## **Biofrontera AG**

("Biofrontera" or "the Company")

#### Half Year Results

# Good progress made in first half of 2015

Leverkusen, 14 August 2015 – Biofrontera (FSE/AIM:B8F), the biopharmaceutical company focusing on sun-induced skin cancer has published its unaudited consolidated results for the six month period ended 30 June 2015, reporting an increase in revenues by 29% to EUR 1.57 million (2014 H1: EUR 1.22 million). The published half-yearly report is available in full on the Company's website www.biofrontera.com.

# Financial highlights

- Significant growth in sales revenue of 29% compared to the same period in the previous year
- Improving sales performance in European countries outside German home market
- Consolidated profit/loss before tax: EUR -7.3 million, reflecting FDA submission fee
- Cash and cash equivalents of EUR 4.1 million as at 30 June 2015
- Capital raise for FDA submission fee successfully completed

# **Operational highlights**

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

The majority of revenues were again recorded in Germany with EUR 1.19 million (2014 H1: EUR 915,000), which represents an increase of 30%. Product revenues in other European countries also developed well with EUR 382,000 being achieved, which represents an increase of 65% compared to the first half of the previous year.

The Company reported a net loss before tax of EUR 7.3 million (2014 H1 loss: EUR 5.4 million) which includes development costs of EUR 4.5 million (2014: EUR 2.1 million). The increase was primarily as a result of the application fee of EUR 2.1 million which was paid to the FDA. This amount may be repaid by the FDA as Biofrontera may be eligible for a waiver for small businesses.

### Milestone Approaching - US filing for Ameluz®

One of Biofrontera's most important strategic goals is entering the US market with its combination prescription drug Ameluz<sup>®</sup> and PDT-lamp BF-RhodoLED<sup>®</sup>. Both products are used together in

photodynamic therapy for the treatment of mild and moderate actinic keratosis. As announced during the period, the Company's phase III actinic keratosis field therapy study with the drug/light combination reported complete clearance in over 90% of treated patients, along with a strong skin rejuvenation effect.

During the first half of 2015, results from all clinical studies were analysed in the format requested by the FDA and the dossier was finalised. Submission to the FDA was initiated on 10 July 2015. This represents an outstanding milestone in the history of Biofrontera. Management believes that globally there are very few biotech companies that have been able to initiate an approval process with the FDA for a drug developed in-house.

Marketing authorization will provide Biofrontera access to the largest pharmaceutical market in the world with the associated significant and transformational revenue potential for the Company.

# European Approval Process for Ameluz® for the treatment of BCC

Biofrontera has also made good progress in its second project of strategic importance, the label extension of the European approval of Ameluz<sup>®</sup> for the treatment of basal cell carcinoma, one of the most frequently occurring forms of skin cancer. Patient recruitment for this study was completed in May. The study will therefore be finished by the end of 2015 and the extended approval is expected to be achieved by mid-2016. This approval will, in management's view, provide further revenue opportunities to the company far greater than with the existing label.

**Prof. Hermann Lübbert, Chief Executive Officer, commented:** "We are well in line with our targets for revenue development and can confirm our annual growth expectation of 30% with revenue of EUR 4 to 5 million for the full year to 31 December 2015. We have also made great progress with the submission of the application in the US as well as with completion of patient recruitment in our Phase III study for basal cell carcinoma. Biofrontera is well underway to become a much larger and much more prominent company in the short to medium term and we will work very hard to secure significant value for all our shareholders".

