



Interim Report

for Biofrontera AG, Leverkusen, Germany
as of 30 September, 2013

Important developments during the 3rd quarter 2013

- Considerable increase in revenues of 69% in comparison with the first 9 months of the previous year
- Successful market launch in Spain, one of the largest markets for PDT in Europe
- Clinical studies for expanded indications and USA approval started according to plan
- Actinic keratosis recognised as occupational disease

Key indicators

	9M 2013	9M 2012
Turnover from product sales	1,867.8	1,102.7
Number of Ameluz tubes sold	15,633	9,257
One-off payments	0.00	1,550.0
Liquidity	4,824.0	4.564,9



1. Biofrontera AG

The company Biofrontera AG, based in Leverkusen in Germany, provides information in this interim report about key aspects and business development based on the consolidated group information (IFRS) for the unaudited third quarter of 2013, in accordance with the TUG transparency guidelines, §37x paragraph 1 sentence 1 WpHG (German Securities Trading Act).

Biofrontera AG is a holding company with four operational subsidiaries. It holds 100% of the shares in Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH and Biofrontera Neuroscience GmbH. The financial year of all the individual companies and the group (hereinafter also referred to as 'Biofrontera' or the 'Biofrontera Group' or the 'Company' or 'Corporation') is the calendar year. All companies have their headquarters at 51377 Leverkusen, Hemmelrather Weg 201.

Biofrontera Bioscience GmbH has been tasked with product research and development. This company is the holder of the approval certification for Biofrontera's first prescription drug, Ameluz®.

Biofrontera Pharma GmbH is responsible for the Group's marketing and sales activities. A cooperation and licensing agreement with Biofrontera Bioscience governs the handling and use of patent and trademark rights

Biofrontera Development GmbH holds the rights to the development candidate BF-derm1.

Biofrontera Neuroscience GmbH holds the rights to the development candidate BF-1.

Biofrontera is one of only a few small corporate groups that have acquired all the necessary authorisations and the necessary group structures for successfully developing and obtaining approval for prescription drugs as well as for medical devices and cosmetics.

2. Business development and finances

Biofrontera succeeded in further increasing its revenues from product sales in comparison with the previous year. In total, revenues amounted to EUR 1,868 thousand in the first nine months of the financial year 2013, in comparison with EUR 2,653 thousand in the same period of the previous year. In the previous year, revenues included one-off payments from licensing partners amounting to EUR 1,550 thousand, so comparable revenues from product sales **which were EUR 1,107.7 thousand in the previous year's period** actually increased by EUR 765 thousand. This corresponds to an increase of 69%.

In the first three quarters of 2013, revenues of EUR 1,070 thousand were generated in Germany and revenues of EUR 798 thousand were generated relating to deliveries to our distribution partners in other European countries.

The market share held by Ameluz® for registered medicinal products applied in photodynamic therapy (PDT) is significantly in excess of 60% while the previously dominant rival product Metvix® and the relatively new ALA patch Alacare® have considerably smaller market shares. As a variety of PDT treatments are still initiated with extemporaneous products prepared in pharmacies, which do not have any official approval as medication, the Ameluz® share still represents only a small part of the overall PDT market and an even smaller part of the overall AK market in Germany. However, as the use of such formulations has now become increasingly problematic due to the introduction of recent legislation and thus involves significant legal risks for physicians, we expect a decline in the use of these formulations and that registered drugs, such as Ameluz® in particular, will benefit from this. In the medical profession, awareness of the legal risks involved with the use of such extemporaneous products is increasing due to increased coverage in medical journals and in lectures at medical conferences. In contrast to other forms of treatment for actinic keratosis, photodynamic therapy is both highly effective and has an excellent cosmetic outcome. The increasing recognition of actinic keratosis as a serious tumour disease should be reflected in the future in the choice of therapy and should thereby lead, as a consequence, to an expansion of the PDT market. A clear signal in this respect is the recognition in August of actinic keratosis as an occupational illness.

On 27 September, Ameluz® was launched in Spain by the distribution partner Allergan. Ameluz® is fully refundable in Spain in the context of photodynamic therapy. Biofrontera has thus created the basis for future growth in revenues in another important market in Europe.

Biofrontera has invested EUR 1,950 thousand in R&D in the first nine months of the 2013 financial year. This investment related in particular to the four clinical studies carried out by Biofrontera for the expansion of Ameluz® indications and for approval of the drug in the USA. We are expecting a significant increase in corporate value as a result of the approval in the USA.

The liquidity on 30 September amounted to EUR 4,824 thousand, compared to EUR 3,366 thousand on 31 December 2012.



3. Products

a. Ameluz®

Biofrontera's prescription drug Ameluz®, which is approved for the treatment of superficial skin cancer (actinic keratosis), combines the active ingredient 5-aminolevulinic acid (ALA) with a patent-protected nano-emulsion, which increases chemical stability and improves skin penetration. Actinic keratosis is a very common skin cancer, occurring in fair-skinned people in particular, and can develop into a life-threatening squamous cell carcinoma. Up to 10% of the European population are affected by actinic keratosis. In photodynamic therapy (PDT) with Ameluz®, the medication is applied to the affected area of skin. Illumination for 10 to 15 minutes with a strong red light three hours later triggers a chemical reaction, which kills the affected skin cells without scarring. If required, the treatment should be applied a second time after three months. Currently, Ameluz® is the only PDT product that has been approved in Europe for mild and moderate actinic keratosis. Clinical approval studies have demonstrated significant superiority over the direct competitor product with regard to healing all keratoses in patients.

