Biofrontera AG | Quarterly report as at March 31, 2016

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Financial developments in the first quarter of 2016

- Revenue: EUR 1.017 million (down 1% on Q1 2015)

  (Muted revenue development in Germany, but increased revenue outside Germany)
- Consolidated earnings: EUR -0.4 million.
- Cash and cash equivalents of EUR 8.0 million
- Two successful financing measures carried out in February and April 2016

Key indicators

Key consolidated figures for the first quarter of the 2016 financial year in accordance with IFRS

In EUR thousand	3M 2016	3M 2015
	unaudited	unaudited
Results of operations (earnings)		
Revenue	1,016.8	1,030.0
of which revenue in Germany	633.1	783.2
of which revenue outside Germany	323.7	246.8
of which down-payments	60.0	0.0
Sales and general administrative costs	-1,984.4	-1,578.1
Research and development costs	-1,004.7	-1,240.1
Operating profit (EBIT)	-154.9	-2,089.5
Earnings before tax	-447.7	-2,362.5
Earnings after tax	-447.7	-2,362.5
Cash flow statement		
Cash flow from operating activities	183.6	-1,818.4
Cash flow from investment activities	-92.0	22.6
Cash flow from financing activities	3,998.8	-830.2

In EUR thousand	3M 2016	3M 2015
Key balance sheet figures	unaudited	unaudited
Balance sheet total	13,505.4	11,374.9
Current liabilities (excluding provisions)	9,814.3	1,375.4
Non-current liabilities	3,241.9	11,241.3
Equity, subscribed capital & capital reserve	109,472.2	98,626.7
Equity ratio	-5.88%	-20.71%
Cash and cash equivalents	8,049.6	5,883.4
Employees as at March 31	59	49
Biofrontera shares	March 31, 2016	March 31, 2015
Outstanding shares	27,847,814	22,196,570
Share price (Xetra closing price)	2.19	2.62
Dividend in EUR	0.00	0.00

Biofrontera's financial instruments

Key details of Biofrontera shares	
Stock exchanges	Düsseldorf, Frankfurt, Berlin, Munich, Stuttgart, Xetra, Tradegate
WKN (German securities ID number)	604611
ISIN	DE0006046113
Shares outstanding as at March 31, 2016	27,847,814
3-month high (January 28, 2016)*	EUR 2.41
3-month low (January 7, 2016)*	EUR 1.83
Closing price March 31, 2016*	EUR 2.19
Market capitalization as at March 31, 2016	EUR 61 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, December 31, 2017
Stepped coupon	4% (2010), 6% (2011), 8% (2012)
3-month high (Q1 2016)	EUR 90.00
3-month low (Q1 2016)	EUR 77.00
Closing price March 31, 2016	EUR 78.00

*(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, December 31, 2016
Coupon	5%
3-month high (Q1 2016)	EUR 92.70
3-month low (Q1 2016)	EUR 77.10
Closing price March 31, 2016	EUR 86.00

*(Price data from the Düsseldorf Exchange)

Group strategy

The strategic objective of the Biofrontera Group is to establish the company at global level as a pharmaceutical company specializing in the dermatological sector. In addition to further expansion of the sale of our products, the main priorities are to increase the range of indications for Ameluz® and to expand international sales activities, particularly in the USA.

Biofrontera was the first small German company to receive centralized European drug approval for a completely independently developed drug, Ameluz®. 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. Ameluz® is available in the UK, but is not to be actively promoted until after approval has been extended to basal cell carcinoma. The drug is sold in other countries of the European Union, as well as in Israel and Switzerland, via 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 short-term strategy is to further expand its business in Europe, achieve market entry of Ameluz® in the USA and extend the indications to include basal cell carcinoma, first in the EU and at a later stage in the USA.

Further preparatory work was carried out for the approval of Ameluz® in the USA in the reporting period. In early July 2015, the approval application (NDA = New Drug Application) was submitted to the FDA (Food and Drug Administration). Ameluz® and BF-RhodoLED® have to be approved as a combination of a drug and a medical device in the USA, and therefore the approval application is unusually complex. In accordance with the guidelines, the FDA made a decision on the formal "acceptance to file" after a period of 60 days, and this was granted on September 11, 2015. In the subsequent "74-day letter", the company was informed on October 2, 2015 that no significant verification issues had been identified in the preliminary review process. In this letter, the FDA also gave the date for the detailed interim report including the proposed labeling as March 30, 2016, and gave an estimated date for issuing the final approval (PDUFA date) of May 10, 2016, provided that no significant problems arise. In a further communication on January 20, 2016, the FDA informed the company that the midcycle review had been completed and the FDA had no further questions arising from this regarding the approval application. The proposed labeling was provided to the company by the FDA at the end of March 2016. After the end of the reporting period, the FDA granted approval for unconditional marketing of Ameluz in combination with the PDT lamp in the USA, as announced on May 10. Approval relates to the treatment of individual tumorous lesions as well as larger areas. No conditions to be fulfilled after approval were imposed here. Consequently, Biofrontera is open to the largest healthcare market in the world, and preparations for the planned market launch in September 2016 are well underway.

