

**Biofrontera AG | Quarterly report as at 30.09.2016**

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## Operational progress in the first nine months of financial year 2016

- Receipt of approval from FDA in the USA for field-directed and lesion-directed treatment of actinic keratoses
- Build-up of sales operations in USA
- Completion of basal-cell carcinoma [BCC] trial with excellent results and submission of the application for an extension to the authorisation with the European Medicines Agency [EMA]
- Approval extension for field cancerisation in the EU
- Granting of qualification for medical cost reimbursement for Ameluz® in Switzerland
- Carrying out of a Phase III trial on daylight therapy

After the end of the 3<sup>rd</sup> quarter:

- Further capital increase for financing the business
- Commencement of marketing Ameluz® and BF-RhodoLED® in USA

## Financial developments in the first nine months of the financial year 2016

- Revenue: EUR 2.9 million (+9% year-on-year)  
(Slow turnover growth in Germany, but increasing turnover abroad and first revenue from development co-operation with Maruho)
- Consolidated earnings: EUR -7.2 million (previous year: EUR -9.3 million)
- Cash and cash equivalents of EUR 5.7 million
- Successful completion of two financing measures in February and April 2016, as well as further measures after the end of 3<sup>rd</sup> quarter in November 2016

## Key indicators

### Key consolidated figures for the first nine months of the financial year 2016 in accordance with IFRS

In EUR thousand	9M 2016 unaudited	9M 2015 unaudited	Q3 2016 unaudited	Q3 2015 unaudited
<b>Earnings performance</b>				
Revenue	2,881.4	2,635.0	1,172.8	1,066.9
of which revenue in Germany	1,476.0	2,091.2	442.4	905.1
of which revenue outside Germany	1,365.4	543.8	730.4	161.8
of which down payments	40.0	0.0	0.0	0.0
Research and development costs	-3,358.4	-5,364.8	-1,506.4	-866.9
Marketing costs	-4,937.4	-2,928.7	-2,105.1	-891.0
General administration costs	-2,080.8	-2,060.3	-708.4	-712.8
Operating profit (EBIT)	-6,262.1	-8,430.3	-3,382.6	-1,667.4
Earnings before tax	-7,163.8	-9,285.8	-3,691.5	-1,962.9
Earnings after tax	-7,163.8	-9,285.8	-3,691.5	-1,962.9

#### Cash flow statement

Cash flow from operating activities	-6,885.0	-8,199.8	-4,374.3	-1,664.1
Cash flow from investment activities	-208.0	-19.4	-64.8	-12.5
Cash flow from financing activities	8,867.1	2,159.4	-0.3	-0.5

In EUR thousand	9M 2016 unaudited	9M 2015 unaudited
<b>Key balance sheet figures</b>		
Total assets	12,531.2	7,454.8
Current liabilities (excluding provisions)	10,458.9	1,196.2
Non-current liabilities	2,949.3	11,408.8
Subscribed capital & capital reserve	114,403.0	101,671.1
Equity ratio	-20.53%	-83.64%
Cash and cash equivalents	5,733.3	2,449.6
<b>Employees as at 30.09.2016</b>	81	55
<b>Biofrontera-Shares</b>	30.09.2016	30.09.2015
Outstanding shares	30,347,813	23,573,842
Share price (Xetra closing price)	3.02	2.13
Dividend in Euro	0.00	0.00

## Biofrontera financial instruments

### Key details of Biofrontera shares

Stock exchanges	Düsseldorf, Frankfurt, Berlin, Munich, Stuttgart, Xetra, Tradegate
WKN	604611
ISIN	DE0006046113
Shares outstanding as at 30.09.2016	30,347,813
9-month high (09.05.2016)*	3.70 Euro
9-month low (07.01.2016)*	1.81 Euro
Closing price on 30.09.2016*	3,019 Euro
Market capitalisation on 30.09.2016	91,642 million Euro

\*(Xetra price data)

### Key details for warrant bond I with warrant \*

Stock exchanges	Düsseldorf
WKN	AOZ169
ISIN	DE000AOZ1690
Term, final maturity	8 years, 31. December 2017
Stepped Coupon	4% (2010), 6% (2011), 8% (2012)
9-month high (9M 2016)	104,00 Euro
9-month low (9M 2016)	75.20 Euro
Closing price 30.09.2016	97.00 Euro

\*(Price data from Düsseldorf stock exchange)

### Key details for warrant bond II with warrant \*

Stock exchanges	Düsseldorf
WKN	A1KQ9Q
ISIN	DE000A1KQ9Q9
Term, final maturity	5 years, 31.12.2016
Coupon	5 %
9-month high (9M 2016)	104.00 Euro
9-month low (9M 2016)	77.10 Euro
Closing price 30.09.2016	95.25 Euro

\*(Price data from Düsseldorf stock exchange)

## Quarterly report for the first nine months of financial year 2016

### Group strategy

The strategic objective of the Biofrontera Group is to establish the company on a global level as a pharmaceutical company specializing in dermatology. In addition to the further development of sales and marketing of our products, the principal activities are the extension of the sales and marketing of our products 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 a centralized European medical approval for a medication Ameluz® that had been developed entirely independently. Since the launch in February 2012, Biofrontera has been selling Ameluz® through its own field sales team to dermatologists in Germany, and also, since March 2015, in Spain. Ameluz® is available in Great Britain, but it will only be actively promoted by Biofrontera after the approval has been extended to basal cell carcinoma. Sales in other countries within the European Union as well as in Israel and Switzerland are carried out via licensing partners. During July, the European regulatory agency EMA gave a positive recommendation to the European Commission concerning the approval of Ameluz® for the treatment of field cancerization, and the actual grant of the authorization by the European Commission was received in September 2016. Since the trial that was required for that purpose with regard to the field-directed treatment also included measuring the skin rejuvenating effects of Ameluz®, these results were also included in the authorized product information.

