

QUARTERLY EARNINGS REPORT FOR THE 9 MONTHS ENDED SEPTEMBER 30, 2019

Dear shareholders,

With positive results in the first nine months of 2019, Biofrontera was able to further expand its global positioning as a leading specialist company in dermatology and thus, continuously create sustainable shareholder value. Compared to the same period last year, we increased our total sales by around 31% to EUR 19.1 million, which was due to our main growth drivers - the German and US markets. In Germany, our revenue rose 59% to EUR 3.3 million, while US sales of Ameluz® amounted to EUR 13.6 million, an increase of around 33%. In Spain, sales were maintained at the previous year's level despite a 27% price reduction imposed by the government. In England, improvements were particularly achieved in access to the major hospitals.

The growth in Germany is a consequence of the European approval for photodynamic therapy (PDT) with daylight last year. Ameluz® is the clear leader in this market ahead of competing products. In the USA, growth is primarily the result of further expanded sales structures and improved reimbursement. Nevertheless, the pace of growth in our most important market slowed somewhat in the summer of this year. However, after the typical seasonality of the summer months in the U.S. market until October, we have again been able to record stronger growth here.

We expect further sustained acceleration of growth in the US once two of Ameluz's current competitive disadvantages over its competitor have been eliminated: On the one hand, our current approved label only allows the reimbursement of one tube per application. Biofrontera is working hard to improve reimbursement modalities and to extend the approval to the treatment of actinic keratoses in the extremities, trunk and neck. Biofrontera has already successfully conducted a Phase III study on the latter, the results of which have been submitted to the European Medicines Agency (EMA) for approval extension. We expect feedback from the US Food and Drug Administration (FDA) regarding approval in the US in January 2020. In order to ensure the reimbursement of several tubes for the treatment of larger peripheral body regions in the future, Biofrontera is planning a pharmacokinetics study in which the safety of treatment with three tubes will be tested. The preparatory work has been completed and the study protocol is currently being discussed with the FDA.

Biofrontera is addressing the second competitive disadvantage currently existing, our PDT lamp BF-RhodoLED®, which is small compared to the competitor's product, by developing the new lamp "BF-RhodoLED-XL®" to allow the use of Ameluz® on larger surfaces. We expect the market launch of this new medical product to further boost sales of Ameluz®.

To further increase our growth opportunities in the U.S. market in the medium term, we are currently conducting a clinical trial in the United States for the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our red-light lamp BF-RhodoLED®. Since September 2018, we have been working intensively on patient recruitment, which, however, takes a considerable amount of time due to the highly demanding study protocol prescribed by the FDA. Following successful FDA approval, Ameluz® would be the only drug in the United States for the treatment of superficial BCC with PDT.

As part of the successful integration of Cutanea Life Sciences, Inc. (Cutanea), Biofrontera has expanded its product portfolio in the USA to include the FDA-approved drug Xepi™. Xepi™ has been the first newly approved superficial antibiotic in approximately 10 years. The approval also includes the treatment of infections with antibiotic-resistant bacterial strains such as MRSA, where we see considerable market potential.

Biofrontera will be completing the full integration of Cutanea by the end of fiscal 2019, including the winding-up of Cutanea as an independent company. While the great market potential of Xepi™ will continue to be exploited and the marketing strategy further optimized, Ameluz® will remain our most important product in the near future.

Progress has also been made in our research collaboration with Maruho Co., Ltd (Maruho) to further develop branded generics based on our nanoe mulsion technology. We have started all necessary investigations and manufacturing steps for the entry into the clinical phase. We have also worked with Maruho to prepare the development plan to expand the indications of Ameluz® for acne and have requested a meeting with the FDA for its approval of the plan. The results of this meeting, which we expect to receive at the end of January, are expected to form the basis for the further contractual arrangement of our cooperation with Maruho.