The extension of the indications for Ameluz® to include the treatment of basal cell carcinoma (BCC) was initiated in 2014. The phase III clinical testing was carried out in direct comparison with the competitor product Metvix®. Patient recruitment was completed in May 2015 and the last patient completed the clinical part of the trial in November 2015. There is then a 5-year follow-up period for all the patients. The results of the trial have been available since January 2016 and prove that Ameluz® is highly clinically effective for the indication of BCC. In comparison with the competitor product Metvix®, it demonstrated higher healing rates, especially with thicker and nodular carcinomas. Despite its statistically significant inferiority for the treatment of mild and moderate actinic keratosis on the face and scalp and the approval restriction as a second-choice therapy, Metvix® has had a major competitive advantage over Ameluz® up to now due to its approval for the treatment of basal cell carcinoma. Particularly in those European countries, where dermatologists are based mainly in hospitals and there are fewer independent practices, the market opportunities of Ameluz® are significantly reduced by the lack of approval for BCC. The extension of the indications currently being sought is therefore expected to put Biofrontera in a significantly

improved market position. The application to extend the indications of Ameluz® to include basal cell carcinoma is due to be made once the trial report has been completed in the 2nd quarter of 2016, and the approval of the European Medicines Agency is then expected in the 4th quarter of 2016.

2016 is therefore a crucial year for Biofrontera in the course is likely to be set for a successful future on several fronts. In light of this and the related challenges facing Biofrontera, the company has also strengthened its staff. The Management Board was expanded to include a Chief Commercial Officer back in November 2015. In recent weeks, Biofrontera has also started to advertise for suitable employees in the USA in order to fill key posts with highly qualified staff there as soon as possible.

Products

Ameluz®

Ameluz® 78 mg/g Gel ("for people who love the light", development name: BF-200 ALA) received a first centralized European approval for the treatment of mild and moderate actinic keratoses on the face and scalp in December 2011. During the phase III development, its superiority compared to its direct competitor product Metvix® was proven for this indication. Actinic keratoses are superficial forms of skin cancer, and there is a risk that they can spread to deeper layers of skin. The combination of Ameluz® with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European Medicines Agency (EMA) explicitly mentions the significant superiority of Ameluz® for removing all of a patient's keratoses compared to its direct competitor product.

In the phase III approval trials, Ameluz® showed excellent healing rates and demonstrated significant superiority compared to the approved comparator product, which was tested in parallel. In the first phase III trial in which the drug was combined with an LED lamp, in 87% of patients treated with Ameluz®, all keratoses were completely removed, and in terms of the number of individual keratosis lesions, as many as 96% were completely eradicated (all the values stated are ITT *(intent to treat)* values). In the second phase III approval trial, the effectiveness of Ameluz® was tested in comparison with the approved standard medication. The results of the trial provided evidence that Ameluz® was clearly superior to the competitor product already available in Europe at the time. Based on the average for all lamps used in the treatment, Ameluz® resulted in the complete healing of actinic keratoses in 78% of patients, whereas the competitor product already approved at the time achieved a healing rate of only 64%. With LED lamps, the healing rates increased to 85% for Ameluz® and 68% for the competitor product. The side-effect profile was comparable for both products.

As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which requires the company to be certified pursuant to the ISO 9001 and ISO 13485 standards. In preparation for approval in the USA, a phase III trial was carried out with a combination of Ameluz® and BF-RhodoLED®. With this combination, keratoses were completely eradicated from 91% of patients, and in terms of the number of individual lesions, 94% were completely removed after treatment (99.1% of mild and 91.7% of moderate lesions). As it has been widely reported in the literature that PDT has pronounced skin-rejuvenating properties, particularly in the case of sun-damaged skin, in this trial, for the first time in a phase III trial of PDT anywhere in the world, the drug was applied over large surface areas (field therapy) and the cosmetic result was established, without taking into account the disappearance or not of the keratotic lesions. All the parameters that were tested improved significantly as a result of the treatment. The proportion of patients without rough, dry and scaly skin increased from 14.8% to 63.0% after treatment with Ameluz®. The group of patients without hyperpigmentation or hypopigmentation increased from 40.7% to 57.4% and from 53.7% to 70.4%, respectively. The proportion of patients with mottled pigmentation who had both hyperpigmentation and hypopigmentation in the treated area decreased from 48.1% to 29.6%. Before treatment, 22.2% of the patients had mild scarring,

which dropped to 14.8% of patients after treatment. Atrophic skin was diagnosed in 31.5% of patients before treatment but in only 16.7% of patients after the treatment.

