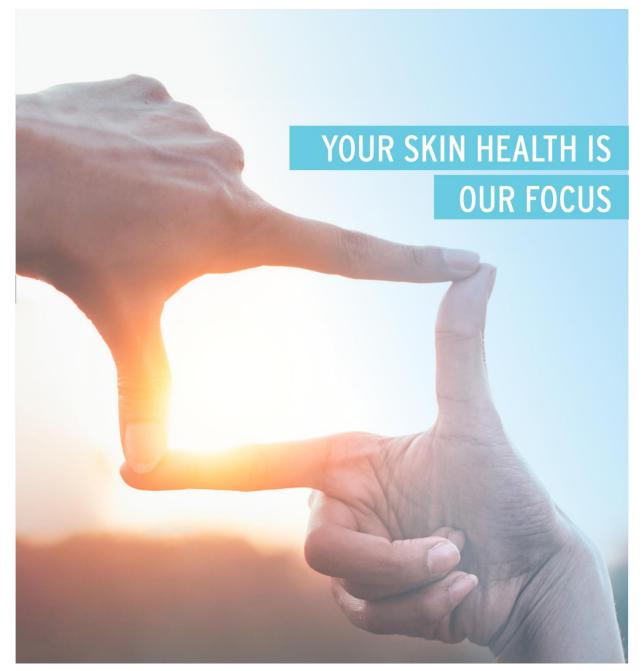


Biofrontera AG 6M Half-Year Report 2023



The skin is our largest organ and it is constantly exposed to massively changing environmental influences. We at Biofrontera would like to make our contribution to your healthy skin. With consistency, Biofrontera has become an expert and innovation driver in the field of photodynamic skin therapy.

Innovation requires vision and the courage to turn ideas into groundbreaking products. This is what the Biofrontera team is totally committed to,because your skin health is our focus.

Highlights 2023

- Biofrontera receives notice of allowance for US patent on innovative photodynamic treatment.
- Start of phase 3 clinical trial in the USA for the treatment of actinic keratosis on extremities, neck and trunk
- Biofrontera completes patient recruitment of the phase 1 trial to investigate the safety and tolerability of the Ameluz® PDT with 3 tubes of Ameluz®
- Confirmation of Prof. Dr. Lergenmüller as a member of the Supervisory Board
- Approval by the Annual General Meeting of all significant resolutions proposed by the Management and Supervisory Board
- Out-of-court settlement with Biofrontera Inc. to withdraw the mutual lawsuits against resolutions of the Annual General Meeting, the appointment of a new member nominated by Biofrontera AG for the Board of Directors of Biofrontera Inc. and the mutual commitment not to significantly increase the shareholding in the respective company and not to implement any additional dilution measures.

Key figures in accordance with IFRS

		01.0130.6.2023 unaudited		.2022 ed
	in EUR tousands	% of revenue	in EUR tousands	% of revenue
Results of operations				
Sales revenue	17,784	100.00%	15,076	100.00%
Gross profit on sales	14,220	79.96%	12,307	81.63%
Result on operations	3,187	17.92%	3,252	21.57%
EBITDA	3,743	21.05%	3,367	22.34%
EBIT	3,357	18.88%	2,990	19.83%
Profit/loss before income tax	(2,179)	(12.25)%	(36,061)	(239.20)%
Profit/loss for the period	(3,145)	(17.68)%	(36,745)	(243.73)%

in EUR thousands	June 30, 2023 unaudited	December 31, 2022		
Balance sheet key figures				
Balance sheet total	27,571	32,725		
Non-current assets	11,638	17,669		
Cash and cash equivalents	4,279	6,376		
Other current assets	8,268	7,301		
Current liabilities	9,559	8,387		
Non-current liabilities	947	4,002		
Equity	17,064	20,336		

	June 30, 2023	December 31, 2022
	unaudited	
Total FTE	94,68	99,32
	0	0
Biofrontera Shares	0	0
Number of shares outstanding	63,807,058	63,807,058
Share price (Xetra closing price in EUR)	0.866	1.53

Interim group management report for the first half of the 2023

Basis of the Biofrontera Group

Group structure

As of 30.June 2023, the Biofrontera Group (hereinafter also called "Biofrontera", "Biofrontera Group", "Group" or the "Company") consists of a parent company, Biofrontera AG and 4 (December 31, 2020: 5 (including Biofrontera Inc., USA)) wholly owned subsidiaries in Germany. The parent company's head office is located in Leverkusen, Germany.

Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH and Biofrontera Neuroscience GmbH are located at the parent company's headquarters in Leverkusen, Germany.

For sales support in Spain and the United Kingdom, two additional entities were founded, firstly Biofrontera Pharma GmbH, sucursal en España in Barcelona (03/2015) and Biofrontera UK Ltd. in Cambridge (11/2022). Biofrontera UK Ltd. is a wholly owned subsidiary of Biofrontera Pharma GmbH.

Business model

The publicly listed entity Biofrontera AG assumes the holding function within the group of companies. It is responsible for the management, strategic planning, internal control and risk management and ensures the necessary financing needs are met. Biofrontera Bioscience GmbH carries out research and development tasks as well as all regulatory functions for the Biofrontera Group and holds the patents and approvals for Ameluz® as well as BF-RhodoLED® and RhodoLED® XL. According to a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also the holder of the CE certificate of BF-RhodoLED®, bears the responsibility for the production, further licensing and marketing of Biofrontera Group's approved products.

The Biofrontera Group has its own sales organizations to distribute Ameluz® and the BF-RhodoLED® lamp in Germany, Spain and the United Kingdom. In some other European countries, sales are handled by independent license partners. Following the separation, Biofrontera Inc. is now the licensee responsible for marketing Ameluz® and the RhodoLED® lamp series in the USA.

Asian and Oceanic markets were licensed to Maruho Co, Ltd, Osaka, Japan under the exclusive license agreement signed in April 2020. Currently, Maruho is conducting the necessary clinical studies to obtain regulatory approval in Japan.

Production of Ameluz® for all markets is carried out by a contract manufacturer in Switzerland. The PDT-lamp series is manufactured at Biofrontera's headquarters in Leverkusen, Germany.

Ameluz® and the RhodoLED® lamp series are supplied to all the licensing partners under a license and supply agreement with Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH, both wholly owned subsidiaries of Biofrontera AG.

Biofrontera AG generates sales on the one hand through its own distribution in Germany, Spain and the United Kingdom. Biofrontera receives 100% of this revenue on the other hand through a licensing partner network.

A fixed transfer price is charged to the license partner in the USA. This is staggered and amounts to 50% of sales for sales of up to USD 30 million. At the beginning of the respective fiscal year, a budgeting of the delivery quantities takes place with subsequent direct payment of the delivered batches. At the end of the year, the deliveries already paid for are offset against product sales on the US market within one year. The offsetting price is currently 50% of the gross price per tube of Ameluz® achieved by Biofrontera Inc. on the market, with a minimum of USD 110 per tube.

The European license partners also charge their license fees via a fixed transfer price. The transfer price varies, but currently averages 50% of annual net sales. Here, too, the delivery quantities are budgeted in advance, which means that there may be jumps in sales during the year.

The license partner for Asia and Oceania initially made a one-time payment of EUR 6 million upon acquisition. Until the product is ready for the market, Biofrontera charges service fees for its involvement in the clinical trials and the regulatory approval process.

Due to these very different sources of income, Biofrontera may experience strong quarterly fluctuations during the year, which do not correlate with the actual revenue generated in the market.

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH were founded in December 2012 and are wholly owned subsidiaries of Biofrontera AG. These two companies are focusing on the development of pipeline products that are not part of Biofrontera's core business at this point in time. The product BF-derm1 (without patent protection since 2009) for the treatment of severe chronic urticaria is owned by Biofrontera Development GmbH, the product BF-1 (patent protection until 2034) for the prophylactic treatment of migraine by Biofrontera Neuroscience GmbH. Both products are currently not being pursued any further, as the corporate strategy focuses on the further development and marketing of Ameluz®. By outsourcing the development projects, a structure has been created which allows to separate the financing of the development of these two products from the general financing of the Biofrontera Group.

Group strategy

The strategic goal of the Biofrontera Group is to optimize the positioning and market potential of Ameluz®, and in doing so to develop the Company into a leading innovative specialty pharma company in dermatology. The focus of activities is on the further territorial expansion of sales and the development of additional market potential through the expansion of the indications for Ameluz®.

Biofrontera has received a centralized approval for its own self-developed drug, which is marketed under the brand name Ameluz®. Since the market launch in February 2012, Biofrontera has been selling Ameluz® with its own sales force to dermatologists in Germany and since March 2015 also in Spain. In the UK, Ameluz® was initially promoted through a distribution partner, and since May 2018 has been actively promoted by Biofrontera's own sales force. Distribution in several other countries of the European Union and Switzerland is carried out through licensing partnerships.

The US-subsidiary, Biofrontera Inc., was set up as the commercial arm of Biofrontera in the USA and became independent with its IPO at the end of October 2021. A license and supply agreement with Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH, both wholly owned subsidiaries of Biofrontera AG, and Biofrontera Inc. defines the responsibilities between the companies. The agreement was entered into for a period of 15 years and will be extended for another 5 years provided that a sales volume in the USA of more than USD 150 million has been achieved in the preceding 5 years. Under this agreement, Biofrontera Inc. acquires Ameluz® and the PDT lamps BF-RhodoLED® and RhodoLED® XL from Biofrontera AG. Up to annual Ameluz® sales of USD 30 million, Biofrontera Inc. will pay 50% of sales as a transfer price. This share decreases in two steps to 30% with sales of more than USD 50 million, thus taking into account the associated higher distribution costs of Biofrontera Inc. Biofrontera AG has committed to maintaining the FDA approval, manufacturing the products, providing a pharmacovigilance database and conducting previously defined clinical trials.

