Biofrontera

Deep in dermatology

Biofrontera AG

6M 2021 half-year financial results

Year-to-date highlights 2021

- Increase in product revenue by 35% in the first half of 2021 compared with the same period of the previous year
- Strong recovery in sales performance since mid-March 2021, with Q2 2021 sales exceeding those of 2019, prior to the onset of pandemic-related sales decline in 2020.
- Completion of the capital increase in February 2021 with gross proceeds of approximately EUR 24.7 million.
- Submission of two applications to the U.S. Food and Drug Administration, intended to allow the simultaneous use of up to three tubes of Ameluz® per photodynamic therapy (PDT) on the one hand and, in parallel, to obtain approval for a larger red-light lamp, the RhodoLED® XL.
- Change in the composition of the Management Board with Ludwig Lutter as the new CFO of Biofrontera AG as of March 1, 2021.
- Announcement of the intention to seek an IPO of Biofrontera Inc. shares on the US stock exchange Nasdaq.
- Signing of a license and supply agreement with Medac for the commercialization of Ameluz® in Poland.

Key figures in accordance with IFRS

in EUR thousands	6M 2021		6M 2020	
Results of operations				
Sales revenue	13,094	100%	16,117	100%
Gross profit on sales	11,082	85%	14,625	91%
Loss from operations	(7,583)	-58%	(4,327)	-27%
EBITDA	(5,768)	-44%	(697)	-4%
EBIT	(7,391)	-56%	(4,519)	-28%
Loss before income tax	(8,835)	-67%	(5,233)	-32%
Loss after income tax	(8,872)	-68%	(5,572)	-35%

in EUR thousands	June 30, 2021	December 31, 2020
Net assets		
Total assets	72,634	56,391
Non-current assets	29,459	30,264
Cash and cash equivalents	32,623	16,546
Other current assets	10,552	9,580
Non-current liabilities	40,090	40,730
Current liabilities	10,971	8,286
Equity	21,574	7,375

	June 30, 2021	December 31, 2020
Employees	159	149
Biofrontera share		
Number of shares outstanding	56,717,385	47,747,515
Share price (XETRA closing price in EUR)	2.75	3.05

Interim group management report for the first half of the 2021

Basis of the Biofrontera Group

Group structure

As of June 30, 2021, the Biofrontera Group (hereinafter also called "Biofrontera", "Biofrontera Group", "Group" or the "Company") consists of a parent company, Biofrontera AG and 5 (December 31, 2019: 5) wholly owned subsidiaries. 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. Biofrontera Inc.'s headquarters are in Woburn, Massachusetts, USA.

On July 6, 2021, the Company announced its intention for an initial public offering (IPO) of Biofrontera Inc. in the United States. At the time of publication of this half-year report 2021, the IPO has not been completed and Biofrontera AG continues to hold 100% of the shares in Biofrontera Inc. (see also section "Events after the interim balance sheet date" in the notes to the financial statements).

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®. 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. Biofrontera Inc. is responsible for the marketing of all Biofrontera Group products in the USA, including the in-licensed drug Xepi®.

Production of Ameluz® for all markets served by Biofrontera is carried out by a contract manufacturer in Switzerland. The PDT lamp is manufactured at Biofrontera's headquarters in Leverkusen, Germany. The production of Xepi® is the responsibility of the licensor Ferrer Internacional S.A., which supplies Biofrontera with the finished product.

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 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® and Xepi®. 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 global positioning and market potential of our products Ameluz® and Xepi®, 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® as well as broader distribution of Xepi®.

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. Ameluz® has been available in the UK for several years, but has only 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.

Our US-subsidiary, Biofrontera Inc., was set up as the commercial arm of Biofrontera in the USA. The US-subsidiary has established all functions and obtained all licenses required for a sales company in the pharmaceutical and medical device sector. Departments supporting sales, such as Finance, Customer Service, Market Access, Medical Affairs, Compliance, Quality Assurance, Logistics, etc. were established

locally. Other group functions necessary for a pharmaceutical company, such as management of regulatory approvals, interaction with regulatory authorities, patents, manufacturing, IT, regulatory relevant clinical trials, etc. continue to be provided exclusively by the German companies of the Biofrontera Group with worldwide responsibility.

