Biofrontera

Deep in dermatology

Biofrontera AG

6M 2022 half-year financial results

Year-to-date Highlights 2022

- Sales increase of around 15% compared to the same period of the previous year
- Positive EBITDA and EBIT from operations due to the restructuring of the Biofrontera Group and the associated cost relief for Biofrontera AG
- Biofrontera receives notice of grant for Australian patent on innovative PDT treatment protocol
- Supervisory Board of Biofrontera AG appoints Paul Böckmann to the Management Board
- Licensing partner Louis Widmer (Switzerland) receives approval extension of Ameluz®
- Biofrontera AG terminates U.S. ADS program and delists from NASDAQ
- Official price decree for Ameluz® in Spain is lifted
- U.S. Food and Drug Administration (FDA) includes the granted patent for the new RhodoLED® XL in the FDA Orange Book
- Biofrontera Pharma is approved by the FDA as a contract laboratory for batch control and stability testing of Ameluz®
- Biofrontera AG achieves further progress in the phase III trial for the treatment of SBCC with Ameluz®

Key figures in accordance with IFRS

	6M 2022 unaudited		6M 2021	
	in EUR thousands	% of revenue	in EUR thousands	% of revenue
Results of operations				
Sales revenue	15,076	100.00%	13,094	100.00%
Gross profit on sales	12,307	81.63%	11,082	84.63%
Result from operating activities	3,252	21.57%	(7,583)	(57.91)%
EBITDA	3,367	22.34%	(5,768)	(44.05)%
EBIT	2,990	19.83%	(7,391)	(56.44)%
Profit/loss before income tax	(36,061)	(239.20)%	(8,835)	(67.47)%
Profit/loss for the period	(36,745)	(243.73)%	(8,872)	(67.76)%

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Net assets		
Total assets	32,609	76,699
Non-current assets	23,352	62,322
Cash and cash equivalents	1,748	6,908
Other current assets	7,509	7,056
Non-current liabilities	9,750	17,467
Current liabilities	1,578	1,235
Equity	21,280	57,997

	Juni 30, 2022 unaudited	December 31, 2021
Number of employees	98	99
Biofrontera Shares		
Number of shares outstanding	56,717,385	56,717,385
Share price (Xetra closing price in EUR)	1.18	1.48

Interim group management report for the first half of the year 2022

Basis of the Biofrontera Group

Group structure

As of June 30, 2022, the Biofrontera Group (hereinafter also called "Biofrontera", "Biofrontera Group", "Group" or the "Company") consists of a parent company, Biofrontera AG and 4 (December 31, 2021: 4) 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.

The IPO of Biofrontera Inc., headquartered in Woburn, Massachusetts, USA, at the end of October 2021 resulted in changes to the Group structure due to the associated dilution of the AG's shareholding. Biofrontera AG's stake in Biofrontera Inc. in the amount of 8 million shares corresponded to an ownership share of approximately 69% after the IPO. After the further issuance of shares as well as the exercise of warrants, the shareholding decreased to approximately 42% by June 30, 2022. The control criteria of IFRS 10 have ceased to be met as of December 29, 2021, so that Biofrontera Inc. no longer qualifies as a subsidiary of Biofrontera AG. The deconsolidation was completed as of December 31, 2021 for reasons of materiality. The investment in Biofrontera Inc. as of the reporting date is reported under investments in associated companies using the at-equity method. Following further capital measures in the current year, the 8 million shares still held by the company in Biofrontera Inc. correspond to a participation share of around 34% at the time of reporting.

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 separation, Biofrontera Inc. is now the licensee responsible for marketing Ameluz® and the RhodoLED® lamp series in the USA. The licensing of Xepi® as part of the acquisition of Cutanea Life Sciences, Inc. in March 2019 was carried out directly via Biofrontera Inc. so that Xepi® will no longer be part of the Biofrontera Group's product portfolio in the future.

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.

The supply of Ameluz® and the RhodoLED® lamp series to Biofrontera Inc. and all other license partners is carried out within the framework of the respective license and supply agreements with Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH, both wholly owned subsidiaries of Biofrontera AG.

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH were founded in December 2012 and are additional wholly owned subsidiaries of Biofrontera AG. These two companies are intended for the development of pipeline products that are not part of Biofrontera's core business at this point in time and therefore currently cannot be sufficiently financed within the normal business activities. 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. Activities are currently focused on the continued sales growth of our products and the development of further market potential through label extensions of 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® has been actively promoted by Biofrontera's own sales force since May 2018. 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. Upon its IPO at the end of October 2021, Biofrontera Inc. became an independent company. Under a license and supply agreement with 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 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 rate decreases in two steps for higher sales, down to 30% for sales in excess of $50 million. 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. It's significant superior effect in combination with an LED lamp compared to the direct competitor product Metvix® for AK was proven during phase III development. Actinic keratoses are superficial forms of skin cancer with a risk of spreading to deeper skin layers and thus developing into potentially fatal squamous cell carcinoma. The combination of Ameluz® with light treatment is an innovative form of treatment that is classified as photodynamic therapy (PDT). The product information authorized by the European Medicines Agency (EMA) expressly states the significant superiority of Ameluz® in the removal of keratosis compared to the direct competitor product, both in conventional light treatment with a special lamp and in application with ordinary daylight.

The overall advantages of Ameluz® in terms of efficacy, handling, user-friendliness and skin rejuvenation as well as the high healing and comparatively low recurrence rates of PDT in the treatment of actinic keratoses lead to the expectation that this treatment option will attract even more attention from dermatologists in the years to come. Contributing to this is also the label extension to include basal cell carcinoma in 2017.

In 2017, Biofrontera submitted an application for approval 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 special lamp. The topically applied drug is activated by natural or artificial 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. As a result, Ameluz® is also reimbursed by the statutory health insurers in Germany for use with daylight-PDT, whereas use of the drug with conventional PDT is generally not reimbursed. The results of the follow-up phase of the clinical comparison study on daylight-PDT with Ameluz® and Metvix® were included in the product information (SmPC) in March 2020. It is expected that the significantly superior efficacy compared to Metvix® one year after treatment will further enhance the market positioning of Ameluz®.

In March 2020, the European Commission granted a label extension for Ameluz® to cover the treatment of mild and moderate actinic keratoses by photodynamic therapy with Ameluz® not only on the head, but also on the extremities and trunk/neck. The extension of the approval by the European Commission followed a positive vote by the European Medicines Agency EMA and is based on the results of a Phase III study involving 50 patients. The patients were treated with Ameluz® on one randomized side of the body and placebo on the other side. If lesions remained on both sides of the body, PDT was repeated three months later. The results for the primary regulatory endpoint show that Ameluz® was highly significantly superior ($p<0.0001$) to placebo based on a mean total lesion clearance rate of 86% versus 33%. The high superiority of Ameluz® was also demonstrated for all secondary parameters studied. In this study, the average lesion recurrence rate 12 months after Ameluz® treatment was 14.1% compared to 27.4% after placebo.

These results in treating AK on all areas of the body further confirm the excellent efficacy of PDT with Ameluz®. The Company expects that this label extension will also further strengthen the market position of Ameluz® 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®. In order to meet the strict requirements of the FDA for the production of a Class III medical device, production of the lamp was transferred to Biofrontera Pharma GmbH in 2016 as part of the FDA approval process and is now carried out at the Company's headquarters in Leverkusen. This makes Biofrontera the responsible manufacturer from the perspective of the regulatory authorities. In the EU, this lamp has already been CE-certified in 2012, which also required ISO 9001 and ISO 13485 certifications for the entire company. The ISO certification was renewed in 2019 at regular intervals. In October 2021, the FDA approved the new, more advanced RhodoLED XL. The approval was granted in accordance with FDA specifications as a combination approval together with the flagship 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 contributes to the protection of the drug Ameluz® in the US market due to the specifics of the FDA's 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 modern active cosmetic product specially developed for irritated and sensitive skin. Biofrontera's patented biocolloid technology, which optimizes epidermal penetration, makes the products unique: pure herbal biocolloids combine with medicinal plant extracts to form an extraordinary combination of active ingredients with a proven depth effect.

Belixos® products are manufactured according to stringent quality and environmental regulations. They are free of paraffins, parabens, ethyl alcohol, animal products, dyes and fragrances that may have negative dermatological effects. Its skin compatibility was certified as "very good" by the independent "Dermatest" Institute. Belixos® is obtainable in selected pharmacies, dermatological institutes and from the online retailer Amazon.

Sales and marketing

USA

In the USA, Ameluz® was launched by Biofrontera in October 2016. The distribution of Ameluz® in the USA is handled by Biofrontera Inc., which was founded in March 2015. Biofrontera Inc., headquartered in Woburn, Massachusetts, USA, has not been a subsidiary of Biofrontera AG since its IPO and a dilution of Biofrontera AG's shareholding to a current 34%, with the marketing of Ameluz and the RhodoLED lamp series in the USA being governed by a licensing agreement. Since the launch, sales of Ameluz® have generated more than 90 million euros in the USA, thus establishing the product in the market.

Germany and Europe

With its central European approval, Ameluz® can be sold and distributed in all EU countries as well as in Norway, Iceland and Liechtenstein. In many European countries, however, the price and reimbursement status have to be determined before market launch, which can be a lengthy process. This process involves reference pricing and re-imports, that might result in low prices in individual EU countries, which in return can have a negative impact on the entire EU market. This is one of the reasons why the drug is only available in certain EU countries. In these countries the drug is available at pharmacy retail prices ranging from EUR 150 to approximately EUR 220 per 2g tube. After a price reduction was imposed on the company in Spain by decree of the Ministry in 2020, the price has now been back at EUR 150 per tube since April 1, 2022.