The patients treated in the field therapy trial were observed by the trial doctors over the course of a year after the final treatment. Here, the long-term nature of the pharmaceutical effect of Ameluz® was analyzed in terms of effectiveness, safety and the cosmetic result. 63.3% of the patients who were initially completely asymptomatic were still asymptomatic one year later. The long-term effectiveness achieved using field therapy is thus in the region of that already observed in previous long-term studies on lesion-directed PDT with Ameluz®. The improvement in the skin appearance of patients treated with Ameluz® that was observed immediately after PDT continued to develop during the follow-up period. Before PDT, only 14.8% of patients had no impairments to the surface of the skin. Whereas twelve weeks after the last PDT, 63% of patients were already free of such cosmetic damage, this percentage rose after a year to 72.2%. Similar results were also observed for pigment disorders. Before PDT, hyperpigmentation occurred in 59.3% and hypopigmentation in 46.3% of patients, with 48.1% exhibiting irregular pigmentation. Twelve weeks after Ameluz® PDT, these percentages initially fell to 42.6%, 29.6% and 29.6% and decreased over the course of a year to 24.1%, 11.1% and 18.5%. These results clearly show that the skin rejuvenation effect achieved using photodynamic therapy with Ameluz® is long-lasting and the repair processes triggered by the therapy remain active for at least 12 months.

It is the first time that data on the aesthetic effect of PDT has been collected within the scope of a phase III approval trial. The results underline the significance of PDT with Ameluz® and BF-RhodoLED® and show that the therapy stands out clearly from many other treatment options.

Both the phase I trials required by the American approval authority, the FDA, were already completed in 2015. These clinical trials were initiated with a total of approximately 240 patients or subjects in order to add the safety data required for registration in the USA to the European approval package for Ameluz®. Specifically, one of the trials was a sensitization study, which determines the potential of Ameluz® to trigger allergies, and the other was a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz®, aminolevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, i.e. the application of a complete tube onto the defective skin. No safety concerns were identified in either of the studies.

Actinic keratosis is classified as a tumor that requires treatment, and the international treatment guidelines list photodynamic therapy as the gold standard for the removal of actinic keratoses, particularly for patients with large keratotic areas. The latest statistics show that actinic keratosis is becoming a widespread disease, with up to 8 million people affected in Germany alone, and that there is a marked upward trend in cases. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this happens to the relevant lesions within two years on average. The fact that doctors are therefore taking actinic keratosis increasingly seriously is illustrated by the fact that actinic keratosis has been recognized as an occupational disease since summer 2013. Since then, occupational insurance associations have been obliged to cover the treatment costs of patients who have worked predominantly outdoors for a long time and who fulfill certain criteria for the duration of these patients' lives. Reimbursement was determined in March 2016. Photodynamic therapy (PDT) is taken into account here, and can be used and invoiced for the treatment of occupational AK.

At present, actinic keratoses are treated using a wide range of methods. Lesions are treated, sometimes for weeks, with topical creams, which are often ineffective, or the diseased skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often leads to scar formation or permanent pigment disorders.

The market for topical creams continues to show constant growth, and medicinally and legally questionable PDT formulations continue to be used in Germany. Because Ameluz® is the market leader among independent dermatologists in Germany in the PDT proprietary medicinal product market, with a market share of over 70%, a significant increase in revenue can and must result from the above-mentioned sectors.

The overall advantages of Ameluz® in terms of effectiveness, handling, user-friendliness and skin rejuvenation effect, as well as the high healing rates of PDT in the treatment of actinic keratoses, will increasingly bring this treatment option to the attention of dermatologists over the next few years. This will be helped by the expansion of the range of indications to include basal cell carcinoma, which the company is currently working on, as the vast majority of PDT treatments are carried out for this indication, particularly in the UK and Spain.

Biofrontera has carried out a phase III trial for the extension of the European approval to include the indication basal cell carcinoma (BCC). BCCs are the most common invasive tumors that affect humans and account for approximately 80% of all invasive white skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in Germany but this can lead to clearly visible scarring, whereas treatment with photodynamic therapy (PDT), which is an alternative particularly in the treatment of thin BCCs, gives rise to excellent cosmetic results. In the pivotal phase III trial, a total of 278 patients were treated. The trial was conducted under the clinical supervision of Prof. Dr. Colin Morton (UK) and Prof. Dr. Markus Szeimies (Germany) and was carried out at 27 clinical trial centers in the UK and Germany. Patient recruitment for the trial, which was carried out in direct comparison with the competitor product Metvix®, was completed in May 2015 and the last patient completed the trial in November 2015. The results of the trial have been available since January 2016. The results confirm the company's positive expectations. In the clinical trial, the effectiveness and safety of Ameluz® were compared with that of Metvix®, a drug already approved in the EU for the treatment of BCC. Non-aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. Ameluz® achieved complete elimination of all BCCs from the patient in 93.4% of cases compared to 91.8% with Metvix®. There were greater differences in the case of thicker BCCs. With Ameluz®, 89.3% of the nodular carcinomas were completely removed, compared to only 78.6% with Metvix®.

