

Biofrontera AG

Quarterly announcement for the third quarter of 2023



Year-to-date Highlights 2023

- Profitability stabilized
- Relevant increase in the revenue streams mainly due to German and US market
- Patent application for new formulation of nanoemulsion without propylene glycol to extend patent protection
- US Food and Drug Administration (FDA) approval of an optimized formulation of Ameluz® for the treatment of actinic keratosis
- Positive results of the Phase 1 safety study investigating photodynamic therapy with three tubes of Ameluz®
- Excellent long-term results published on clinicaltrials.gov from Phase III clinical trial of Ameluz® PDT (CT007) in actinic keratosis
- Completion of patient enrolment in pivotal study of Ameluz®-PDT for the treatment of basal cell carcinoma
- Appointment of Dr. Heikki Lanckriet to the Board of Directors of Biofrontera Inc. in accordance with the terms of the settlement agreement between Biofrontera AG and Biofrontera Inc.
- Launch of belixos® ACTIVE CARE, an innovative cosmetic foam
- Out-of-court settlement with Biofrontera Inc. regarding the withdrawal of mutual lawsuits against shareholders' resolutions, the appointment of a new member of the Board of Directors of Biofrontera Inc. nominated by Biofrontera AG and mutual commitments not to significantly increase their respective shareholdings in the company and to refrain from further dilution measures
- Approval by the Annual General Meeting of all major management proposals
- Commencement of the Phase 3 clinical trial in the US for the treatment of actinic keratosis on the extremities, neck and trunk
- US patent granted for innovative photodynamic treatment protocol
- Revenues and EBITDA in line with the year guidance

Key figures in accordance with IFRS

	01.01.-30.9.2023		01.01.-30.9.2022		01.07.-30.9.2023		01.07.-30.9.2022	
	kEUR	% from sales	kEUR	% from sales	kEUR	% from sales	kEUR	% from sales
Results of operations								
Sales revenue	24,799	100.00%	21,908	100.00%	7,015	100.00%	6,832	100.00%
Gross profit on sales	19,991	80.61%	18,050	82.39%	5,771	82.27%	5,743	84.07%
Result from operations	4,129	16.65%	4,712	21.51%	942	13.43%	1,460	21.38%
EBITDA	4,851	19.56%	5,008	22.86%	1,108	15.79%	1,641	24.02%
EBIT	4,349	17.54%	4,437	20.25%	992	14.14%	1,447	21.18%
Profit/loss before income tax	(4,624)	(18.65)%	(40,673)	(185.66)%	(2,445)	(34.86)%	(4,612)	(67.51)%
Profit/loss for the period	(6,286)	(25.35)%	(41,847)	(191.02)%	(3,141)	(44.78)%	(5,103)	(74.69)%

in EUR thousands	September 30, 2023 unaudited	December 31, 2022
Key Balance Sheet Figures		
Total assets	24,019	32,725
Non-current assets	8,066	17,669
Cash and cash equivalents	2,105	6,376
Other current assets	13,848	8,680
Total Liabilities	24,019	32,725
Current liabilities	9,277	8,387
Non-current liabilities	854	4,002
Equity	13,888	20,336

	September 30, 2023	December 31, 2022
Total FTE	91.78	99.32
Biofrontera Shares		
Number of shares outstanding	63,807,058	63,807,058
Share price (Xetra closing price in EUR)	0.550	1.53

Business performance

Biofrontera AG can look back on a positive result for the first nine months of 2023 thanks to a significant upturn in business. The company was able to fully overcome its business performance, which had previously been impacted by the effects of the coronavirus pandemic and the price reduction of Spanish goods, over the course of this year. This enabled both our sales teams and our distribution partners to significantly increase their marketing activities, allowing us to further stabilize profitability despite increased expenses aimed at medium-term business development.

Biofrontera was once again the growth driver in the German PDT market in the first nine months of 2023 with an impressive 48% increase in sales, thus further expanding Ameluz®'s market leadership. Sales increased to EUR 4,568 thousand compared to the previous year's figure of EUR 3,082 thousand. Photodynamic therapy with daylight, or short daylight PDT, continued to establish itself on the market, allowing this reimbursable treatment option to be increasingly offered to the much larger group of people with statutory health insurance.