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 down payment and the regional partners buy Ameluz® from Biofrontera at a price that is linked to their own sales price. Depending on the market conditions of a country, Biofrontera's share of the sales price varies somewhat, but averages 50% of net sales. Overall, however, marketing through Biofrontera's own sales force has proven to be much more successful in recent years, so that sales to distribution partners now only account for a small percentage of total sales.

In December 2020, the Biofrontera Group was able to cover sales in Scandinavia through an exclusive license and supply agreement for the marketing of Ameluz® and BF-RhodoLED® with Galenica AB, Malmö, Sweden. Sales of the products in the Scandinavian region commenced with the delivery of the first batch of Ameluz® in June 2021, and a second batch was already delivered in April 2022.

In July 2021, Biofrontera announced that it had signed a license and supply agreement with Medac Gesellschaft für klinische Spezialpräparate mbH, for the commercialization of Ameluz® and BF-RhodoLED® in Poland. The commencement of product commercialization in Poland is still expected in 2022, for which Medac was supplied with a first batch of Ameluz during the second quarter of 2022.

Other regions

In April 2020, Biofrontera signed an exclusive license and supply 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 distribution in the countries covered by the agreement. More information on the license and supply agreement can be found in Biofrontera AG's Annual Report 2020.

Market overview

Actinic keratosis

Non-melanoma skin cancer and its precursor actinic keratosis (AK) is the main market for our 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, and 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. Over many years, UV radiation 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); simple 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 takes into account the disease progression to date, the extent of the existing skin damage, and the patient's condition (age, possible existing concomitant 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 remains 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

Germany is Biofrontera's single largest European sales market. In Germany, around 1.7 million people annually are treated by dermatologists for AK, which represents more than 2% of the total population. However, the number of people suffering from the disease is probably higher. In 2021, a total of 851,143 prescriptions were issued for the treatment of AK (previous year: 814,410). Self-applied topicals such as prescription creams and gels containing active ingredients were used most widely, taking a market share of 93.3%, followed by PDT (the combination of a surface-applied medication with light therapy) at 6.7% (previous year: 92.9% and 7.1%, respectively). The overall AK market increased 4% in 2021 primarily due to the market launch of an additional topical drug. PDT treatments did not continue to grow (-2%), but this is mainly attributable to the loss of sales of PDT competitor drug.

Although the total number of cryotherapy or simple curettage treatments for actinic keratosis in Europe is not publicly accessible, we assume that only a small number of patients with actinic keratosis are treated with cryotherapy or simple curettage treatments.

In Germany, the largest European market for Ameluz®, the market share for PDT drugs segment was approximately 64% in 2021 compared to approximately 62% in 2020. The continued uptake of daylight PDT has allowed Ameluz® to continue to prove itself as a strong leader in the PDT market compared to competing products. We estimate that daylight PDT will continue to capture additional market share previously reserved for self-applied topical creams. This is mainly due to the fact that daylight PDT is reimbursable by statutory health insurers, which has multiplied the number of patients who in principle have access to treatment with Ameluz®. However, there are still no signs of a recovery in market development in the first half of 2022. Corona-related effects still seem to play a role here. In addition to practice closures due to illness, older patients in particular often cancel planned appointments with dermatologists for fear of corona disease. As a result, the AK market stagnated throughout the first half of the year and the market share of Ameluz was also unable to develop positively.

Actinic keratosis has been recognized as an occupational disease by the Federal Ministry of Labor and Social Affairs in Germany since 2013. As a result of such recognition, occupational insurance associations in Germany must cover, for the duration of the patients' lives, the treatment costs of patients who have worked predominantly outdoors for extended periods of time and who meet Biofrontera AG Annual Report 2020 6 certain other criteria. In Germany since March 2016, photodynamic therapy has been included as an approved treatment option for occupational actinic keratosis, which means it can be reimbursed by the government.

Personnel matters

Management Board

As of June 30, 2022 the Management Board consisted of Ludwig Lutter (CFO) and Paul Böckmann.

Name	Nationality	Age	Position	Date of first appointment	Term
Ludwig Lutter*	German	55	CFO	March 01, 2021	August 13, 2022
Paul Böckmann**	Austrian	45	Management Board Member	June 09, 2022	August 31, 2022

* Effective August 13, 2022, Mr. Ludwig Lutter left the Management Board of Biofrontera AG.

** Effective June 09, 2022, Mr. Paul Böckmann was appointed to the Management Board of Biofrontera AG. The appointment of Mr. Böckmann is time-limited and ends on August 31, 2022 with an extension option until December 09, 2022.

Employees

As of June 30, 2022 the Biofrontera Group had 98 employees (December 31, 2021: 99) who were distributed as follows:

	June 30, 2022	December 31, 2021
Total number of employees	98	99
Full-time	78	76
With academic degree	20	24
By business segments	98	99
Production	11	15
Research and development	8	5
Clinical and regulatory tasks	22	15
Marketing and sales	29	29
Quality management	7	7
Management, business development, finance, HR and administration	21	28
By countries	98	99
Germany	87	88
Spain	8	8
United Kingdom	3	3

Due to the IPO of Biofrontera Inc., headquartered in Woburn, Massachusetts, USA, at the end of October 2021, changes have occurred in the Group structure as a result of the associated dilution of the AG shareholding. On December 29, 2021, Biofrontera AG announced the reduction of its shareholding in Biofrontera Inc. below 50%. After legal review, Biofrontera Inc. is thus no longer considered a subsidiary of Biofrontera AG in accordance with IFRS 10. As of the reporting date of December 31, 2021, the employees of the former US subsidiary are therefore no longer listed.

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.

Change in the Supervisory Board

On February 22, 2022, the Company announced that Prof. Dr. Franca Ruhwedel has resigned from the Supervisory Board for cause with immediate effect.

Research and development projects

All research and development activities of the Biofrontera Group regarding the nanoemulsion and Ameluz® are carried out by Biofrontera Bioscience GmbH, which is responsible for clinical studies as well as for the granting, maintenance and expansion of our approvals. Responsibility for the project management of all development activities is assumed internally; individual tasks such as data management and statistics are partially or completely outsourced. The development of the new red-light lamp RhodoLED® XL was the responsibility of Biofrontera Pharma GmbH. All our ongoing clinical studies are carried out in the USA. Research and development costs for both Ameluz®, the approved drug, and the other research and development projects, with the exception of the further development of the new RhodoLED® XL red light lamp, are recognized as expenses in the period in which they are incurred. In the reporting period, 22 people were employed in research and development as well as regulatory affairs (previous year: 20).

The following are the studies currently being conducted:

Development and FDA-approval of the RhodoLED® XL

The future use of the RhodoLED® XL will allow the application of Ameluz® on larger areas as well as the simultaneous illumination of several interspersed lesions. Furthermore, the RhodoLED® XL will offer a significantly improved user experience with highly customizable settings. Combined with a modern and high-quality design, we expect strong customer acceptance, especially in the USA, and consequently an increase in PDT in general and thus in Ameluz® sales. Following submission of the application for approval to the FDA in the first half of the year, the Group received US approval for the new RhodoLED® XL red light lamp in October 2021. As with the predecessor model BF-RhodoLED®, this was granted in accordance with FDA requirements as a combination approval with Ameluz®.

Phase I safety study and pharmacokinetics study with Ameluz®-PDT

In December 2021, the Biofrontera Group commenced patient enrollment for its Phase I safety study to evaluate the safety and tolerability of PDT for the treatment of mild-to-severe AK on the face and scalp using three tubes of Ameluz® together with the new RhodoLED® XL lamp. The non-randomized, open-label, multicenter study evaluates the safety and tolerability of Ameluz® in the treatment of AK located on the face and scalp with PDT together with the new RhodoLED® XL lamp. The study includes 100 patients with mild to severe AK. Each patient will receive the content of three tubes of Ameluz® for a field-directed treatment of AK. A total of eight clinical sites are participating in the study.

The Phase I study follows a maximal-usage pharmacokinetics (PK) clinical study that was completed in October 2020 and the results were submitted to the FDA in early 2021. After consultation with the FDA in June 2021, the regulatory agency requested another safety study focusing on short-term side effects before the product information can be amended to include the concurrent use of up to three tubes of Ameluz®.

Phase II trial for the treatment of moderate to severe acne

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

The multicenter, randomized, double blind phase II study with four arms uses conventional Ameluz®-PDT and includes 126 adult patients suffering from moderate to severe acne, which will be treated with Ameluz®-PDT or placebo. Efficacy and safety of Ameluz®-PDT will be tested with respect to incubation periods of one and three hours compared to placebo. The primary endpoint of the study is the absolute change in the number of inflammatory lesions and an improvement in acne severity scoring. To ensure collection of highly consistent data across all participating sites, the study will combine clinical assessments performed by the physicians conducting the study with a cutting-edge, FDA-approved, artificial intelligence analysis platform that will provide a lesion count along with a severity assessment. A total of seven sites are participating in the study. Of the planned 126 patients, 10% have been enrolled in the study so far.