Products

Ameluz® and BF-RhodoLED®

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 significance 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.

The medical device BF-RhodoLED® is a lamp with LEDs emitting light with a wavelength of about 635 nm. 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 BF-RhodoLED® combines a controlled and constant light output in the desired wavelength with easy and clear operation and energy efficiency. In the European version, 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® is available throughout the EU as well as in the USA.

Xepi®

The acquisition of Cutanea Life Sciences, Inc. in March 2019 has enabled Biofrontera to market a FDA-approved drug that has been introduced in the US market. Xepi® (ozenoxacin cream, 1%) contains a non-fluorinated quinolone that not only inhibits bacterial growth but also kills the bacteria directly. This results in an unusually rapid and sustained efficacy of the drug. It is the first new topical antibiotic to enter the American market in 10 years. The approved indication is impetigo, a common skin infection. Xepi® has an excellent safety profile that even allows for use on infants from the age of two months. To date, no antibiotic resistance to Xepi® is known and it has been specifically approved by the FDA for the treatment of certain antibiotic-resistant bacteria.

The drug Xepi® in-licensed by Biofrontera is protected by two patent families in the USA and other countries. With regard to the USA, patent protection applies to the composition of Xepi® until January 29, 2032 and for the approved treatment of impetigo until December 15, 2029. Thus, approval of generic drugs is not expected before 2032.

Belixos®

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated 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. The Belixos® series includes the following products: Belixos® Liquid and Belixos® Protect.

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 the subsidiary Biofrontera Inc. which was founded in March 2015. All key positions in the USA were filled locally and the development of distribution structures was further advanced in the reporting period. Our US sales and marketing team currently consists of around forty employees. The sales force is supported by our Scientific Advisory team, our Market Access and our Customer Service Team. Since its launch, we have sold Ameluz® worth well over EUR 50 million in the United States, thus establishing the product in the market. In March 2019, Biofrontera acquired all shares of Cutanea Life Sciences, Inc. and was thus able to expand its sales in the USA with the FDA-approved drug Xepi®.

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. In Spain, the price was reduced by decree of the Ministry, against which the Company filed an administrative complaint as well as a lawsuit.

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 force 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 started with the delivery of the first batch of Ameluz® in June 2021.

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 expected in 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 around 2 to 3% of the total population. However, the number of people suffering from the disease is probably higher. In 2020, a total of 814,410 prescriptions were issued for the treatment of AK (previous year: 831,073). Self-applied topicals such as prescription creams and gels containing active ingredients were used most widely, taking a market share of 92.9%, followed by PDT (the combination of a topically applied drug with light therapy) at 7.1% (previous year: 93.4% and 6.6%, respectively). Due to the impact of the coronavirus crisis and the market exit of a widely used topical drug at the beginning of 2020, the overall AK market declined by 2% in 2020. However, PDT treatments were able to slightly increase market share in the process, mainly due to the growth in sales of Ameluz®.

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. 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®, our market share in the PDT drug segment was approximately 62.3% in 2020, compared to approximately 57.0% in 2019. The continued uptake of daylight PDT has allowed Ameluz® to prove itself as a strong leader in the PDT market against competing products. We estimate that daylight PDT will continue to capture additional market share previously reserved for self-applied topical creams. The fact that Ameluz® is reimbursed by statutory health insurers when prescribed for daylight PDT is particularly interesting. Thus, the number of patients who have access to treatment with Ameluz® has multiplied, which is also reflected in an increase in prescriptions for Ameluz® in Germany of around 17% in 2020.

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 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.

Market overview and competitive situation in the USA

The United States represents the most important pharmaceutical market in the world and is also Biofrontera's major sales market. According to the Skin Cancer Foundation, actinic keratosis affects approximately 58 million people in the USA. In 2020, we estimate a total of 12.7 million treatments for actinic keratosis were performed. The US market for actinic keratosis treatment differs significantly from the European market. In the United States, the most common treatment for actinic keratosis remains cryotherapy, with approximately 11 million procedures performed per year in 2020 and an 86.3% market share. Topical drugs for the treatment of AK took a market share of about 11.9% in the reporting year, followed by PDT drugs at 1.8%. Simple curettage is generally not used to treat actinic keratosis in the US. As in Germany, the overall market, i.e. the number of total AK treatments, declined in 2020 due to the coronavirus crisis. In the USA, we saw a decline of 17% compared to the previous year (15. 1 million treatments). Rising infection rates and the associated official recommendation by the American Academy of Dermatology to provide patients with remote diagnosis and treatment whenever possible led to significantly declining patient numbers and widespread, albeit temporary, closures of physicians' offices.