Our business performance demonstrates that we remain on a stable growth course. Due to the unfavorable circumstances described above, sales in the third quarter in particular fell short of our expectations; even though the comparison with the previous year is only of limited benefit, as a price increase as of October 1, 2018 had promoted strong summer sales in 2018. We

therefore need to adjust our expectations for sales and earnings for the 2019 financial year. This adjustment is also due to the strong increase in legal costs as a result of the litigation with DUSA Pharmaceuticals, Inc., which were higher than expected. We now expect sales of between EUR 28 and 31 million instead of the previously planned EUR 32 to 35 million. We are revising our forecast for net loss in 2019 to EUR 4 to 6 million, compared with a net profit of EUR 4 to 7 million previously. This will be influenced in particular by adjustments to other income as part of the purchase price allocation following the Cutanea acquisition. This was still provisional at the time of the last quarterly report. Even though, contrary to our expectations, we might not be able to reach the operating break-even in the fourth quarter of 2019, Biofrontera continues to see the fourth quarter as the main revenue driver for its growing business in all markets. We believe that the company is ideally positioned to achieve the operational and clinical goals it has set itself and to continue its dynamic growth.

Finally, we would like to invite you, our shareholders, to the Extraordinary Shareholders Meeting to be held on Thursday, December 19, 2019, at 3 p.m. at the Best Western Leoso Hotel Leverkusen, Room "Lüttich / Ludwigshafen", Am Büchelster Hof 11, 51373 Leverkusen, Germany. At this point, we would like to clarify that Biofrontera complies with the request of Deutsche Balaton AG and Deutsche Balaton Biotech AG to convene the meeting solely in order to fulfill its obligations under stock corporation law. Biofrontera does not adopt the contents of the request for convening the meeting as its own and has commented on the agenda items requested by Deutsche Balaton AG and Deutsche Balaton Biotech AG in the invitation letter, which you can download [here](#). In addition, Biofrontera has put a compromise proposal for the establishment of authorized capital to the vote.

Key group IFRS figures

In EUR thousands (if not stated otherwise)	9M 2019 unaudited	9M 2018 unaudited	Q3 2019 unaudited	Q3 2018 unaudited
Results of operations				
Sales revenue	19,059	14,552	5,155	5,582
Gross profit	14,865	11,770	3,445	4,454
Research & development costs	(3,215)	(3,219)	(894)	(1,031)
General administrative costs	(12,108)	(7,283)	(4,340)	(3,204)
Sales costs	(20,635)	(12,658)	(6,440)	(4,348)
Loss on operations	(21,093)	(11,390)	(8,229)	(4,129)
Other expenses and income	20,828	549	(2,407)	(90)
Financial result	(2,259)	(1,411)	(914)	(349)
Loss before income tax	(2,524)	(12,252)	(11,550)	(4,568)
Total result for the period	(3,265)	(12,728)	(11,823)	(4,633)

In EUR thousands (if not stated otherwise)	9M 2019 unaudited	December 31, 2018
Net assets		
Total assets	72,416	39,133
Current assets	32,437	27,587
Non-current assets	39,979	11,546
Current liabilities	16,315	7,770
Non-current liabilities	41,850	15,007
Equity	14,251	16,356
Cash and cash equivalents	11,986	19,451

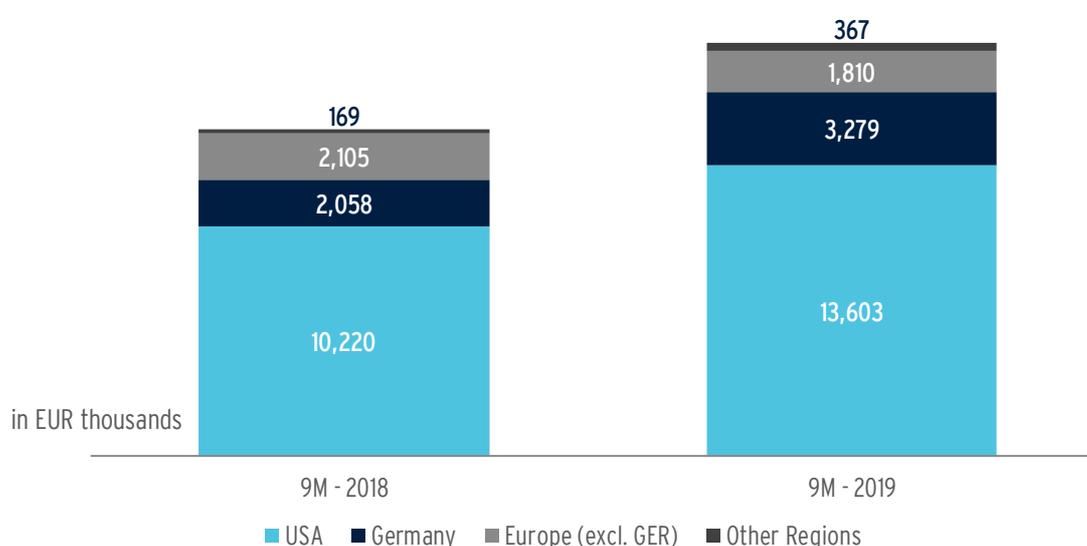
	9M 2019 unaudited	9M 2018 unaudited
Employees (as of September 30)	191	149
Biofrontera Share		
Number of shares outstanding (as of Sep, 30)	44,849,365	44,573,174
Share price (XETRA closing price in EUR on Sep, 30)	6,00	5,89

