the company in October 2015 that no major review issues were identified in a preliminary review. FDA stated that the intended date for the detailed interim report is 30 March 2016 and the planned approval date (PDUFA Date) is 10 May.

Clinical trials: 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 finished the course of treatment after 6 months, i.e. in November 2015, and results could therefore be available already by the end of the year.

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

Biofrontera Group profit/loss account (summary)

	9 M 2015 in kEUR unaudited	9 M 2014 in kEUR unaudited	Change in %	Q3 2015 in kEUR unaudited	Q3 2014 in kEUR unaudited	Change in %
Sales revenue	2,635	1,992	32	1,067	775	38
Cost of sales	860	875	-2	326	527	-38
Research and development costs	5,365	3,146	71	867	1,083	-20
Distribution costs	2,929	2,789	5	891	781	14
General administrative costs	2,060	2,442	-16	713	702	2
Other operating income and expenses	149	129	16	63	38	66
EBIT	-8,430	-7,131	18	-1,667	-2,279	-27
Financial result	-856	-825	4	-296	-264	12
Profit/loss before income tax	-9,286	-7,956	17	-1,963	-2,543	-23
Income tax	0	9	-100	0	3	-100
Profit/loss after tax	-9,286	-7,965	17	-1,963	-2,546	-23

Sales revenue

The Biofrontera Group recorded sales of EUR 2,635 Thousand in the first nine months of the 2015 financial year (same period in the previous year: EUR 1,992 Thousand), corresponding to an increase of 32% compared to the same period in the previous year. Turnover from sales of our products in Germany increased by 49% to EUR 2,091 Thousand (same period in the previous year: EUR 1,399 Thousand), sales in other countries rose by 4% to EUR 544 Thousand (same period in the previous year: EUR 523 Thousand). No down payments were collected during the first nine months of the 2015 financial year (same period in previous year: EUR 70 Thousand).

Cost of sales, gross profit from sales

The gross profit from sales improved from EUR 1,117 Thousand in the first nine months of the 2014 financial year to EUR 1,775 Thousand in the first nine months of the 2015 financial year. The gross margin increased to 67% compared to 56% in the same period of the previous year.

Overall, the cost of sales fell slightly (by 2%) in the first nine months of the 2015 financial year, from EUR 875 Thousand to EUR 860 Thousand. This was due to cost reductions resulting from the training measures for new manufacturers carried out in previous years.

At the same time, the above-average sales growth in Germany and the establishment of the company's own direct sales operation in Spain as of March 2015 had a positive effect on the gross profit. In these cases, the margins achieved remain solely with Biofrontera, whereas in the case of foreign sales in countries with licensing agreements, part of the margin goes to the license partners.

Research and development costs, distribution and administration costs

The research and development costs, which amounted to EUR 3,146 Thousand in the first nine months of the 2014 financial year, rose to EUR 5,365 Thousand in the first nine months of the 2015 financial year. This is in line with Biofrontera's strategy, which provides for investment in research and development for extending the range of indications and the approval for Ameluz[®] 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[®] 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, although this could not yet be processed at the time of submission as the US approval authority FDA had not put a process in place to handle such applications. Biofrontera has since requested a refund of this fee from the FDA.

Sales costs increased only slightly, at EUR 2,929 Thousand compared to the same period in the previous year (EUR 2,789 Thousand). The administrative costs decreased by EUR 382 Thousand, to EUR 2,061 Thousand compared to the same period in the previous year, primarily due to lower financing costs.

Financial result

The interest expenses included in the financial result, which amount to EUR 865 Thousand, are almost entirely the result of interest payments for the two warrant bonds, and of the compounding of interest on the two warrant bonds using the effective interest method. The interest payments for the 2014 calendar year from warrant bond I and warrant bond II were made in January 2015.