In 2020, the market share within the PDT drug segment in our largest sales market for Ameluz® was 24.5%, compared to approximately 22.6% in 2019. We were thus able to slightly improve our market positioning compared to competing PDT product despite the corona crisis and greatly reduced face-to-face interaction in doctors' offices. Our goal is to continue to improve the market positioning of Ameluz® to become the leading PDT drug for the treatment of AK in the United States. In addition, we believe there is an opportunity to expand the PDT market as a therapy for the treatment of actinic keratosis as a first-line option compared to cryotherapy due to the advancement of the medical understanding of how squamous cell carcinomas develop from actinic keratoses as well as reimbursement options available to the physicians.

Market overview for topical antibiotics in the USA

As described in the "Products" section, the acquisition of Cutanea Life Sciences, Inc. in March 2019 enabled the Company to expand its U.S. portfolio with the addition of the drug Xepi®, which was already approved by the FDA and launched in the U.S. market. The approved indication is impetigo, a common skin infection primarily in children. Xepi® has an excellent safety profile, even allowing its use in infants

as young as two months of age. To date, there is no known antibiotic resistance to Xepi® and it has been specifically approved by the FDA for the treatment of certain antibiotic-resistant bacteria.

The U.S. market for topical antibiotics is dominated by generic products containing the active ingredient mupirocin. American dermatologists write about 1.5 million prescriptions annually for drugs in indications where Xepi® may be effective. Rising resistance to known antibiotics is a problem taken very seriously by American physicians. Although sales from Xepi® are still low, we are confident that Xepi® is an innovative, promising product with great market potential in our portfolio. Xepi® is the next innovation for the American dermatology market.

Personnel matters

Employees

As of June 30, 2021, the Biofrontera Group had 159 employees (December 31, 2020: 149) who were distributed as follows:

	June 30, 2021	December 31, 2020
Total number of employees	159	149
Full-time	137	127
With doctorate	26	22
By business segments	159	149
Production	15	16
Research and development	4	5
Clinical and regulatory tasks	16	16
Marketing and sales	63	60
Quality management	8	7
Management, business development, finance, HR and administration	53	45
By countries	159	149
Germany	84	81
USA	63	56
Spain	9	9
United Kingdom	3	3

In order to remain attractive as an employer in the competition for employees in the future, the Company must continue to be in a position to offer attractive compensation benefits and employment conditions in line with the market. This includes, among other things, the share- or securities-based compensation under our employee option program and the compensation from our stock appreciation rights program.

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 is the responsibility of Biofrontera Pharma GmbH. 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, 20 people were employed in research and development as well as regulatory affairs (previous year: 21).

Development 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 thus an

increase in Ameluz® sales. The application for approval was submitted to the FDA in March 2021. In the June 2021 meeting with the FDA, the regulatory agency confirmed that the data are sufficient for the submission and has since initiated the evaluation process.

Phase I and pharmacokinetics study with Ameluz®-PDT

In October 2020, the Company was able to complete the phase I pharmacokinetics study (PK study), which tested the safety of photodynamic therapy (PDT) with simultaneous use of three tubes of Ameluz® on larger or multiple areas. Subsequently, the study data were analyzed, the study report was written and incorporated into the registration dossier (NDA). In February 2021, the Company announced that it had submitted an application to the FDA to amend the product information, which currently limits use to one tube of Ameluz® per treatment.

In the June 2021 meeting with the FDA, the submission was discussed. The regulatory agency did not express any concerns related to efficacy or to the results from the phase I pharmacokinetics study underlying the application. However, to amend the product information, which currently limits the use to one tube of Ameluz® per treatment, the FDA recommended the submission of expanded safety data. The FDA agreed with the proposal to observe systemic and local side effects during treatment with three tubes of Ameluz® in 100 patients. This safety study is scheduled to start in the second half of 2021.