We recorded moderate growth in Spain and the UK in the reporting period. In Spain, sales remained at the previous year's level, while a slight increase in sales of 8% was recorded in the UK. Sales in the Spanish market amounted to EUR 1,224 thousand (9M 2022: EUR 1,228 thousand) and sales of EUR 601 thousand were generated in the UK, compared to EUR 559 thousand in the same period of the previous year.

Revenue generated by our European sales partners amounted to EUR 848 thousand in the reporting period, down 17% on the previous year's figure of EUR 1,017 thousand. Due to the structure of the license agreements and the agreed delivery of budgeted sales goods, sales often fluctuate during the year, which can deviate from actual market developments in the respective countries. Sales by our license partners in the market are currently on the rise.

In the USA, product sales of EUR 17,334 thousand (9M 2022: EUR 15,246 thousand) were generated with license partner Biofrontera Inc. in the reporting period, meaning that Biofrontera was also able to benefit from the significant increase in marketing activities and the new sales momentum in this key market.

As part of the license agreement concluded with Maruho Ltd., income of EUR 96 thousand was generated from services and the delivery of goods for clinical development in the reporting period (previous year: EUR 225 thousand). The decline is due to an one-off payment of EUR 200 thousand in 2022 in conjunction with a patent transfer.

Overall, the Biofrontera Group generated total sales of EUR 24.8 million in the period from January 1 to September 30, 2023 compared to EUR 21.9 million in 2022, an increase of around 13%. The USA remains our largest sales market, accounting for 70% of total sales, followed by Germany with a share of 18% and the rest of Europe with 11%.

Total sales of EUR 7,015 thousand were generated in the third quarter, around 2,7% more than in the third quarter of 2022 (EUR 6,832 thousand).

Gross profit amounted to EUR 19,991 thousand in the first nine months, compared to EUR 18,050 thousand in the same period of the previous year. The gross margin amounted to 81% (previous year: 82%).

The operating result decreased slightly and amounted to EUR 4,129 thousand compared to EUR 4,712 thousand in the first nine months of 2022. EBITDA amounted to EUR 4,851 thousand in the reporting period (previous year: EUR 5,008 thousand). EBIT amounted to EUR 4,349 thousand in the first nine months compared to EUR 4,437 thousand in the first three quarters of 2022.

Research and development costs amounted to EUR 6,241 thousand in the reporting period compared to EUR 4,944 thousand in the same period of the previous year, which corresponds to a percentage increase of 26%. As already reported in the first half of 2023, this significant increase in costs is due to the intensification of clinical activities in the first half of the year, aiming to increase our market penetration in US.

General and administrative expenses amounted to EUR 4,453 thousand in the first nine months of 2023, an increase of EUR 783 thousand compared to the previous year (EUR 3,670 thousand). The increased costs are primarily due to additional expenses in connection with consulting costs and legal costs.

Sales costs increased to a total of EUR 5,168 thousand in the first nine months of 2023, compared to EUR 4,724 thousand in the previous year. This increase was primarily caused by arrangements to intensify and expand our sales activities in Europe.

The Group's cash and cash equivalents amounted to EUR 2,105 thousand as of September 30, 2023 (December 31, 2022: EUR 6,376 thousand).

Biofrontera AG has made visible progress in clinical development. Following the completion of patient treatment in May 2023, Biofrontera received the positive results of the phase I study to investigate the safety and tolerability of photodynamic therapy (PDT) with 3 tubes of Ameluz® in August. The frequency of treatment-related adverse events (TEAEs) was in line with the information in the US technical information, which is essentially based on studies with a single tube of Ameluz®. The treatment thus proved to be well tolerated overall and the TEAEs were in line with the expected results associated with the therapeutic principles of photodynamic therapy. It is planned to submit these results to the U.S. Food and Drug Administration (FDA) in the fourth quarter of this year.

Furthermore, patient recruitment in the clinical phase III trial to extend the approval of Ameluz® to superficial basal cell carcinoma (BCC) in the USA has been completed. Basal cell carcinoma is a solid skin tumor and is the most common type of skin cancer. The study protocol specified by the FDA was extremely demanding and the recruitment of 186 patients was correspondingly lengthy. The results of the Phase III trial are expected by mid-2024.

These studies are an integral part of a clinical development program that lays the foundation for expanding the approval of Ameluz® in the USA. This should enable our licensing partner Biofrontera Inc. to gain broader access to the US market in the medium term, so that we can optimally exploit the growth potential of Ameluz® in this key market.

