# QUARTERLY EARNINGS REPORT FOR THE 3 MONTHS ENDED 31 MARCH 2019



# Dear shareholders,

The first three months of 2019 mark another successful quarter for Biofrontera. Once again, we were able to increase product sales and the reporting period now marks the fourth consecutive quarter-over-quarter revenue growth. Biofrontera Group sales for the period January to March 2019 amounted to 6.8 million euros. This reflects a revenue growth of 46% compared to the previous year, with pure product sales growing by 48%.

On March 19, we announced the start of the next project phase of the development partnership with Maruho Co, Ltd. (Maruho). As part of the newly agreed project phase, we will prepare one of the four active ingredients, which we have tested for stability in combination with our proprietary nanoemulsion, for testing in clinical trials. As in the first phase of this development cooperation, the work will be carried out at Biofrontera and the costs are borne by Maruho. Existing IP, specifically Biofrontera's nanoemulsion technology, remains with the original owner, while the results of the development are equally shared by both parties. In addition, Maruho and Biofrontera are currently negotiating a collaboration to research and develop Ameluz<sup>®</sup> for the treatment of acne, as well as a license to market Ameluz<sup>®</sup> in parts of Asia and Oceania. Looking ahead, we expect that the development of Ameluz for acne and the continued collaboration agreement with Maruho to develop branded generics will further improve our future growth profile.

The quarter was characterized by the acquisition of Cutanea Life Sciences, Ltd. (Cutanea) on March 25, 2019 from our strategic partner Maruho. The transaction supports our position with dermatologists and thus, our growth in the US tremendously. As such, it is an important part of the portfolio for the future of Biofrontera. Through our acquisition of Cutanea, we have added two FDA-approved prescription drugs to our US-product portfolio: Aktipak<sup>®</sup> and Xepi<sup>™</sup>. These will now be added for distribution through our established sales and marketing infrastructure in the US. Our sales representatives are excited to now have even better access to our customers, the dermatologists, with an expanded product offering.

Through the acquisition of Cutanea and its products, Biofrontera has expanded its strategic orientation and thus, has transformed from a highly specialized expert in photodynamic therapy to a diversified specialty pharmaceutical company in dermatology.

In March, we also announced the very positive results of our Phase III clinical trial on the safety and efficacy of conventional photodynamic therapy with Ameluz<sup>®</sup> in combination with the BF-RhodoLED<sup>®</sup> lamp for the treatment of actinic keratoses on the extremities or trunk/neck. The results of the primary endpoint of the study demonstrate the superiority of Ameluz<sup>®</sup> with a mean lesion healing rate of 86% compared to placebo with 33% (p<0.0001). Our excellent results in the treatment of these body regions will further differentiate Ameluz<sup>®</sup> from other therapies following successful approval in both Europe and the US. The results of the study will be the basis for applications to the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) for an extension of the marketing authorization, which Biofrontera plans to submit during the third quarter of 2019.

At the beginning of 2019, Biofrontera received approval from the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA) to increase the batch size for Ameluz<sup>®</sup> production. The fivefold increase in the batch size ensures the supply of Ameluz<sup>®</sup> in the face of increasing demand in the U.S. Upscaling the manufacturing process will also increase the gross margin of Ameluz<sup>®</sup>. In addition, the FDA and EMA have approved another producer for the aminolevulinic acid used in Ameluz<sup>®</sup>, which was necessary to ensure security of supply.

The acquisition of Cutanea from Maruho was a decisive step, both for us and for Maruho. With the label expansion of Ameluz<sup>®</sup> and the expansion of our US-product portfolio, Biofrontera is now a multi-product company for dermatology. Looking to the future, we will now be able to offer our larger product portfolio through our distribution structure in the U.S. to realize the full potential of Biofrontera.