In May 2016 the US Food and Drug administration (FDA) granted approval for Ameluz® in the USA in combination with the BF-RhodoLED® lamp for lesion-directed or field-directed photodynamic therapy (PDT) for actinic keratosis (AK). At the beginning of July 2015 the company had applied for approval (NDA = New Drug Application) from the FDA. Since Ameluz® and BF-RhodoLED® had to be approved in the USA as the combination of a drug and a medical device, the application was unusually complex. During the months following the application the FDA performed extensive reviews and inspections. The approval was then granted without restrictions for lesion-directed and field-directed treatment of mild to moderate actinic keratoses on the face and scalp. Thus, Biofrontera gains access to the largest healthcare market in the world. For sales and marketing in the USA, an American subsidiary has been set up in the form of Biofrontera Inc., with its headquarters in Wakefield, Massachusetts. For the market introduction into the USA, all the required infrastructure has been created, and further Ameluz® was produced for the USA market in Switzerland and imported into the USA. The PDT Lamp is also being produced for the American market at Biofrontera's Corporate Headquarters in Leverkusen.

Biofrontera has thus established itself as a specialist pharmaceutical company operating on an international basis. The short-term group strategy is focussed on the further expansion of business in Europe and in the USA, as well as the extension of indications to include basal cell carcinoma, initially in the EU, and then, as a further step, in the USA.

The extension of the indications of Ameluz® for the treatment of basal cell carcinomas (BCC) was initiated in 2014. The Phase III clinical testing was conducted in direct comparison with the competitor product Metvix®. Patient recruitment was completed in May 2015 and the last patient ended the clinical part of the trial in November 2015. There was then a 5-year follow-up period for all patients. The results of the trial have been available since January 2016 and prove the high clinical effectiveness of Ameluz® also for indications of BCC. The recently published recurrence rates after 12 months confirm the superior effect of Ameluz®. A comparison with the competitor product Metvix® demonstrated higher healing rates, especially for thicker and nodular carcinomas. In spite of its statistically significant inferiority for the treatment of mild and moderate actinic keratoses on the face and scalp, and the restriction in the approval as a second choice therapy only, its approval for the treatment of basal cell carcinomas

provides Metvix® a major competitive advantage over Ameluz®. In particular, in foreign countries within Europe, where dermatologists are principally employed in hospitals and fewer of them are working in independent practices, the market opportunities for Ameluz® are significantly reduced by the lack of approval for BCC. The extension in the indication, which is currently being sought, is therefore expected to put Biofrontera in a significantly improved market position. The application for extending indications for Ameluz® to include basal cell carcinoma was submitted to the EMA in July 2016, the processing and inspection of the application by the European agency will probably take six months.

Hence, the year 2016 has been very decisive for Biofrontera, in which the course was set for a successful future. Against this background, and the associated challenges for Biofrontera, the company has also strengthened its workforce. In addition to the employment of suitable personnel in the USA, the German organization also requires a moderate addition, since many tasks for the USA are being carried out in Germany, and since the development collaboration with Maruho also ties up further personnel resources.

## Products

### Ameluz®

Ameluz® 78 mg/g Gel ("for people who love the light", development name BF-200 ALA) received an initial centralized European approval for the treatment of mild and moderate actinic keratoses in the face and scalp in December 2011. During the Phase III development, its superiority with regard 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 the skin. The combination of Ameluz® with light treatment represents an innovative approach constituting a form of photo-dynamic therapy (PDT). The product information approved by the European Medicines Authority (EMA) explicitly mentions the significant superiority of Ameluz® for removing all keratoses of a patient, 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 medication was combined with an LED lamp, all keratoses were completely removed in 87% of patients treated with Ameluz®, and in terms of the number of individual keratosis lesions, as many as 96% were completely eradicated (all 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 a drug and a lamp, Biofrontera developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which requires the company to be certified in line with the ISO 9001 and ISO 13485 standards. In preparation for approval in the USA, a phase III trial was carried out with the combination of Ameluz® and BF-RhodoLED®. With this combination, keratoses were completely eradicated in 91% of patients, and in terms of the number of individual lesions, 94% were completely removed after treatment (99.1% of mild lesions 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 the drug was applied over large surface areas (field therapy) for the first time in a phase III trial of PDT anywhere in the world, and the cosmetic result was established without reference to the disappearance 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<sup>®</sup>. 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, this decreased 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 followed up by the trial doctors over the course of a year after the final treatment. The sustained nature of the pharmaceutical effect of Ameluz<sup>®</sup> 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<sup>®</sup>. The improvement in the skin appearance of patients treated with Ameluz<sup>®</sup> 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 63% of patients were already free of such cosmetic damage twelve weeks after the last PDT, this percentage rose to 72.2% after a year. 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<sup>®</sup> PDT, these percentages initially fell to 42.6%, 29.6% and 29.6%, decreasing over the course of a year to 24.1%, 11.1% and 18.5%. These results are impressive, and show that the skin rejuvenation effect achieved using photodynamic therapy with Ameluz<sup>®</sup> is long-lasting and the repair processes triggered by the therapy remain active for at least twelve months

This 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<sup>®</sup> and BF-RhodoLED<sup>®</sup> and show that the therapy stands out clearly from many other treatment options. . In the meantime, these results have been included in the official EU product information.