PDT illumination protocol

Following the phase I safety study, these same clinical centers are scheduled for a phase III trial for the treatment of actinic keratoses on the face and scalp with 3 tubes of Ameluz® and the RhodoLED® XL lamp. A unique feature of this study is the investigation of an illumination protocol for which Biofrontera has filed a patent application, in comparison with the standard protocol currently used. The aim of the study is to evaluate the efficacy and safety of AK treatment on the face and scalp with 3 tubes of Ameluz® in combination with the new RhodoLED® XL, while reducing pain during illumination using an innovative, dynamic illumination protocol.

Phase III trial for the treatment of actinic keratoses on the extremities or trunk/neck

Comparable to the European approval expansion of Ameluz® for the treatment of mild and moderate actinic keratoses on the extremities and trunk/neck with PDT, the Company is currently preparing phase III trials for this approval expansion in the USA. Patient recruitment is expected to start in the first half of 2022.

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

To further increase our growth potential in the US market in the medium term, we are currently conducting a clinical trial in the USA for the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our BF-RhodoLED® lamp. We have been working intensively on patient recruitment since September 2018. To date, approximately 60% 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 only drug in the United States for the treatment of superficial BCC with PDT.

Phase II trial for the treatment of mild to severe acne

With regard to the potential expansion of the Ameluz® approval to moderate and severe acne in the USA, the Company has finalized the design of the phase IIb trial, taking into account the regulatory recommendations agreed upon with the FDA in 2020. A multicenter, randomized, double-blind study with four arms is planned for conventional PDT with Ameluz® involving 126 patients aged 16 years and older. Ameluz® incubation times of one and three hours will be compared with placebo. The aim of the study is to collect data on the efficacy and safety when using Ameluz® PDT for moderate and severe acne. As previously announced, the trial is scheduled to start in the second half of 2021.

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 the 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. 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" 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. In addition, a continuation-in-part application was filed in the USA on April 19, 2021.

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, for which a continuation-in-part application was also filed in the USA on March 29, 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.

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. Patent protection expires on January 31, 2034.

Xepi®

The drug product Xepi®, in-licensed by Biofrontera, is protected by two patent families in the USA as well as other countries. As far as the USA is concerned, patent protection exists for the active ingredient molecule ozenoxacin contained in Xepi® until November 09, 2023, for the composition of Xepi® until January 29, 2032 and for the treatment of impetigo, for which it is approved, until December15, 2029 (for more information see section "Products").

Management report for the first six months of the 2021 financial year

Business performance

Following the challenges resulting from the COVID 19 pandemic, Biofrontera Group saw a significant recovery in sales development in the first half of 2021. Moreover, in our key market, the USA, the Company has been achieving sales comparable to pre-pandemic levels again since the mid-March.

For the period January 1 to June 30, 2021, Biofrontera Group generated total sales of EUR 13.1 million, a 19% decrease compared to EUR 16.1 million in sales in the same period last year. Total revenue in the prior-year period included a one-time payment of EUR 6.0 million received by the Company under the license agreement signed on April 20, 2020 from Maruho Co., Ltd. (Maruho). Revenues from product sales in the first half of 2021 were EUR 13.1 million, up 35% compared to EUR 9.7 million in the first half of 2020. The year-on-year sales recovery already perceived in mid-March 2021, especially in our largest sales market, the U.S., continued, based on the recovery of the general pandemic situation in the U.S. as well as in Germany.

Due to the pandemic, sales development in the reporting period is compared to sales in the first half of 2019 for better comparability. As a result, a slight decline of 5% in product sales was recorded across all markets in the first half of 2021 compared to 2019 (EUR 13.7 million). The lower product sales are mainly due to the months of January and February 2021, which were still affected by the pandemic and which had a strong impact on sales, especially in the USA. A comparison of monthly product sales in 2021 with those in 2019 also shows a significant recovery in sales from mid-March of this year in the USA, which is the largest sales market. In the second quarter of 2021, total product sales already exceeded those in 2019.

Commercialization of Ameluz® in the USA

In the USA, the Company generated revenues from product sales in the amount of EUR 8.7 million in the first half of the year, compared to EUR 6.3 million in the same period last year (+38%). While sales in the USA in January and February 2021 were significantly lower than in the previous year due to the pandemic, Biofrontera Group was able to record a considerable year-on-year sales recovery as early as mid-March 2021.