### **Ends**

## **Enquiries, please contact:**

Biofrontera AG +49 (0) 214 87 63 2 0
Prof. Hermann Lübbert, Chief Executive Officer press@biofrontera.com
Thomas Schaffer, Chief Financial Officer www.biofrontera.com
IR Germany: Brainwell Asset Solutions +49 (0) 152 08931514

Jürgen Benker

Nomad and Broker: Shore Capital +44(0) 20 7408 4090

Bidhi Bhoma / Toby Gibbs

IR UK: Seton Services +44(0) 20 7603 6797

Toni Vallen

**Financial PR: Gable Communications** +44(0) 20 7193 7463 John Bick / Justine James +44 (0)7872 061007

### Background:

**Biofrontera Group** (FSE/AIM: B8F, ISIN DE0006046113) is a biopharmaceutical company specialising in the development, sale and distribution of drugs and medical cosmetics for the care and treatment of skin diseases. Biofrontera's most important product is **Ameluz**<sup>®</sup>, a prescription drug which is approved in Europe for the treatment of mild and moderate actinic keratosis (superficial skin cancer) with photodynamic therapy (light therapy). Biofrontera is the first German pharmaceutical start-up company to obtain centralised approval for a drug it has developed itself. The company also plans for Ameluz<sup>®</sup> to be approved for basal cell carcinoma and is currently preparing for approval in other countries, especially in the largest pharmaceutical market in the world, the United States.

The company also markets the Belixos<sup>®</sup> dermatological range of cosmetics. Belixos<sup>®</sup> products, a cream, a gel and a scalp tonic, contain combinations of active substances extracted from plants, relieve itching and redness and are used for the regenerative care of chronic skin conditions such as atopic dermatitis or psoriasis. The Belixos<sup>®</sup> Protect, a daily skincare for sun-damaged skin, complements this dermo-cosmetic line. All products are available through Amazon.

The Biofrontera Group was established in 1997 by Prof. Dr Hermann Lübbert, the Chairman of the company's Management Board, and has its headquarters in Leverkusen, Germany.

### www.biofrontera.com

This communication expressly or implicitly contains certain forward-looking statements concerning the business activities of Biofrontera AG. These forward-looking statements reflect the opinion of Biofrontera at the time of this communication and involve certain known and unknown risks. The actual results achieved by Biofrontera may differ significantly from future results or performances which are published in its forward-looking statements. Biofrontera assumes no responsibility to update its forward-looking statements.

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

in EUR	6 M 2015	6 M 2014
Sales revenue	1,568,102	1,216,529
Cost of sales	(533,797)	(348,231)
Gross profit from sales	1,034,305	868,298
Operating expenses:		
Research and development costs	(4,497,894)	(2,063,034)
General administrative costs	(1,347,526)	(1,740,272)
of which financing costs	(150,746)	(231,028)
Cost of sales	(2,037,748)	(2,007,732)
Loss from operations	(6,848,863)	(4,942,740)
Financial result		
Interest expenses and similar	(568,810)	(594,062)
Interest income and similar	8,822	32,992
Other income and expenses		
Other expenses	(19,929)	(12,688)
Other income	105,900	103,909
Profit/loss before income tax	(7,322,880)	(5,412.589)
Income tax	0	(6,124)
Profit or loss for the period	(7,322,880)	(5,418,713)
Expenses and income not included in profit/loss	(1,322,000)	(3,410,713)
Subsequent valuation of financial assets		
available for sale	0	0
Other expenses and income not included in	0	0
profit/loss Total result for the period	(7,322,880)	(5,418,713)
Total roods for the period	(1,022,000)	(0,110,710)
Undiluted (= diluted) earnings per share	(0.33)	(0.25)

# Consolidated balance sheet as at 30 June 2015

Assets		
in EUR	30 June 2015	31 December 2014
Non-current assets		
Tangible assets	345,108	339,532
Intangible assets	2,240,059	2,580,077
	2,585,167	2,919,609
<u>Current assets</u>		
Current financial assets		
Trade receivables	287,769	308,984
Other financial assets	714,529	726,790
Cash and cash equivalents	4,126,619	8,509,398
	5,128,918	9,545,173
Other current assets		
Inventories		
Raw materials and supplies	630,557	684,455
Unfinished products	179,448	107,784
Finished products and goods	798,822	601,281
Income tax reimbursement claims	38,043	62,072
Other assets	190,193	90,118
	1,837,065	1,545,713
	6,965,983	11,090,886
Total assets	9,551,151	14,010,495