Based on the results of this phase III trial, Biofrontera will shortly apply to the European Medicines Agency for approval for the treatment of BCC with Ameluz®. As the existing Ameluz® approval has to be extended for this only, the extended approval should be issued as early as this year.

BF-RhodoLED®

BF-RhodoLED® is a lamp designed for photodynamic therapy (PDT), and uses LEDs emitting red light at a wavelength of approx. 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. The light energy and fan power settings can be adjusted during a PDT treatment session in order to reduce any discomfort caused by the treatment. No other lamp on the market offers comparable power and flexibility. BF-RhodoLED® has been CE-certified since November 2012 and is distributed throughout the EU.

Belixos®

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated skin. The biocolloid technology patented by Biofrontera, which optimizes epidermal penetration, makes the products unique: pure plant biocolloids are combined with medicinal plant extracts to form an extraordinary combination of active substances with proven depth penetration, bringing together the best of nature and science.

Belixos® Cream rapidly and reliably soothes itching and is the ideal basic treatment for inflamed, reddened, and flaky skin. It soothes the skin, reduces scratching, and allows the skin to regenerate naturally. Belixos® Cream, which has been available since 2009, has thus proved particularly useful as an effective basic treatment for atopic dermatitis and psoriasis.

Over the past two years, other specialist regenerative cosmetic products for skin problems have been developed. The typical deep yellow color is the unmistakable mark of quality. This is derived from the traditional medicinal plant extract obtained from the roots of Mahonia aquifolium. Belixos® products use only natural active substance extracts with clinically proven effects.

Belixos® Liquid is an innovative scalp tonic with a practical pipette for dosing, which soothes scalps irritated by psoriasis or eczema, for example, and restores their balance. For itchy and flaky scalps, a combination of anti-inflammatory mahonia, moisturizing oats, irritation-relieving panthenol, and a special zinc PCA complex is used.

Belixos® Gel is specially formulated for skin that is inflamed, reddened and prone to skin blemishes, providing an effective support for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin, and regulates sebum.

Belixos® Protect is a modern daily skincare product specially developed for sun-damaged skin with an exceptional lipid matrix formulation and skin-regenerating properties. Highly concentrated niacinamide smooths the skin and helps repair skin damage. It also contains UVA and UVB broad spectrum protection with SPF15 to protect against further light-induced skin aging and hyperpigmentation.

Irritate skin requires the highest level of care. Belixos® products are manufactured in accordance with strict quality and environmental requirements. They are free of paraffins, parabens, ethyl alcohol, animal products, dyes and fragrances that may have negative dermatological effects. Their skin-compatibility was dermatologically tested without the use of animal testing and was assessed as "very good" by the independent institute 'Dermatest'. Belixos® is available at selected pharmacies, dermatological institutes and on Amazon

A further product launch is planned for 2016.

4. Sales and markets

With its central European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland and Liechtenstein. However, in many European countries, the price and the reimbursement status have to be defined prior to market launch, which can be a very lengthy process. To date, the company has commenced sales in Germany, the UK, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway, Switzerland and Slovenia. The drug is available in these countries at a pharmacy retail price of between just under EUR 200 and approx. EUR 270 per 2g tube.

Ameluz® is marketed in Germany and, since March 2015, also in Spain by Biofrontera's own field sales force, and in other European countries using marketing partners. In the UK, Biofrontera is currently preparing its own sales operation, and the contract with a local marketing company was terminated on July 31, 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 generally takes place via pharmaceutical wholesalers, whereas hospital pharmacies are supplied directly. In addition to regular visits by the field sales force to dermatologists, Biofrontera has presented Ameluz® at the major dermatological conferences both in Germany and in other European countries since it was introduced onto the market. The response from dermatologists has been extraordinarily positive. The market share of Ameluz® in the segment of PDT drugs dispensed by German public pharmacies is consistently over 70%. In spite of this, Ameluz® has only a small

share of the overall market for preparations used to treat actinic keratosis, because only approximately 5% of patients are treated with proprietary medicinal products for photodynamic therapy (PDT). Although PDT achieves by far the highest healing rates, the complexity of the treatment and the time required by medical practices to administer it have so far prevented significant market penetration in the statutory health insurance sector. In this sector in Germany, doctors do not usually receive any compensation from statutory health insurance for performing PDT. A film about PDT is available to view on YouTube (http://www.youtube.com/watch?v=aK4a3R5kqMA, and in English http://www.youtube.com/watch?v=2xE08DWC08o).