Products

Ameluz® and PDT-lamps BF-RhodoLED® and RhodoLED® XL

In December 2011, Ameluz® 78 mg/g gel (Spanish for "love the light", development name BF-200 ALA) received its first centralized European approval for the treatment of mild and moderate actinic keratoses (AK) on the face and scalp in combination with Photodynamc Therapy (PDT). Actinic keratoses are precancerous lesions located in the epidermis with a risk of spreading to deeper skin layers and developing into potentially fatal invasive squamous cell carcinoma. Photodynamic therapy, which involves application of a PDT-drug, such as Ameluz®, followed by illumination with an appropriate light source, is an innovative form of treatment). The product information authorized by the European Medicines Agency (EMA) expressly states the significant superiority of Ameluz® compared to the direct competitor product, Metvix®, in the clearance of actinic keratosis in combination with red-light PDT lamps.

Ameluz® has a number of product advantages in terms of efficacy, handling, stability and user-friendliness. This, together with the associated skin rejuvenation effect and comparatively low recurrence rates, leads to the expectation that this treatment option will become even more of a focus for dermatologists in the coming years.

In 2017, Biofrontera submitted an extension to the Marketing Authorisation for daylight-PDT with Ameluz® and was granted approval by the European Commission in March 2018. The label extension now includes the treatment of actinic keratoses and field cancerization with daylight-PDT. Daylight-PDT is a cost-effective and painless alternative to traditional PDT treatment with a redlight PDT lamp. The topically applied drug is activated by natural daylight. As daylight-PDT does not require the treatment to be carried out in a doctor's office, it competes directly with self-applied topical drugs, which are used much more widely in Europe. Ameluz® is reimbursed by the statutory health insurers in Germany for use with daylight-PDT and in all its applications in the majority of other markets where it is commercially available. Since March 2020 Ameluz®-PDT also covers the treatment of mild and moderate actinic keratoses not only on the head, but also on the extremities and trunk/neck in Europe.

In May 2016, Biofrontera received the marketing approval for Ameluz® in the USA. The approved indication is "lesion and field directed PDT in combination with the BF-RhodoLED® lamp of mild and moderate actinic keratoses on the face and scalp". As the approval in the USA includes a combination of drug and lamp according to FDA guidelines, Biofrontera has developed its own PDT lamp, the BF-RhodoLED®. To meet the strict requirements of the FDA to produce a Class III medical device, production of the lamp is carried out at the company's headquarters in Leverkusen. This makes Biofrontera AG the responsible manufacturer from the perspective of the regulatory authorities. In the EU, this lamp was CE-certified in 2012, which also required ISO 13485 certifications. The ISO 13485 certification has been since then renewed at regular intervals. In October 2021, the FDA approved the new, more advanced RhodoLED XL. This approval was also granted as a combination approval of lamp and the prescription drug Ameluz®. With the new RhodoLED® XL, larger areas can be illuminated, enabling simultaneous treatment of multiple interspersed lesions. The new lamp is protected by several patents, which also helps to protect the drug Ameluz® in the U.S. market due to the combination approval.

Both RhodoLED® lamps emit light with a wavelength of approx. 635 nm via their LEDs. Light at this wavelength, which is optimal for illumination in PDT with ALA or methyl ALA containing drugs, emits red light, but is still below the warming infrared range. The RhodoLED® lamp series combines controlled and constant light output in the desired wavelength with simple and clear operability and energy efficiency. Light energy and fan power can be changed during PDT treatment to respond to treatment-related pain. No other lamp on the market offers comparable performance and flexibility. The BF-RhodoLED® can be distributed throughout the EU as well as the USA. The use of the RhodoLED® XL is currently only planned for the US market.

Belixos®

Belixos® is a medical skin care series developed for irritated and sensitive skin. It was initially designed as a cosmetic series in which various products precisely addressed different skin problems. Pure plant biocolloids were combined with medicinal plant extracts to form an extraordinary combination of active ingredients with a proven deep-acting effect. Also marketed under this brand was Belixos® Protect, a day cream with protective anti-aging properties specifically for photodamaged skin.

Since mid-2022, the Belixos® range has been undergoing a transformation. With a new type of foam formulation that delivers more deeply the ingredients to the skin, Belixos® has been adapted even more to the needs of damaged skin. This product is so innovative that a patent application has been filed for the underlying formulation. The product was initially launched only in the German market. Further expansions in other markets are planned for the coming years.

Sales and marketing

Germany and Europe

With its Central European approval, Ameluz® can be sold and distributed in all EU countries as well as Norway, Iceland, Liechtenstein and UK. However, in many European countries, pricing and reimbursement status must be determined prior to launch, which can be a lengthy process. Reference pricing and re-importation can lead to low prices in individual EU countries, which in turn can have a negative impact on the overall EU market. For this reason, the drug is currently only available in certain EU countries. However, due to changing framework conditions, it is always necessary to monitor whether a territorial expansion might make sense. Ameluz® is available at pharmacy retail prices ranging from EUR 150 to approximately EUR 220 per 2 gr. tube.

In Europe, Ameluz® and BF-RhodoLED® are marketed in Germany (since 2012), Spain (since 2015) and Great Britain (since May 2018) by our own sales forces whereby Germany is by far the largest European market for Ameluz®. In other EU countries and in Switzerland, the products are distributed with the help of distribution partners. In Switzerland, independent approval procedures were required, which were carried out by our local marketing partner in collaboration with Biofrontera. The contracts with distribution partners were concluded in such a way that Biofrontera received no or only a moderate upfront payment and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their own sales price. Depending on the market conditions in each country, Biofrontera's share of the sales price varies somewhat, but averages 50% of net sales.

In December 2020, the Group covered sales in Scandinavia through an exclusive licensing partnership with Galenica AB, Malmö, Sweden. Sales of the products in the Scandinavian region started with the delivery of the first batch of Ameluz® in June 2021, following initial product launches in Norway, Sweden and Denmark. Since November 2022 Ameluz® is also marketed in Finland.

In July 2021, a license agreement was signed with Medac Gesellschaft für klinische Spezialpräparate mbH for the commercialization of Ameluz® and BF-RhodoLED® in Poland. Medac started marketing Ameluz® and BF-RhodoLED® to selected customers in the fall of 2022. To date, activities have been limited to the private healthcare sector, as Ameluz® PDT is currently not reimbursed by public payers. Medac expects that the reimbursement of Ameluz® will be possible by the end of the year 2023.

In general, Biofrontera was able to significantly increase its presence in the European market through its own sales structures and the territorial expansion through additional licensing partners.

USA

Ameluz® was commercially launched by Biofrontera in the USA in October 2016. For marketing purposes, Biofrontera AG established its own sales organization in the USA for this purpose in March 2015, the Biofrontera Inc. based in Woburn. With the IPO of Biofrontera Inc. in 2021, it became a licensing holder. Since its launch, Ameluz®-PDT has gradually established itself in the US PDT market segment, and the increased sales efforts by Biofrontera Inc. and its sales expansion efforts promise further significant market growth. The clinical program defined in the licensing agreement also holds further market potential in the longer term through several label extensions.

Other regions

In April 2020, an exclusive license and supply agreement was entered into with Maruho Co., Ltd., Osaka, Japan (Maruho) for the development and marketing of Ameluz® for all indications in East Asia and Oceania. Under the agreement, the product will be marketed for a period of 15 years from the start of sales in the countries covered by the contract. A first batch of investigational medication was delivered to Maruho at the end of 2022. The clinical development program on which approval will be granted will initially focus on actinic keratosis as an indication.

Market overview

Actinic keratosis

Non-melanoma skin cancer and its precursor actinic keratosis (AK) is the main market for the flagship prescription drug Ameluz®. Actinic keratoses are superficial potentially pre-cancerous skin lesions caused by chronic sun exposure that may, if left untreated, develop into a form of potentially life-threatening skin cancer called squamous cell carcinoma. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots.

These skin lesions occur not only isolated, but in many cases also over a large area. Such an area of the skin is called field cancerization. In this case, visible and not yet visible skin damage can be in direct proximity to each other on the affected skin areas. In about one in ten patients with AK, a malignant form of non-melanoma skin cancer (squamous cell carcinoma) can develop from a skin lesion or in its vicinity. Even AK that are not yet visible already carry a high risk of transitioning into squamous cell carcinoma.

Lifetime dose of UV radiation plays an important role in the development of AK. UV radiation over many years damages the skin cells, which then mutate and proliferate, which can lead to abnormal keratinization (hyperkeratosis). This is why AK occurs most frequently in older people: in Germany, for example, more than 11 out of every 100 people between the ages of 60 and 70 are affected. Men are more frequently affected than women, as, among other things, it is not uncommon for men to work outdoors and thus be exposed to the sun, usually without protection. Particularly at risk are, for example, farmers and forestry workers, roofers, carpenters, gardeners and lifeguards. In addition to age and gender, other factors can promote the development of AK. These include a fair skin type, severe sunburns, or treatment with medications that weaken the immune system.