Share capital

On 30 September 2015, the fully paid-up share capital of the parent company, Biofrontera AG, amounted to EUR 23,573,842.00. This 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 over the course of the first nine months 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 value of shares held by the shareholders on 30 September 2015, based on the most recent compulsory disclosures of the shareholders, are as follows:

	30 September 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 the managing partners.	1,035,849
Universal-Investment-Gesellschaft mbH, Frankfurt, Germany *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 September 2015 may deviate significantly from this information.	981,438*
Professor Hermann Lübbert, Leverkusen, Germany	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 of the development of the company's equity capital, please see the equity reconciliation statement.

The cash flow from operating activities decreased on 30 September 2015 in comparison to 30 September 2014, from EUR -6,322 Thousand to EUR -8,200 Thousand.

Due to interest received on cash investments, cash flow from investment activities improved by EUR 10 Thousand, from EUR -29 Thousand to EUR -19 Thousand.

The cash flow from financing activities decreased by EUR 11,220 Thousand compared to the same period in the previous year, due to the proceeds received in the first nine months of the 2014 financial year from shares issued in a capital increase. This cash flow fell from EUR 13,379 Thousand to EUR 2,159 Thousand. Only a relatively small capital increase was implemented in the period currently being reported.

The company has been able to meet its payment obligations at all times, but it will also be dependent on further financing 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 2014 and 2015, the company currently still has liquidity at its disposal. However, further financing measures are needed until break even has been reached, in particular for obtaining approval and for marketing preparation in the USA.

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.

According to IFRS, the group has negative equity amounting to EUR 6,235 Thousand. As at 30 September 2015, Biofrontera AG has positive shareholders' equity of EUR 68,078 Thousand.

Personnel details

Staff

On 30 September 2015, 55 (31 December 2014: 46) employees worked for the Biofrontera Group. This figure comprises 15 employees of Biofrontera AG (31 December 2014: 16), 6 employees of Biofrontera Bioscience GmbH (31 December 2014: 6), and 33 employees of Biofrontera Pharma GmbH including the Spanish branch (31 December 2014: 24). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. One member of staff is currently employed by Biofrontera Inc.

Supplementary report

Events of special significance occurring since 30 September 2015

Following a decision by the Supervisory Board on 09 July 2015, Christoph Dünwald was appointed as member of the Management Board effective 16 November 2015. Within the Management Board he will be responsible for sales and marketing.

On 2 October 2015, the FDA informed the company, in the so-called 74-day-letter, that according to a preliminary review, no major review issues were identified in the approval application. In this letter, the FDA gave the intended date for the detailed interim report as 30 March 2016 and the approval date (PDUFA date) as 10 May 2016.

On 27 October 2015, the company announced that to secure the further financing of the company, a capital increase with subscription rights will be carried out in which up to 5,893,460 shares will be issued. The issue price of the new shares was set at EUR 1.90 on 5 November 2015.

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 September 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 most recently published consolidated management report.

Forecast of key tax-related 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 to 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.

In order to extend the range of indications, and to receive approval in 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 as, at the time, the FDA did not have a process for dealing with requests for the waiver of this fee. Biofrontera has since requested a reimbursement of this fee from the FDA. If this reimbursement takes place in 2015, we assume that the development costs will be as originally planned for the full year, i.e. EUR 4 - 5 million. If no reimbursement is made this year, the development costs will rise accordingly.

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 -9 to -10 million in 2015. The achievement of this result depends heavily on progress in terms of turnover. If the submission fee is not reimbursed in 2015, the net loss will be EUR 2.1 million higher.

Leverkusen, 20 November 2015

Biofrontera AG



Professor Hermann Lübbert



Thomas Schaffer

Consolidated balance sheet as at 30 September 2015

Assets

in EUR	30 September 2015 unaudited	31 Dec 2014
Non-current assets		
Tangible assets	327,971.29	339,532.00
Intangible assets	2,070,046.45	2,580,077.17
	2,398,017.74	2,919,609.17
Current assets		
Current financial assets		
Trade receivables	228,199.63	308,984.35
Other financial assets	725,524.58	726,790.94
Cash and cash equivalents	2,449,605.83	8,509,398.16
	3,403,330.04	9,545,173.45
Other current assets		
Inventories		
Raw materials and supplies	624,582.66	684,455.83
Unfinished products	280,584.19	107,784.39
Finished products and goods	618,401.24	601,281.83
Income tax reimbursement claims	38,122.30	62,072.99
Other assets	91,751.35	90,118.27
	1,653,441.74	1,545,713.31
	5,056,771.78	11,090,886.76
Total assets	7,454,789.52	14,010,495.93