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

To further increase the growth potential in the US market in the medium term, the Company is currently conducting a clinical trial in the USA for the treatment of superficial basal cell carcinoma (sBCC) with Ameluz® in combination with our BF-RhodoLED® lamp. Patient recruitment has been ongoing since September 2018. To date, more 80% of the planned 186 patients have been enrolled in the study. Due to the demanding study protocol, patient recruitment has been very time-consuming and was additionally slowed down by the pandemic last year but has recently picked up again. Following successful FDA approval, Ameluz® would be the on

Patent development

The Company maintains five different company-owned patent families worldwide. The Group's patents are held by Biofrontera Bioscience GmbH and Biofrontera Pharma GmbH.

The patent families refer to our technologies related to our nanoemulsion, our red-light lamp for photodynamic therapy (PDT), photodynamic therapy itself and migraine prophylaxis.

Nanoemulsion

Patents have been issued for our nanoemulsion technology in Europe (for France, Germany, Italy, Spain, Switzerland/Liechtenstein, and the UK), Australia, Belarus, Canada, Chile, China, Hong Kong, Israel, Japan, Mexico, New Zealand, Russian Federation, South Africa, Singapore, and Ukraine. Patent protection in these jurisdictions will expire on December 21, 2027. A corresponding patent application has been filed and is pending in the United States.

On November 12, 2019, protection for the patent family describing the combination of nanoemulsions with aminolevulinic acid hydrochloride, the active ingredient in Ameluz®, expired. However, Ameluz® continues to be protected by the nanoemulsion technology patent family, which continues until December 2027, although the corresponding patent application in the USA is still pending. This patent has not yet been and possibly may never be granted in the USA and thus will not provide patent protection for Ameluz® in this market. However, we believe that the risk presented by future generic competition is mitigated by specific challenges in developing generic topical dermatological products. In particular, Biofrontera was able to obtain registration of a patent (US11235169B1) in the Orange Book, granted on the medical product RhodoLED®XL, which is regulatory linked to Ameluz® (see below). This has resulted in Ameluz® not being placed on the FDA's list of potentially generic drugs ("Prescription List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic"). As part of Biofrontera's patent strategy to further protect Ameluz®, additional patent applications have been submitted (see below).

Red-light lamp for photodynamic therapy

An international patent application titled "Illumination for photodynamic therapy" (PCT/EP2019/064642) was filed with the EPO (European Patent Office) on June 5, 2019. All countries that were members of the PCT (Patent Cooperation Treaty) on the filing date were designated in the application. On November 17, 2020, the national phase was initiated in the USA. To expedite obtaining property rights, a partial application was also filed in the USA on April 19, 2021. This was already granted on January 11, 2022 and expires on June 5, 2039. In addition, the national phase of the original application was initiated in Australia, China, Europe (excluding extension & validation states), Hong Kong, Japan, New Zealand and Singapore.

Another new patent application "Illumination device for photodynamic therapy, method for treating a skin disease and method for operating an illumination device" was filed in the USA on October 15, 2020. A partial application for this was also granted in the USA on February 1, 2022. The resulting patent protection (US11235169B1), which protects the combination product with Ameluz® through the link in the Orange Book, is valid until Oct. 15, 2040. Furthermore, an international application (PCT/EP2021/078045) was filed with the EPO on Oct. 11, 2021.

To protect the FDA-approved RhodoLED®XL red light lamp from imitation, a design application for the lamp's LED panel was filed as a partial application of the previously mentioned patent on Oct. 19, 2021.

Photodynamic therapy

An international patent application "Photodynamic therapy comprising two light exposures at different wavelengths" was filed with the EPO on August 23, 2018. Entry into the regional/national phases was initiated for the EU, USA, Japan, Australia, China, Hong Kong, New Zealand and Singapore, and examination requests were made in each case. On July 30, 2022, the patent was granted in Australia (AU2018437303B2) and is valid until August 23, 2038.

Migraine prophylaxis BF-1

An international patent application regarding anti-migraine compounds and their use was submitted to the EPO. Patents were granted to the Group in Europe (nationalized for Germany, Spain, France, United Kingdom, Italy) and in the United States. The Company has decided not to renew the patents in Europe, resulting in protection expiring on January 31, 2022.

Patent transfers under the license agreement with Maruho Co., Ltd.

Limited to use under the existing license agreement with our partner Maruho Co., Ltd. the patent assignment of the following patents in Japan has been initiated:

- Nanoemulsion
- Illumination for photodynamic therapy
- Photodynamic therapy comprising two light exposures at different wavelengths.

Management report for the first six months of the 2022 fiscal year

Business performance

Biofrontera can look back on a positive sales growth of 15% in the first half of 2022 due to a significant business recovery in the European business, but primarily in the US business. After sales in Germany fell short of expectations, the European business developed very positively with a sales increase of 53%. These two opposing developments are largely attributable to the price decree in Spain, which was terminated in April 2022. The previously significantly lower price of Ameluz in Spain triggered reimports, which have now been reduced in the German market in the second quarter of 2022. In contrast, sales increased in Spain, where the higher selling price and positive demand led to a significant increase in sales. Great Britain was also able to contribute to this plus through further increases in revenues.

Biofrontera generated total revenues of EUR 15,076 thousand in the period from January 1 to June 30, 2022, compared to EUR 13,094 thousand in 2021, an increase of around 15%. There has been a shift in the proportion of product sales and licensing income due to the deconsolidation of Biofrontera Inc. and the recognition of sales from the USA as licensing income. License revenue increased to EUR 11,347 thousand in the first half of 2022 (prior-year period: EUR 883 thousand) and revenue from pure product sales decreased from EUR 12,211 thousand in the first half of 2021 to EUR 3,360 thousand in the first half of this year.

Commercialization of Ameluz® in the USA

Biofrontera Inc. generated revenues of USD 14.2 million in the first half of the year from the sale of Ameluz and BF-RhodoLED, representing a 34% increase in revenues compared to the same period last year. In particular, the extremely strong first quarter of 2022, with a sales increase of over 100% compared to the first quarter of 2021, contributed to the positive sales development through licensing income in the first half of 2022 at the Biofrontera Group.

The USA remains the largest sales market for Ameluz®, making the licensing income generated via Biofrontera Inc. also account for 70% of total sales of Biofrontera AG.

Commercialization of Ameluz® in Europe

Sales development in Germany was subdued compared to the previous year. The problem of re-imports, but also the generally weak market development for products against actinic keratosis, meant that sales fell significantly short of expectations. In the first half of 2022, Biofrontera achieved sales of EUR 2,084 thousand in Germany compared to EUR 2,718 thousand in the same period of the previous year 2021, thus a decline of 23%. In the remaining European countries, Biofrontera achieved product sales of EUR 1,276 thousand in the first 6 months of 2022, compared to EUR 836 thousand in the same period of 2021, a significant increase of 53%. After Galenica AB already started sales of Ameluz® and BF-RhodoLED® in the Scandinavian countries in mid-2021 and has already called off a second sales batch, sales are now also about to start in Poland, so that a sales batch for initial stocking was also sent out here in the second quarter, which could be booked as licensing income from Poland.

Regulatory and clinical progress

The objective of Biofrontera's commercial and clinical development strategy is to successively align Ameluz® with market requirements and patient needs and to use it for additional indications. The full treatment and market potential of Ameluz® can only be achieved with appropriate extensions to the approval. The company also made regulatory and clinical progress in the reporting period.

In the first half of the year, Biofrontera Pharma was approved as a contract laboratory by the FDA, a step that had already been taken by the European Medicines Agency (EMA). This places the quality assurance of Ameluz® on a broader footing. Previously, quality assurance was carried out entirely by Biofrontera's contract manufacturers in collaboration with third-party providers, but now Biofrontera Pharma can conduct part of this necessary inspection of production batches in Leverkusen itself. This reduces dependence on external suppliers and the risk of production failures.

In addition, Biofrontera's licensing partner and marketing authorization holder in Switzerland, Louis Widmer SA, has obtained an extension of the marketing authorization for Ameluz® for the treatment of actinic keratosis to include the extremities, trunk and neck. The use of Ameluz® PDT for actinic keratosis, which has already been approved by the European Medicines Agency (EMA) since 2020, also in the body periphery, was submitted separately by Louis Widmer to the Swiss medicines authority, Swissmedic. After approval was granted, the Swiss product label of Ameluz® covers the same range of applications, which has already been approved in the countries of the European Union and the United Kingdom since 2020.

In the area of clinical development, Biofrontera had initiated two studies in the fourth quarter of 2021 to expand the US approval of Ameluz®. One concerns the safety data required by the FDA for the use of three tubes of Ameluz® in a PDT session, in which more than 50% of patients have now already been treated with doses. The second study involves testing the efficacy of Ameluz® PDT in moderate to severe forms of acne in adults. Here, the inclusion criteria in the trial protocol were revised once again, which meant a certain delay in the start of the trial, so that the last trial center could not be initiated until July. Nevertheless, due to the innovative nature of the study, there was a high recruitment dynamic, which has resulted in 10% of patients already being included in the study here as well.

In the clinical trial to test the efficacy of Ameluz in the photodynamic therapy of superficial basal cell carcinoma, 80% of patients have now been recruited and have already completed the treatment phase. The trial, which started in 2018, continues to be sluggish due to the exceedingly challenging treatment protocol.