Biofrontera Group financial position and performance

Results of operations

Revenue

During the first nine months of 2019, the Biofrontera Group generated sales of EUR 19,059 thousand, an increase of 31% over the previous year period (previous year: EUR 14,552 thousand). Sales in the U.S. increased by 33% to EUR 13,603 thousand (previous year: EUR 10,220 thousand). This includes sales of EUR 677 thousand with the new products Xepi™ and Aktipak®. The growth is due to the further expansion of our sales structures and improvements in the reimbursement of PDT for dermatologists in the U.S. since the beginning of 2019. Sales in Germany increased by EUR 1,221 thousand or 59% to EUR 3,279 thousand compared to the same period of the previous year (previous year: EUR 2,058 thousand). In other European countries, sales decreased by 14% to EUR 1,810 thousand (previous year: EUR 2,105 thousand). The reason for the decline compared to the previous year was a decrease in deliveries to our license partners. The sales increase in Europe as a whole is due in particular to the introduction of daylight-PDT approved in March 2018. Sales from other regions amounted to EUR 367 thousand (previous year: EUR 169 thousand).



Gross profit

The gross profit on sales increased by EUR 3,095 thousand in the first nine months of 2019 to EUR 14,865 thousand compared to EUR 11,770 thousand in the same period last year. The gross margin decreased from 81% in the first nine months of 2018 to 78% in the first nine months of 2019.

Research and development costs

Research and development costs in the first nine months 2019 amounted to EUR 3,215 thousand. The costs were slightly below last year's cost of EUR 3,219 thousand and include costs for clinical studies as well as regulatory expenses, i.e. the granting, maintenance and expansion of our approvals.

General administrative costs

General administrative expenses amounted to EUR 12,108 thousand in the first nine months of 2019 (previous year: EUR 7,283 thousand), an increase of EUR 4,825 thousand. This was due to significantly higher legal and consulting costs as well as administrative costs in the U.S. In addition, administrative expenses of EUR 2,057 thousand for Cutanea were included in the first nine months of 2019.

Sales and marketing costs

Sales and marketing costs amounted to EUR 20,635 thousand in the first nine months of 2019, an increase of EUR 7,977 thousand compared to the previous year (EUR 12,658 thousand). This was due to two reasons: costs for the further expansion of our sales activities in the U.S. as well as sales costs incurred by Cutanea of EUR 4,620 thousand. Sales costs include the expenses for our own sales force in Germany, Spain, Great Britain and the U.S. as well as marketing expenses.

Loss on operations

The loss on operations amounted to EUR 21,093 thousand (previous year period: EUR 11,390 thousand) during the first nine months of 2019, an increase of EUR 9,703 thousand compared to the previous year. The increase is primarily due to the first-time consolidation of Cutanea. Cutanea's operating expenses of EUR 6,524 thousand were offset by the reimbursement of expenses, so far, in the amount of EUR 4,464 thousand paid by Maruho.