Approval for basal cell carcinoma is a prerequisite for the widespread use of Ameluz® in hospitals, as most basal cell carcinoma is treated there, whereas this is only very rarely the case for actinic keratosis. This indication plays an essential role for the breakthrough of Ameluz®, particularly elsewhere in Europe, where dermatologists are predominantly based in hospitals. BCCs are the most common invasive tumors that affect humans and account for 50-80% of all invasive white skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and this is a rapidly growing trend worldwide due to increased exposure to UV light. BCCs are normally removed surgically, often resulting in substantial scarring. Treatment with photodynamic therapy (PDT) is a highly effective alternative which also leads to excellent cosmetic results. According to a market study published in 2014 by Technavio, the international market for actinic keratosis medications is expected to grow by approx. 8% annually, from approx. USD 546 million to USD 942 million in 2020. However, during the same period, the market for basal cell carcinoma medications is expected to grow at a phenomenal rate, from approx. USD 236 million today to nearly USD 5 billion, because the availability of new drugs (Ameluz® is mentioned in this context) will mean that fewer and fewer patients undergo operations.

In Denmark, Sweden and Norway, Ameluz® is marketed by Desitin Arzneimittel GmbH, in Benelux by Bipharma N.V. and in Austria, by Pelpharma Handels GmbH. Biofrontera carries out its own sales activities in Slovenia and is supported in its marketing activities by PHA Farmed. The cooperation with Spirit Healthcare in the UK was terminated by Biofrontera as of July 31, 2015, and Biofrontera is currently preparing to set up its own sales operation in the UK. Sales in Spain were initially handled by Allergan SA, but since March 2015 Biofrontera has marketed its products itself in Spain via its own branch, Biofrontera Pharma GmbH sucursal en España. Louis Widmer SA has been granted the Ameluz® distribution license for Switzerland and Liechtenstein, and the Ameluz® distribution license for Israel has been allocated to Perrigo Israel Agencies LTD. In these countries, it was necessary to undergo an independent approval process, which was carried out by the above-mentioned sales partners in collaboration with Biofrontera. In Switzerland, both the approval and the reimbursement approval were issued in December 2015. Market launch took place at the beginning of 2016. In Israel, Ameluz® has been included in the National Health Basket and thus accepted for reimbursement. Approval was also granted by the Israeli health authorities in April 2016. Consequently, marketing is expected to start in the next few months.

The contracts with the respective sales partners have been concluded in such a way that Biofrontera has received no down payment, or only a modest down payment, and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their own sales price. Biofrontera's share of the sales price varies considerably depending on the market conditions in each country, ranging from 35% to 60% of net revenue.

Biofrontera has already started preparations for its sales operation in the USA. With the help of a consulting firm specializing in market access and a team of medical advisors, Biofrontera has started to analyze the actinic keratosis drug market and the reimbursement systems in the American healthcare system. For this, Biofrontera can draw on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick®. Sales in the USA will be handled via a wholly-owned subsidiary, Biofrontera Inc., which was established for this purpose back in March 2015 and has already recruited its first staff. After approval was granted by the FDA on May 10, 2016, the plan is to launch Ameluz® on the US market on September 1, 2016. As the drug and lamp are approved as a combined product in the USA, the speed of market penetration in the USA will depend in particular on how quickly the BF-RhodoLED® PDT lamp are positioned on the market.

Operational progress in the 1st quarter of 2016

Approval of Ameluz® in the USA: Further progress was made with the approval process in the USA in the 1st quarter. In January, the FDA announced that the midcycle review had been completed with no reservations. The proposed labeling was provided as planned at the end of March. After the end of the 1st quarter, the FDA granted approval for marketing of Ameluz in combination with BF-RhodoLED® in the USA on May 10. No conditions to be fulfilled after approval were imposed.

Clinical trials: The phase III clinical trial on the treatment of basal cell carcinomas was completed in the 1st quarter with outstanding results. Biofrontera will apply for approval to extend the indications in the 2nd quarter, and expects to obtain approval towards the end of the financial year.

Preparations for a phase III clinical trial on daylight therapy were started in the 1st quarter. This trial is to be conducted at clinical centers in Germany and Spain. The study is likely to be completed in fall 2016, so approval could be granted in the 1st half of 2017.

International marketing: Further progress was also achieved in the international marketing of Ameluz® and BF-RhodoLED®. In Switzerland, Ameluz® was approved by Swissmedic and made reimbursable. Biofrontera's partner Louis Widmer commenced marketing of the products in Switzerland in the 1st quarter.

Approval for Ameluz® was also granted in Israel in April 2016. Biofrontera's partner Perrigo is currently preparing for market launch.