Resolution on the increase of the share capital

At the Extraordinary General Meeting on April 7, 2022, a resolution was passed to increase the share capital by up to EUR 8 million. Maruho Deutschland GmbH filed an action against this resolution of the Annual General Meeting with the Regional Court of Cologne. The action was served to the Company on May 29, 2022. The Company subsequently initiated so-called release proceedings in accordance with section 246a of the German Stock Corporation Act (AktG) before the Cologne Higher Regional Court. In the event that the Cologne Higher Regional Court grants the Company's motion for release, the capital increase resolved by the Annual General Meeting on April 07, 2022 can be implemented despite the action filed by Maruho Deutschland GmbH.

Litigation

On December 13, 2021, Deutsche Balaton AG filed a declaratory action with the Regional Court of Cologne regarding the authority of the Annual General Meeting for the initial public offering and IPO of Biofrontera Inc.

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

Change in the composition of the Management Board

On June 6, 2022, the Company announced an enlargement of the Company's Management Board. Effective June 6, 2022, Mr. Böckmann was appointed to the Management Board of Biofrontera AG. Mr. Böckmann will support the until then sole member of the Management Board, Mr. Ludwig Lutter, as interim member of the Management Board.

On August 13, 2022, the Company announced that the Supervisory Board, by resolution of August 13, 2022, dismissed and terminated the Chief Financial Officer, Mr. Ludwig Lutter, for cause.

Change in the composition of the Supervisory Board

On February 22, 2022, the Company announced that Prof. Dr. Franca Ruhwedel has resigned from her position as a member of the Supervisory Board with immediate effect for good cause.

Delisting of ADS from Nasdaq

On February 14, 2022, Biofrontera AG decided that its American Depositary Shares ("ADS") will be delisted from the Nasdaq Capital Market ("Nasdaq"), the registration with the Securities and Exchange Commission ("SEC") will be cancelled and thus all reporting obligations in the US capital market will be removed. This has already significantly reduced the complexity of financial reporting and lowered costs in the first half of the year. In June 2022, the underlying ADS program was terminated and subsequently BNY Mellon has given at a minimum 90 days' notice to customers of the termination and will liquidate the remaining ADSs after this period.

Effects of the COVID-19 pandemic and Ukraine war

Having almost overcome the effects of the COVID 19 pandemic, the Company's business performance has been positive and the Biofrontera Group was able to look back on a significant business rebound towards the middle of the reporting year with revenue growth from product sales of 20%. The company also experienced a sales recovery in our key market, the USA, from mid-March.

The war in Ukraine is contributing to a slowdown in global growth and is particularly exacerbating inflation. The World Economic Outlook published by the International Monetary Fund (IMF) on July 26, 2022, forecasts a decline in global growth from around 6.1% in 2021 to 3.2% in 2022, another 1.2 percentage points lower than initially forecast in January 2022. Global growth is also expected to continue to decline in 2023 and then level off to a percentage value of 2.9%. For Biofrontera AG, the war-related rise in raw material prices and the increasing price pressure are having a significant impact on the procurement of raw materials for the production of the lamp series and are also delaying the actual manufacturing process. The high inflation rate may also have an impact on Biofrontera's costs.

The stock markets have also declined significantly since the beginning of 2022 due to the economic forecasts. The German share index DAX, but also the SDAX and TecDAX ended the first half of the year well over 20% down.

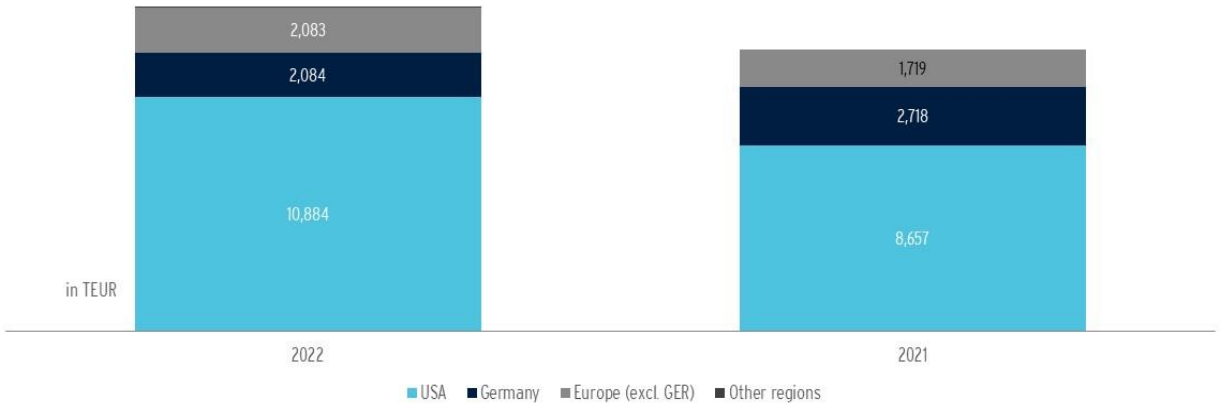
Biofrontera Group financial position and performance

Results of operations of the Biofrontera Group

The results of operations as of June 30, 2022 are as follows:

	6M 2022 unaudited	6M 2021
Sales revenue	15,076	13,094
Gross profit on sales	12,307	11,082
Research and development costs	(3,134)	(2,921)
General administrative costs	(2,563)	(5,553)
Sales and marketing costs	(3,357)	(10,191)
Result from operations	**3,252**	**(7,583)**
Other expenses and income	(261)	192
EBITDA		
EBIT	**2,990**	**(7,391)**
Financial result	(39,051)	(1,444)
Loss before income tax	**(36,061)**	**(8,835)**
Loss after income tax	**(36,745)**	**(8,872)**

Sales revenue



The Biofrontera Group generated total revenues of EUR 15,076 thousand in the first half of 2022, an increase of 15% compared to the prior-year figure (previous year: EUR 13,094 thousand). As a result of the deconsolidation of Biofrontera Inc. the Group's revenues from Biofrontera Inc. are recognized as revenues from licensing income from this financial year onwards. As a consequence, license revenues increased by EUR 10,464 thousand year-on-year to EUR 11,347 thousand (previous year: EUR 883 thousand), whereas revenues from product sales decreased by EUR 8,851 thousand year-on-year to EUR 3,360 thousand (previous year: EUR 12,211 thousand).

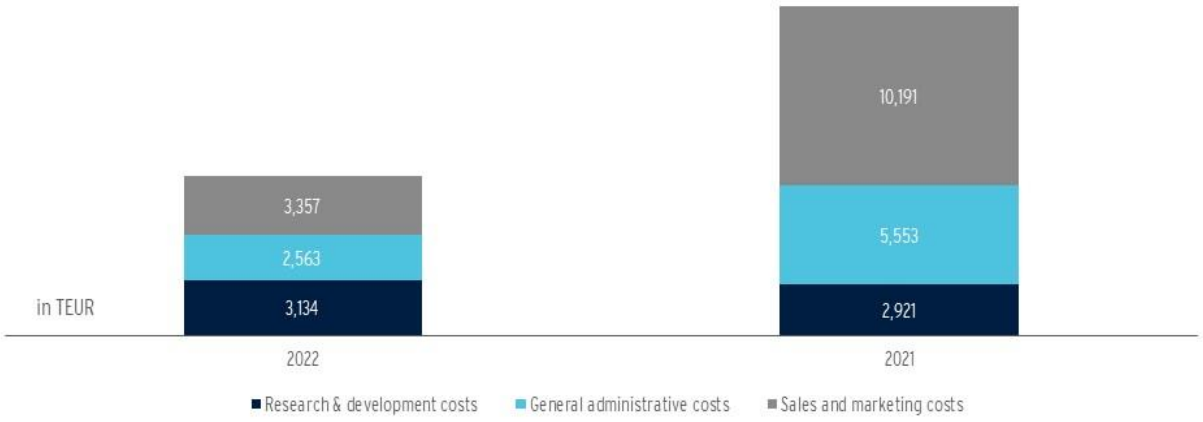
Revenues in Germany declined by 23% year-on-year to EUR 2,084 thousand (previous year: EUR 2,718 thousand). This decline is largely attributable to re-imports.

In the other European countries, sales increased by 53 % to EUR 1,276 thousand (previous year: EUR 836 thousand), which was due not only to the increase in sales volumes, but also to the reversal of the government-ordered price reduction in Spain.

As in the previous year, no sales were generated from other regions in the financial year.

Gross profit on sale

Gross profit improved by EUR 1,225 thousand in the first half of 2022 to EUR 12,307 thousand compared to EUR 11,082 thousand in the prior-year period. The gross margin decreased to 82% compared to 86% in the prior-year period. This is mainly due to the fact that the Company no longer consolidates U.S. sales, but only reports the license portion in the income statement.



Research and development costs

Research and development costs increased by 7% to EUR 3,134 thousand in the reporting period compared to EUR 2,921 thousand in the previous year, primarily due to increased activities in the area of clinical research and studies. In addition to clinical trial costs, 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 2,563 thousand in the first half of 2022 (previous year: EUR 5,553 thousand) and thus decreased by a total of EUR 2,990 thousand compared to the previous year. The previous year's figure included a cost share of EUR 2,604 thousand attributable to the former subsidiary Biofrontera Inc. which left the scope of consolidation.

Sales and marketing costs

Selling expenses amounted to EUR 3,357 thousand in the first half of 2022, a decrease of EUR 6,834 thousand compared to the previous year (EUR 10,191 thousand), mainly due to the cost portion of EUR 7,275 thousand included in the previous year's figure, which relates to the former subsidiary Biofrontera Inc. 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 improved by EUR 9,135 thousand to EUR 3,367 thousand in fiscal year 2022 compared to the prior-year period (EUR minus 5,768 thousand), mainly due to the previously described follow-up effects from the deconsolidation of Biofrontera Inc. as of December 31, 2021.