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Liabilities		
in EUR	30 June 2015	31 December
		2014
Equity	00 570 040	
Subscribed capital	23,573,842	22,196,570
Capital reserve	78,070,354	76,402,715
Loss carried forward	(98,620,285)	(87,899,306)
Net loss for the year	(7,322,880)	(10,720,978)
	(4,298,969)	(21,000.13)
Long-term liabilities		
Long-term financial liabilities	11,321,181	10,774,298
Current liabilities		
Current financial liabilities		
Trade payables	812,426	967,437
Short-term financial debt	415,087	1,224,598
Other financial liabilities	37,716	27,012
	1,265,229	2,219,047
Other current liabilities		
Other provisions	1,171,652	951,944
Other current liabilities	92,057	86,205
	1,263,709	1,038,149
	2,528,939	3,257,197
Total liabilities	9,551,151	14,010,495
1 otal naomilio	3,331,131	17,010,490

	6 M 2015
	EUR
Cash flows from operations	
Total result for the period	(7,322,880)

Cash flow statement for the first half of 2015 and 2014

Adjustments to reconcile net profit or loss for the period with		. , , ,
cash flow into operations:		
Financial result	559,988	561,070
Depreciation	404,814	409,484
(Gains)/losses from disposal of assets	115	2,632
Non-cash expenses and income	23,814	(5,922)*
Changes in operating assets and liabilities:		
Trade receivables	21,215	408,699
Other assets and income tax assets	(118,539)	(203,431)
Inventories	(215,307)	845
Trade payables	(155,011)	(178,511)
Provisions	249,467	175,774
Other liabilities	16,555	(8,296)
Net cash flow into operations:	(6,535,768)	(4,256,367)
Cash flows from investment activities:		
Purchase of intangible and tangible assets	(79.808)	(85,524)
Interest received	63,574	3,326
Revenue from the sale of intangible and tangible assets	9,320	45,144

6 M 2014

EUR

(6,913)

(5,418,713)

(37,053)

Cash flows	from	financing	activities:

Net cash flow from (into) investment activities

Cash news from infancing activities.		
Proceeds from the issue of shares	2,990,076	15,333,626
Payouts from the repurchase of own warrant bonds	0	(199,038)
Interest paid	(830,174)	(454,416)
Increase/(decrease) in long-term financial debt	(20,663)	(1,716,163)*
Increase/(decrease) in short-term financial debt	20,663	415,087*
Net cash flow from financing activities	2,159,902	13,379,095
Net increase (decrease) in cash and cash equivalents	(4,382,778)	9,085,673
Cash and cash equivalents at beginning of period	8,509,398	2,933,578
Cash and cash equivalents at end of period	4,126,619	12,019,252
Composition of financial resources at end of period:	·	
Cash and bank balances and cheques	4.126.619	12.019.252

<sup>\*</sup>Adjustment to the statement of the previous year's figures

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

	Ordinary shares Number	Subscribed capital EUR	Capital reserve EUR	Accumulated loss EUR	Total EUR
Account balance on 1 January 2014 Capital increase Costs of capital procurement Changes in the capital procure especiated with the repurchase of	17,753,168 4,443,402 0	17,753,168 4,443,402 0	65,598,778 11,105,950 (215,725)		(4,547,359) 15,549,352 (215,725)
Changes in the capital reserve associated with the repurchase of own Warrant Bonds I  Change in the capital reserve resulting from transaction costs in	0	0	(198,939)	0	(198,939)
connection with the repurchase of own Warrant Bonds I Increase in capital reserves from the stock option programme	0	0	(99) 54,522	0	(99) 54,522
Net loss for the year	0	0	0	(5,418,713)	(5,418,713)
Account balance on 30 June 2014 Capital increase	22,196,570 0	22,196,570 0	76,344,486 0	(93,318,020) 0	5,223,036 0
Costs of capital procurement Changes in the capital reserve associated with the repurchase of own Warrant Bonds I	0	0	0	0	0
Changes in the capital reserve resulting from transaction costs in connection with the sale/repurchase of own Warrant Bonds I and				0	U
	0	0	0	0	0
Increase in capital reserves from the stock option programme	0	0	58,228	(F 202 205)	58,228
Net loss for the year Account balance on 31 December 2014	22,196,570	0 22,196,570	0 76,402,715	(5,302,265) (98,620,285)	(5,302,265) (21,000)
Capital increase	1,377,272	1,377,272	1,790,453	0	3,167,725
Costs of capital procurement	0	0	(177,648)	0	(177,648)
Changes in the capital reserve associated with the repurchase of	0	0	0	0	0
own Warrant Bonds I Changes in the capital reserve resulting from transaction costs in	U	0	U	U	U
connection with the sale/repurchase of own Warrant Bonds I and					
in .	0	0	0	0	0
Increase in capital reserves from the stock option programme	0	0	54,834	0	54,834
Net loss for the year Account balance on 30 June 2015	23,573,842	23,573,842	78,070,354	(7,322,880) (105,943,165)	(7,322,880) (4,298,969)