At the beginning of 2013, the European Medicines Agency (EMA) increased the approved shelf life of Ameluz® from two to three years based on new stability data. The agency also approved usage for up to three months after first opening the tube and removal of the warning text with respect to freezing of the product. These changes make the use of Ameluz® more cost-effective and significantly simplify production planning.



b. BF-RhodoLED®

The BF-RhodoLED® is a lamp designed for photodynamic therapy (PDT). It uses LEDs emitting red light at a wavelength of approx. 635 nm. This wavelength is ideally suited for illumination during PDT with medicinal products containing Ameluz®. The option to regulate light energy and blower power during PDT treatment enables adjustments during therapy in order to alleviate treatment-related discomfort. Currently, no other lamp available on the market offers comparable performance and flexibility. The BF-RhodoLED® has been approved as a medicinal product (CE certification). The CE certificate was issued in November 2012 and provides authorisation for sales throughout the EU.



c. The medical cosmetic Belixos

Biofrontera has been selling the medical cosmetic Belixos®, which was launched on the German market in the autumn of 2009, for a number of years. Belixos® is available in pharmacies and via an online store operated by Biofrontera, with the majority of sales currently going via the wholesale / pharmacy distribution channel. Belixos® contains valuable ingredients obtained in a complex and very gentle process from the plant *mahonia aquifolium*, which has been used for centuries in traditional medicine by North American Indians. It is supplemented by the antibacterial properties of green tea and the soothing effects of genuine camomile to create a unique active ingredient combination. Brand-building activities are particularly important for a cosmetic such as Belixos®. To date, Biofrontera has, for reasons of cost, only pursued this in terms of distributing sample tubes. However, the very positive response to such activities allows for somewhat more extensive advertising, which will start in social media channels in the coming months. Following the launch of this campaign the Belixos® product line will be expanded. Additional products of the Belixos series will be available from Q1 of next year.

d. Other projects

BF-derm1: This tablet contains an active ingredient with a completely new active profile that aims to provide alleviation or possibly even a cure for chronically ill patients with severe urticaria (hives) for whom existing treatment is insufficient. A phase II study has confirmed the good effect of BF-derm1 in such severely affected patients. Besides improving the clinical manifestation of the disease, the patients in the study were also able to largely dispense with antihistamine treatments that often induce drowsiness.

BF-1: BF-1 is a highly potent active agent from the Biofrontera drug portfolio that is based on research results from the first years of operation after the founding of the Company, before it focused on dermatology. It is intended for use in the prophylactic treatment of patients who suffer from frequent and painful migraine attacks. The excellent pharmacokinetic properties demonstrated in the first clinical trial with voluntary healthy subjects provide the preclinical basis for further clinical trials of the product. Relevant side effects have so far not yet occurred in humans or in animal experiments.

Biofrontera does not currently have the resources to actively pursue both projects. These products were therefore transferred to dedicated companies in 2012 in order to facilitate financing.



4. Research and Development

Ameluz[®] is registered in the European Union as first-line therapy for the treatment of actinic keratosis. Biofrontera aims additionally at the registration of Ameluz[®] in the treatment of basal cell carcinomas and intends to approve the medicine in the USA. While the data presented in the European approval process can also be used in the USA, some additional questions were raised by the Food and Drug Administration (FDA). The clinical studies required to answer these questions have been initiated by Biofrontera in recent months. For the years 2013-2015 Biofrontera has budgeted a total of EUR 10 million for the expansion of the approval of Ameluz[®] to the indication basal cell carcinoma and the registration in the USA. The major parts of this amount will be required in 2013 and 2014. EUR 1,950 thousand were already spent in the first 9 months of 2013. The filing of the approval document in the USA is foreseen for the second half of the year 2014.



5. The share (ISIN DE0006046113)

A number of analysts have issued analyses of Biofrontera in recent months. Some of these are available in English. These assessments, each with a calculation of the fair value of the **Company by the stock analysts, are available on the Company's website** for shareholders and other potential investors. The London Investment Bank FinnCap recently added Biofrontera to the group of companies monitored by analysts.

The share price has stabilised at a level of around EUR 3.50 at the time of this report, following significant fluctuations in the past months that **in Biofrontera's view** could not be accounted for by company news.

As of 1 August 2013, Biofrontera has secured M.M.Warburg & CO Kommanditgesellschaft auf Aktien as new corporate sponsor.

6. Outlook

In the months ahead, Biofrontera will focus its activities on further growth of revenues in Germany, and on supporting its distribution partners in other European countries in order to create the conditions for generating additional sales volumes.

Depending on the development of the business in Q4, we expect based on the fundamental trends and developments discussed earlier revenues between EUR 3,300 thousand and EUR 3,800 thousand for the year 2013.

In parallel to this, Biofrontera will continue carrying out clinical studies for securing approval in the USA, in accordance with the previously defined schedule.

Discussions with Maruho about potential business collaborations have been very constructive and will be continued.

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Biofrontera AG



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