These effects also had a corresponding impact on EBIT, which improved year-on-year to EUR 2,990 thousand (prior-year period: EUR minus 7,391 thousand). EBIT includes earnings before interest and taxes.

Financial result

In addition to the interest result, the financial result totaling minus EUR 39,051 thousand (previous year: minus EUR 1,444 thousand) mainly includes expenses from the subsequent measurement of the carrying amount of the investment in Biofrontera Inc. amounting to minus EUR 38,941 thousand (previous year: EUR 0 thousand).

The interest result amounts to minus EUR 110 thousand (previous year: minus EUR 1,444 thousand) and mainly includes expenses from interest on overdue payments for liabilities to Biofrontera Inc. as part of a settlement with DUSA Pharmaceuticals Inc.

Other income and expenses

Other expenses and income totaled minus EUR 261 thousand in the reporting period (previous year: EUR 192 thousand) and mainly include expenses and income from currency translation.

Income taxes

This item includes current income taxes of EUR 254 thousand (prior-year period: EUR 38 thousand) and deferred tax expenses of EUR 430 thousand (prior-year period: EUR 0 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 June 30, 2022 is as follows:

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Non-current assets	23,352	62,322
Current financial assets	3,689	8,171
Other current assets	5,568	6,206
Total assets	**32,609**	**76,699**
Equity	21,280	57,997
Non-current liabilities	1,578	1,235
Current financial liabilities	2,332	10,478
Other current liabilities	7,418	6,990
Total equity and liabilities	**32,609**	**76,699**

Non-current assets

Non-current assets as of June 30, 2022 totaling EUR 23,352 thousand (December 31, 2021: EUR 62,322 thousand) include recognized deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of EUR 5,317 thousand (December 31, 2021: EUR 5,747 thousand), property, plant and equipment in the amount of EUR 2,729 thousand (December 31, 2021: EUR 2,281 thousand), and intangible assets (EUR 1,093 thousand; December 31, 2021: EUR 1,139 thousand). This also includes the investment in Biofrontera Inc. accounted for using the equity method in the amount of EUR 14,213 thousand (December 31, 2021: EUR 53,154 thousand).

Current financial assets

Current financial assets totaled EUR 3,689 thousand as of June 30, 2022 (December 31, 2021: EUR 8,171 thousand). This includes cash and cash equivalents of EUR 1,748 thousand (December 31, 2021: EUR 6,908 thousand), trade receivables of EUR 726 thousand (December 31, 2021: EUR 793 thousand) and receivables from associates of EUR 910 thousand (December 31, 2021: EUR 413 thousand), as well as other current financial assets of EUR 304 thousand (December 31, 2021: EUR 57 thousand).

Other current assets

Other current assets mainly contain inventories. These increased to EUR 4,942 thousand (December 31, 2021: EUR 4,814 thousand). No impairment losses were recognized on inventories in the reporting period (December 31, 2021: EUR 172 thousand).

Equity

The Group reports equity of EUR 21,280 thousand under IFRS (December 31, 2021: EUR 57,997 thousand). The equity ratio decreased to 65% compared to 76% in the previous year.

Non-current liabilities

Non-current liabilities amounted to EUR 1,578 thousand as of June 30, 2022 (December 31, 2021: EUR 1,235 thousand). This includes liabilities from leases of EUR 1,227 thousand (December 31, 2021: EUR 851 thousand), to be recognized in accordance with IFRS 16, under financial liabilities, and liabilities under the SAR program (EUR 351; December 31, 2021: EUR 384) under other non-current financial liabilities.

Current financial liabilities

Current financial liabilities include in particular trade payables of EUR 1,660 thousand (December 31, 2021: EUR 2,735 thousand) and liabilities to associated companies of EUR 106 thousand (December 31, 2021: EUR 5,279 thousand) as well as current financial liabilities of EUR 545 thousand (December 31, 2021: EUR 2,449 thousand).

Current financial liabilities mainly include current liabilities from leases under IFRS 16 amounting to EUR 445 thousand (December 31, 2021: EUR 357 thousand) and advance payments received amounting to EUR 100 thousand (December 31, 2021: EUR 0 thousand).

Other current liabilities

Other current liabilities amounted to EUR 7,418 thousand (December 31, 2021: EUR 6,990 thousand) and include in particular provisions of EUR 1,325 thousand (December 31, 2021: EUR 1,012 thousand) and other accrued liabilities of EUR 5,856 thousand (December 31, 2021: EUR 5,840 thousand).

Financial position of the Biofrontera Group

The Company's capital management body regularly reviews the equity ratio of both the Biofrontera Group and the parent company. The objective is to ensure an appropriate equity base, within the framework of the expectations of the capital market, and creditworthiness with respect to national and international business partners. The Group's Management Board ensures that all Group companies have sufficient liquidity at their disposal.

in EUR thousands	6M 2022 unaudited	6M 2021
Net cash flow used in operating activities	(2,638)	(5,620)
Net cash flow used in investment activities	(111)	(287)
Net cash flows used in (from) financing activities	(2,411)	21,674
Cash and cash equivalents	1,748	32,623
Non-current financial liabilities	1,227	21,042
Current financial debt	545	3,195
Net liquidity	(24)	8,386

Net cash flow used in operating activities of minus EUR 2,638 thousand improved in the first half of 2022 compared with the prior-year period, amounting to minus EUR 5,620 thousand. This increase is mainly due to the improvement in the net result for the period adjusted for the non-cash effects from the valuation of investments (EUR 38,941 thousand) to EUR 2,196 thousand (previous year: minus EUR 8,872 thousand).

The net cash flow used in investment activities decreased from minus EUR 287 thousand to minus EUR 111 thousand in fiscal year 2022 and includes investments in property, plant and equipment and intangible assets.

Net cash flow used in financing activities amounted to minus EUR 2,411 thousand (previous year: EUR 21,764 thousand) and mainly includes the cash outflows from the repayment of the convertible bond 2017/2022 in January 2022.

Cash and cash equivalents

Cash and cash equivalents in the Group amounted to EUR 1,748 thousand as of June 30, 2022 (December 31, 2021: EUR 6,908 thousand).

Outlook and forecast

General conditions and forecast

At the time of publication of this half-year report, the Company continues to adhere to the general conditions published in the "Outlook and Forecast" section of the 2021 Annual Report as well as the forecast of the key performance indicators relevant to management for the 2022 financial year. Thus, the Group continues to expect sales of EUR 24 to 27 million in fiscal year 2022. Sales by our own sales teams as well as our licensing partners in the U.S.A. and Europe, and thus business operations, are highly dependent on the further regional recovery from the COVID19 pandemic and the impact of the Ukraine crisis.

Under the above conditions, Biofrontera AG expects EBITDA to be close to break-even in 2022 and negative EBIT in the low single-digit million range. If the markets continue to recover, the company also expects to generate further sales increases and positive EBITDA and EBIT in the low single-digit million range from 2023 onwards.

From today's perspective, both the Group and Biofrontera AG have sufficient liquidity and short-term liquid funds for the next 12 months, taking into account the earnings expectations, the capital increase resolved on April 7, 2022, a level of cash and cash equivalents of EUR 1.7 million in the Group as of June 30, 2022, debt financing of also EUR 1.7 million in July 2022 and the ownership of 8 million liquid shares in Biofrontera Inc. with a stock market value of around USD 12 million on the date of preparation of the consolidated financial statements.

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, 2021. As of June 30, 2022, 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

External influences and global risks

The increasing integration of the global economy due to globalization and digitalization can exert a negative influence on the achievement of Biofrontera's targets in the context of macroeconomic developments. Furthermore, political developments in our sales markets can have an influence on the structures relevant to Biofrontera in the respective healthcare sector.

In addition to effects on individual markets, global crises may arise in this context that could have a significant impact on Biofrontera.

The ongoing COVID 19 pandemic may have further negative effects on the Biofrontera Group's business operations. The maintenance of business processes may be impaired by, among other things, the ordering of (regional) regulatory measures that do not allow full business operations or by employees of the Biofrontera Group or of relevant suppliers becoming infected with COVID-19. However, the Executive Board currently expects to be able to counteract these potential effects by taking appropriate measures.

To this end, the company had already taken appropriate measures immediately after the start of the pandemic to counter these risks and safeguard business operations through comprehensive cost reductions, contingency planning to maintain central processes, and activities to protect employees. These could be implemented again if required.

For further risks in connection with the ongoing pandemic, please refer to the comments in the section on "Liquidity, profitability and capital market access".

Although the war in Ukraine that broke out at the end of February currently has no direct impact on Biofrontera, as the company is not active in either Ukraine or Russia. However, there are negative indirect factors influencing the company's performance, such as price increases in procurement markets and further impairment of supply chains that have already been impacted in the context of the COVID 19 pandemic. The associated risks may increase as the war continues. There is also the possibility of further escalations and the resulting beyond-regional economic risks.

These risks cannot be influenced by Biofrontera. In the past, however, the monitoring processes and standards implemented in the company have enabled Biofrontera to always adapt external effects or risks appropriately and successfully.

Liquidity, profitability and capital markets access

Liquidity risks can arise from uncertainties regarding the future business development or from not being able to exploit market potentials in line with Biofrontera's business strategy due to insufficient liquidity or from not being able to meet its financial obligations, in particular from the settlement with DUSA Pharmaceuticals, Inc.