Therapy options for the treatment of actinic keratosis

Because actinic keratosis can develop into squamous cell carcinomas, actinic keratosis is classified by The European Academy of Dermatology and Venereology and other international treatment guidelines as a tumor that requires treatment. In order to minimize the risk of developing cancer, AK must be detected and treated early.

Actinic keratoses are treated using a wide range of methods. The traditional methods of treating actinic keratoses are cryotherapy (or the deep freezing of skin with liquid nitrogen); curettage; self-administered prescription topical medications (usually creams, gels, or solutions containing active ingredients that must be applied to the damaged areas of the skin, usually regularly over an

extended period of time); and combining a drug with photodynamic therapy (PDT). When deciding on the treatment option, the physician considers the disease progression to date, the extent of the existing skin damage, and the patient's condition (age, possible co-existing diseases, medications to be taken).

The international treatment guidelines list photodynamic therapy as the "gold standard" for the treatment of actinic keratoses, especially for patients with large areas of actinic keratoses. In this process, a gel containing the active ingredient, such as Biofrontera's Ameluz®, is first applied to the affected areas of skin. The active ingredient is preferentially absorbed by cells with high metabolic activity, such as cancer cells and their precursors, and converted into its light-activatable form. As a result, they become more light-sensitive and are destroyed within a few hours by targeted illumination, while healthy skin cells remain unharmed. The dead cells are broken down and the skin renews itself. Usually, no scarring develops, and the appearance of the skin visibly improves over the next weeks and months. There are two forms of PDT: one using an artificial light source (conventional PDT) and one using natural/simulated daylight (daylight PDT). Compared to conventional PDT with red light or another suitable light source, the treatment time for daylight PDT is shorter at about two and a half hours and the treatment is associated with less pain.

Market overview and competitive landscape in Germany

In Germany, about 1.7 million people are treated by dermatologists for AK, which corresponds to about 2 to 3% of the total population. In 2022, a total of 965,848 prescriptions were issued for the treatment of AK (previous year: 851,143). The most prevalent of these are surface-applied medications such as prescription drug-containing creams and gels (topicals), which account for a market share of 93.9%, followed by PDT (the combination of a surface-applied medication with light therapy) at 6.1% (previous year: 93.3% and 6.7%, respectively). The overall 2022 market increased by 13% mainly due to the market entry of another topical preparation.

Although information on the frequency of application of cryotherapy or simple curettage treatments for actinic keratosis is not available in Europe, we assume that a large number of patients are treated in this way due to the ease of application and low price of these therapies.

In Germany, as the largest European market for Ameluz®, the market share in the PDT drugs segment was stable at around 64% in the first half of 2023. Above all, the establishment of daylight PDT enabled Ameluz® to continue to prove itself as the market leader in the PDT market compared to competitor products. The ability of daylight PDT to be reimbursed by statutory health insurers creates the basis for multiplying the number of patients who would in principle have access to treatment with Ameluz®. This opens up the possibility of being able to penetrate more strongly into the sector of topicals that currently dominate the market, and to achieve a significantly more significant higher market share in the future. In the period under review, a strong sales growth of 45% was achieved compared with the same period of the previous year. The problem of reimported goods from Spain, which had significantly weakened sales in the previous year's half-year, was overcome by the end of 2022, with the result that German sales increased significantly in the reporting period.

Market overview and competitive situation in the additional, proprietary markets of Spain and the United Kingdom (UK)

Spanish sales in the reporting period remained virtually at the same level as in the previous year, although in the last half of 2022 sales were significantly impacted by the price reduction ordered by the Ministry of Health. This had led to increased sales of Spanish products into the German market. Tube sales declined in the first half of 2023, largely as a result of the price increase perceived by physicians and the aforementioned lack of exports to higher-priced markets. The market share in the PDT market compared with the main competitor Metvix was 48.5%.

In the UK market, Ameluz® showed growth of 8%, with sales generally still at a low level.

Market overview and competitive situation in the USA

The USA is the most important pharmaceutical market in the world. According to the Skin Cancer Foundation, approximately 58 million people in the USA have actinic keratosis. In 2022, the market size was USD 2.3 billion for this indication, according to the Grand View Research Report (01/2023). The US market differs from the European market in that cryotherapy dominates the market here with a market share of just over 75%. PDT has only a very small share of the market. Segment expansion is forecasted for the coming years, based not only on general market growth but also on market share gains within the PDT market and from taking away market share of cryotherapy in patients with more than 14 AK lesions.

The PDT segment currently has a share of only around 2%, with Ameluz® PDT expanding its market share within this segment by 12% in the year under review.

It is therefore important to increase the acceptance of PDT, which with its clear advantages, especially in scar-free healing and in the treatment of field cancers, would be preferable to surgical intervention. To this end, our U.S. licensing partner has further expanded its U.S. sales force and significantly increased its marketing expenditure. U.S. sales increased by 19% to EUR 12.6 million compared to the first half of 2022 and, at over 70%, represent the significant share of total sales of EUR 17.8 million.

Personnel matters

Employees

As of 30. June 2023 the Biofrontera Group had 104 employees (December 31, 2022: 110) representing 95 FTE (December 31, 2022: 99 FTE) who were distributed as follows:

	June 30, 2023 unaudited	December 31, 2022
FTE Total	94,68	99,32
Full-time	78	81
With a PhD degree	23,45	25,29
By business segments	94,68	99,32
Production	10,75	11,81
Research and development	7,35	8,65
Clinical and regulatory tasks	18,7	19,67
Marketing and sales	28,38	29,53
Quality management	7,85	5,85
Management, business development, finance, HR and administration	21,65	23,81
By countries	94,68	99,32
Germany	84,05	87,94
Spain	7,63	8,38
United Kingdom	3	3

In order to remain attractive as an employer in the competition for employees in the future, the Company must continue to be in a position to offer attractive compensation benefits and employment conditions in line with the market. This includes, among other things, the share- or securities-based compensation under our employee option program and the compensation from our stock appreciation rights program. The company is working on a new program that is simpler and even more attractive than the current one, to be rolled out by the end of 2024.

Research and development projects

All research and development activities of the Biofrontera of the Biofrontera Group's research and development activities relating to nanoemulsion and Ameluz® are based at Biofrontera Bioscience GmbH, which is responsible for pharmaceutical development, conducting preclinical and clinical studies, and also for granting, maintaining, and extending regulatory approvals. Responsibility for project management of all development activities is assumed internally; individual work steps such as data management and statistics for clinical studies are outsourced in part or in full. The development of the new red light lamp RhodoLED® XL was the responsibility of Biofrontera Pharma GmbH. All ongoing clinical trials are currently being conducted in the USA as part of the agreement entered into with Biofrontera Inc. to expand labeling for the US market. Both for the approved drug Ameluz® and for the other research and development projects, with the exception of the further development of the new red light lamp RhodoLED® XL, research and development costs are recognized as expenses in the period in which they are incurred. In the reporting period, 30 people were employed in the Research and Development and Regulatory departments (previous year: 22).

Update for 2023 on the ongoing clinical development program:

Phase I safety trial with Ameluz®-PDT

This Phase I safety study, which started in December 2021, evaluates the safety and tolerability of photodynamic therapy (PDT) for the treatment of mild to severe actinic keratosis (AK) on the face and scalp with the simultaneous use of three tubes of Ameluz® together with the new RhodoLED® XL lamp.

This is a non-randomized, open-label, multicenter study in which 100 patients with mild to severe actinic keratosis are being treated. Each patient received the contents of three tubes of Ameluz® for field-directed treatment of actinic keratosis. Nine clinical centers in the USA are involved in the study. The active part of the trial (last patient visit) was completed in April 2023. Currently, the final report for the study is being prepared. It is expected that an NDA supplement can be submitted to the FDA at the end of 2023.

This study follows a pharmacokinetics (PK) study that was completed in October 2020. The study results were submitted to the FDA in early 2021. In June 2021 the FDA had subsequently requested an additional Phase I study focusing on short-term side effects.

Phase II trial for the treatment of moderate to severe acne

The phase IIb trial to test the safety and efficacy of photodynamic therapy with Ameluz® in combination with the BF-RhodoLED® red light lamp for the treatment of moderate to severe acne began in December 2021.

In the multicenter, randomized, double-blind, four-arm study, 126 adult patients suffering from moderate to severe acne are treated with Ameluz® PDT or placebo. The efficacy and safety of Ameluz® PDT will be tested at exposure times of one and three hours compared to placebo. The primary endpoint of the study is the reduction in the number of inflammatory lesions in combination with an improvement in the severity of acne to "Free of acne" or "Almost free of acne". To ensure that the most consistent data possible is collected, the study uses a state-of-the-art, FDA-approved, artificial intelligence analysis platform to count lesions and to assess severity, in addition to the clinical evaluation by the treating physician. Nine clinical centers in USA are involved in the study.

By mid-2023, 51 (40%) patients were enrolled in the study.

Phase III trial for the treatment of superficial basal cell carcinoma (sBCC) with Ameluz®-PDT

To further increase growth opportunities in the American market in the medium term, the company is conducting a clinical trial for the treatment of superficial basal cell carcinoma (sBCC) with Ameluz® together with the BF-RhodoLED® red light lamp in the USA. Intensive work on patient recruitment has been ongoing since September 2018. By mid-year, 178 (96%) of the planned 186 patients had been enrolled and treated in the study. Patient enrollment, which takes a long time due to the challenging study protocol and was additionally impacted by the pandemic in recent years, will be able to be completed in the next few weeks. Upon successful FDA approval, Ameluz® would be the only PDT-drug in the US for the treatment of a skin cancer indication (namely superficial BCC). A total of 19 clinical centers are involved in the trial.