Liabilities

in EUR	30 September 2015 unaudited	31 Dec 2014
Equity		
Subscribed capital	23,573,842.00	22,196,570.00
Capital reserve	78,097,292.26	76,402,715.36
Loss carried forward	(98,620,285.49)	(87,899,306.51)
Net loss for the year	(9,285,816.87)	(10,720,978.98)
	(6,234,968.10)	(21,000.13)
Long-term liabilities		
Long-term financial liabilities	11,408,814.29	10,774,298.38
Current liabilities		
Current financial liabilities		
Trade payables	397,557.81	967,437.66
Short-term financial debt	622,630.71	1,224,598.00
Other financial liabilities	59,545.60	27,012.10
	1,079,734.12	2,219,047.76
Other current liabilities		
Other provisions	1,084,703.63	951,944.41
Other current liabilities	116,505.58	86,205.51
	1,201,209.21	1,038,149.92
	2,280,943.33	3,257,197.68
Total liabilities	7,454,789.52	14,010,495.93

Consolidated statement of comprehensive income for the first nine months of the 2015 and the 2014 financial years

in EUR	9M 2015	9M 2014	Q3 2015	Q3 2014
	unaudited	unaudited	unaudited	unaudited
Sales revenue	2,634,979.07	1,991,847.38	1,066,876.40	775,317.78
Cost of sales	-860,090.74	-874,790.20	-326,293.21	-526,558.85
Gross profit from sales	1,774,888.33	1,117,057.18	740,583.19	248,758.93
Operating expenses:				
Research and development costs	-5,364,765.48	-3,145,992.02	-866,870.60	-1,082,957.54
General administrative costs	-2,060,303.86	-2,441,994.90	-712,777.65	-701,722.57
of which financing costs	-233,645.46	-723,128.74	-82,899.14	-83,482.83
Distribution costs	-2,928,731.08	-2,789,041.95	-890,983.08	-781,309.73
Loss from operations	-8,578,912.09	-7,259,971.68	-1,730,048.14	-2,317,230.91
Financial result				
Interest expenses and similar	-864,694.79	-877,979.74	-295,884.30	-283,916.83
Interest income and similar	9,132.21	53,376.64	309.93	20,384.04
Other income and expenses				
Other expenses	-21,788.56	-15,389.33	-1,859.42	-2,700.86
Other income	170,446.36	144,558.53	64,545.50	40,648.76
Profit/loss before income tax	-9,285,816.87	-7,955,405.58	-1,962,936.43	-2,542,815.80
Income tax	0.00	-9,186.00	0.00	-3,062.00
Profit or loss for the period	-9,285,816.87	-7,964,591.58	-1,962,936.43	-2,545,877.80
Expenses and income not included in profit/loss				
Subsequent valuation of financial assets available for sale	0	0	0	0
Other expenses and income not included in profit/loss	0.00	0.00	0.00	0.00
Total profit/loss for the period	-9,285,816.87	-7,964,591.58	-1,962,936.43	-2,545,877.80
Diluted (= diluted) earnings per share	-0.41	-0.37	-0.09	-0.12

Consolidated cash flow statement for the first nine months of the 2015 and the 2014 financial years