Key financial figures in the 1st quarter of 2016:

Revenue: Revenue totaled EUR 1,017 thousand in the first quarter, down by approx. 1% on the previous year. At EUR 633 thousand, revenue in Germany was lower than we expected, falling EUR 150 thousand short of the figure for the 1st quarter of the previous year. This was mainly due to destocking by some pharmaceutical wholesalers. Sales figures of pharmacists grew by 3% in the first quarter. Revenue outside Germany progressed very pleasingly in the 1st quarter, rising by 31% to EUR 324 thousand. The sales trend in Spain was particularly positive. License income (one-off payments) amounted to EUR 60 thousand in the first quarter of 2016 (same period in the previous year: 0).

The company continues to expect total revenue of EUR 6-7 million for 2016.

Operating costs: Biofrontera has continued to invest in research & development and enhancement of its products. Research & development costs totaled EUR 1,005 thousand in the 1st quarter, down EUR 235 thousand or 19% year-on-year.

Sales costs came to EUR 1,196 thousand, an increase of EUR 251 thousand or 27% on the 1st quarter of the previous year. This increase is mainly attributable to the start of sales activities in the USA.

Administrative costs in the 1st quarter of 2016 amounted to EUR 789 thousand. The increase of EUR 156 thousand or 25% compared to the previous year is mainly due to higher financing costs as a result of the capital increase performed in Q1.

Other income: The submission fee (PDUFA fee) of the EUR 2.072 million paid to the FDA in 2015 was refunded in March 2016 after a small business waiver was granted. The fee was reported in the income statement for 2015 under research & development costs. The refund was reported under other income.

Net earnings before tax: Net earnings before tax for the 1st quarter of 2016 totaled EUR -448 thousand, an improvement of EUR 1,915 thousand on the 1st quarter of the previous, mainly as a result of the repayment of the submission fee by the FDA.

Liquidity: The liquidity situation was improved significantly in the 1st quarter of 2016. Net cash in hand amounted to EUR 8.0 million as at March 31, 2016, EUR 4.1 million higher than on December 31, 2015.

Share capital, capital measures

As at March 31, 2016, the fully paid-up share capital of the parent company, Biofrontera AG, amounted to EUR 27,847,814.00. It was divided into 27,847,814 registered shares with a nominal value of EUR 1.00 each. On December 31, 2015, the share capital amounted to EUR 25,490,430.00 and was increased by EUR 2,357,384.00, divided into 2,357,384 registered shares, during the course of the 1st quarter of the 2016 financial year by means of a capital increase.

In the context of the capital increase carried out in February 2016, the company's share capital was increased from authorized capital against cash contributions by EUR 2,357,384.00 through the issue of 2,357,384 new registered shares. The subscription right of the shareholders was excluded. The new shares were offered to selected institutional investors for an issue amount of EUR 1.90 per new share, i.e. for a total issue amount of EUR 4,479,029.60, and placed in full. The net issue proceeds amounted to EUR 4.4 million.

Financial position

The company's capital management body regularly reviews the equity ratio of the group and the group subsidiaries. The management's objective is to ensure an appropriate equity base, within the framework of the expectations of the capital market, and creditworthiness with respect to national and international business partners. The Management Board of the company ensures that all group companies have sufficient capital at their disposal in the form of equity and debt capital. The statement of changes in equity provides further information about the development of equity.

Cash flow from operating activities increased compared to the previous year, from EUR -1,818 thousand to EUR 183.6 thousand as at March 31, 2016.

Cash flow from interest revenue fell by EUR 55 thousand to EUR 1 thousand. Investments in fixed assets increased slightly by EUR 63 thousand. These factors led to a decrease in cash flow from investment activities of EUR 115 thousand from EUR 23 thousand to EUR -92 thousand.

Cash flow from financing activities improved by EUR 4,829 thousand compared to the same period in the previous year, from EUR -830 thousand to EUR 3,999 thousand. This change primarily results from proceeds from the issuance of shares with issue proceeds of EUR 4.4 million; no capital increase was carried out in the same period of the previous year.

The company was able to meet its payment obligations at any time, but will continue to depend on additional financing measures in the future. To date, Biofrontera has always succeeded in providing the necessary financing for its business operations through injections of equity. Following the capital increases in 2015 and a further two capital increases in February and April 2016, the company currently has sufficient liquidity at its disposal. However, approval in the USA, the planned investments in marketing in the US and compliance with obligations from the issued option bond particularly constitute a necessity for further capital measures during the 2016 financial year.

On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that the liquidity required for business activities can be further ensured. If these valid estimates are, contrary to expectations, not realized, this could constitute a threat to the company's continued existence.

Supplementary report

Events of special significance occurring since March 31, 2016

On May 10, 2016, the US approval authority, FDA, granted approval for unlimited marketing of Ameluz® in combination with the PDT lamp BF-RhodoLED® in the USA. No conditions to be fulfilled after approval were imposed here. This approval covers lesion-directed and field-directed treatment.