# Key group figures in accordance with IFRS

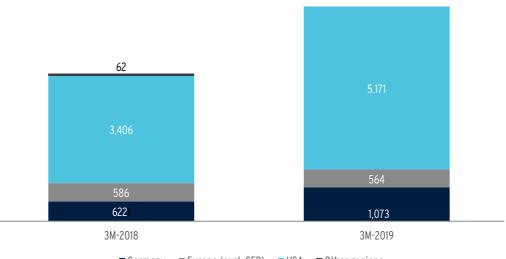
In EUR thousands (unless stated otherwise)	3M 2019 unaudited	3M 2018 unaudited
Results of operations		
Sales revenue	6,808	4,676
Gross profit	5,846	4,005
Research & development costs	(1.088)	(938)
General administrative costs	(1,974)	(1,416)
Sales costs	(5,554)	(4,301)
Loss from operations	(2,770)	(2,650)
Loss before income tax	(2,637)	(3,412)
Total loss for the period	(2,980)	(3,172)

In EUR thousands (unless stated otherwise)	3M 2019 unaudited	31 Dec 2018
Key balance sheet figures		
Total assets	43,732	39,133
Current liabilities	7,690	7,770
Non-current liabilities	22,558	15,007
Equity	13,484	16,356
Cash and cash equivalents	21,759	19,451
Employees as of 31 March	171	126
Biofrontera share		
Shares outstanding (number as of 31 March)	44,632,674	44,632,674
Share price (Xetra closing price on 29 March in EUR)	5.60	5.01

# Biofrontera Group financial position and performance

#### Sales revenue

In the first quarter, total revenues were EUR 6,808 thousand, 46% higher than in the same period last year (previous year period: EUR 4,676 thousand), of which pure sales revenue increased by 48%. The increase was mainly due to the strong US-sales growth, which accumulated to EUR 5,171 thousand in the reporting period (previous year period: EUR 3,406 thousand). Sales in Germany amounted to EUR 1,073 thousand, which reflects an increase of 72%, compared to the first quarter 2018 (previous year period: EUR 622 thousand). In the remainder of Europe, sales were EUR 564 thousand, almost flat compared to EUR 586 thousand in the previous year period us to the elimination of re-imports within the EU.



■ Germany ■ Europe (excl. GER) ■ USA ■ Other regions

#### **Gross profit**

Gross profit on sales improved by EUR 1,841 thousand in the reporting period to EUR 5,846 thousand compared to EUR 4,005 thousand in the same period last year. The gross margin was stable at 86%.

#### **Research and development costs**

Research and development costs amounted to EUR 1,088 thousand in the first three months of 2019, an increase of EUR 150 thousand or 16% compared to the same period last year (previous year period: 938 thousand). Research and development costs primarily include costs for clinical studies as well as regulatory expenses, i.e. fees for maintaining and extending our regulatory approvals.

#### General administrative costs

General administrative expenses amounted to EUR 1,974 thousand in the first three months of 2019, an increase of EUR 558 thousand or 39% compared to the first quarter 2018 (previous year period: EUR 1,416 thousand). The increase is mainly due to the expansion of our business activities as well as higher legal costs.

#### Sales costs

Sales and marketing costs totaled EUR 5,554 thousand, an increase of EUR 1,253 thousand or 29% compared to the same period in 2018 (previous year period: EUR 4,301). The increase reflects the growing sales activities in the USA as well as the start of our own sales force in the UK.

#### Loss before income tax

In the first three months of 2019, the loss before tax amounted to EUR -2,637 thousand, an improvement of EUR 775 thousand compared to EUR -3,412 thousand in the prior-year period. This development is mainly due to the sales development described above.

#### Net assets

Total assets increased from EUR 39,133 thousand as of 31 December 2018 to EUR 43,732 thousand as of 31 March 2019.

The fully paid in share capital of Biofrontera AG amounted to EUR 44,632 thousand as of 31 March 2019 and is divided into 44,632,674 registered shares with a nominal value of EUR 1.00 each. On 31 March 2019, the share capital amounted to EUR 13,484 thousand compared to EUR 16,356 thousand on 31 December 2018.