	9M 2015 unaudited EUR	9M 2014 unaudited EUR	Q3 2015 unaudited EUR	Q3 2014 unaudited EUR
Cash flows from operations				
Total profit/loss for the period	-9,285,816.87	-7,964,591.58	-1,962,936.43	-2,545,877.80
Adjustments to reconcile earnings for the period to cash flows in operating activities:				
Financial result	855,562.58	824,603.10	295,574.37	263,532.79
Depreciation	604,732.54	605,744.90	199,918.02	196,260.00
(Gains) / losses from the disposal of assets	115.00	2,632.00	0.00	0.00
Non-cash expenses and income	24,510.52	23,618.88	696.32	29,541.00
Changes in operating assets and liabilities:				
Trade receivables	80,784.72	312,395.19	59,569.61	-96,304.66
Other assets and income tax assets	-31,171.87	-214,378.17	87,367.87	-10,947.16
Inventories	-130,046.04	173,350.42	85,260.96	172,505.15
Trade payables	-569,879.85	-257,938.88	-414,868.54	-79,427.66
Provisions	188,530.88	169,239.44	-60,936.43	-6,535.47
Other liabilities	62,833.57	3,546.65	46,278.01	11,843.61
Net cash flow into operations:	-8,199,844.82	-6,321,778.05	1,664,076.24	2,065,409.20
Cash flows from investment activities:				
Purchase of intangible and tangible assets	-94,811.12	-113,860.51	-15,002.38	-28,336.01
Interest received	63,884.70	6,663.20	309.93	3,337.09
Revenue from the sale of intangible and tangible assets	11,555.01	78,085.30	2,234.30	32,940.72
Net cash flow from (into) investment activities	-19,371.41	-29,112.01	-12,458.15	7,941.80
Cash flows from financing activities:				
Proceeds from the issuing of shares	2,989,597.90	15,333,626.29	-479.00	0.00
Payouts from the repurchase of own warrant bonds	0.00	-199,038.00	0.00	0.00
Interest paid	-830,174.00	-454,416.67	0.00	0.00
Increase/(decrease) in long-term financial debt	-228,206.71	-1,923,721.71	-207,543.57	-207,558.57
Increase/(decrease) in short-term financial debt	228,206.71	622,630.72	207,543.57	207,543.58
Net cash flow from financing activities	2,159,423.90	13,379,080.63	-479.00	-14.99
Net increase (decrease) in cash and cash equivalents	-6,059.792.33	7,028,190.57	-1,677,013.39	2,057,483.39
Cash and cash equivalents at beginning of period	8,509,398.16	2,933,578.47	4,126,619.22	12,019,252.43
Cash and cash equivalents at end of period	2,449,605.83	9,961,769.04	2,449,605.83	9,961,769.04
Composition of financial resources at end of period:				
Cash and bank balances and cheques	2,449,605.83	9,961,769.04	2,449,605.83	9,961,769.04

Consolidated statement of changes in equity for the first nine months of the 2015 and 2014 financial years

	Ordinary shares	Subscribed capital	Capital reserve	Accumulated loss	Total
unaudited	Quantity	EUR	EUR	EUR	EUR
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	84,894.00	0.00	84,894.00
Net loss for the year	0	0.00	0.00	(7,964,591.58)	(7,964,591.58)
Balance on 30 September 2014	22,196,570	22,196,570.00	76,374,858.86	(95,863,898.09)	2,707,530.77
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 sale/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	27,856.50	0.00	27,856.50
Net loss for the year	0	0.00	0.00	(2,756,387.40)	(2,756,387.40)
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	(178,127.70)	0.00	(178,127.70)
Changes in the capital reserve associated with the sale/repurchase of own Warrant Bonds I and II	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	82,251.00	0.00	82,251.00
Net loss for the year	0	0.00	0.00	(9,285,816.87)	(9,285,816.87)
Balance on 30 September 2015	23,573,842	23,573,842.00	78,097,292.26	(107,906,102.36)	(6,234,968.10)

Selected notes on the consolidated interim financial statement as at 30 September 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 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 a 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 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[®], 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. This was followed in July 2015 by Belixos[®] Protect, a day cream with protective anti-aging properties designed especially for photo-damaged skin.

The product Ameluz[®] (development name BF-200 ALA), which was approved at the end of 2011, was tested for the European 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), which is chemically stabilised by the ALA and has good skin penetration properties. 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 a medication was submitted in early July 2015 to FDA and was accepted by FDA for intensive examination ("acceptance to file") in September 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 along with the drug as a combination product.