In addition, long-term data from the phase III trial of the field directed Ameluz® PDT (CT007) for the treatment of actinic keratosis was published on the online portal clinicaltrials.gov. In 90.9% of cases, initially healed lesions did not recur after 12 months. In addition, 77.8% of patients rated the cosmetic results as "very good" or "good".

In the reporting period, an optimized formulation of Ameluz® was also approved by the FDA for the treatment of actinic keratosis. By eliminating propylene glycol, this advanced Ameluz® formulation eliminates potential risks, particularly regarding the formation of impurities and allergic reactions. The application for an amendment to the European marketing authorization is in preparation. Biofrontera has already filed a patent application to protect this novel formulation. If this patent is granted, the protection of Ameluz® could be considerably extended, which would represent a significant milestone.

Biofrontera Group financial position and performance

Results of operations of the Biofrontera Group

The results of operations as of September 30, 2023 are as follows:

in EUR thousands	01.01 -30.09.2023	01.01 -30.09.2022	01.07 -30.09.2023	01.07 -30.09.2022
	unaudited	unaudited	unaudited	unaudited
Sales revenue	24,799	21,908	7,015	6,832
Gross profit on sales	19,991	18,050	5,771	5,743
Research and development costs	(6,241)	(4,944)	(2,315)	(1,809)
General administrative costs	(4,453)	(3,670)	(1,010)	(1,107)
Sales and marketing costs	(5,168)	(4,724)	(1,504)	(1,367)
Result from operations	4,129	4,712	942	1,460
Other expenses and income	220	(275)	50	(14)
EBITDA	4,851	5,008	1,108	1,641
EBIT	4,349	4,437	992	1,447
Financial result	(8,973)	(45,110)	(3,437)	(6,059)
Loss before income tax	(4,624)	(40,673)	(2,445)	(4,612)
Loss after income tax	(6,286)	(41,847)	(3,141)	(5,103)

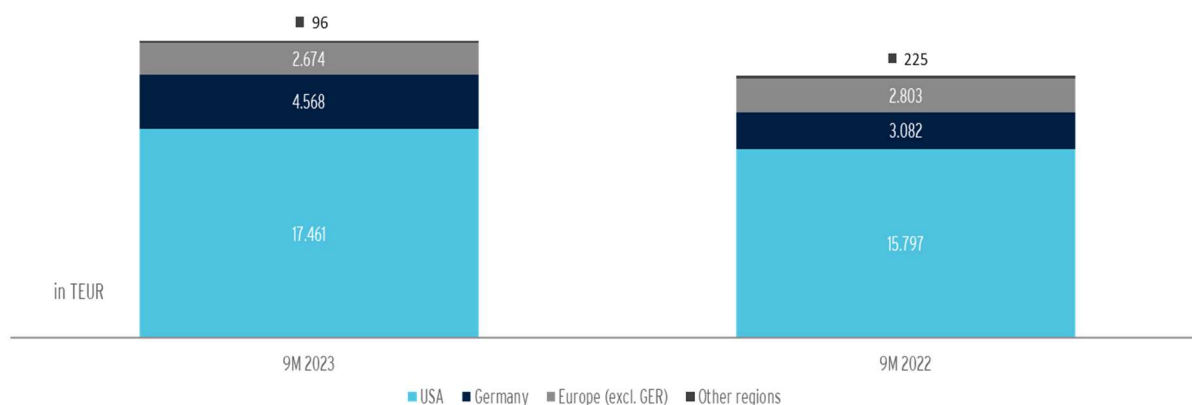
Sales revenue

In the reporting period, the Biofrontera Group generated total sales of EUR 24,799 TEUR an increase of EUR 2,891 thousand compared to the previous year (previous year: EUR 21,908 thousand).

In the reporting period from January 1 to September 30, 2023, product sales of EUR 17,334 thousand were generated in the United States, which corresponds to an increase of 13.7% compared to the same period of the previous year (EUR 15,246 thousand). Services amounting to EUR 127 thousand were also invoiced to Biofrontera Inc. (prior-year period: EUR 551 thousand).

Total sales in Europe increased by 23% year-on-year to EUR 7,242 thousand (previous year: EUR 5,886 thousand). Sales in Germany rose by 48% compared to the same period of the previous year to EUR 4,568 thousand (previous year: EUR 3,082 thousand). In the rest of Europe, total sales decreased by 5% to EUR 2,674 thousand (previous year: EUR 2,804 thousand).