Phase III trial for the treatment of actinic keratosis on the extremities, neck and trunk with Ameluz®-PDT

In December 2022, a randomized, double-blind, placebo-controlled, multicenter Phase 3 clinical trial was started to investigate the safety and efficacy of Ameluz® in a field-directed treatment of actinic keratosis (AK) on the extremities, neck and trunk. Biofrontera's new red-light lamp RhodoLED® XL is being used in this study. At multiple trial sites across the U.S., 165 patients, each with 4-15 AK lesions on the extremities or trunk/neck, will be enrolled in the study. The study design also addresses a promising approach to alleviate PDT pain, which is often a hurdle in PDT treatment for patients and physicians, by introducing an optimized illumination profile. Mild to moderate actinic keratoses are treated with one or, if necessary, two PDT treatments. Patients will have their final examination three months after their last PDT. The clinical study phase will be followed by a follow-up period of twelve months after the last PDT. The primary endpoint of the study is efficacy in terms of the rate of complete healing of all lesions three months after the last treatment.

To date, 54 (33%) patients have been enrolled in the study. A total of 11 centers are involved in this study.

Patent development

The Company currently maintains nine different patent families worldwide. As of June 30, 2023, the patent portfolio consisted of 25 issued patents and 28 pending patent applications, including international patent applications. (December 31, 2022: 23 issued patents and 18 pending patent applications).

As of January 03, 2023, the Company was granted a patent for nanoemulsion technology in the United States by the United States Patent and Trademark Office (USPTO).

Also in January 2023, the Company announced that it had received a notice of allowance for the patent application "Photodynamic Therapy with Two Light Exposures at Different Wavelengths" (US Appl. No. 17/269,816) by the United States Patent and Trademark Office (USPTO). The patent was granted on May 09, 2023, and protects a number of innovations relating to a new illumination method for the treatment of dermatological skin diseases with photodynamic therapy (PDT).

Management report for the first six months of the 2023 fiscal year

Business performance

The positive EBITDA already achieved in the last financial year was also clearly positive in the first half of 2023 at EUR 3.9 million. Compared to the prior-year period, an increase of 24% was generated. Despite increased expenses, the development towards sustainable profitability could be continued due to the increased revenue side. Research & development, general and administrative and selling expenses were balanced at EUR 3.9 million, EUR 3.4 million and EUR 3.7 million, respectively, with significantly higher costs in clinical development and especially in the area of administrative expenses compared to the previous year, mainly due to the increase of legal cost. On the revenue side, the two first quarters showed an increase in sales of up to 18% to EUR 17.8 million compared to the same period in 2022 (EUR 15.1 million). With U.S. license revenues of EUR 12.6 million for the first half of 2023, U.S. license revenues are again the largest revenue contributor in this reporting period, accounting for more than 70% of total revenues.

Marketing & Sales of Ameluz® in Europe

Sales development in Germany was very positive in the reporting period. With a growth rate of 45% compared to the previous year, sales amounted to EUR 3 million (prior-year period: EUR 2.1 million). In the same period of the previous year, the German market segment was still heavily burdened by reimports from Spain.

In the rest of Europe, Biofrontera achieved product sales of EUR 2.03 million as of June 30, 2023, compared with EUR 2.09 million as of the first half of 2022, thus remaining at the same level. In the Spanish market, a weakness in sales caused by the price increase almost cancelled out with the increase in the price per tube, so that the sales level remained almost the same at EUR 0.96 million in the reporting period. The market share in the Spanish PDT segment is currently just below 50%.

Ameluz® also showed restrained growth of 8% in the UK market, still at a generally low sales level.

Our license partners in other European countries generated sales of EUR 0.72 million in the reporting period, compared with EUR 0.81 million as of June 30, 2022

Sales of Ameluz® in the USA

Biofrontera Inc. generated sales of around EUR 12.6 million in the reporting period, an increase of 19% compared to the same period of the previous year (EUR 10.5 million). The USA is supplied with relatively large product batches, which are then sold into the market. Therefore, it can also happen in the future that certain quarters show a significant increase in sales, whereas other quarterly comparisons are significantly weaker. According to Biofrontera Inc.'s half-year financial report, sales of \$14.6 million were generated in the first half of 2023, compared with \$14.2 million in the first half of 2022. Biofrontera Inc increased their stock in the first half of the year to cover the expected relevant growth for the second half (they have confirmed their guidance of 25% yearly growth compared to 2022), ensuring their capacity to deliver on time. Anyhow, they already communicated to us their intention to reduce their stock level during 2024, what will affect our 2024 revenues.

Regulatory and clinical progress

The aim of Biofrontera's commercial and clinical development strategy is to adapt Ameluz® to market requirements and patient needs. The aim of Biofrontera's commercial and clinical development strategy is to successively improve the adaptation of Ameluz® to market requirements and patient needs and to use it for additional indications. The full treatment and market potential of Ameluz® can only be developed with appropriate extensions to the approval.

The company is currently conducting four independent clinical trials in parallel to expand the US approval of Ameluz®. A phase I clinical trial is collecting FDA-required safety data on the use of three tubes of Ameluz® in a PDT session. In this trial, all patients were enrolled in the period under review and the active part of the trial was completed. The final report of the trial is currently being prepared, so Biofrontera expects to submit an extended registration dossier at the end of 2023. The second trial is testing the efficacy of Ameluz® PDT in moderate to severe forms of acne in adults. Patient enrollment has been improved as a result of the protocol changes made in 2022. To date, 51 (40%) patients have been enrolled in the study. The phase III trial launched in December 2022 to test the efficacy of Ameluz PDT on the extremities, trunk and neck in combination with a new illumination profile for pain relief had already been able to enroll 54 (33%) patients by the middle of the year.

The trial to test Ameluz® PDT in superficial basal cell carcinoma, which has been ongoing since 2018, showed progress in patient recruitment, with 178 (96%) of patients already enrolled in the trial as of the balance sheet date. Patient enrollment was completed in July 2023.

Litigation

On the basis of an action filed by Deutsche Balaton AG, the Regional Court of Cologne ruled in a declaratory judgment on December 9, 2022, that the resolutions of approval of the then Management Board and the then Supervisory Board for the IPO of Biofrontera Inc. were unlawful because the prior approval of the Annual General Meeting for the IPO required under the Holzmüller doctrine was unlawfully not obtained. The further action was dismissed. As all the former members of the Management Board and Supervisory Board have been served with notices of disputes concerning possible claims for damages. Biofrontera AG has decided not to appeal the ruling. Due to appeals by the former board members, the judgment is not yet final and is continued by the former board members in the second instance.

In two actions before the Cologne Regional Court, Mr. Ludwig Lutter is contesting his dismissal as a member of the Management Board and the termination of his employment contract and is claiming (partial) continuation of his remuneration. The Cologne Regional Court has not yet ruled on the actions.

In an action before the Cologne Regional Court, an interim injunction was obtained by, among others, Biofrontera Inc. in January 2023 prohibiting Biofrontera AG from accessing data from certain e-mail accounts relating, among others, to a former employee and a former member of the Management Board. The parties to the lawsuit are currently in settlement negotiations.

Further information on the legal disputes can be found in the opportunities and risks report.

General Meetings

Extraordinary General Meeting in January 2023

At the Extraordinary General Meeting on 09 January 2023, a resolution was adopted, based on the proposal of the Management and the Supervisory Board, to increase the share capital of the Company by up to EUR 7,089,673.00 million by issuing new shares. Due to the current market price of the Biofrontera AG shares, the Management Board has decided in July 2023, with the approval of the Supervisory Board, not to execute the resolved capital increase and to withdraw the application for approval of a corresponding securities prospectus. Furthermore, a resolution proposal was submitted to the Extraordinary General Meeting for the creation of authorized capital in the amount of €12.7 million, which is intended to enable the Management to issue shares, either in full or in partial amounts, if required, until December 2027. Such a contingency resolution provides Biofrontera with some flexibility in raising liquidity to be able to react quickly to changing market conditions or market opportunities.

Annual General Meeting 2023

The Annual General Meeting of Biofrontera took place on June 20, 2023. A total of 68% of the registered share capital of Biofrontera AG was represented. The shareholders approved the proposed resolutions 2 to 8 of the Management Board and Supervisory Board, only the proposed resolution on the discharge of Prof. Dr. Ruhwedel for the past financial year 2022 was not approved. No vote was required on agenda item 1. The approval of agenda item 8 authorizes the Company to issue bonds with warrants or convertible bonds, profit participation rights or participating bonds, also excluding subscription rights, and to create conditional capital. The authorization is primarily intended to enable the Company to strengthen its capital resources quickly and flexibly if necessary. The fact that the terms and conditions for the issuance of the aforementioned financing instruments are largely open at the present time enables the Company to respond appropriately to current market conditions and to raise new capital at the lowest possible cost.