#### **Financial position**

Cash and cash equivalents amounted to EUR 21,759 thousand as of 31 March 2019, an improvement of EUR 2,308 thousand compared to 31 December 2018. This includes a EUR 5 million tranche of the EIB Ioan drawn in February 2019, to ensure the right to disbursement would not forfeit. From today's perspective, the Company has sufficient liquidity to implement Biofrontera's strategy.

# Outlook

The business development in the first quarter of 2019 is in line with the expectations of the Management Board. The Management Board therefore fully maintains its forecast for fiscal year 2019 published on 29 April 2019. Among other things, the Management Board therefore expects annual sales of around EUR 35-40 million and a result from operating activities of EUR -7 to -9 million. Details of the forecast can be found in the 2018 Annual Report, which is published on Biofrontera's website at <a href="https://www.bio-frontera.com/en/investors/financial-reports.html">https://www.bio-frontera.com/en/investors/financial-reports.html</a>.

### Condensed consolidated balance sheet as of 31 March 2019

in EUR thousands	31 March 2019 unaudited	31 December 2018
Non-current assets		
Tangible assets	3,278	794
Intangible assets	507	352
Deferred taxes	10,400	10,400
Total non-current assets	14,185	11,546
Current assets		
Current financial assets		
Trade receivables	2,663	3,397
Other financial assets	640	794
Cash and cash equivalents	21,759	19,451
Total current financial assets	25,062	23,642
Other current assets		
Inventories		
Raw materials and supplies	1,179	1,098
Unfinished products	393	320
Finished products and goods	1,977	1,759
Income tax reimbursement claims	3,549	3,177
Other assets	53	53
Total other current assests	883	715
	4,485	3,945
Total current assets	29,547	27,587
Total assets	43,732	39,133

#### Equity and liabilities

in EUR thousands	31 March 2019 unaudited	31 December 2018
Equity		
Subscribed capital	44,632	44,632
Capital reserve	117,184	117,109
Capital reserve from foreign currency conversion ad-	(344)	(2)
Loss carried forward	(145,351)	(136,505)
Loss for the period	(2,637)	(8,878)
Total equity	13,484	16,356
Non-current liabilities		
Non-current financial debt	21,013	13,462
Other non-current provisions	1,545	1,545
Total non-current financial liabilities	22,558	15,007
Current liabilities		
Current financial liabilities		
Trade payables	2,381	1,806
Current financial debt	154	165
Other financial liabilities	83	29
Total current financial liabilities	2,618	2,000
Other current liabilities		
Other provisions	2,350	2,891
Other current liabilities	2,722	2,879
Total other current liabilities	5,072	5,770
Total current liabilities	7,690	7,770
Total equity and liabilities	43,732	39,133

# Condensed consolidated statement of comprehensive income for the first three months of the 2019 and 2018 financial years

in EUR thousands	Q1 2019 unaudited	Q1 2018 unaudited
Sales revenue	6,808	4,676
Cost of sales	(963)	(671)
Gross profit from sales	5,846	4,005
Operating expenses		
Research and development costs	(1,088)	(938)
General administrative costs	(1,974)	(1,416)
Sales costs	(5,554)	(4,301)
Loss from operations	(2,770)	(2,650)
Interest expenses	(357)	(469)
Effective interest expenses	(51)	(35)
Interest income	5	2
Other expenses	(58)	(322)
Other income	594	60
Loss before income tax	(2,637)	(3,412)
Income tax	-	-
Deferred income tax	-	-
Loss for the period	(2,637)	(3,412)
Expenses and income not included in loss	(2,637)	(3,412)
Items, which may in future be regrouped into the comprehensive income statement under certain conditions. Translation differences resulting from the conversion of foreign business operations	(342)	241
Other income total	(342)	241
Total loss for the period	(2,980)	(3,172)
Basic / diluted earnings per share in EUR	(0.06)	(0.08)

# Financial calendar

July 10, 2019	Annual General Meeting
August 30, 2019	Half Year 2019 Earnings Report
November 2019	Analysts' Conference 2019, German Equity Forum, Frankfurt
November 2019	Q3 2019 Earnings Report

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