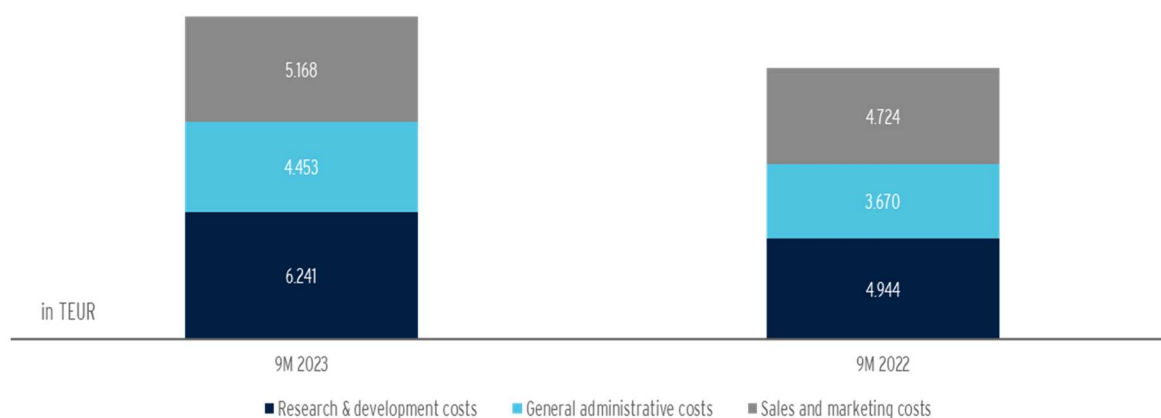
Revenues from other regions amounted to EUR 96 thousand in the fiscal year (previous year: EUR 225 thousand) and include both license income and revenues from the sale of study materials.



in EUR thousands	01.01.-30.9.2023			01.01.-30.9.2022		
	Product revenues	Service revenues	Licensing revenues	Product revenue	Development revenues	Licensing revenues
Germany	4,568	-	-	3,082	-	-
Europe	1,826	-	848	1,786	-	1,017
U.S.	-	127	17,334	-	551	15,246
Other regions	-	-	96	-	-	225
Total	6,394	127	18,278	4,868	551	16,488

Gross profit on sale

Gross profit increased by EUR 1,941 thousand in the reporting year 2023 to EUR 19,991 thousand compared to EUR 18,050 thousand in the prior-year period. The gross margin decreased from 82% in 2022 to 81% in fiscal year 2023 due to the mix of customers and products (lamps and Ameluz®).



Research and development costs

R&D cost had an increase of 26% to EUR 6,241 thousand in the reporting compared with the previous year's figure of EUR 4,944 thousand. In addition to costs for clinical trials, research and development costs also include regulatory expenses, i.e., for the granting, maintenance, and extension of our marketing authorizations.

General and administrative costs

General and administrative expenses in the first nine months of 2023 amounted to EUR 4,453 thousand (previous year: EUR 3,670 thousand) and thus increased by a total of EUR 783 thousand compared to the previous year. On the cost side, additional expenses were incurred for legal and consulting fees.

Sales and marketing costs

Sales and marketing expenses amounted to EUR 5,168 thousand in the first nine months of 2023 financial year, an increase of EUR 444 thousand compared with the previous year (EUR 4,724 thousand), mainly due to preparations to intensify and expand sales in Europe. Selling expenses include the costs for our own sales force in Germany, Spain, and the United Kingdom as well as marketing expenses.

EBITDA and EBIT

The Group's EBITDA includes earnings before interest, taxes, depreciation of property, plant and equipment and amortization of intangible assets decreased by EUR 157 thousand to EUR 4,851 thousand in the first nine months of 2023 financial year, compared with the prior-year period (EUR 5,008 thousand) as a result of the circumstances described above.

EBIT includes earnings before interest and taxes and decreased year-on-year to EUR 4,349 thousand (previous year: EUR 4,437 thousand).

Financial result

In addition to the interest result, the financial result totaling EUR -8,973 thousand (previous year: loss of EUR 45,110 thousand) includes expenses from the subsequent measurement of the carrying amount of the investment in Biofrontera Inc. amounting to EUR -8,982 thousand (previous year: profit of EUR -44,979 thousand).

Other income and expenses

Other expenses and income totaled a gain of EUR 220 thousand in the reporting period (previous year: EUR -275 thousand), this mainly reflects expenses and income from currency translation amounting and reversal of provisions.