Both of 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 to the European approval package for Ameluz<sup>®</sup> the safety data required for registration in the USA. Specifically, one of the trials was a sensitization study, which determines the potential of Ameluz<sup>®</sup> to trigger allergies, and the other was a maximal use trial, which tests the absorption in the blood of the active ingredient in Ameluz<sup>®</sup>, aminolevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, i.e. the application of a complete tube onto the defective skin. No safety concerns were identified in either of the trials.

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 eight million people affected in Germany alone, and that there is a marked upward trend. In the USA there are even as many as 58 million AK sufferers. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this happens to the lesions in question 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 for the duration of these patients' lives the treatment costs of patients who have worked predominantly outdoors for a long period and who fulfil certain criteria. Reimbursement methods were determined in March 2016. Accordingly photodynamic therapy (PDT) is taken into account 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<sup>®</sup> is the market leader among independent dermatologists in Germany in the PDT proprietary medicinal product market, a significant increase in sales can and must result from the aforementioned sectors.

The overall advantages of Ameluz<sup>®</sup> 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 involve this indication, particularly in the UK and Spain.

Biofrontera has conducted a phase III trial for the extension of the European approval to include the indication of basal cell carcinoma (BCC). BCCs are the most common invasive tumors affecting humans, accounting for approximately 50- 80% of all skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used in the USA but this can lead to clearly visible scarring, whereas treatment with 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. Colin Morton (UK) and Prof. Markus Szeimies (Germany) and was carried out at 27 clinical trial centers in the UK and Germany. Patient recruitment for the trial, which was conducted in direct comparison with the competitor product Metvix<sup>®</sup>, 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<sup>®</sup> were compared with that of Metvix<sup>®</sup>, a medication 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<sup>®</sup> achieved the complete elimination of all BCCs from the patient in 93.4% of cases compared to 91.8% with Metvix<sup>®</sup>. There were greater differences in the case of thicker BCCs. With Ameluz<sup>®</sup>, 89.3% of the nodular carcinomas were completely removed, compared to only 78.6% with Metvix<sup>®</sup>. After 12 months the recurrence rates were higher for Metvix<sup>®</sup> than for Ameluz<sup>®</sup>.

Based on the results of this phase III trial, Biofrontera applied to the European Medicines Agency for approval for the treatment of BCC with Ameluz<sup>®</sup> in July 2016. The review of the application by the agency is expected to take around six months.

Between June and September 2016, the first patients were treated in a phase III clinical trial to evaluate the safety and efficacy of Ameluz<sup>®</sup> in combination with daylight photodynamic therapy (PDT) in comparison with Metvix<sup>®</sup> for the treatment of mild to moderate actinic keratosis. The head-to-head, randomized, observer-blinded, multi-center trial encompassing 52 patients has been carried out at 7 trial centers in Spain and Germany. All of the participants had between three and nine mild to moderate actinic keratoses (Olsen grade 1 and 2) in each of two comparable

treatment areas on the face and/or scalp. The medication for each treatment site was selected at random. The last patient is expected to conclude the clinical phase of the trial in December 2016, so that the results are expected by the end of 2016. Daylight PDT offers a convenient and painless alternative to PDT with a specialized lamp. The topical medication is activated by exposure to natural or artificial daylight. The clinical endpoint of the trial is the total clearance rate for all lesions at each treatment site twelve weeks after treatment. The secondary clinical endpoint includes evaluating the safety of the medication and supplementary efficacy parameters. The trial is being co-led by Dr. Susana Puig, Research Director at the Biomedical Research Institute August Pi I Sunyer and a professor at the University of Barcelona, as the coordinating investigator in Spain and Prof. Thomas Dirschka, founder of the private dermatology practice Centro Derm, as the coordinating investigator in Germany. Since the daylight PDT treatment does not have to be carried out in the doctor's surgery, it competes directly with the self-applied topical medications that are much more frequently used in Europe, and is consequently reimbursed by the statutory health insurance companies in Germany.

### **BF-RhodoLED®**

BF-RhodoLED® is a red light lamp designed for photodynamic therapy (PDT). It uses LEDs emitting red light at a wavelength of approx. 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with medications containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. In the European version 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. For the purpose of sales operations in the USA, the final assembly of the PDT lamp has been transferred to Biofrontera's facilities and performed by the company itself since July 2016, meaning that Biofrontera is the responsible manufacturer from the FDA's perspective.

### **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 for example soothes scalps irritated by psoriasis or eczema, 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 treatment for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin, and regulates sebum.

**belixos® Protect** is a modern daily 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.

A handy and practical on-the-go solution: **belixos® to go**, the new acute care roll-on with a specially developed stainless steel ball, has been available since July 2016, providing effective and targeted relief for itchiness, insect bites, and minor skin irritation. Inflammation and redness subside more quickly thanks to anti-inflammatory mahonia, calming sea mayweed, and the anti-irritative Sepicalm S Complex.

Irritated skin conditions require 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.

## Sales and markets

With its central European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland, and Liechtenstein. In many European countries, however, the price and the medical reimbursement status have to be defined prior to market launch, which can be an extremely lengthy process. To date, in Europe the company has commenced sales in Germany, the UK, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway, Switzerland, and Slovenia. The medication 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, the contract with a local marketing company was terminated in mid-2015. Biofrontera is also taking over the sales operation in Slovenia, but marketing there is supported by a local company.

Distribution to public pharmacies generally takes place via pharmaceutical wholesalers, whereas hospital pharmacies are also supplied directly. In addition to regular visits by the field sales force to dermatologists, Biofrontera has presented Ameluz® at 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 was consistently over 70% for a long time, although in recent months the share has fallen back somewhat due to the introduction of the medication Luxerm® a product identical with Metvix®. In spite of this, all

PDT products collectively still only have 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. 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>).