In the context of a capital increase carried out in April 2016, the company's share capital was increased from authorized capital against cash contributions by EUR 2,499,999.00 through the issue of 2,499,999 new registered shares. The statutory subscription right was granted to the shareholders. In addition, an "additional subscription" was offered, i.e. shareholders executing subscription rights were allowed to apply to subscribe to unsubscribed new shares at the subscription price. The subscription price per new share was EUR 2.00, and the capital increase was placed in full. The net issue proceeds amounted to EUR 4.9 million.

In April 2016, the Israeli Ministry of Health (IMOH) granted Biofrontera's partner Perrigo Israel Agencies LTD drug approval for Ameluz for the treatment of actinic keratosis (AK) with photodynamic therapy in Israel.

In addition, subscription prices arising from option rights were adjusted in April 2016. The subscription price of option rights arising from the warrant bond from 2011/2016 was reduced for each share by EUR 0.04 to EUR 2.96. The subscription price of option rights arising from the warrant bond from 2009/2017 was reduced for each share by EUR 0.04 to EUR 4.96.

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 December 31, 2015. No other significant changes in the risks described there have occurred as at March 31, 2016.

Forecast of key financial figures (report on forecast changes if applicable)

The current outlook for the 2016 financial year is unchanged from the forecast contained in the 2015 Annual Report.

Leverkusen, May 25, 2016

Signed by Prof. Hermann Lübbert

Chief Executive Officer

Signed by Christoph Dünwald

Chief Commercial Officer

Signed by Thomas Schaffer

Chief Financial Officer

Consolidated balance sheet as at March 31, 2016

Assets

in EUR	March 31, 2016 Unaudited	December 31, 2015
Non-current assets		
Tangible assets	434,389.33	372,834.23
Intangible assets	1,730,913.93	1,901,927.93
	2,165,303.26	**2,274,762.16**
Current assets		
Current financial assets		
Trade receivables	650,469.28	894,558.96
Other financial assets	1,006,219.94	730,440.34
Cash and cash equivalents	8,049,580.74	3,959,207.16
	9,706,269.96	**5,584,206.46**
Other current assets		
Inventories		
Raw materials and supplies	627,559.08	590,420.47
Unfinished products	79,072.87	42,723.50
Finished products and goods	763,317.85	900,505.05
Income tax reimbursement claims	32,365.57	32,220.80
Other assets	131,551.25	72,879.33
	1,633,866.62	**1,638,749.15**
	11,340,136.58	**7,222,955.61**
Total assets	**13,505,439.84**	**9,497,717.77**

Liabilities

in EUR	March 31, 2016 Unaudited	December 31, 2015
Equity		
Subscribed capital	27,847,814.00	25,490,430.00
Capital reserve from foreign currency conversion adjustments	5,703.64	(1,188.65)
Capital reserve	81,624,394.38	79,525,292.28
Loss carried forward	(109,823,695.69)	(98,620,285.49)
Net loss for the year	(447,743.50)	(11,203,410.20)
	(793,527.17)	**(4,809,162.06)**
Non-current liabilities		
Non-current financial liabilities	3,241,945.97	11,229,946.00
Current liabilities		
Current financial liabilities		
Trade payables	962,462.07	1,043,425.65
Short-term financial debt	8,674,936.03	830,174.00
Other financial liabilities	52,178.41	37,622.28
	9,689,576.51	**1,911,221.93**
Other current liabilities		
Other provisions	1,242,695.19	1,041,860.80
Other current liabilities	124,749.34	123,851.10
	1,367,444.53	**1,165,711.90**
	11,057,021.04	**3,076,933.83**
Total liabilities	**13,505,439.84**	**9,497,717.77**

Consolidated statement of comprehensive income for the first quarter of the 2016 and 2015 financial year

in EUR	3M 2016	3M 2015
	Unaudited	Unaudited
Revenue	1,016,794.06	1,030,011.30
Cost of sales	-360,985.36	-310,182.09
Gross profit from sales	655,808.70	719,829.21
Operating expenses:		
Research and development costs	-1,004,685.90	-1,240,073.31
General administrative costs	-788,889.09	-633,178.56
of which financing costs	-301,743.45	-81,400.13
Marketing costs	-1,195,558.55	-944,943.27
Loss from operations	**-2,333,324.84**	**-2,098,365.92**
Financial result		
Interest expenses and the like	-293,354.60	-280,684.69
Interest income and the like	558.61	7,658.65
Other income and expenses		
Other expenses	-13,999.64	-16,433.79
Other income	2,192,376.97	25,345.65
Earnings before income tax	**-447,743.50**	**-2,362,480.10**
Income tax	0.00	0.00
Earnings for the period	**-447,743.50**	**-2,362,480.10**
Expenses and income not recognized in income		
Subsequent valuation of financial assets available for sale	0	0
Other expenses and income not recognized in income	0	0
Total earnings for the period	**-447,743.50**	**-2,362,480.10**
Undiluted (=diluted) earnings per share	-0,02	-0,11