Income taxes

Total amount of Income Taxes in the first nine months of 2023 was EUR 1,662 thousand (prior-year period: EUR 1,174 thousand). This item includes current income taxes of EUR 712 thousand (prior-year period: EUR 501 thousand) and deferred tax expenses of EUR 950 thousand (prior-year period: EUR 673 thousand) from the reduction of tax-deductible loss carryforwards at Biofrontera Pharma GmbH.

Net assets of the Biofrontera Group

The net assets position as of September 30, 2023 is as follows:

in EUR thousands	September 30, 2023	December 31, 2022
Non-current assets	8,066	17,669
Current financial assets	9,297	9,324
Other current assets	6,656	5,732
Total assets	24,019	32,725
Equity	13,888	20,336
Non-current liabilities	854	4,002
Current financial liabilities	5,575	5,109
Other current liabilities	3,702	3,277
Total equity and liabilities	24,019	32,725

Non-current assets

Non-current assets as of September 30, 2023 in the amount of EUR 8,066 thousand (previous year: EUR 17,669 thousand) include recognized deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of EUR 3,425 thousand (previous year: EUR 4,375 thousand), property, plant and equipment in the amount of EUR 3,370 thousand (previous year: EUR 3,012 thousand), intangible assets EUR 1,197 thousand (previous year: EUR 1,198 thousand), and other non-current assets in the amount of EUR 74 thousand (previous year: EUR 101 thousand). Also included here is the investment in Biofrontera Inc. valued at equity in the amount of EUR 0 thousand (previous year: EUR 8,982 thousand).

Current financial assets

Current financial assets totaled EUR 9,297 thousand as of September 30, 2023 (previous year: EUR 9,324 thousand). This includes cash and cash equivalents of EUR 2,105 thousand (previous year: EUR 6,376 thousand), trade receivables of EUR 866 thousand (previous year: EUR 691 thousand), receivables from associated companies of EUR 4,949 thousand (previous year: EUR 1,344 thousand), and other current financial assets of EUR 1,342 thousand (previous year: EUR 878 thousand).

Other current assets

Other current assets mainly contain inventories. As of September 30, 2023, this increased slightly to EUR 5,728 thousand (previous year: EUR 4,794 thousand). In the reporting year, no impairment losses were recognized on inventories (previous year: EUR 42 thousand).

Other current assets include also short-time receivables in amount of EUR 113 thousand (previous year: EUR 146 thousand), as well as Prepaid expenses and deferred charges in total amount of EUR 813 thousand (previous year: EUR 791 thousand).

Equity

In accordance with IFRS, the Group reported equity of EUR 13,888 thousand (previous year: EUR 20,336 thousand). The equity ratio decreased from 62% to 58%.

Non-current liabilities

Non-current liabilities include financial liabilities (EUR 763 thousand; previous year: EUR 1,055 thousand), the obligations under the SAR program in the amount of EUR 91 thousand (previous year: EUR 304 thousand).

Non-current financial liabilities include liabilities from leases to be reported in accordance with IFRS 16 in the amount of EUR 763 thousand (previous year: EUR 1,055 thousand).

Current financial liabilities

Current financial liabilities include in particular trade accounts payable of EUR 2,418 thousand (previous year: EUR 1,984 thousand) and liabilities to associated companies of EUR 2,648 thousand (previous year: EUR 2,653 thousand) as well as current financial liabilities of EUR 466 thousand (previous year: EUR 446 thousand).

Current financial debt includes current liabilities from leases in accordance with IFRS 16 in the amount of EUR 427 thousand (previous year: EUR 446 thousand)

Other current liabilities

Other current liabilities amounted to EUR 3,702 thousand (previous year: EUR 3,277 thousand) and include in particular provisions of EUR 693 thousand (previous year: EUR 603 thousand) and other accruals of EUR 2,142 thousand (previous year: EUR 2,518 thousand).

Financial position of the Biofrontera Group

Cash and cash equivalents

Cash and cash equivalents in the Group amount to EUR 2,105 thousand as of September 30, 2023 (previous year: EUR 6,376 thousand).

Further information on the liquidity of the Biofrontera Group and Biofrontera AG can be found in the section "Outlook".

Outlook

Business development in the first nine months of 2023 is in line with the expectations of the Executive Board. It is therefore fully upholding its forecast for the 2023 financial year published on April 27, 2023. Among other things, the Executive Board expects annual sales of EUR 27 to 33 million, positive EBITDA of EUR 3 to 5 million and positive EBIT of EUR 2 to 4 million. Details on the forecast can be found in the 2022 Annual Report, which is published on the Biofrontera AG website at <https://www.biofrontera.com/en/investors/financial-reports>.