Biofrontera offsets 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 liquidity planning across the Group in order to enable us to take timely measures to achieve our goals, if necessary.

The Biofrontera Group might not be able to meet existing or future payment obligations due to insufficient availability of cash. So far, the Group has been able to meet its payment obligations at all times. Through the injection of equity or debt capital, Biofrontera has so far always succeeded in providing the financial requirements necessary for its business operations. As a result of the capital measures carried out in the past, the company has had sufficient liquidity at its disposal throughout the reporting period, so that the Group has been able to meet its payment obligations at all times to date.

However, the current liquidity position, including the obligations under the settlement with DUSA Pharmaceuticals Inc. is not sufficient until the operating break-even is reached. For this purpose, the Company is considering several alternative financing measures at its disposal.

The additional capital requirement could be covered by the capital increase resolved by the Annual General Meeting on April 07, 2022. Maruho Deutschland GmbH filed an action for annulment against this resolution of the Annual General Meeting with the Regional Court of Cologne. The action was served on the Company on May 29, 2022. The Company subsequently initiated so-called release proceedings pursuant to Art. 246a AktG before the Cologne Higher Regional Court. In the event that the Cologne Higher Regional Court grants the Company's application for release, the capital increase resolved by the Annual General Meeting on April 07, 2022 can be implemented despite the action filed by Maruho Deutschland GmbH. In addition, there is the possibility of an external provision of debt capital. As part of interim financing, the Company has issued a bond in the amount of EUR 1.7 million with maturity in December 2022.

Following the initial public offering (IPO) of Biofrontera Inc. in the USA and the existing investment of Biofrontera AG with 8,000,000 shares in Biofrontera Inc. the Group also has sufficient additional liquidity potential available in the event of the possible sale of the shares.

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 provisions or regulatory requirements may result in criminal and civil sanctions, including considerable fines, as well as other financial disadvantages, could cause harm to the Company's reputation and ultimately have a negative impact on our business success or our access to the capital markets.

In November 2021, the Company announced that it had found a solution to the aforementioned legal disputes and other differences in the mediation process with Mr. Zours and the Deutsche Balaton Group. With the conclusion of the mediation agreement, all of the aforementioned legal disputes have been resolved through the out-of-court settlement of November 19, 2021. The mediation agreement does not include a review of the background to the IPO of Biofrontera Inc. in the USA. On December 13, 2021, the day before the Annual General Meeting, Deutsche Balaton AG then filed a corresponding action for a declaratory judgment with the Cologne Regional Court, of which the Company only learned by court service on February 9, 2022. The subject matter of the action is again the legal examination and determination of any unwritten authority of the Annual General Meeting for the IPO of Biofrontera Inc.

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

Moreover, third-party claims regarding Biofrontera's potential infringement of patents or other protective rights may hinder or completely prevent the development or manufacturing of certain products and may obligate us to pay damages or royalties to third parties. Our patent department regularly reviews the current patent situation, in cooperation with the relevant operational departments, and monitors possible patent infringement attempts, so that it can take suitable legal steps if necessary.

On November 12, 2019, protection for the patent family, describing the combination of nanoemulsions with aminolaevulinic acid hydrochloride, the active ingredient in Ameluz®, expired. However, Ameluz® continues to be protected by the nanoemulsion technology patent family, which also continues until December 2027, although the corresponding patent application in the USA is still pending. This patent has not yet been and may never be granted in the US and thus would not provide patent protection for Ameluz® in this market. However, we believe that the risk presented by future generic competition is mitigated by specific challenges in developing generic topical dermatological products, including regulatory hurdles. As part of Biofrontera's patent strategy to further protect Ameluz®, additional patent applications have been filed in recent years to protect the use of the combination of Ameluz® and BF-RhodoLED®. With the granting of these patents in December 2021, a substantial contribution has been made to limiting this risk.

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

Condensed interm consolidated financial statements as of June 30, 2022

Consolidated balance sheet as of June 30, 2022

Assets

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Non-current assets		
Tangible assets	2,729	2,281
Intangible assets	1,093	1,139
Deferred tax	5,317	5,747
Investments accounted for using the equity method	14,213	53,154
Total non-current assets	**23,352**	**62,322**
Current assets		
Financial assets		
Trade receivables	726	793
Receivables from associated companies	910	413
Other financial assets	304	57
Cash and cash equivalents	1,748	6,908
Total financial assets	3,689	8,171
Other assets		
Inventories	4,942	4,814
Income tax	0	0
Other assets	626	1,392
Total other assets	5,568	6,206
Total current assets	**9,257**	**14,377**
Total assets	**32,609**	**76,699**

Equity and liabilities

in EUR thousands	June 30, 2022 unaudited	December 31 , 2021
Equity		
Subscribed capital	56,717	56,717
Capital reserve	137,359	137,332
Capital reserve from foreign currency conversion adjustments	0	0
Loss carried forward	(136,052)	(169,909)
Loss for the period	(36,745)	33,857
Total equity	**21,280**	**57,997**
Non-current liabilities		
Financial debt	1,227	851
Other financial liabilities	351	384
Total non-current liabilities	**1,578**	**1,235**
Current liabilities		
Financial liabilities		
Trade payables	1,660	2,735
Liabilities to associated companies	106	5,279
Current financial debt	545	2,449
Other financial liabilities	22	14
Total financial liabilities	**2,332**	**10,478**
Other liabilities		
Income Tax	0	0
Other provisions	1,325	1,012
Other liabilities	6,093	5,977
Total other liabilities	7,418	6,990
Total current liabilities	**9,750**	**17,467**
Total equity and liabilities	**32,609**	**76,699**

Consolidated statement of comprehensive income for the first six months of the fiscal years 2022 and 2021

in EUR thousands	6M 2022 unaudited	6M 2021
Sales revenue	15,076	13,094
Cost of sales	(2,769)	(2,012)
Gross profit from sales	**12,307**	**11,082**
Operating expenses		
Research and development costs	(3,134)	(2,921)
General administrative costs	(2,563)	(5,553)
Sales costs	(3,357)	(10,191)
Result from operations	3,252	(7,583)
Depreciation and amortization	377	1,623
Other Expenses	(514)	(142)
Other Income	253	334
EBITDA	3,367	(5,768)
Depriciation and amortization	(377)	(1,623)
EBIT	2,990	(7,391)
Effective interest expenses	0	(197)
Interest expenses	(110)	(1,255)
Interest Income	0	8
Income from investments accounted for using the equity method	(38,941)	0
Profit/loss before income tax	(36,061)	(8,835)
Income tax	(684)	(38)
Profit/loss for the period	(36,745)	(8,872)
	0	
	(36,745)	(8,872)
Other comprehensive income after income taxes		
Items which may in future be regrouped into the profit and loss statement under certain conditions.		
Translation differences resulting from the conversion of foreign business operations	0	(1,866)
Total profit/loss for the period	(36,745)	(8,587)
Basic earnings per share in EUR	(0.65)	(0.16)
Diluted earnings per share in EUR	(0.65)	(0.16)

Consolidated statement of changes in equity for the first six months of the fiscal year 2022 and 2021

	Number of ordinary shares	Subscribed capital	Capital reserve	Capital from foreign currency conversion	Accumulated loss	Total
	Anzahl	TEUR	TEUR	TEUR	TEUR	TEUR
Balance as of January 01, 2021	**47,747,515**	**47,747**	**123,493**	**1,867**	**(165,732)**	**7,375**
Loss for the period	0	0	0	0	(8,872)	(8,872)
Foreign currency conversion	0	0	0	284	0	284
Total loss for the period	**0**	**0**	**0**	**284**	**(8,872)**	**(8,588)**
Capital increase	8,969,870	8,970	15,697	0	0	24,667
Cost of equity procurement	0	0	-2,000	0	0	-2,000
Increase in capital reserve from the stock option program	0	0	120	0	0	120
Balance as of June 30, 2021	**56,717,385**	**56,717**	**137,310**	**2,151**	**(174,604)**	**21,574**
Loss for the period	0	0	0	0	42,729	42,729
Foreign currency conversion	0	0	0	-2,151	0	-2,151
Total loss for the period	**0**	**0**	**0**	**-2,151**	**42,729**	**40,578**
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	0	0	0	0
Increase in capital reserve from the stock option program	0	0	22	0	0	22
Decrease in scope of consolidation	0	0	0	0	(4,177)	(4,177)
Balance as of December 31, 2021	**56,717,385**	**56,717**	**137,332**	**0**	**(136,052)**	**57,997**
Balance as of January 01, 2021	**56,717,385**	**56,717**	**137,332**	**0**	**(136,052)**	**57,997**
Loss for the period	0	0	0	0	(36,745)	(36,745)
Foreign currency conversion	0	0	0	0	0	0
Total loss for the period	**0**	**0**	**0**	**0**	**(36,745)**	**(36,745)**
Capital increase	0	0	0	0	0	0
Cost of equity procurement	0	0	0	0	0	0
Increase in capital reserve from the stock option program	0	0	27	0	0	27
Balance as of June 30, 2022 (unaudited)	**56,717,385**	**56,717**	**137,359**	**0**	**(172,797)**	**21,280**