The treatment of actinic keratosis using daylight therapy will play an increasingly important role in Europe in future. The competitor preparation Metvix<sup>®</sup> has already obtained approval and has recently begun to be specifically marketed for daylight application under the brand name Luxerm<sup>®</sup>. As this removes the need for additional PDT treatment at the physician's office and the drug can be administered by the patient, daylight PDT can be expected to be prescribed far more frequently in future as an alternative to purely topical creams. Biofrontera is currently conducting a phase III clinical trial of daylight PDT and also expects to obtain approval in 2017.

Approval for basal cell carcinoma is a prerequisite for the widespread use of Ameluz<sup>®</sup> in hospitals, as basal cell carcinoma is mainly treated there, whereas this is only very rarely the case for actinic keratosis. This indication plays an essential role for the breakthrough of Ameluz<sup>®</sup>, 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 around the world 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. During the same period, however, 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<sup>®</sup> is mentioned in this context) will mean that fewer and fewer patients undergo operations.

In Denmark, Sweden, and Norway, Ameluz<sup>®</sup> 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 on 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 Biofrontera has marketed its products itself in Spain via its own branch, Biofrontera Pharma GmbH sucursal en España, since March 2015. Louis Widmer SA has been granted the Ameluz<sup>®</sup> distribution license for Switzerland and Liechtenstein, and the Ameluz<sup>®</sup> 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 aforementioned 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, approval for Ameluz<sup>®</sup> was granted by the Israeli health agency in April 2016 and 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<sup>®</sup> 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.

In the USA Ameluz<sup>®</sup> was launched on the market in October 2016. With the help of a consulting firm specializing in market access and a team of medical advisors, Biofrontera had intensively analysed of the actinic keratosis drug market and the reimbursement mechanisms in the US healthcare system last year. Biofrontera was also able to draw on the experience of DUSA Pharmaceuticals Inc. with a competitor product already sold and distributed in the USA, Levulan Kerastick<sup>®</sup>. Sales in the USA are handled via a wholly-owned subsidiary, Biofrontera Inc., which was established for this purpose back in March 2015. Key posts in the USA have already been filled with highly qualified and experienced local employees, with further appointments to follow in the near future. Many employees have transferred over to Biofrontera directly from the competitors. As the medication and lamp are approved as a combination product in the USA, the speed of market penetration in the USA will also depend on how quickly the BF-RhodoLED<sup>®</sup> PDT lamp is positioned on the market.

Further progress can be demonstrated in the continued international marketing of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup>. In Switzerland the approval for Ameluz<sup>®</sup> was granted by Swissmedic, along with the possibility of reimbursement by health insurance companies. Biofrontera's Partner Louis Widmer began marketing the products in Switzerland during the 1<sup>st</sup> Quarter.

In Israel, the approval for Ameluz<sup>®</sup> was also granted in April 2016. In the meantime, Biofrontera's Partner Perrigo has been preparing its introduction onto the market.

## Product pipeline

In July, the company agreed a research co-operation with Maruho Co., Ltd, ("Maruho"), a Japanese pharmaceutical company specializing in Dermatology, within the scope of which possibilities for the joint development of pharmaceutical products are to be developed, based on Biofrontera's proprietary Nanoemulsion technology. Ameluz<sup>®</sup> was developed based on a similar strategy. The active ingredient was stabilized via the nanoemulsion technology, and penetration into the skin was improved, which led to an increased clinical effectiveness. In accordance with the agreement, Maruho will bear all the costs connected with the explorative investigation of four new product candidates. It is planned that Maruho will become the owners of the new products, and Biofrontera will receive a license for marketing them in Europe.

### Operational progress up to 30 September 2016:

**Approval of Ameluz<sup>®</sup> in USA:** On 10 May 2016 the FDA granted approval for the marketing of Ameluz<sup>®</sup> in combination with BF-RhodoLED<sup>®</sup> in the USA. The approval covers both field and lesion-directed treatment of actinic keratoses. No conditions were imposed needing be fulfilled after approval.

**Clinical trials:** The phase III clinical trial on the treatment of basal cell carcinomas was completed in the first quarter with excellent results. The application for approval to extend the indications was submitted in July 2016. Biofrontera expects approval at the beginning of the next financial year.

A phase III clinical trial on daylight therapy began in June 2016. This trial is being conducted at clinical centers in Germany and Spain. The last patient is expected to conclude the clinical phase of the trial in December 2016, such that results are expected towards the end of the year. Approval is expected in 2017.

Extension of approval for field cancerization was granted in September 2016.

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

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

In the USA, the marketing of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> was commenced after completion of the 3<sup>rd</sup> Quarter in October.

### **Important financial figures at 30 September 2016:**

**Revenue:** During the period from January to September 2016 total turnover of EUR 2,881 thousand was achieved, which represented an increase of 9% on the previous year. The turnover in Germany was EUR 1,476 thousand which was lower than the previous year's figure of EUR 2,091 thousand, and was lower than we expected. This was caused on the one hand by the build-up of unusually high stocks at a number of pharmaceutical wholesalers during August of last year, and on the other hand, because after the market introduction of Luxerm<sup>®</sup> for daylight therapy, no further market share was able to be acquired for Ameluz<sup>®</sup>. However, turnover outside Germany showed a very satisfactory development in the first nine months of the financial year 2016, with a growth of 38% to EUR 753 thousand. The development of sales in Spain was particularly positive. The development projects with Maruho resulted in revenues of EUR 613 thousand during the period. The license income (once-off payments) amounted to EUR 40 thousand during the first nine months of 2016 (previous year: 0).