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

### 1. Information about the company

Biofrontera AG (www.biofrontera.com), with its head office at Hemmelrather Weg 201, 51377 Leverkusen, Germany, registered in the Commercial Register of Cologne District Court, Department B under no. 49717, and its wholly-owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc., which is based in Wilmington, Delaware, USA, research, develop and market dermatological products. The main focus is on the discovery, development and distribution of dermatological drugs and dermatologically tested cosmetics for the treatment and care of diseased skin. Biofrontera AG (hereinafter also the "company") pursues this goal along with its subsidiaries. All the companies together form the "Biofrontera Group".

The Biofrontera Group was the first small German pharmaceutical company to receive a centralised European drug approval for an independently developed drug, Ameluz<sup>®</sup>. Ameluz<sup>®</sup> was approved for the treatment of mild and moderate actinic keratoses in December 2011. Two further clinical development projects, one dermatological project and one for the prevention of migraines, are in the pipeline but are not being actively pursued at the present time. In addition, a range of cosmetic products is to be expanded; the first product in this range, Belixos<sup>®</sup>, was launched in the autumn of 2009. A hair tonic, Belixos<sup>®</sup> LIQUID, was introduced in the spring of 2014 and a Belixos<sup>®</sup> gel skin care for rosacea and acne was launched at the beginning of December 2014. The launch of Belixos<sup>®</sup> Protect, a day cream with protective anti-aging properties designed especially for photodamaged skin, followed in July 2015.

The product Ameluz<sup>®</sup> (development name BF-200 ALA), which was approved at the end of 2011, has been tested in one phase II and two phase III clinical trials for the European approval to treat actinic keratosis. In preparation for approval in the USA, two further phase I trials and a phase III trial have been conducted. Ameluz<sup>®</sup> consists of a combination of the active agent aminolevulinic acid (ALA) and a nanoemulsion (BF-200), which gives the ALA chemical stability and enables it to penetrate the skin effectively. The clinical results regarding the treatment of actinic keratosis have shown its clear superiority to the competitor product against which it was compared in the phase III trials. An application for centralised European approval was submitted on 1 September 2010, and this approval was granted by the European Commission on 16 December 2011. Ameluz<sup>®</sup> has been sold in Germany since February 2012 and in several other European countries since autumn 2012. The application for regulatory approval (NDA = New Drug Application) was submitted to the FDA (Food and Drug Administration) in early July 2015.

In November 2012, Biofrontera's BF-RhodoLED<sup>®</sup> PDT lamp received pan-European approval for use as a medical device and has since been sold in parallel with Ameluz<sup>®</sup>. In Europe, doctors can choose to use any of the lamps approved for PDT, whereas in the USA the approval of Ameluz<sup>®</sup> will be intrinsically linked to that of the lamp. This will therefore be approved as a combination product along with the drug.