Compared to the product sales in 2019, the Company recorded a decrease of 15% in the months of January to June 2021. As mentioned above, product sales in January and February 2021 were still heavily impacted by the pandemic. However, second-quarter revenue from sales of Ameluz® in the U.S. increased by about 7% compared to the second quarter of 2019.

Commercialization of Ameluz® in Europe

In Germany, the Company generated product sales of EUR 2.7 million compared to EUR 2.4 million in the same period last year, an increase of 15%.

Compared to the first half of 2019, i.e. before the pandemic, the Company recorded an increase of around 26% for the current reporting period. To complement this, it is worth mentioning that revenues from product sales in Germany increased in 2020, despite pandemic-related restrictions and the initial "Corona shock freeze" in April 2020. This was aided by the possibility of daylight PDT, which can be performed without direct contact with a physician, and the March 2020 EU approval expansion to include treatment of actinic keratoses on trunk and extremities.

In the rest of Europe, sales improved by 78% to EUR 1.7 million, compared to EUR 1.0 million in the first half of 2020. Here, the Company recorded a large increase in sales in the second quarter particularly compared to the second quarter of 2020, in part because June 2021 sales included the first batch of Ameluz® for reintroduction in the Scandinavian market by Galenica AB. Compared to the first half of 2019, the Company generated approximately 27% more sales in the 2021 reporting period. Sales with distribution partners in other European countries account for only a small share of total sales.

Effects of the COVID-19 pandemic

As a result of the coronavirus crisis, the number of treatments during the comparison year 2020 declined, leading to a sharp drop in sales, particularly in our most important sales market, the United States. On March 20, 2020, i.e. shortly after the pandemic spread of the virus became known, the Company therefore announced that it would take comprehensive cost-cutting and cost-control measures on a precautionary basis.

Due to the COVID-19 crisis, the challenging business environment in 2020 has impacted the valuation of some of the Company's assets and liabilities. The reduced sales of Xepi® led to a reassessment of the medium-term business and earnings prospects for Xepi® as well as the liability to Maruho in the first quarter of 2020 and thus to an impairment of the Xepi® license.

Regulatory and clinical progress

On the regulatory side, the Company also made progress in the first half of 2021. In February and March 2021, the Company announced two submissions to the U.S. Food and Drug Administration (FDA), enabling the simultaneous use of up to three tubes of Ameluz® per photodynamic therapy (PDT) on the one hand, while seeking approval for a larger red-light lamp, the RhodoLED® XL, on the other. In June 2021, the meeting with the FDA previously announced for both submissions took place, in which the further proceeding was determined. With regard to the approval process of RhodoLED® XL, the FDA has confirmed that the data are sufficient for the submission and that the evaluation process has been initiated.

Further, the meeting with the FDA included the other submission, the application for amendment of the product information to extend the posology allowing the simultaneous use of three tubes of Ameluz®. The regulatory agency did not express any concerns related to efficacy or to the results from the phase I pharmacokinetics study underlying the application. However, to amend the product information, which currently limits the use to one tube of Ameluz® per treatment, the FDA recommended the submission of expanded safety data. The FDA agreed with the proposal to observe systemic and local side effects during treatment with three tubes of Ameluz® in 100 patients. This safety study is scheduled to start in the second half of 2021.

Completion of the capital increase resolved on May 28, 2020

On February 26, 2021, the Company announced the completion of the capital increase resolved by the annual general meeting on May 28, 2020. In total, the Company issued 8,969,870 new ordinary shares, bringing their total number to 56,717,385 after registration in the Commercial Register. The capital measure was fully placed, with the Company raising total gross funds of approximately EUR 24.7 million.

Change in the composition of the Management Board

On February 2, 2021, the Company announced a change in the composition of the Company's Management Board. Effective March 1, 2021, Mr. Ludwig Lutter was appointed as the new Chief Financial Officer (CFO) of Biofrontera AG. He took over from Thomas Schaffer and is responsible for Finance, Administration, Controlling and Human Resources within the Company. Thomas Schaffer left the Company on February 28, 2021, in order to devote himself to new personal endeavors outside the Company. The change in the finance department was a result of the succession planning by the Supervisory Board and the Management Board already announced in summer 2020.