The company continues to expect total revenues of EUR 6 -7 million for the year 2016.

#### **Cost of sales**

The gross profit from sales improved from EUR 1,775 thousand for the first nine months of 2015 to EUR 1,853 thousand in the first nine months of 2016. The Gross Margin fell from 67% in the previous year to 64%, in particular due to a change in the revenue mix with proportionately lower revenue in Germany where margins are higher than international revenue, for which Biofrontera only receives about 50% of the final retail price.

Cost of sales were EUR 1,029 thousand, amounting to 36% of revenue, and have increased in comparison with the previous year (corresponding period in previous year: EUR 860 thousand or 33%).

**Operating costs:** Biofrontera has continued to invest in research and development and the further evolution of its products. During the reporting period, research and development costs amounted to EUR 3,358 thousand, a reduction of EUR 2,006 thousand or 37% compared with the previous year. The reduction is principally due to the FDA submission fee that was paid in the previous year.

Marketing costs amounted to EUR 4,937 thousand, an increase of EUR 2,009 thousand or 69% compared with the previous year. This increase is caused mainly by the start of sales activities in the USA.

Administrative costs during the first nine months of the year 2016 amounted to EUR 2,081 thousand and were roughly on the same level of those of the previous year, EUR 2,060 thousand.

## **Financial result**

The interest expenses included in the financial result, amounting to EUR 904 thousand, are almost entirely due to interest payments for the two warrant bonds and the compounded interest on the two warrant bonds using the effective interest method. The interest payment for Warrant bond I for the financial year 2015 was made at the end of December 2015, while the interest payment for Warrant bond II was made at the beginning of January 2016.

## **Other income and expenses**

The submission fee (PDUFA-Fee) paid to the FDA was refunded in March 2016 with an amount of EUR 2,140 million after the granting of a "small business waiver". This fee had been reported in 2015 in the income statement, as research and development costs. The refund was shown under other income.

## **Net earnings before tax**

Net earnings before tax during the reporting period was EUR -7,164 thousand, an improvement of EUR 2,122 thousand compared with the same period for the previous year, mainly due to the repayment of the submission fee by the FDA.

## **Liquidity**

The Net cash-in-hand at 30 September 2016 was EUR 5.7 million, an increase of EUR 1.8 million compared with 31 December 2015.

## **Share capital, Capital measures**

The fully paid-up share capital of the parent company, Biofrontera AG, amounted to EUR 30,347,813.00 on 30 September 2016. It was divided into 30,347,813 bearer shares with a nominal value of EUR 1.00. On 31 December 2015 the share capital amounted to EUR 25,490,430.00 and during the first nine months of 2016 it has been increase initially through a capital increase in February 2016 of EUR 2,357,384.00, divided into 2,357,384 bearer shares and a further capital increase in April 2016 of EUR 2,499,999.00, divided into 2,499,999 bearer shares.

In the context of the capital increase conducted in February 2016, the company's share capital was increased by EUR 2,357,384.00 in cash contributions through the issue of 2,357,384 new no par value bearer shares from authorized capital. Statutory subscription rights of the shareholders were excluded. The new shares were offered to selected institutional investors for an issue price 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.

In the context of a capital increase conducted in April 2016, the company's share capital was increased by EUR 2,499,999.00 from authorized capital in exchange for cash contributions through the issue of 2,499,999 new no-par value bearer shares. Statutory subscription rights were granted to the shareholders. In addition, an "additional subscription" was offered, i.e. shareholders executing subscription rights were allowed to subscribe for unsubscribed new shares at the subscription price. The subscription price per new share was EUR 2.00. The net issue proceeds amounted to EUR 4.9 million.

## Financial position

The company's capital management body regularly reviews the equity ratio of the Group and its subsidiaries. The management's objective is to ensure an appropriate equity base within the framework of the expectations of the capital markets, as well as 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.

The cash flow from operating activities during the first nine months of the year 2016 was EUR -6,885 thousand, showing an improvement of EUR 1,315 thousand compared with the previous year.

The cash flow from Investment activity fell by EUR 189 thousand to EUR -208 thousand, particularly due to investments in long-term assets, which are increased by EUR 135 thousand to EUR 230 thousand.

The cash flow from financing activities improved by EUR 6,708 thousand, from EUR 2,159 thousand to EUR 8,867 thousand. This change is attributable primarily to proceeds from the issue of shares for an amount of EUR 9.3 million; no capital increase was carried out during the corresponding period in the previous year.

The company was able to meet its payment obligations at all times, but will continue to depend on additional financing measures in the future. Hitherto, Biofrontera has always succeeded in providing the necessary financing for its business operations through increases in equity. The capital increases in 2015, two further capital increases in February and April 2016, as well as the capital increase in November 2016 mean that the company currently has sufficient liquidity at its disposal. However, during the financial year 2107, further capital measures will be necessary, in particular because of the planned investments in marketing in the USA, and in order to meet obligations from the issued option bond.