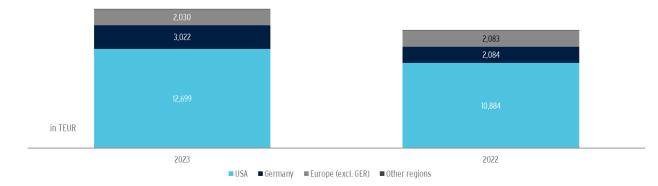
Biofrontera Group financial position and performance

Results of operations of the Biofrontera Group

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

in EUR thousands	01.0130.06. 2023	01.0130.06. 2022	
	unaudited	unaudited	
Sales revenue	17,784	15,076	
Gross Profit on Sales	14,220	12,307	
Research and development costs	(3,925)	(3,134)	
General administrative costs	(3,443)	(2,563)	
Sales and marketing costs	(3,665)	(3,357)	
Result on operations	3,187	3,252	
Other expenses and income	(79)	(514)	
EBITDA	3,743	3,367	
EBIT	3,357	2,990	
Financial result	(5,536)	(39,051)	
Loss before income tax	(2,179)	(36,061)	
Loss after income tax	(3,145)	(36,745)	

Sales revenue



The Biofrontera Group generated total sales of EUR 17,784 thousand in the first half year of 2023, an increase of 18% compared to the previous year's figure (previous year: EUR 15,076 thousand).

Sales in Germany increased by 45% to EUR 3,022 thousand compared to the prior-year period (previous year: EUR 2,084 thousand). With this increase in turnover, the market was able to recover from last year's problems with Spanish re-imports.

Sales in the rest of Europe decreased slightly by 3% year-on-year to EUR 2,030 thousand (previous year: EUR 2,083 thousand). Even in Spain, the development of sales almost stagnated and amounted to 957,000 euros (previous year: 943,000 euros), with the price increase offsetting the weakness in sales caused by the higher selling price of Ameluz®. The company's own sales in UK realized an 8% growth in revenues to EUR 358,000. Noteworthy, we won 10 additional NHS hospital formularies in the first half of this year bringing us to covering about 40% of all NHS hospitals in England.

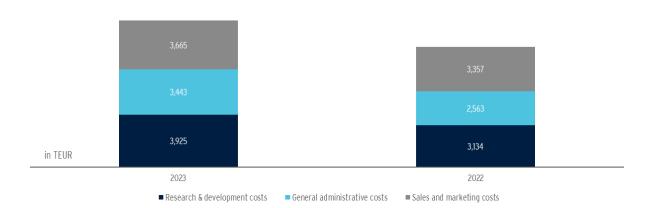
Through European licensees, Biofrontera generated revenues of EUR 715 thousand in the first 6 months of 2023, compared to EUR 809 thousand in the same period of the previous year 2022, a decrease of 12%. This is due to a shift in the ordering pattern of the drug product. In-market unit sales with our partners for Austria, Nordics and Switzerland show a very solid growth of about +19%.

Sales in the USA amounted to EUR 12,699 thousand in the reporting period, an increase of 19% compared to the prior-year period figure of EUR 10,884 thousand.

Revenues from other regions amounted to EUR 34 thousand in the reporting period (previous year: EUR 25 thousand) and include both license income and revenues from services.

Gross profit on sale

In the first half of 2023 gross profit increased by EUR 1,913 thousand (15,5%) to EUR 14,220 thousand compared to EUR 12,307 thousand in the prior-year period. Gross margin decreased from 82% in 2022 to 80% due to mixture of sales.



Research and development costs

Research and development costs increased by 25% to EUR 3,925 thousand in the reporting period compared to EUR 3,134 thousand in the previous year due to increased clinical trials activities. In addition to the 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 amounted to EUR 3,443 thousand in the first half of 2023 (previous year: EUR 2,563 thousand) and thus increased by a total of EUR 880 thousand compared to the previous year. On the cost side, additional expenses were incurred for legal, due to litigations, and consulting fees due to the restructuring of the company following the deconsolidation of the former US subsidiary Biofrontera Inc.

Sales and marketing costs

Selling expenses amounted to EUR 3,665 thousand in the first half of 2023, an increase of EUR 308 thousand compared with the previous year (EUR 3,357 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 and increased by EUR 376 thousand to EUR 3,743 thousand in the first half of 2023 compared with the prior-year period (previous year: EUR 3,367 thousand) as a consequence of all described above.

EBIT includes earnings before interest and taxes and improved year-on-year to EUR 3,357 thousand (previous year: EUR 2,990 thousand).

Financial result

The financial result totaling EUR -5,536 thousand (previous year: EUR -39,051 thousand) includes, in addition to the interest result, mainly the adjustment of the investment value of the Biofrontera Inc. stock holdings in the amount of EUR -5,529 thousand (previous year: EUR -38,941 thousand)

Other income and expenses

Other expenses and income totaled EUR -79 thousand in the reporting period (previous year: EUR -514 thousand), reflecting expenses and income from currency effects of EUR 42 thousand (previous year: EUR -390 thousand).

Income taxes

This item includes current income taxes of EUR 426 thousand (prior-year period: EUR 254 thousand) and deferred tax expenses of EUR 540 thousand (prior-year period: EUR 430 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 30. Juni, 2023 is as follows:

in EUR thousands	June 30, 2023	December 31, 2022
	unaudited	
Non-current assets	11,638	17,669
Current financial assets	10,155	9,324
Other current assets	5,778	5,732
Total assets	27,571	32,725
Equity	17,064	20,336
Non-current liabilities	947	4,002
Current financial liabilities	6,010	5,109
Other current liabilities	3,549	3,277
Total equity and liabilities	27,571	32,725

Non-current assets

Non-current assets as of June 30, 2023 totaling EUR 11,638 thousand (December 31, 2022: EUR 17,669 thousand) include recognized deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of EUR 3,835 thousand (December 31, 2022: EUR 4,375 thousand), property, plant and equipment in the amount of EUR 3,030 thousand (December 31, 2022: EUR 3,012 thousand), and intangible assets (EUR 1,236 thousand; December 31, 2022: EUR 1,198 thousand). Also included here is the investment in Biofrontera Inc. accounted for using the equity method in the amount of EUR 3,453 thousand (December 31, 2022: EUR 8,982 thousand).

Current financial assets

Current financial assets totaled EUR 10,155 thousand as of June 30, 2023 (December 31, 2022: EUR 9,324 thousand). This mainly includes cash and cash equivalents of EUR 4,279 thousand (December 31, 2022: EUR 6,376 thousand), trade receivables of EUR 1,144 thousand (December 31, 2022: EUR 691 thousand) and other current financial assets of EUR 1,346 thousand (December 31, 2022: EUR 878 thousand).

Other current assets

Other current assets mainly comprise inventories. This increased slightly to EUR 4,949 thousand as of June 30, 2023 (December 31, 2022: EUR 4,794 thousand). No impairment losses were recognized on inventories in the reporting year (December 31, 2022: EUR 42 thousand).

Equity

The Group reported equity of EUR 17,064 thousand under IFRS (December 31, 2022: EUR 20,336 thousand). The equity ratio decreased from 63% to 62%.

Non-current liabilities

Non-current liabilities include financial liabilities (EUR 856 thousand; December 31, 2022: EUR 1,055 thousand) and obligations under the SAR program in the amount of EUR 91 thousand (December 31, 2022: EUR 304 thousand), as well as non-current liabilities to associates (EUR 0 thousand; December 31, 2022: EUR 2,642 thousand).

Non-current financial liabilities include liabilities from leases in the amount of EUR 856 thousand (December 31, 2022: EUR 1,055 thousand) to be recognized in accordance with IFRS 16.

Current financial liabilities

Current financial liabilities include in particular trade payables of EUR 2,068 thousand (December 31, 2022: EUR 1,984 thousand) and liabilities to associates of EUR 3,476 thousand (December 31, 2022: EUR 2,653 thousand) as well as current financial liabilities of EUR 448 thousand (December 31, 2022: EUR 446 thousand).

Current financial debt includes current liabilities from leases in accordance with IFRS 16 amounting to EUR 444 thousand (December 31, 2022; EUR 357 thousand).

Other current liabilities

Other current liabilities amounted to EUR 3,549 thousand (December 31, 2022: EUR 3,277 thousand) and include in particular provisions of EUR 591 thousand (December 31, 2022: EUR 603 thousand) and other accruals of EUR 2,377 thousand (December 31, 2022: EUR 2,518 thousand).

Financial position of the Biofrontera Group

The Company's capital management regularly reviews the level of the equity ratio of the Group and the AG. The aim is to maintain an appropriate level of equity in line with the expectations of the capital market and to maintain creditworthiness vis-à-vis national and international business partners. The Management Board of the Group ensures that sufficient liquidity is available to all Group companies.

in EUR thousands	01.0130.06. 2023	01.0130.06. 2022 unaudited	
III EOR LIIOUSAIIUS	unaudited		
Cash flow from/in operating activities	(1,300)	(2,638)	
Cash flow from/in operating activities	(408)	(111)	
Cash flow from/in financing activities	(390)	(2,411)	
Cash and cash equivalents	4,279	6,376	
Non-current financial liabilities	856	1,055	
Current financial debt	448	446	
Net liquidity	2,974	4,874	

Net Cash Flow from operating activities of EUR -1,299 thousand improved in the first half of 2023 compared with EUR -2,638 thousand in the same period of the previous year. This increase results mainly from the improvement of the net result for the period adjusted for the non-cash effects from the valuation of investments (TEUR 5,529) to TEUR 2,384 k (prior year: TEUR 38,941).

Net Cash Flow from investing activities increased from -111 TEUR to -408 TEUR in the financial year 2023 and includes, in addition to investments in property, plant and equipment and intangible assets in the amount of 408 TEUR (previous year: 111 TEUR).