Consolidated cash flow statements for the first six months of the fiscal years 2022 and 2021

in EUR thousands	6M 2022 unaudited	6M 2021
Cash flow from operating activities		
Loss before income tax	-36,061	-8,835
Adjustments to reconcile loss before income tax to cash flow into operations		
Income tax	-684	-38
Financial result	39,051	1,444
Depreciation	377	1,623
Other non-current provisions	0	0
Losses from disposal of assets	0	3
Non-cash (income) and expenses	429	333
Changes in operating assets and liabilities		
Trade receivables	-431	172
Other assets and income tax assets	520	-1,931
Inventories	-128	787
Trade payables	-6,249	584
Provisions	347	89
Other liabilities	191	149
Net cash flow used in operating activities	**-2,638**	**-5,620**
Cash flow from investment activities		
Purchase of intangible and tangible assets	-111	-287
Proceeds from sale of intangible and tangible assets	0	0
Net cash flow used in investment activities	**-111**	**-287**
Cashflows from financing activities		
Proceeds from the issue of shares	0	24,667
Costs of equity procurement	0	-2,000
Repayment of convertible bond 2017/2022	-2,031	0
Proceeds from exercise of employee stock options	0	0
Leasing payments	-218	-668
Interest paid	-162	-235
Net cash flows used in (from) financing activities	**-2,411**	**21,764**
Net increase/(decrease) in cash and cash equivalents	-5,160	15,857
Changes from exchange rate differences	0	220
Cash and cash equivalents at the beginning of the period	6,908	16,546
Cash and cash equivalents at the end of the period	**1,748**	**32,623**

Select explanatory notes to the interim consolidated financial statements as of June 30, 2022

Information about the Company

Biofrontera AG (www.biofrontera.com), 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, as well as the Spanish branch Biofrontera Pharma GmbH sucursal en España with registered offices in Cornellá de Llobregat and Biofrontera Inc. headquartered in Woburn, Massachusetts, USA, research, develop and market dermatological products.

The IPO of Biofrontera Inc., headquartered in Woburn, Massachusetts, USA, at the end of October 2021 has resulted in changes to the Group structure due to the associated dilution of the AG shareholding. Biofrontera AG's stake in Biofrontera Inc. in the amount of 8 million shares corresponded to an ownership share of approximately 69% after the IPO. After the further issuance of shares as well as the exercise of warrants, the shareholding decreased to approximately 47% by December 29, 2021. The control criteria of IFRS 10 are therefore no longer met, so that Biofrontera Inc. is no longer considered a subsidiary of Biofrontera AG. Accordingly, the company was deconsolidated, with December 31, 2021 selected as the date of deconsolidation for reasons of materiality. The time lag between the actual loss of control and deconsolidation has no material impact on the consolidated financial statements. The investment in Biofrontera Inc. as of the reporting date is reported under investments in associates using the equity method. As of June 30, 2022 Biofrontera AG's ownership interest in Biofrontera Inc. still amounted to 42%.

Summary of significant accounting policies

Basis for preparation of the consolidated financial statements

Pursuant to the provisions of Section 115 of the German Securities Trading Act (WpHG) in conjunction with Section 117 of the German Securities Trading Act (WpHG), the half-year financial report as of June 30, 2022 comprises condensed interim consolidated financial statements, an interim group management report and a responsibility statement by the legal representatives in accordance with the requirements of Section 264 (2) sentence 3, Section 289 (1) sentence 5 of the German Commercial Code (HGB).

The condensed interim consolidated financial statements as of June 30, 2022 of Biofrontera AG have been prepared in accordance with the International Financial Reporting Standards (IFRS) issued by the International Accounting Standards Board (IASB) and the Interpretations issued by the International Financial Reporting Standards Interpretations Committee (IFRS IC) for "Interim Financial Reporting" under IAS 34, as adopted by the European Union. They therefore do not contain all the information and disclosures required for consolidated financial statements and should be read in conjunction with the consolidated financial statements for the year ended December 31, 2021.

The interim 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 interim consolidated financial statements as of June 30, 2022 are presented in EUR or EUR thousand. Rounding differences may occur in the tables due to commercial rounding.

This interim financial report of Biofrontera AG was approved for publication by resolution of the Management Board on August 18, 2022.

The interim financial reporting as of June 30, 2022 does not include separate segment reporting, as the activities of the Biofrontera Group are limited to one operating segment within the meaning of IFRS 8. All business activities are focused on the sale of dermatological products, in particular Ameluz® including the complementary products BF-RhodoLED® (PDT lamp) and Belixos® , and are accordingly monitored and managed internally on a uniform basis. For further information, please refer to our comments in the section on sales.

Changes in accounting standards

For the preparation of the condensed interim consolidated financial statements, the accounting policies applied for the preparation of the consolidated financial statements as of December 31, 2021 have been adopted unchanged. The new IFRS rules to be applied for the first time from January 01, 2022 have no material impact on the interim consolidated financial statements.

Basis of consolidation

The condensed interim financial statements as of June 30, 2022 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 companies listed below have been included in the consolidated financial statements. The shareholdings are unchanged from the previous year:

1. Biofrontera Bioscience GmbH, Leverkusen, with a direct shareholding of 100%.
2. Biofrontera Pharma GmbH, Leverkusen, Germany, in which the company holds a direct interest of 100%.
3. Biofrontera Development GmbH, Leverkusen, with a direct investment of 100%.
4. Biofrontera Neuroscience GmbH, Leverkusen, with a direct shareholding of 100%.

The basis for the consolidation of the companies included in the consolidated financial statements were the interim financial statements (or HBII according to IFRS) of these companies as of June 30, 2022, prepared in accordance with uniform principles. The consolidated financial statements as of June 30, 2022 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, as have intercompany profits and losses.

Effects of the COVID-19 pandemic

Having almost overcome the effects of the COVID 19 pandemic, the Company's business performance has been positive and the Biofrontera Group was able to look back on a significant business recovery at mid-year with revenue growth from product sales of 20%. The company also experienced a sales revival in our key market, the USA, from mid-March.

Notes to the consolidated balance sheet and consolidated statement of comprehensive income

Intangible and tangible assets

Intangible assets mainly include the internally generated property right from the development of the RhodoLED® XL red light lamp at EUR 1,006 thousand (previous year: EUR 1,055 thousand).

Biofrontera uses external and internal sources of information to review at each reporting date whether there are any indications of impairment or a reversal of impairment. As of June 30, 2022, Biofrontera has not identified any indications of further impairment or reversal of impairment.

Financial assets

Financial assets include the carrying amount of the investment in Biofrontera Inc. measured at fair value of EUR 14,213 thousand (previous year: EUR 53,154 thousand). The expenses from the impairment of the carrying amount of the investment amount to EUR 38,941 thousand in fiscal year 2022 (previous year: EUR 0 thousand) and are recognized in the financial result.

Deferred income tax

As of June 30, 2022, deferred taxes on loss carryforwards amounting to EUR 5,317 thousand (previous year: EUR 5,747 thousand) are recognized. These are capitalized to the extent that they can most probably be offset against future taxable profits. A planning period of five years is taken as a basis. Deferred tax assets relate to loss carryforwards to be recognized for Biofrontera Pharma GmbH, which were reduced in the first half of the year as a result of their utilization due to the positive tax result. For the full year 2022 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 56,717,385.00 as of June 30, 2022. It consisted of 56,717,385 registered shares with a notional value of EUR 1.00 each. On December 31, 2021, the share capital had also amounted to EUR 56,717,385.00.

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 share certificates are traded as American Depositary Shares (ADS) under the ticker symbol BFRA. One ADS certifies the right to two ordinary shares of Biofrontera AG. Biofrontera AG has decided on February 14, 2022 that its American Depositary Shares ("ADS") should be delisted from the Nasdaq Capital Market ("Nasdaq"), its registration with the Securities and Exchange Commission ("SEC") should be cancelled and its reporting obligations should be terminated. The main purpose of the delisting is to reduce financial reporting complexity and administrative costs. Biofrontera AG intends to maintain an adjusted ADS program on a Level I basis to allow investors to continue to hold its securities in the form of ADSs and to trade the ADSs in the U.S. over-the-counter (OTC) market. The ADSs will automatically transition to the new ADS program in connection with the delisting and will be tradable under a new ticker to be determined.

Biofrontera AG's ordinary shares will continue to be traded on the Prime Standard of the German Stock Exchange under the symbol B8F. Holders of ADSs have the option to exchange their ADSs for ordinary shares listed on Deutsche Börse.

The share capital was held as follows on June 30, 2022:

	June 30, 2022	December 31, 2021
Maruho Deutschland 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.	13,399,965	13,399,965
Wilhelm Konrad Thomas Zours The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours: • DELPHI Unternehmensberatung AG • VV Beteiligungen AG • Deutsche Balaton AG • Deutsche Balaton Biotech AG • Prisma Equity AG • Sparta AG • ABC Beteiligungen AG • AEE Ahaus-Enscheder AG •MARNA Beteiligungen AG •Youbisheng Green Paper AG •Strawtec Group AG	16,990,199	16,990,199

Free float	26,327,221	26,327,221
Total	**56,717,385**	**56,717,385**

Only those shareholders are listed who are subject to reporting requirements under the German Securities Trading Act (WpHG) and the Securities and Exchange Commission (SEC) and have made a corresponding notification. This includes all shareholders who hold at least 3% of the outstanding shares or voting rights. The number of shares listed here refers to the last notification of the respective shareholders, since then they may have changed their holdings within the respective notification thresholds without informing the Company.