The BF-derm1 project is not currently being actively developed, but it has been tested in a three-part phase II trial for the treatment of chronic, antihistamine-resistant urticaria (hives). The trial demonstrated the good effect of the drug, which reduced the intensity of urticaria rashes and itching, as well as reducing the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is an innovative substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007. They show that the substance is almost completely absorbed in the gut, and that it takes around two days for 50% of the substance to be broken down or excreted. These results are an excellent starting point for developing the substance for administration in tablet form.

The intention is to finance the development of both BF-derm1 and BF-1 independently of Biofrontera's normal budget, using funds that are specifically sought for and directly allocated to the development of these products. For this reason, both projects were acquired from Biofrontera AG and allocated as partner's investments to the two newly-founded subsidiaries, Biofrontera Development GmbH and Biofrontera Neuroscience GmbH, in December 2012. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is now the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products can be uncoupled from the normal group financing. As a result, the company's short-term financial plans can focus on the market launch of Ameluz® in North America and the extension of its range of indications, as well as the establishment of the group as a specialist pharmaceutical company.

### 2. Accounting and valuation principles

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

As at 30 June 2015, the half-yearly financial statement of Biofrontera AG from 1 January 2015 to 30 June 2015 has been prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) for "Interim Financial Reporting" pursuant to IAS 34, as applicable in the European Union. In the opinion of the Management Board, these half-yearly financial statements contain all the half-yearly business transactions that are necessary for presentation of the financial position, cash flows and results of operations for the periods ending on 30 June 2015 and 2014.

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

In the context of the preparation of the consolidated interim financial statements, the Management Board has to make estimates and assumptions that influence the application of accounting principles in the group as well as the reported amounts of the assets and liabilities and the income and expenses. The actual

amounts may deviate from these estimates. The results achieved in the first half of the 2015 financial year do not permit any forecasts to be made concerning the further progress of business performance.

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

The consolidated financial statement as at 31 December 2014 contains no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz<sup>®</sup>, including the supplementary products BF-RhodoLED<sup>®</sup> (PDT lamp), and Belixos<sup>®</sup>, and are internally monitored and managed accordingly.

The statement of profit/loss is prepared using the cost of sales method. In this reporting format, the net turnover is set against the expenses incurred in achieving it, broken down into cost of sales, research and development costs, distribution costs and general administration costs.

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

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

### Deferred taxes

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

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

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

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

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

### Employee stock option programme 2010

In order not to be at a disadvantage in the future regarding staff recruitment and retention, the company must continue to be able to offer share and/or securities-based remuneration. Moreover, in accordance with the German act concerning the appropriateness of management board remuneration, such schemes must be linked to the long-term success of the company. As the stock option programme approved by the Annual General Meeting of the company on 24 May 2007 could not be used, the Annual General Meeting held on 2 July 2010 granted the Management Board and the Supervisory Board the authorisation to issue, within the next 5 years, up to 839,500 options to directors and employees. Further provisions governing this action were specified in the invitation to the Annual General Meeting and are available on the company's website. The issue of a first tranche of these options is described in the consolidated financial statements of 31 December 2010. The second tranche took place in the 2011 calendar year and is noted in the consolidated financial statements of 31 December 2011. A further 116,500 option rights (third tranche) were issued in the first half of 2012 at an exercise price of EUR 3.30 or EUR 4.09 each. On 2 September 2013, 179,500 options (fourth tranche) were issued with an exercise price of EUR 3.373. In a further tranche (fifth tranche), on 2 April 2014 159,350 option rights were issued with an exercise price of EUR 3.43 each. All in all, 115,750 option rights were forfeited by employees leaving the company. There were therefore still 181,350 options outstanding on 30 June 2015. In the period under review, the expenditure booked was EUR 55 thousand (30 June 2014: EUR 55 thousand).

#### 5. Shares / earnings per share

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

	30 June 2015	30 June 2014
Number of weighted ordinary shares in circulation (on average)	22,424,847	21,311,811
Net loss for the year in EUR	(7,322,880)	(5,418,713)
Earnings per share in EUR, related to net loss for the	(0.33)	(0.25)
vear		

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

### 6. Transactions with related persons

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

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

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

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

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