Net Cash Flow from financing activities amounted to EUR -390 thousand (previous year: EUR -2,411 thousand), with the previous year's figure including the repayment of the convertible bond 2017/2022 in the amount of EUR 2,031 thousand.

Cash and cash equivalents

Cash and cash equivalents in the Group amount to EUR 4,279 thousand as of June 30, 2023 (December 31, 2022 : EUR 6,376 thousand).

For furter information on the liquidity of Biofrontera Group and Biofrontera AG, can be found in the section "Outlook and forecast".

Outlook and forecast

Business development in the first half of 2023 is in line with the expectations of the Management Board. It therefore fully maintains its forecast for the financial year 2023 published on April 27, 2023. Among other things, the management 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 Annual Report 2022, which is published on the website of Biofrontera AG at http://www.biofrontera.de/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 match that of 2022 and that Biofrontera Inc. will fulfill its purchase obligations agreed for 2023 and pay them on time.

Risk and opportunity report

The risks and opportunities existing in the Group are described in detail in the Risk and Opportunity Report of the Group Management Report as of December 31, 2022. As of June 30, 2023, there have been no further significant changes to the risks and opportunities described therein, with the exception of the risks and legal disputes described below.

Risks and opportunities relating to future business development and growth

Liquidity, profitability and capital markets access

Liquidity risks can arise from possible loss situations of the company and uncertainties regarding future business development, or from not being able to use market potential in line with Biofrontera's business strategy due to an insufficient liquidity position.

As a result of the continuing loss situation at Biofrontera Inc., this risk for the Biofrontera Group also consists indirectly of Biofrontera Inc. not being able to sufficiently fulfill the market potential for Biofrontera's products on the US market. Due to the high importance of the license partner Biofrontera Inc. for the Group, this could have a significant impact on its business performance, especially regarding liquidity, profitability and access to the capital market.

Biofrontera balances this risk with a long-term capital market strategy. In addition, potential risks are regularly identified and assessed as part of our short-, medium- and long-term Group-wide liquidity planning in order to be able to take timely measures to achieve targets if necessary.

The Biofrontera Group might not be able to meet current or future payment obligations due to insufficient availability of cash. So far, the Group has been able to fulfill its payment obligations at all times. Through the injection of equity or debt capital, Biofrontera has so far always succeeded in providing the financing necessary for its business operations.

Law and compliance

The Group may be exposed to litigation or legal proceedings in the future. These include in particular risks from the areas of product liability, antitrust law, competition law, patent law, tax law and environmental protection. Risks may also arise in connection with disclosure and information requirements on the capital market. Investigations and inquiries into possible infringements of statutory or regulatory requirements may result in criminal and civil sanctions, including substantial monetary penalties, as well as other financial disadvantages, damage our reputation and ultimately have a negative impact on our business success or our access to the capital markets.

An action was filed by Biofrontera Inc. against all resolutions of the Company's Extraordinary General Meeting of January 9, 2023, i.e., among others, against the resolutions under agenda item 1 (resolution on authorized capital) and agenda item 2 (resolution on the increase of the share capital). The action was withdrawn on April 13, 2023, on the basis of an out-of-court settlement with Biofrontera Inc. The settlement is reproduced in detail in an announcement by Biofrontera AG in the Federal Gazette pursuant to section 248a of the German Stock Corporation Act (AktG) Based on another out-of-court settlement with Maruho Deutschland GmbH, the last pending action directed against resolutions of the Annual General Meeting of Biofrontera AG was also withdrawn. The withdrawn action was directed against resolutions of the Annual General Meeting of August 23, 2022, and the Extraordinary General Meeting of January 9, 2023. The election of Prof. Dr. Lergenmüller to the Supervisory Board, which was the subject of the resolution, is thus final. The out-of-court settlement also resolved a dispute about possible voting rights losses of Maruho Deutschland GmbH at past Annual General Meetings. Furthermore, a procedure for avoiding voting right losses at future Annual General Meetings was agreed. This settlement is reproduced in detail in an announcement by Biofrontera AG in the Federal Gazette pursuant to section 248a AktG.

Further information on litigation is provided separately in the section "Litigation".

Consolidated financial statements as of June 30, 2023

Consolidated balance sheet as of June 30, 2023

Assets

in EUR thousands	June 30, 2023	December 31, 2022
	unaudited	
Non-current assets		
Tangible assets	3,030	3,012
Intangible assets	1,236	1,198
Deferred tax	3,835	4,375
Investments accounted for using the equity method	3,453	8,982
Non-current contractual assets	83	101
Total non-current assets	11,638	17,669
Current assets		
Financial assets		
Trade receivables	1,144	691
Receivables from associated companies	3,350	1,344
Other financial assets	1,346	878
Cash and cash equivalents	4,279	6,376
Current contractual assets	35	35
Total financial assets	10,155	9,324
Other assets		
Inventories	4,949	4,794
Other assets	829	938
Total other assets	5,778	5,732
Total current assets	15,932	15,056
Total assets	27,571	32,725

Equity and liabilities

in EUR thousands	June 30, 2023	December 31, 2022
	unaudited	
Equity		
Subscribed capital	63,807	63,80
Capital reserve	137,193	137,31
Capital reserve from foreign currency conversion adjustments	(2)	(
Loss carried forward	(180,789)	(136,623
Loss for the period	(3,145)	(44,166
Total equity	17,064	20,336
Non-current liabilities		
Financial debt	856	1,05
Liabilities to associated companies	0	2,64
Other Liabilities	91	304
Total non-current liabilities	947	4,002
Current liabilities		
Financial liabilities		
Trade payables	2,068	1,98
Liabilities to associated companies	3,476	2,65
Current financial debt	448	44
Other financial liabilities	18	2
Total financial liabilities	6,010	5,10'
Other liabilities		
Income Tax	582	150
Other provisions	591	60
Other liabilities	2,377	2,51
Total other liabilities	3,549	3,27
Total current liabilities	9,559	8,38
Total equity and liabilities	27,571	32,725

Consolidated statement of comprehensive income for first half year of 2023

in EUR thousands	01.0130.6.2023	01.0130.6.2022
	unaudited	unaudited
Sales revenue	17,784	15,076
Cost of sales	(3,564)	(2,769)
Gross profit from sales	14,220	12,307
Operating expenses		
Research and development costs	(3,925)	(3,134)
General administrative costs	(3,443)	(2,563)
Sales costs	(3,665)	(3,357)
Result from operations	3,187	3,252
Depreciation and amortization	386	377
Other Expenses	(79)	(514)
Other Income	250	253
EBITDA	3,743	3,367
Depriciation and amortization	(386)	(377)
EBIT	3,357	2,990
Interest expenses	(7)	(110)
Income from investments accounted for using the equity method	(5,529)	(38,941)
Profit/loss before income tax	(2,179)	(36,061)
Income tax	(966)	(684)
Profit/loss for the period	(3,145)	(36,745)
Profit attributable to owners of the parent company	(3,145)	(36,745)
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	(3,146)	(36,745)
Basic earnings per share in EUR	(0.05)	0.69
Diluted earnings per share in EUR	(0.05)	0.68
** Addition of depreciation and amortization for the transparent		

** Addition of depreciation and amortization for the transparent determination of the EBITDA performance indicator.

Consolidated statement of changes in equity for the first half year of 2023

	Ordinary shares Number of	Subscribed capital in EUR	Capital reserve in EUR	Reserve from foreign currency conversion adjustment (OCI) in EUR	Loss carried forward Loss for the period in EUR	Total in EUR
Delence co of January 01	shares	thousands	thousands	thousands	thousands	thousands
Balance as of January 01, 2022	56,717,385	56,717	137,332	0	-136,623	57,426
Loss for the period	0	0	0	0	-44,166	-44,166
Error correction (according to IAS 8)	0	0	0	0	0	0
Foreign currency conversion	0	0	0	0	0	0
Total loss for the period	0	0	0	0	-44,166	-44,166
Capital increase	7,089,673	7,090	0	0	0	7,090
Conversion of stock options from the stock option program	0	0	0	0	0	0
Cost of equity procurement	0	0	-64	0	0	-64
Increase in capital reserve from the stock option program	0	0	50	0	0	50
Disposal scope of consolidation	0				0	0
Balance as of December 31, 2022	(10) 63,807,058	63,807	137,318	0	-180,789	20,336

		Ordinary shares	Subscribed capital	Capital reserve	Reserve from foreign currency conversion adjustment (OCI)	Loss carried forward Loss for the period	Total
		Number of shares	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands
Balance as of December 31, 2022	(10)	63,807,058	63,807	137,318	0	-180,789	20,336
Loss for the period		0	0	0	0	-3,145	-3,145
Foreign currency conversion		0	0	0	-2	0	-2
Total loss for the period		0	0	0	-2	-3,145	-3,147
Capital increase		0	0	0	0	0	0
Conversion of stock options from the stock option program		0	0	0	0	0	0
Cost of equity procurement		0	0	-142	0	0	-142
Increase in capital reserve from the stock option program		0	0	17	0	0	17
Balance as of June 30, 2023	(10)	63,807,058	63,807	137,193	-2	-183,934	17,064