In the event of the Company achieving an annual surplus, the Management and Supervisory boards are authorized to transfer all or part of the annual surplus that remains, after deduction of the sums to be placed in the legal reserves and of a loss carried forward, to retained earnings. It is not permissible to transfer more than half of the annual surplus to retained earnings if, after such a transfer, the other retained earnings would exceed half of the share capital. The shareholders' share of profits is calculated based on the size of their holding of the share capital.

Financial liabilities

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Non-current financial liabilities		
Leasing liabilities	1,227	851
Total non-current financial liabilities	**1,227**	**851**
Current financial liabilities		
Leasing liabilities	445	357
Other current liabilities	100	2,092
Total current financial liabilities	**545**	**2,449**

Other financial liabilities

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Non-current other financial liabilities		
Liability from SAR program	351	384
Total non-current other financial liabilities	**351**	**384**
Current financial liabilities	**22**	**14**

Stock Appreciation Rights Program 2019

In April 2019, the Executive Board, with the approval of the Supervisory Board, established a stock appreciation rights plan under which the Company grants virtual options ("stock appreciation rights" or "SARs") entitling the "beneficiary" to receive cash payments in accordance with the specific terms of the SAR plan. However, SARs do not confer any right to subscribe to shares of the Company. SARs may be issued to members of the Management Board of the Company, to members of the management of affiliated companies as well as to employees of the Company and affiliated companies (hereinafter collectively referred to as "beneficiaries"). The exact number of beneficiaries and the number of SARs to be granted to them are determined by the Company's

Management Board. To the extent that members of the Management Board are to receive SARs, the Supervisory Board alone is responsible for determining and deciding on the issue of the SARs. In accordance with the SAR Plan, a maximum of 4,000,000 SARs may be issued until March 31, 2024, of which a maximum of 1,600,000 SARs may be granted to members of the Management Board and a maximum of 2,400,000 SARs to other beneficiaries. The SAR Plan sets the dates for the payment of cash in connection with the SARs, unless there are legally binding regulations that conflict with the payout for the beneficiary. In addition, the eligible party must meet certain conditions for the grant of SARs and must enter into a written contract ("SAR Agreement") with the Company prior to exercise and delivery. Finally, SARs are subject to regulations on vesting periods, expiry and forfeiture. In particular, the SARs may be exercised for the first time after a "vesting period" has expired:

a) The vesting period for 15 % of the SARs granted on an issue date is one year after the issue date;
b) The vesting period for an additional 25% of the SARs granted on an issue date is two years after the issue date;
c) The vesting period for an additional 25% of the SARs granted on an issue date is three years after the issue date;
d) The vesting period for the remaining 35% of the SARs granted at an issue date is four years after the issue date.

After expiry of the respective vesting period, SARs may be exercised until six years after the respective issue date, unless mandatory legal provisions stipulate otherwise in individual cases. If the SARs have not been exercised by that date, they expire without replacement. The beneficiary has no claim to payment if the SARs are not exercised on time and no further compensation will be granted.

SARs may only be exercised as long as their holder is in an ongoing employment or service relationship with the Company or with an affiliated company or as a member of the Company's Management Board.

SARs may only be exercised if the reference price at the beginning of the respective exercise window exceeds the issue price by at least 20%. Furthermore, the reference price must be at least as high as the MSCI World Health Care Index TR or a comparable successor index in the time between the last trading day before the issue date and the 5th trading day before the beginning of the respective exercise window.

Upon effective exercise of the SARs, the Company is obligated, subject to certain adjustments, to make a payment (gross) for each SAR exercised as follows: reference rate - base amount = payout amount per SAR (gross).

SAR program 2019	June 30, 2022 unaudited	December 31, 2021
Outstanding at the beginning of the period	569,205	727,750
Granted during the period	0	429,529
Forfeited during the period	86,183	588,074
Exercised during the period	0	0
Outstanding at the end of the period	483,022	569,205
Exercisable at the end of the period	0	0
Fair value at the end of the period	69 TEUR	102 TEUR
Cost during the period	-33 TEUR	-81 TEUR

The fair value of a stock option under this option program is determined on the basis of a Monte Carlo risk simulation. The pro rata temporis amounts are recognized ratably as personnel expense over the vesting period until the end of the blocking period and are reported under other financial liabilities.

Other provisions

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

in EUR thousands unaudited	January 01, 2022	Utilized	Released	Added	June 30, 2022
Outstanding invoices	510	(270)	(3)	252	489
Auditing costs	383	(180)	0	200	403
Other provisions	119	(52)	0	27	94
Total	**1,012**	**(502)**	**(3)**	**480**	**987**

Reporting on financial instruments

The financial instruments held by the Biofrontera Group at the balance sheet date mainly consist of cash and cash equivalents, trade receivables and payables, other non-current financial liabilities, and financial debt. Biofrontera does not use derivative financial instruments.

Financial assets

in EUR thousands	Fair value as of June 30, 2022 unaudited	Carrying amount as of June 30, 2022 unaudited	Fair value as of December 31, 2021	Carrying amount as of December 31, 2021
Category: Held				
Cash and cash equivalents	1,748	1,748	6,908	6,908
Trade receivables	1,636	1,636	1,206	1,206
Other financial asstes	304	304	57	57
Total	**3,689**	**3,689**	**8,171**	**8,171**

Financial liabilities

	Fair value as of June 30, 2022 unaudited	Carrying amount as of June 30, 2022 unaudited	Fair value as of December 31, 2021	Carrying amount as of December 31, 2021
Financial liabilities at amortized cost				
Financial liabilities, current	545	545	2,449	2,449
Trade payables	1,765	1,765	8,014	8,014
Other financial liabilities	22	22	14	14
Financial liabilities, non-current	1,227	1,227	851	851
Total	**3,559**	**3,559**	**11,328**	**11,328**
Financial liabilities at fair value through profit or loss				
Financial liabilities, non-current				
Other financial liabilities, non-current	351	351	384	384
Total	**351**	**351**	**384**	**384**

Financial assets continue to be allocated to the category "Financial assets at amortized cost". The carrying amounts correspond to the fair values.

The other financial liabilities, with the exception of liabilities under the SAR program, which are measured at fair value, continue to be assigned to the category "Financial liabilities measured at amortized cost". The carrying amounts correspond to the fair values disclosed.

Sales revenue

	6M 2022 unaudited			6M 2021		
in EUR thousands	Product revenues	Service revenues	Licensing revenues	Product revenue	Service revenues	Licensing revenues
Germany	2,084	-	-	2,718	-	-
Europe	1,276	-	807	836	-	883
U.S.	-	369	10,515	8,657	-	-
Other regions	-	-	25	-	-	-
Total	**3,360**	**369**	**11,347**	**12,211**	**-**	**883**

Result from investments

The result from investments exclusively contains expenses from the fair value change in the carrying amount of the investment in Biofrontera Inc. amounting to EUR 38,941 thousand (previous year: EUR 0 thousand).

Personnel costs

in EUR thousands	6M 2022 unaudited	6M 2021
Wages and salaries	3,616	8,637
Social security charges	707	1,337
Cost for pension schemes	31	137
Total	**4,354**	**10,111**

Related party disclosures

As a result of the IPO of Biofrontera Inc. and the associated change in the Group structure, the company was deconsolidated as of December 31, 2021; 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, 2022 unaudited	December 31, 2021
Sales revenues*	10,515	7,992
Other revenue	416	610
	0	0
Clinical trial expenses*	113	263
Other expenses*	34	86
	0	0
Trade receivables	219	413
Trade payables	106	302
Payables from DUSA settlement	0	4,977

* The income statement items mentioned here have been eliminated in the course of consolidation in the previous year.

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 in excess of 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, IT and investor relations.

The following relationships exist with the Maruho Group from the license agreement and a sublease agreement:

in EUR thousands	June 30, 2022 unaudited	December 31, 2021
Sales revenues	25	0
Income from subleases	15	33
Trade receivables	13	0
Trade payables	150	0

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. No payments were made under this license agreement in the reporting year.

In the 2022 financial year, there were no further reportable transactions or relationships with related parties beyond those described above.

The group of related parties is limited to the group of persons and companies mentioned there. The group of key management personnel is limited to the Management Board and Supervisory Board.

In the context of the underlying holding structure, Biofrontera AG is responsible for the administrative and management tasks. Biofrontera AG is also responsible for the financing of the currently still loss-making business areas, as it is a listed company and consequently enjoys optimal access to the capital market.

Due to the close cooperation between the Group companies, intercompany billing is applied, which is adjusted annually according to requirements.

Contingent liabilities

As of the balance sheet date, there were no contingent liabilities (previous year: EUR 50 thousand).

Subsequent events

Change in the Management Board

On August 13, 2022, the Company announced that Mr. Ludwig Lutter has ceased to be Chief Financial Officer of the Company.

Financing through bond

As part of interim financing, the Company issued a bond in the amount of EUR 1.7 million maturing in December 2022.

Takeover offer by Deutsche Balaton

On June 07, 2022, Deutsche Balaton AG, based in Heidelberg, Germany, announced its decision to make a voluntary public takeover offer for all shares of Biofrontera AG. The offer document was published on July 15, 2022. The offer document was transmitted to Biofrontera AG by Deutsche Balaton AG on July 20, 2022. The acceptance period for the offer expired on August 12, 2022.

No other events occurred after the balance sheet date.

Leverkusen, August 18, 2022

Paul Böckmann

Biofrontera AG

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 18, 2022

Biofrontera AG

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