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



## Supplementary report

### Significant events since 30 September 2016

In October 2016 Biofrontera received the results of the 12-month follow-up period of the clinical Phase III study with Ameluz<sup>®</sup> for the treatment of basal cell carcinomas (BCCs). Analysis showed that the recurrence rate of BCC lesions after 12 months of using the photo-dynamic treatment with Ameluz<sup>®</sup> was lower than for the comparison product Metvix<sup>®</sup>. The results from the 12-month follow-up period for the trial showed that the recurrence rate of the BCC lesions after a PDT treatment with Ameluz<sup>®</sup> was 6.7%, compared with 8.2% after a PDT treatment with the comparison product Metvix<sup>®</sup>. The lower recurrence rate was confirmed in a subgroup analysis. In the case of a treatment of superficial BCC, the recurrence rate for patients treated with Ameluz<sup>®</sup> was 5.4%, compared with 7.9% for Metvix<sup>®</sup>. In the case of nodular BCC, the recurrence rates were 9.1% with Ameluz<sup>®</sup> compared with 10.0% for Metvix<sup>®</sup>. The recurrence rates for BCCs on the scalp were 7.7% for Ameluz<sup>®</sup> and 18.2% for Metvix<sup>®</sup>. For BCCs on the trunk, recurrences occurred at a rate of 6.7% for Ameluz<sup>®</sup> and 7.6% for Metvix<sup>®</sup>.

Also in October, Biofrontera introduced Ameluz<sup>®</sup> and the PDT Lamp BF-RhodoLED<sup>®</sup> into the USA pharmaceuticals market. The first larger-scale presentation was made at the Fall Clinical Dermatology Conference in Las Vegas, where Biofrontera promoted the product and organized a VIP Event for important opinion leaders.

On 31 October 2016 the company reported that with the approval of the Supervisory Board, it would increase the share capital of the company by up to EUR 5,012,950 from the current value of EUR 30,347,813 to a total of up to EUR 35,360,763 by means of a capital increase in return for cash contributions by issuing up to 5,012,950 new no-par value bearer shares with a proportionate contribution to the share capital of EUR 1.00 per individual no-par share ("New shares"). The new shares are entitled to profits from 1 January 2016. The shareholders are granted the statutory subscription right at a ratio of 6:1 via Lang & Schwarz Broker GmbH, Düsseldorf, at a subscription price of EUR 3.00 per new share.

Furthermore, on 31 October 2016 the Management Board, with the approval of the Supervisory Board, decided on the issue of up to 49,990 subordinated convertible bonds („convertible bonds“) each with a nominal value of EUR 100 and a total nominal value of up to EUR 4,999,000. They mature on 31 December 2020. Each of these convertible bonds can in accordance with the bond conditions be converted into no-par value shares in the company having a calculated proportion of the capital stock of EUR 1.00 per share and entitlement to profits from the year of the share issue. The conversion price is initially EUR 3.00 per share, from 1 January 2017 EUR 4.00 per share and und from 1 January 2018 EUR 5.00 per share. The shareholders are granted the statutory subscription right at a ratio of 607:1 at a subscription price of EUR 100.00 per convertible bond.

On 1 November 2016 the company announced that it had binding commitments from investors under which they were obliged to purchase new shares and/or convertible bonds in accordance with the conditions notified, to a volume of EUR 14.8 million.

On 17 November 2016 the company announced that all shares from the capital increase were placed.

On 24 November 2016 the company announced that the convertible bond could also be placed in full.

In November 2016 the European Commission consented with an unlimited extension of the EU approval for Ameluz<sup>®</sup>. In the EU, approvals for new drugs are initially limited to five years, after which a thorough assessment of all then available efficacy and safety data is performed by the EMA before the approval gets an unlimited extension.

## **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 31.12.2015. At the reporting date of 30 September 2016 no other significant changes in the risks described there had occurred, with the exception of the following legal disputes.

### **Risk management system**

The risk and opportunity management system for the Biofrontera Group applies equally to Biofrontera AG. By virtue of its holding function, Biofrontera AG controls all of the legally independent entities within the Biofrontera Group. Therefore, it is necessary to assess the risks and opportunities on a uniform basis throughout the entire Group.

The primary objective of the Biofrontera Group is to achieve long-term growth and hence increase the company's value on a consistent basis. Risk management plays a major role in achieving this objective. At Biofrontera, risk management involves the identification of risks that could have a lasting or significant adverse impact on the company's net assets, financial position, and results of operations, as well as the responsible analysis and monitoring of these risks and the adoption of suitable countermeasures. To this end, it is necessary to have established guidelines, organizational structures, and measuring and monitoring processes that are specifically geared to the Biofrontera Group's activities.

Correspondingly detailed risk prevention measures are essential in order to fully exploit the opportunities arising from Biofrontera's business activities. In the 2015 financial year, Biofrontera's existing risk management structures were enhanced within the scope of the quality management system required for pharmaceutical manufacturers and entrepreneurs and medical device manufacturers. This system incorporates sales and marketing activities, as well as the international responsibilities of license holders with regard to the manufacture and sale of drugs, medical devices and cosmetics.

### **Legal disputes**

In August 2016, the Cologne Regional Court served the company with an action brought by a shareholder on June 30, 2016, claiming the invalidity of or alternatively contesting some of the resolutions adopted by the Annual General Meeting of the company on May 31, 2016. In particular, the election of Mr. John Borer, Mr. Jürgen Baumann, and Mr. Kevin Weber to the Supervisory Board of the company is disputed. An oral hearing took place at the Cologne Regional Court on November 04, 2016. The company considers the action and the justification given for the action to be unfounded and expects the action to be rejected.

## **Forecast of key financial figures relevant to the management of the Group (report on forecast change, if applicable)**

Biofrontera still expects a revenue of EUR 6-7 million for the financial year 2016. However, compared with the original forecast, turnover in Germany will be lower than expected which, on the one hand, is due to destocking on the part of wholesalers, as well as competition resulting from the launch of Luxerm® for daylight PDT. This would be offset by additional income from the development partnership with Maruho and higher revenue outside Germany.