Consolidated cash flow statement for the first half year of 2023

in EUR thousands	01.0130.6.2023	01.0130.6.2022
	unaudited	unaudited
Cashflows from operations		
Loss before income tax	(2,179)	(36,061)
Adjustments to reconcile loss before income tax to cash flow into operations		
Income tax	(966)	(684)
Financial result	5,536	39,05
Depreciation	386	377
Losses from disposal of assets	11	C
Non-cash (income) and expenses	482	429
Changes in operating assets and liabilities		
Trade receivables	(2,459)	(431)
Other assets and income tax assets	(359)	520
Inventories	(154)	(128)
Trade payables	907	(6,249)
Provisions	57	347
Other liabilities	(2,580)	19
Net cash flow from/in operational activities	(1,300)	(2,638)
Cash flow from investment activities		
Purchase of intangible and tangible assets	(408)	(111)
Net cash flow from/in investment activities	(408)	(111)
Cashflows from financing activities		
Costs of equity procurement	(142)	C
Proceeds from draw down of EIB loan	0	(2,031)
Leasing payments	(237)	(218)
Interest paid	(11)	(162)
Net cash flows from/in financing activities	(390)	(2,411)
Net increase/(decrease) in cash and cash equivalents	(2,098)	(5,160)
Cash and cash equivalents at the beginning of the period	6,376	6,908
Cash and cash equivalents at the end of the period	4,278	1,748

Notes to the consolidated financial statements as of June 30, 2023

Information about the Company

Biofrontera AG (hereinafter also referred to as "Biofrontera" or the "Company"), registered in the Commercial Register of the Local Court of Cologne, Department B under No. 49717, and its wholly owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, and Biofrontera Neuroscience GmbH, all with registered offices at Hemmelrather Weg 201, 51377 Leverkusen, Germany, and the Spanish branch Biofrontera Pharma GmbH sucursal en España with registered offices in Cornellá de Llobregat, research, develop and distribute dermatological products.

The declarations on the German Corporate Governance Code required by § 161 of the German Stock Corporation Act have been submitted and made available to the shareholders on Biofontera's website (www.biofrontera.com).

The shareholding in Biofrontera Inc. as at the reporting date amounts to 29,96% and is reported under investments in associates using the at-equity method.

Segment reporting

Biofrontera's main business activity is the sale of pharmaceuticals and medical products and the associated research and development activities to optimize their market potential. The Biofrontera Group is essentially a single-product company. Accordingly, segmentation is based exclusively on geographical aspects and only with regard to sales revenues, as internal reporting to management and corporate controlling are also based exclusively on these criteria. Internal reporting to management is a condensed presentation of the consolidated statement of comprehensive income. The results of the companies are monitored separately by management in order to be able to measure and assess their performance.

For further information, please refer to our comments in the notes on "Sales revenue".

Summary of significant accounting policies

Basis for preparation of the consolidated financial statements

The consolidated financial statements of Biofrontera AG for the financial year from January 1, 2023 to December 31, 2023 have 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) valid at the reporting date and recognized by the European Union (EU). In addition, the provisions of German commercial law applicable under Section 315e (1) of the German Commercial Code (HGB) have been observed.

The consolidated financial statements have been prepared on a going concern basis.

Biofrontera AG is the ultimate controlling company preparing consolidated financial statements for the group of consolidated companies.

The consolidated financial statements as of June 30, 2023 are prepared in EUR or EUR thousand. Rounding differences may occur in the tables due to commercial rounding.

The consolidated financial statements as of June 30, 2023 were authorized for issue by the Management Board on August 30, 2023.

Changes in accounting standards

The accounting policies applied are consistent with those used as of June 30, 2022, with the exception of the new and revised standards and interpretations described below, the application of which was mandatory for the first time as of fiscal year 2023.

Basis of consolidation

The consolidated financial statements as of June 30, 2023 include the financial statements of the parent company, Biofrontera AG, and the subsidiaries in which the parent company holds a direct majority of the voting rights.

The basis for the consolidation of the companies included in the consolidated financial statements was the annual financial statements (or HBII according to IFRS) of these companies as of June 30, 2023, prepared in accordance with uniform principles. The consolidated financial statements as of June 30, 2023 were prepared on the basis of standard accounting and valuation principles (IFRS).

The subsidiaries are fully consolidated from the date of acquisition. The date of acquisition is the date on which the parent company obtained control of these group companies. Subsidiaries are included in the consolidated financial statements until control of these entities is lost.

All intercompany receivables and payables as well as income and expenses have been eliminated in the course of consolidation.

Associated companies in which the companies of the Biofrontera Group hold a share of between 20% and 50% of the voting rights, or in which relevant indicators point to significant influence, are accounted for using the equity method. For investments accounted for using the equity holdings, the carrying amounts are increased or decreased by the changes in equity corresponding to Biofrontera's equity interest. The changes in the proportionate equity recognized in profit or loss are included in the result from investments accounted for using the equity method.

Notes to the consolidated balance sheet of the first half year of 2023

Intangible and tangible assets

As in the previous year, no impairment losses were recognized on property, plant and equipment or intangible assets during the reporting period. Biofrontera uses external and internal sources of information to determine at each reporting date whether there are any indications of impairment or a reversal of impairment losses.

Financial assets accounted for using the equity method

Financial assets include the carrying amount of the investment in Biofrontera Inc. of EUR 3,453 thousand (previous year: EUR 8,982 thousand), which is included and measured in the consolidated financial statements using the at-equity method.

Deferred income tax

As of June 30, 2023, deferred taxes on loss carryforwards amounting to EUR 3,835 thousand (previous year: EUR 4,375 thousand) are recognized. These are capitalized to the extent that they can probably be offset against future taxable profits. A planning period of five years is taken as a basis. These relate to the deferred tax assets to be recognized on loss carryforwards for Biofrontera Pharma GmbH, which were reduced in the first half of the year as a result of utilization due to the positive tax result. For the full year 2023 and also in the future, it is still assumed that Biofrontera Pharma GmbH will generate positive results and thus utilize its tax loss carryforwards.

Equity

Share capital

The fully paid-in share capital of the parent company, Biofrontera AG, amounted to EUR 63,807,058.00 as of June 30, 2023. It consisted of 63,807,058 registered shares with a nominal value of EUR 1.00 each. On December 31, 2022, the share capital had amounted to EUR 63,807,058.00.

The shares of Biofrontera AG were listed on the Regulated Market of the Düsseldorf Stock Exchange in 2006. In August 2012, at the request of the Company, admission to trading on the Regulated Market of the Frankfurt Stock Exchange was also granted. The shares

are also traded on the Xetra computer trading system and on all other German stock exchanges. On June 03, 2014, the shares were admitted to the Prime Standard of the Frankfurt Stock Exchange.

The listing on the NASDAQ Capital Market in the USA took place on February 14, 2018, where Biofrontera AG's share certificates were traded as American Depositary Shares (ADS) under the ticker symbol BFRA. In early March 2022, Biofrontera delisted the ADSs from the Nasdaq Capital Market ("Nasdaq"), in June the registration with the Securities and Exchange Commission ("SEC") was cancelled and subsequently the ADS Level I program was terminated.

The share capital was held as follows on June 30, 2023:

	June 30, 2023	December 31,2022
	unaudited	
Maruho Co., Ltd., Osaka Japan		
The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former. Mr Koichi Takagi has announced "acting i concern" for the entire shareholding of Maruho Deutschland GmbH on 31.01.2023.	13,399,965 in	13,399,965
Wilhelm Konrad Thomas Zours		
 The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours: DELPHI Unternehmensberatung Aktiengesellschaft; VV Beteiligungen Aktiengesellschaft; Deutsche Balaton Aktiengesellschaft; Heidelberger Beteiligungsholding AG; SPARTA AG; Deutsche Balaton Biotech AG (*no longer included in the group of companies listed in 2021 - AEE Ahaus- Enscheder AG; MARNA Beteiligungen AG; Youbisheng Green Paper AG; Strawtec Group AG) 	17,021,057	17,021,057
Biofrontera Inc., Woburn, USA	6,360,146	6,466,946
Free float	27,025,890	26,919,090
Total	63,807,058	63,807,058

Only those shareholders are listed who are subject to reporting requirements under the German Securities Trading Act (WpHG) and have submitted a corresponding report. This includes all shareholders who hold at least 3% of the shares or voting rights in circulation. The number of shares listed here refers to the last notification by the respective shareholders; since then, they may have changed their holdings within the respective reporting limits without notifying the Company.

Financial liabilities

in EUR thousands	June 30, 2023 unaudited	December 31, 2022
Non-current financial liabilities		
Leasing liabilities	856	1,055
Total non-current financial liabilities	856	1,055
Current financial liabilities		
Leasing liabilities	448	446
Other current liabilities	0	0
Total current financial liabilities	448	446

Income taxes

Income tax liabilities of EUR 582 thousand (previous year: EUR 156 thousand) relate to corporate income tax liabilities (EUR 242 thousand) and trade tax liabilities (EUR 340 thousand).