The further business development and liquidity of the Group and Biofrontera AG are largely dependent on the development of the US business with Biofrontera Inc. The current planning is based on the assumption that the business development of Biofrontera Inc. in the next 12 months will at least correspond to that of 2022 and that Biofrontera Inc. will fulfill its purchase obligations agreed for 2023.

Consolidated interim financial statements as of September 30, 2023

Consolidated interim balance sheet as of September 30, 2023

Assets

in EUR thousands	September 30, 2023 unaudited	December 31, 2022
Non-current assets		
Tangible assets	3,370	3,012
Intangible assets	1,197	1,198
Deferred tax	3,425	4,375
Investments accounted for using the equity method	0	8,982
Non-current contractual assets	74	101
Total non-current assets	8,066	17,669
Current assets		
Financial assets		
Trade receivables	866	691
Receivables from associated companies	4,949	1,344
Other financial assets	1,342	878
Cash and cash equivalents	2,105	6,376
Current contractual assets	36	35
Total financial assets	9,297	9,324
Other assets		
Inventories	5,728	4,794
Other assets	928	938
Total other assets	6,656	5,732
Total current assets	15,953	15,056
Total assets	24,019	32,725

Equity and liabilities

in EUR thousands	September 30, 2023 unaudited	December 31, 2022
Equity		
Subscribed capital	63,807	63,807
Capital reserve	137,157	137,318
Capital reserve from foreign currency conversion adjustments	(2)	0
Loss carried forward	(180,789)	(136,623)
Loss for the period	(6,286)	(44,166)
Total equity	13,888	20,336
Non-current liabilities		
Financial debt	763	1,055
Liabilities to associated companies	0	2,642
	91	
Total non-current liabilities	854	4,002
Current liabilities		
Financial liabilities		
Trade payables	2,418	1,984
Liabilities to associated companies	2,648	2,653
Current financial debt	466	446
Other financial liabilities	43	26
Total financial liabilities	5,575	5,109
Other liabilities		
Income Tax	867	156
Other provisions	693	603
Other liabilities	2,142	2,518
Total other liabilities	3,702	3,277
Total current liabilities	9,277	8,387
Total equity and liabilities	24,019	32,725

Consolidated interim statement of comprehensive income for the first nine months of the fiscal year 2023 and 2022

in EUR thousands	01.01.-30.9.2023	01.01.-30.9.2022	01.07. -30.09.2023	01.07. -30.09.2022
	unaudited	unaudited	unaudited	unaudited
Sales revenue	24,799	21,908	7,015	6,832
Cost of sales	(4,807)	(3,858)	(1,244)	(1,089)
Gross profit from sales	19,991	18,050	5,771	5,743
Operating expenses				
Research and development costs	(6,241)	(4,944)	(2,315)	(1,809)
General administrative costs	(4,453)	(3,670)	(1,010)	(1,107)
Sales costs	(5,168)	(4,724)	(1,504)	(1,367)
Result from operations	4,129	4,712	942	1,460
Depreciation and amortization	502	571	116	194
Other Expenses	(157)	(585)	(77)	(70)
Other Income	376	310	127	57
EBITDA	4,851	5,008	1,108	1,641
Depreciation and amortization	(502)	(571)	(116)	(194)
EBIT	4,349	4,437	992	1,447
Interest expenses	(12)	(132)	(4)	(21)
Interest Income	21	0	20	0
Income from investments accounted for using the equity method	(8,982)	(44,979)	(3,453)	(6,038)
Profit/loss before income tax	(4,624)	(40,673)	(2,445)	(4,612)
Income tax	(1,662)	(1,174)	(696)	(491)
Profit/loss for the period	(6,286)	(41,847)	(3,141)	(5,103)
Profit attributable to owners of the parent company	(6,286)	(41,847)	(3,141)	(5,103)
Other comprehensive income after income taxes				
Items which may in future be regrouped into the profit and loss statement under certain conditions.				
Total profit/loss for the period	(6,288)	(41,847)	(3,141)	(5,103)
Basic earnings per share in EUR	(0.10)	(0.74)	(0.05)	(0.09)
Diluted earnings per share in EUR	(0.10)	(0.66)	(0.05)	(0.08)