Development and approval costs will increase from EUR 4-5 million to EUR 5-6 million in connection with the activities of the cooperation with Maruho, although sales and marketing costs will amount to around EUR 9-10 million, as opposed to the previous forecast of EUR 10-11.

The forecast for the financial result and other income remains unchanged compared with the previous forecast.

Accordingly, Biofrontera still expects net earnings of EUR-11 to -12 million.

Leverkusen, 30 November 2016



Signed: Prof. Dr Hermann Lübbert

Chief Executive Office



Signed: Christoph Dünwald

Chief Commercial Officer



Signed: Thomas Schaffer

Chief Financial officer

## Consolidated balance sheet at 30 September 2016

Assets in EUR	30 September 2016 unaudited	31 December 2015
<b>Non-current assets</b>		
Tangible assets	476,554.93	372,834.23
Intangible assets	1,397,035.88	1,901,927.93
	<b>1,873,590.81</b>	<b>2,274,762.16</b>
<b>Current assets</b>		
<b>Current financial assets</b>		
Trade receivables	515,105.76	894,558.96
Other financial assets	1,498,491.92	730,440.34
Cash and cash equivalents	5,733,276.21	3,959,207.16
	<b>7,746,873.89</b>	<b>5,584,206.46</b>
<b>Other current assets</b>		
Inventories		
Raw materials and consumables	1,156,859.60	590,420.47
Unfinished products	495,442.92	42,723.50
Finished products and goods	931,161.67	900,505.05
Income tax reimbursement claims	32,837.18	32,220.80
Other assets	294,481.44	72,879.33
	<b>2,910,782.81</b>	<b>1,638,749.15</b>
	<b>10,657,656.70</b>	<b>7,222,955.61</b>
<b>Total assets</b>	<b>12,531,247.51</b>	<b>9,497,717.77</b>

## Liabilities

in EUR	30 September 2016 unaudited	31 December 2015
<b>Equity</b>		
Subscribed capital	30,347,813.00	25,490,430.00
Capital reserve	84,055,203.06	79,525,292.28
Capital reserve from currency translation adjustments	11,389.99	(1,188.65)
Loss carried forward	(109,823,695.69)	(98,620,285.49)
Net loss for the period	(7,163,777.92)	(11,203,410.20)
	<b>(2,573,067.56)</b>	<b>(4,809,162.06)</b>
<b>Non-current liabilities</b>		
Non-current financial liabilities	2,949,274.45	11,229,946.00
<b>Current liabilities</b>		
<b>Current financial liabilities</b>		
Trade payables	737,391.16	1,043,425.65
Short-term financial debt	9,576,190.55	830,174.00
Other financial liabilities	25,748.25	37,622.28
	<b>10,339,329.96</b>	<b>1,911,221.93</b>
<b>Other current liabilities</b>		
Other provisions	1,696,151.12	1,041,860.80
Other current liabilities	119,559.54	123,851.10
	<b>1,815,710.66</b>	<b>1,165,711.90</b>
	<b>12,155,040.62</b>	<b>3,076,933.83</b>
<b>Total liabilities and Equity</b>	<b>12,531,247.51</b>	<b>9,497,717.77</b>

## Consolidated comprehensive income statement for the first nine months of the financial years 2016 and 2015

in EUR	9M 2016 unaudited	9M 2015 unaudited	Q3 2016 unaudited	Q3 2015 unaudited
Revenue	2,881,440.53	2,634,979.07	1,172,835.48	1,066,876.40
Cost of sales	-1,028,869.50	-860,090.74	-265,202.15	-326,293.21
Gross profit on sales	1,852,571.03	1,774,888.33	907,633.33	740,583.19
<b>Operating expenses:</b>				
Research and development costs	-3,358,375.51	-5,364,765.48	-1,506,366.77	-866,870.60
General administrative costs	-2,080,805.86	-2,060,303.86	-708,414.28	-712,777.65
Of which financing costs	-484,986.83	-233,645.46	-112,620.77	-82,899.14
Marketing costs	-4,937,363.43	-2,928,731.08	-2,105,094.32	-890,983.08
<b>Loss from operations</b>	<b>-8,523,973.77</b>	<b>-8,578,912.09</b>	<b>-3,412,242.04</b>	<b>-1,730,048.14</b>
<b>Financial result</b>				
Interest and similar expenses	-904,015.99	-864,694.79	-309,536.59	-295,884.30
Interest and similar income	2,359.90	9,132.21	651.59	309.93
<b>Other income and expenses</b>				
Other expenses	-35,466.08	-21,788.56	-21,445.98	-1,859.42
Other income	2,297,318.02	170,446.36	51,061.91	64,545.50
<b>Earnings before income tax</b>	<b>-7,163,777.92</b>	<b>-9,285,816.87</b>	<b>-3,691,511.11</b>	<b>-1,962,936.43</b>
Income tax	0.00	0.00	0.00	0.00
<b>Earnings for the period</b>	<b>-7,163,777.92</b>	<b>-9,285,816.87</b>	<b>-3,691,511.11</b>	<b>-1,962,936.43</b>
<b>Expenses and income not recognised in income</b>				
Subsequent measurement of financial assets available for sale	0.00	0.00	0.00	0.00
Other expenses and income not recognised in income	0.00	0.00	0.00	0.00
<b>Total earnings for the period</b>	<b>-7,163,777.92</b>	<b>-9,285,816.87</b>	<b>-3,691,511.11</b>	<b>-1,962,936.43</b>
Basic (= diluted) earnings per share	-0.25	-0.41		