Other provisions

The development of other provisions of the Biofrontera Group is as follows:

in EUR thousands	December 31, 2022	Utilized	Released	Added	June 30, 2023 unaudited
Provisions for litigation costs	518	(18)	0	0	500
Other provisions	85	(2)	0	7	91
Total	603	(20)	0	7	591

Other current liabilities

in EUR thousands	June 30, 2023	December 31, 2022
	unaudited	
Liabilities from SAR program	91	304
Total other non-current liabilities	91	304
Accrual for employee bonuses	439	563
Accrual for outstanding vacation	118	117
Accrual for settlement payment	148	0
Payroll tax	159	101
Accruals for outstanding invoices	1,210	1,187
Accruals for financial statement and audit costs	116	215
Other accruals	187	335
Total other current liabilities	2,377	2,518

Reporting on financial instruments

The following tables present the carrying amounts and fair values of the individual financial assets and liabilities for each category of financial instrument in accordance with IFRS 9:

Financial assets

in EUR thousands	Valuation category	Fair value as of	Carrying amount as of	Fair value as of	Carrying amount as of	Hierarchy level
	according to IFRS 9	June 30, 2023	June 30, 2023	June 30, 2022*	June 30, 2022*	
Cash and cash equivalents	AC	-	4,279	6,376	6,376	-
Trade receivables	AC	-	1,144	2,035	2,035	-
Other financial asstes	AC	-	1,346	878	878	-
Total		-	6,769	9,289	9,289	

	Valuation category	Fair value as of	Carrying amount as of	Fair value as of	Carrying amount as of	Hierarchy level
	according to IFRS 9	June 30, 2023*	June 30, 2023*	June 30, 2022*	June 30, 2022*	June 30, 2023
Financial liabilities, current	AC	0	448	446	446	0
Trade payables	AC	0	2,068	1,984	1,984	0
Liabilities to associated companies current	AC					
Other financial liabilities	AC	0	18	26	26	0
Financial liabilities, non-current	AC	0	856	1,055	1,055	0
Liabilities to associated companies non-current	AC					0
Total		0	3,390	8,807	8,807	

Based on the input factors used at the valuation methods fair values are divided into different steps of the fair value hierarchy:

Level 1: Fair value valuations using prices listed on active markets (not adjusted) for identical assets or liabilities.

Level 2: Fair value valuations using inputs for the asset or liability that are either directly observable (as prices) or indirectly observable (derived from prices), but which do not constitute listed prices pursuant to Level 1.

Level 3: Fair value valuations using inputs for the asset or liability that are not based on observable market data (unobservable input data).

During the reporting period, no reclassifications were made between the individual levels of the fair value hierarchy. For further details, please refer to the disclosures in the general accounting policies and the notes to the statement of financial position and statement of comprehensive income.

Due to the predominantly short-term maturities of trade receivables and payables as well as receivables from and payables to associates, other financial receivables and payables, and cash and cash equivalents, the carrying amounts at the balance sheet date do not differ significantly from the fair values.

Notes to the consolidated statement of comprehensive income

01.0130.6.2023			0130.6.2023 unaudited			01.0130.6.2022 unaudited	
in EUR thousands	Product revenues	Service revenues	Licensing revenues	Product revenue	Service revenues	Licensing	
Germany	3,022	-	-	2,084	-	-	
Europe	1,315	-	715	1,276	-	807	
U.S.	-	137	12,562	-	369	10,515	
Other regions	-	-	34	-	-	25	
Total	4,337	137	13,311	3,360	369	11,347	

Sales revenue

Result from investments

Income from investments includes the amortization of the carrying amount of the investment in Biofrontera Inc. in the amount of EUR 5,529 thousand (previous year: EUR 38,941 thousand).

Personnel costs

in FUD the week de	30.06 2023	21 12 2022
in EUR thousands	unaudited	31.12 2022
Wages and salaries	4,242	6,904
Social security charges	673	1,123
Cost for pension schemes	64	94
Total	4,979	8,121

Related party disclosures

Within the framework of the underlying holding structure, Biofrontera AG assumes the administrative and control tasks. Biofrontera AG is also responsible for the financing of the currently still in the loss-making business areas, since as a listed company it has the best access to the capital market. Against the background of the close cooperation between the Group companies, an internal settlement is carried out which is adjusted annually to meet current requirements.

All contracts with related parties are concluded at market conditions.

The investment in Biofrontera Inc. as of the reporting date is reported under investments in associates using the equity method.

The following relationships exist with Biofrontera Inc.:

in EUR thousands	June 30, 2023	December 31, 2022	
	unaudited	December 31, 2022	
Sales revenues*	12,699	17,135	
Other income			
Clinical trial expenses*	417	436	
Other expenses*	877	64	
Trade receivables	3,350	1,344	
Trade payables	839	11	
Payables from DUSA settlement	2,642	5,295	

Biofrontera Inc. was established to market our products in the USA. Under a license and supply agreement between Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH, both wholly owned subsidiaries of Biofrontera AG, and Biofrontera Inc. the responsibilities between the companies are regulated. The agreement was concluded for a period of 15 years and will be renewed for another 5 years, provided that a sales volume in the USA of more than USD 150 million has been achieved in the preceding 5 years. Under this agreement, Biofrontera Inc. acquires Ameluz® and the PDT lamps BF-RhodoLED® and RhodoLED® XL from Biofrontera AG. Up to annual Ameluz® sales of USD 30 million, Biofrontera Inc. pays 50% of sales as a transfer price. This share decreases in two steps for higher sales, down to 30% for sales more than USD 50 million. Biofrontera AG has agreed to maintain FDA approval, to manufacture the products, to provide a pharmacovigilance database and to conduct predefined clinical trials.

Additionally, services that were previously invoiced as part of intercompany billing are now performed and invoiced on the basis of corresponding service agreements with Biofrontera Inc. This relates primarily to services in the areas of pharmacovigilance, quality management and IT. In the financial year 2022, Biofrontera entered into a sublease agreement for business premises and a service agreement for accounting services with Bio-FRI GmbH, the German subsidiary of Biofrontera Inc.

The following relationships exist with the Maruho Group:

in EUR thousands	June,30 2023 unaudited	December 31, 2022
Revenue from patent transfer	0	200
Revenue from license agreements	0	141
Income from subleases	17	32
Trade receivables	0	34

In April 2020, Biofrontera entered into an exclusive license agreement with Maruho Co, Ltd, Osaka, Japan (Maruho) for the development and commercialization of Ameluz® for all indications in East Asia and Oceania. The agreement has a term of 15 years from the start of sales in the countries covered by the agreement. Under the agreement, Maruho receives exclusive development and marketing rights, including permission to sublicense Ameluz® in Japan, China, Korea, India, Pakistan, Vietnam, the Philippines, Australia, New Zealand, and surrounding countries and islands (territory of applicability). Maruho is entitled, with Biofrontera's consent, to conduct its own research and development under the license agreement. Maruho will grant to Biofrontera a royalty-free and perpetual license to any results of such research and development conducted by Maruho for commercialization outside the Territory. Under the License Agreement, Biofrontera will supply Ameluz® to Maruho at cost plus 25%, while Maruho has an obligation to use commercially reasonable efforts to develop, register and commercialize Ameluz® in all countries in the Applicable Territory. Under the license agreement, Maruho has made a one-time payment of EUR 6 million to Biofrontera AG in 2020. Further future payments will be due upon the achievement of certain regulatory and sales milestones. Maruho will also pay royalties of initially 6% of net sales in the countries of the scope, which may increase to 12% depending on sales volumes and will decrease in the event of

generic launches in these countries. In the reporting year, revenue from this licensing agreement was recognized for the supply of materials for clinical trials and the recharging of associated costs.

In December 2021, Biofrontera Pharma GmbH and Maruho Ltd. agreed in a license agreement that the patent "Illumination for photodynamic therapy" in Japan will be transferred to Maruho Ltd. The patent transfer and the resulting revenue recognition in the amount of EUR 200 thousand took place in 2022.

In the reporting period, there were no further reportable transactions or relationships with related parties other than those mentioned above.

1. Subsequent events

Cancellation of the capital measure increase approved in January 2023

On July 24, 2023, the Company published that due to the current market price of the share, the Management Board, with the approval of the Supervisory Board, has decided not to carry out the capital increase to increase the Company's share capital by up to EUR 7,089,673.00 million by issuing new shares, which was approved at the Extraordinary General Meeting on January 09, 2023, and to withdraw the application for approval of a corresponding securities prospectus. In the capital increase resolution, the Annual General Meeting specified a subscription price of EUR 1.05, at which the implementation of the capital increase does not appear possible given the current market development.

Legal issues

On July 10, 2023, Biofrontera announced that on July 4, 2023, the major shareholder Maruho Deutschland GmbH withdrew its action for rescission against resolutions of the Annual General Meeting of August 23, 2022, and the Extraordinary General Meeting of January 9, 2023. As a result, the election of Prof. Dr. Lergenmüller to the Supervisory Board, which is the subject of the resolution, became final. The withdrawal is part of an out-of-court settlement which at the same time settled a dispute about possible voting rights losses of Maruho Deutschland GmbH at past Annual General Meetings. Furthermore, a procedure to avoid voting right losses at future Annual General Meetings was agreed.

The agreement is reproduced in detail in the announcements of Biofrontera AG in the Federal Gazette pursuant to § 248a AktG.

No other events occurred after the balance sheet date.

Leverkusen, August 31, 2023

Pilar de la Huerta Martinéz Chief Financial Officer

Responsibility statement

Responsibility statement pursuant to section 297 (2) sentence 4 HGB and section 315 (1) sentence 5 HGB

We affirm that, to the best of our knowledge and in accordance with the applicable accounting principles, the consolidated financial statements give a true and fair view of the Group assets, financial position and results of operations of the Group and that the combined management and group management report presents the course of business, including the business results and the position of the Biofrontera Group and Biofrontera AG, in such a way that a true and fair view is given and that the main opportunities and risks of the expected future development of the Biofrontera Group and Biofrontera AG are described.

Leverkusen, August 31, 2023

Biofrontera AG

Pilar de la Huerta Martínez CFO