The BF-Derm1 project, which is not currently being actively pursued, was 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, 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 both founded 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

The quarterly financial statement of Biofrontera AG on 30 September 2015 for the period from 1 January 2015 to 30 September 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 quarterly financial statements contain all the business transactions that are necessary for presentation of the financial position, cash flows and results of operations for the periods ending on 30 September 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 nine months 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 nine months of the 2015 financial year 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 statements for December 2014 contain no separate segment 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.

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 interim financial statement of Biofrontera AG was approved for publication by resolution of the Management Board in November 2015.

In 2014, the German Financial Reporting Enforcement Panel (DPR) subjected the consolidated financial statement for 31 December 2013 and the group management report 2013 to an audit (sampling inspection). 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 the interim financial statement for 30.09.2015, and correspondingly for the previous year.

3 Deferred taxes

On 30 September 2015, the company had considerable tax losses carried forward.

Under the current tax regulations in Germany these tax losses have no expiry date and can be offset against the future taxable profit 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 long-term success of the company. As the stock option programme decided by the company's Annual General meeting 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. A further tranche (fifth tranche) of 159,350 option rights was issued on 2 April 2014 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 September 2015. In the period under review, the expenditure booked was EUR 82 Thousand (30 September 2014: EUR 85 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 September 2015 unaudited	30 September 2014 Unaudited
Number of weighted ordinary shares in circulation (on average)	22,812,054.19	21,609,971.75
Net loss for the year in EUR	(9,285,816.87)	(7,964,951.58)
Earnings per share in EUR, related to net loss for the year	(0.41)	(0.37)

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 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)
- A decision was made on 27 March 2015 by the Supervisory Board to extend the management contract with Prof. Hermann Lübbert for a further five years, until 31 October 2020.
- A decision was made on 9 April 2015 by the Supervisory Board to extend the management contract with Thomas Schaffer for a further five years, until 30 November 2020.

In the first nine months of the 2015 financial year, the remuneration of the members of the Management Board amounted to EUR 487 Thousand (during the same period in the previous year: EUR 462 Thousand).

7 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 pharmaceuticals, resident in Monheim, Germany
Prof. Dr. 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	Member of the management board, Xolaris Service Kapitalverwaltungs AG, Munich, Germany; 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, Switzerland

The members of the Supervisory Board held the following other positions on Supervisory Boards or other such comparable domestic and foreign bodies during the reporting period:

Alfred Neimke

Board of directors at DERPHARM AG in Zürich, Switzerland

In the first nine months of the 2015 financial year, the remuneration of the members of the Supervisory Board amounted to EUR 84 Thousand (during the same period in 2014: EUR 84 Thousand).

8 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 applications for approval submitted to the supervisory authorities in Europe and the USA. During the course of the first nine months of the 2015 financial year, advisory services amounting to EUR 60 Thousand (during the same period in the previous year: EUR 82 Thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 1 Thousand on 30 September 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 contract was approved in consideration of the statutory provisions.

9 Significant events occurring after the interim balance sheet date.

Following a decision by the Supervisory Board on 09 July 2015, Christoph Dünwald was appointed as member of the Management Board effective 16 November 2015. Within the Management Board he will be responsible for sales and marketing.

On 2 October 2015, the FDA informed the company, in the so-called 74-day-letter, that according to a preliminary review, no major review issues were identified in the approval application. In this letter, the FDA gave the intended date for the detailed interim report as 30 March 2016 and the approval date (PDUFA date) as 10 May 2016.

On 27 October 2015, the company announced that to secure the further financing of the company, a capital increase with subscription rights will be carried out in which up to 5,893,460 shares will be issued. The issue price of the new shares was set at EUR 1.90 on 5 November 2015.

Leverkusen, 20 November 2015



Professor Hermann Lübbert

Chairman of the Management Board



Thomas Schaffer

Chief Financial Officer

Editor

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