## Consolidated Cash Flow statement for the first nine months of the financial years 2016 and 2015

	9M 2016 unaudited	9M 2015 unaudited	Q3 2016 unaudited	Q3 2015 unaudited
	EUR	EUR	EUR	EUR
<b>Cash Flow from operations:</b>				
<b>Totals earnings for the period</b>	-7,163,777.92	-9,285,816.87	-3,691,511.11	-1,962,936.43
<b>Adjustments for reconciling total earnings for the period to cashflow through operations:</b>				
Financial result	901,656.09	855,562.58	308,885.00	295,574.37
Depreciation	606,689.70	604,732.54	202,411.49	199,918.02
(Gains)/losses from disposal of assets	4,836.33	115.00	0.00	0.00
Non-cash expenses and income	88,522.98	24,510.52	42,152.23	696.32
<b>Changes in operating assets and liabilities:</b>				
Trade receivables	379,453.20	80,784.72	-2,668.86	59,569.61
Other assets and income tax claims	-990,273.42	-31,171.87	-651,673.00	87,367.87
Inventories	-1,049,815.17	-130,046.04	-907,525.13	85,260.96
Trade payables	-306,034.49	-569,879.85	-260,742.36	-414,868.54
Provisions	659,908.15	188,530.88	576,822.06	-60,936.43
Other liabilities	-16,165.59	62,833.57	9,557.98	46,278.01
<b>Net Cash Flow into operations:</b>	<b>-6,885,000.14</b>	<b>-8,199,844.82</b>	<b>-4,374,291.70</b>	<b>-1,664,075.24</b>
<b>Cash Flows from investment activities:</b>				
Purchase of intangible and tangible assets	-229,517.28	-94,811.12	-74,911.26	-15,002.38
Interest received	2,363.25	63,884.70	654.95	309.93
Revenue from sale of intangible and tangible assets	19,162.60	11,555.01	9,491.23	2,234.30
<b>Net Cash Flow from (into) Investment activities</b>	<b>-207,991.43</b>	<b>-19,371.41</b>	<b>-64,765.08</b>	<b>-12,458.15</b>
<b>Cash Flows from financing activities:</b>				
Proceeds from the issue of shares	9,303,174.28	2,989,597.90	0.00	-479.00
Disbursements from the redeeming own option bonds	0.00	0.00	0.00	0.00
Interest paid	-436,113.66	-830,174.00	-310.86	0.00
Increase/(decrease) in long-term financial debt	-8,280,671.55	-228,206.71	-110,590.47	-207,543.57
Increase/(decrease) in short-term financial debt	8,280,671.55	228,206.71	110,590.47	207,543.57
<b>Net Cash Flow from financing activities</b>	<b>8,867,060.62</b>	<b>2,159,423.90</b>	<b>-310.86</b>	<b>-479.00</b>
<b>Net Increase/(decrease) in cash and cash equivalents</b>	<b>1,774,069.05</b>	<b>-6,059,792.33</b>	<b>-4,439,367.64</b>	<b>-1,677,013.39</b>
<b>Cash and cash equivalents at the beginning of the period</b>	<b>3,959,207.16</b>	<b>8,509,398.16</b>	<b>10,172,643.85</b>	<b>4,126,619.22</b>
<b>Cash and cash equivalents at the end of the period</b>	<b>5,733,276.21</b>	<b>2,449,605.83</b>	<b>5,733,276.21</b>	<b>2,449,605.83</b>
<b>Composition of cash and cash equivalents at the end of the period:</b>				
<b>Cash, bank balances and checks</b>	<b>5,733,276.21</b>	<b>2,449,605.83</b>	<b>5,733,276.21</b>	<b>2,449,605.83</b>

## Consolidated statement of changes in equity for the first nine months of the financial years 2016 and 2015

unaudited	Ordinary shares	Subscribed capital	Capital reserve	Currency translation adjustments	Accumulated loss	Total
	Number	EUR	EUR	EUR	EUR	EUR
Balance as at 1 January 2015	22,196,570	22,196,570.00	76,402,715.36	0	-98,620,285.49	-21,000.13
Capital increase	1,377,272	1,377,272.00	1,790,453.60	0	0	3,167,725.60
Costs of equity procurement	0	0	-178,127.70	0	0	-178,127.70
Increase in capital reserves from the stock option program	0	0	82,251.00	0	0	82,251.00
Net loss for the year	0	0	0	0	-9,285,816.87	-9,285,816.87
Balance as at 30 September 2015	23,573,842	23,573,842.00	78,097,292.26	0	-107,906,102.36	-6,234,968.10
Capital increase	1,916,588	1,916,588.00	1,724,929.20	0	0	3,641,517.20
Costs of equity procurement	0	0	-317,642.18	0	0	-317,642.18
Currency translation adjustments	0	0	0	-1,188.65	0	-1,188.65
Increase in capital reserves from the stock option program	0	0	20,713.00	0	0	20,713.00
Net loss for the year	0	0	0	0	-1,917,593.33	-1,917,593.33
Balance as at 31 December 2015	25,490,430	25,490,430.00	79,525,292.28	-1,188.65	-109,823,695.69	-4,809,162.06
Capital increase	4,857,383	4,857,383.00	4,621,644.60	0	0	9,479,027.60
Costs of equity procurement	0	0	-175,853.32	0	0	-175,853.32
Currency translation adjustments	0	0	0	12,578.64	0	12,578.64
Increase in capital reserves from the stock option program	0	0	84,119.50	0	0	84,119.50
Net loss for the year	0	0	0	0	-7,163,777.92	-7,163,777.92
Balance as at 30 September 2016	30,347,813	30,347,813.00	84,055,203.06	11,389.99	-116,987,473.61	-2,573,067.56



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