Other income and expenses

Other income and expenses totaled EUR 20,828 thousand in the reporting period. This includes the negative difference of EUR 14,813 thousand in asset and liability items measured at fair market value resulting from the purchase price allocation, including income of EUR 6,278 thousand from the offsetting of start-up costs to Maruho. This item also includes settlements to Maruho under the Share Purchase Agreement in the amount of EUR 4,464 thousand. The previously reported estimate income from the purchase price allocation as well as income from the offsetting of expenses incurred by Cutanea to Maruho were adjusted to EUR -3,595 thousand in the reporting period. There was no actual cash settlement to Maruho in the reporting period. Expenses and income from currency translation are also included in this item.

Interest expenses

Interest expenses amounted to EUR 2,644 thousand in the first nine months of 2019 and mainly comprise the interest expenses for the EIB loan made available in July 2017, which were increased by a further tranche in February 2019. In addition, higher amounts from the compounding of long-term liabilities are reported under interest expenses.

Group assets

The changes in the financial position are primarily due to the first-time consolidation of Cutanea Life Sciences, Inc. and its subsidiaries Dermarc LLC and Dermapex LLC, and are as follows as of September 30, 2019:

in EUR thousands	September 30, 2019	December 31, 2018
Non-current assets	39,979	11,546
Current financial assets	26,841	23,642
Other current assets	5,596	3,945
Total assets	72,416	39,133
Equity	14,251	16,356
Non-current liabilities	41,850	15,007
Current financial liabilities	4,294	2,000
Other current liabilities	12,021	5,770
Total equity and liabilities	72,416	39,133

Non-current assets

Non-current assets totaling EUR 39,979 thousand include deferred tax assets on tax losses carried forward at Biofrontera Pharma GmbH in the amount of EUR 10,400 thousand reported for the first time as of 31 December 2018 and, above all, the acquired Xepi™ license in the amount of EUR 23,254 thousand.

Current financial assets

Current financial assets totaled EUR 26,841 thousand as of September 30, 2019. This includes cash and cash equivalents of EUR 11,986 thousand (December 31, 2018: EUR 19,451 thousand), trade receivables of EUR 3,813 thousand (December 31, 2018: EUR 3,397 thousand) as well as receivables from Maruho from contractual obligations under the share purchase agreement of EUR 11,338 thousand.

Other current assets

Other current assets mainly include inventories amounting to EUR 4,335 thousand (December 31, 2018: EUR 3,177 thousand). This includes inventories at Cutanea amounting to EUR 458 thousand.

Equity

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 44,849 thousand as of September 30, 2019. It was divided into 44,849,365 registered shares with a nominal par value of EUR 1.00 each. Total equity as of September 30, 2019 amounted to EUR 14,251 thousand compared to EUR 16,356 thousand as of December 31, 2018.

Non-current liabilities

Non-current liabilities include financial liabilities (EUR 22,186 thousand; December 31, 2018: EUR 13,462 thousand), non-current provisions (EUR 1,029 thousand; December 31, 2018: EUR 1,545 thousand) and other non-current financial liabilities from the purchase price for Cutanea Life Sciences, Inc. (TEUR 18,635). The non-current financial liabilities include the loan from the EIB including the performance component in the amount of EUR 17,207 thousand (December 31, 2018: EUR 10,967 thousand), the non-converted portion of the convertible bond 2017-22 in the amount of EUR 1,970 thousand (December 31, 2018: EUR 2,495 thousand) and, for the first time, liabilities from leasing agreements in the amount of EUR 3,009 thousand to be recognized under IFRS 16.

Current financial liabilities

Current financial liabilities mainly include trade payables of EUR 3,198 thousand (December 31, 2018: EUR 1,806 thousand), including trade payables of Cutanea in the amount of EUR 941 thousand.

Other current liabilities

Other current liabilities amounted to EUR 12,021 thousand (December 31, 2018: EUR 5,770 thousand) and relate in particular to outstanding obligations of Cutanea totaling EUR 5,809 thousand.

Cash and cash equivalents

Compared to December 31, 2018, cash and cash equivalents decreased by EUR 7,465 thousand to EUR 11,986 thousand as of September 30, 2019. This includes cash on the balance sheet at Cutanea in the amount of EUR 2,091 thousand.