Consolidated cash flow statement for the first quarter of the 2016 and 2015 financial year

	3M 2016 Unaudited EUR	3M 2015 Unaudited EUR
Cash flows from operations:		
Total earnings for the period	-447,743.50	-2,362,480.10
Adjustments to reconcile total earnings for the period to cash flow into operations:		
Financial result	292,795.99	273,026.04
Depreciation	197,211.95	199,493.00
(Gains)/losses from disposal of assets	4,836.33	115.00
Non-cash expenses and income	21,685.79	27,256.85
Changes in operating assets and liabilities:		
Trade receivables	244,089.68	-231,377.57
Other assets and income tax claims	-334,596.29	-4,895.12
Inventories	63,699.22	31,299.70
Trade payables	-80,963.58	58,103.74
Provisions	207,135.60	161,938.04
Other liabilities	15,454.37	29,116.74
Net cash flow into operations:	**183,605.56**	**-1,818,403.68**
Cash flows from investment activities:		
Purchase of intangible and tangible assets	-100,897.81	-37,473.12
Interest received	558.61	55,358.65
Revenue from the sale of intangible and tangible assets	8,308.43	4,742.01
Net cash flow from (into) investment activities	**-92,030.77**	**22,627.54**
Cash flows from financing activities:		
Proceeds from the issue of shares	4,434,585.60	0.00
Interest paid	-435,786.81	-830,174.00
Increase/(decrease) in long-term financial debt	-8,280,512.03	186,871.27
Increase/(decrease) in short-term financial debt	8,280,512.03	-186,880.43
Net cash flow from financing activities	**3,998,798.79**	**-830,183.16**
Net increase (decrease) in cash and cash equivalents	**4,090,373.58**	**-2,625,959.30**
Cash and cash equivalents at beginning of period	**3,959,207.16**	**8,509,398.16**
Cash and cash equivalents at end of period	**8,049,580.74**	**5,883,438.86**
Composition of financial resources at end of period:		
Cash and bank balances and checks	**8,049,580.74**	**5,883,438.86**

Consolidated statement of changes in equity for the first quarter of the 2016 and 2015 financial year

Unaudited	Ordinary shares Number	Subscribed capital EUR	Capital reserve EUR	Capital reserve from foreign currency conversion adjustments EUR	Accumulated loss EUR	Total EUR
Balance as at January 1, 2015	**22.196.570**	**22.196.570,00**	**76.402.715,36**	**0,00**	**(98.620.285,49)**	**(21.000,13)**
Capital increase	0	0,00	0,00	0,00	0,00	0,00
Cost of equity procurement	0	0,00	0,00	0,00	0,00	0,00
Increase in capital reserves from the stock option program	0	0,00	27.417,00	0,00	0,00	27.417,00
Net loss for the year	0	0,00	0,00	0,00	(2.362.480,10)	(2.362.480,10)
Balance as at March 31, 2015	**22.196.570**	**22.196.570,00**	**76.430.132,36**	**0,00**	**(100.982.765,59)**	**(2.356.063,23)**
Capital increase	3.293.860	3.293.860,00	3.515.382,80	0,00	0,00	6.809.242,80
Cost of equity procurement	0	0,00	(495.769,88)	0,00	0,00	(495.769,88)
Foreign currency conversion adjustments	0	0,00	0,00	(1.188,65)	0,00	(1.188,65)
Increase in capital reserves from the stock option program	0	0,00	75.547,00	0,00	0,00	75.547,00
Net loss for the year	0	0,00	0,00	0,00	(8.840.930,10)	(8.840.930,10)
Balance as at December 31, 2015	**25.490.430**	**25.490.430,00**	**79.525.292,28**	**(1.188,65)**	**(109.823.695,69)**	**(4.809.162,06)**
Capital increase	2.357.384	2.357.384,00	2.121.645,60	0,00	0,00	4.479.029,60
Cost of equity procurement	0	0,00	(44.444,00)	0,00	0,00	(44.444,00)
Foreign currency conversion adjustments	0	0,00	0,00	6.892,29	0,00	6.892,29
Increase in capital reserves from the stock option program	0	0,00	21.900,50	0,00	0,00	21.900,50
Net loss for the year	0	0,00	0,00	0,00	(447.743,50)	(447.743,50)
Balance as at March 31, 2016	**27.847.814**	**27.847.814,00**	**81.624.394,38**	**5.703,64**	**(110.271.439,19)**	**(793.527,17)**

Issued by

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