Outlook

Business in the first nine months of fiscal 2019 was below the Management Board's expectations despite the notable growth. Particularly during the summer months, the growth momentum in the U.S. had slowed down. Even though sales have picked up significantly since October, especially in the U.S., the previous sales forecast cannot be maintained. The Management Board now expects annual sales of between EUR 28 million and 31 million. The lower gross margin from the reduced sales, legal costs for the defense of DUSA Pharmaceuticals, Inc. lawsuits that continue to be well above expectations as well as some adjustments to other income from the previously only provisional values from the purchase price allocation of the Cutanea acquisition will lead to an overall reduction in net income before taxes. The Management Board now expects a net loss of EUR 4 to 6 million. Due to these effects, we will probably not reach the operating break-even point in the fourth quarter 2019.

Condensed consolidated balance sheet as of September 30, 2019

Assets

in EUR thousands	September 30, 2019 unaudited	December 31, 2018
Non-current assets		
Tangible assets	5,602	794
Intangible assets	23,977	352
Deferred taxes	10,400	10,400
Total non-current assets	39,979	11,546
Current assets		
Current financial assets		
Trade receivables	2,813	3,397
Other financial assets	12,042	794
Cash and cash equivalents	11,986	19,451
Total current financial assets	26,141	23,642
Other current assets		
Inventories	4,335	3,177
Income tax reimbursement claims	16	53
Other assets	1,245	715
Total other current assets	5,596	3,945
Total current assets	32,437	27,587
Total assets	72,416	39,133

Equity and liabilities

in EUR thousands	September 30, 2019 unaudited	December 31, 2018
Equity		
Subscribed capital	44,849	44,632
Capital reserve	118,020	117,109
Capital reserve from foreign currency conversion adjustments	(718)	(2)
Loss carried forward	(145,351)	(136,505)
Loss for the period	(2,549)	(8,878)
Total equity	14,251	16,356
Non-current liabilities		
Financial debt	22,186	13,462
Other provisions	1,029	0
Other financial liabilities	18,635	1,545
Total non-current liabilities	41,850	15,007
Current liabilities		
Current financial liabilities		
Trade payables	3,198	1,806
Current financial debt	144	165
Other financial liabilities	952	29
Total current financial liabilities	4,294	2,000
Other current liabilities		
Other provisions	3,736	2,891
Other current liabilities	8,285	2,879
Total other current liabilities	12,021	5,770
Total current liabilities	16,315	7,770
Total equity and liabilities	72,416	39,133

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

in EUR thousands	9M 2019 unaudited	9M 2018 unaudited	Q3 2019 unaudited	Q3 2018 unaudited
Sales revenue	19,059	14,552	5,155	5,582
Cost of sales	(4,193)	(2,782)	(1,710)	(1,128)
Gross profit from sales	14,865	11,770	3,445	4,454
Operating expenses				
Research and development costs	(3,215)	(3,219)	(894)	(1,031)
General administrative costs	(12,108)	(7,283)	(4,340)	(3,204)
Sales costs	(20,635)	(12,658)	(6,440)	(4,348)
Loss from operations	(21,093)	(11,390)	(8,229)	(4,129)
Interest expenses	(1,694)	(1,300)	(637)	(310)
Effective interest expenses	(950)	(122)	(453)	(45)
Interest income	385	11	176	6
Other expenses	(255)	(147)	(66)	(104)
Other income	6,269	696	169	14
Badwill	14,813	-	(2,510)	-
Profit/loss before income tax	(2,524)	(12,252)	(11,550)	(4,568)
Income tax	(25)	(4)	0	(4)
Profit/loss for the period	(2,549)	(12,256)	(11,550)	(4,572)
Expenses and income not included in profit/loss				
Items which may in future be regrouped into the profit and loss statement under certain conditions, Translation differences resulting from the conversion of foreign business operations,	(716)	(472)	(272)	(61)
Other expenses and income total	(716)	(472)	(272)	(61)
Profit/loss for the period	(3,265)	(12,728)	(11,822)	(4,633)
Basic earnings per share in EUR	(0.06)	(0.28)	-	-

Financial calendar

November 25, 2019	Analyst conference 2019, Deutsches Eigenkapitalforum, Frankfurt
December 19, 2019	Extraordinary shareholder meeting, Leverkusen

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