Biofrontera Group financial position and performance

Result of operations

The results of operations as of June 30, 2021 are as follows:

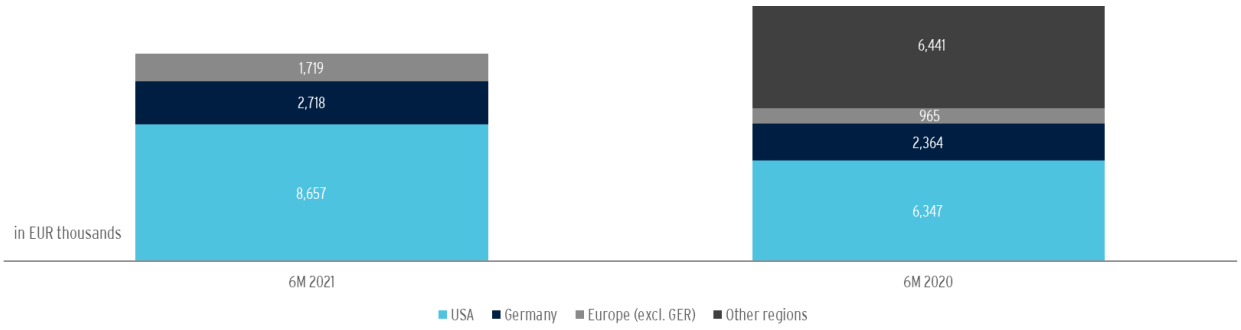
in EUR thousands	6M 2021	6M 2020
Sales revenue	13,094	16,117
Gross profit on sales	11,082	14,625
Research and development costs	(2,921)	(2,389)
General and administrative costs	(5,553)	(4,413)
Sales and marketing costs	(10,191)	(12,151)
Loss from operations	**(7,583)**	**(4,327)**
Other expenses and income	192	(192)
EBITDA	**(5,768)**	**(697)**
EBIT	**(7,391)**	**(4,519)**
Interest result	(1,444)	(714)
Loss before income tax	**(8,835)**	**(5,233)**
Loss after income tax	**(8,872)**	**(5,572)**

Sales revenue

During the first half of 2021, Biofrontera Group generated revenues in the amount of EUR 13,094 thousand, a decrease of 19% compared to last year's figure (previous year: EUR 16,116 thousand). Total revenues in the prior-year period included a one-time payment of EUR 6,000 thousand received by the Company as part of the license agreement signed on April 20, 2020 with Maruho Co., Ltd. (Maruho). Revenues from product sales in the amount of EUR 13,094 thousand were generated, an increase of 35% compared to the first half of 2020 (previous year: EUR 9,676 thousand).

In the U.S., the Company generated revenues from product sales of EUR 8,657 thousand in the first half of 2021, compared to EUR 6,347 thousand in the same period of the previous year, an increase of 36%. This includes EUR 53 thousand (previous year: EUR 157 thousand) from revenues with the product Xepi®. While revenues in the USA in January and February 2021 were significantly below those of the previous year due to the pandemic, Biofrontera Group has recorded a considerable year-on-year revenue recovery starting as early as mid-March 2021.

Sales in Germany increased by EUR 354 thousand or 15% year-on-year to EUR 2,718 thousand (previous year: EUR 2,364 thousand). In other European countries, sales improved by 78% to EUR 1,719 thousand (previous year: EUR 965 thousand). In this context, the Company recorded a large increase in sales particularly in the second quarter this year compared to the second quarter of 2020, partly because June sales included the first batch of Ameluz® for reintroduction by Galenica AB in the Scandinavian market. Sales from other regions, which included revenues from licensing fees as well as development projects with Maruho Co., Ltd. (Japan) in the previous year, were not generated in the reporting period (prior-year period: EUR 6,441 thousand).



Gross profit on sales

Gross profit decreased by EUR 3,543 thousand in the first half of 2021 to EUR 11,082 thousand compared to EUR 14,625 thousand in the prior-year period. The gross margin decreased to 85% compared to 91% in the prior-year period. This is mainly due to the revenues from licenses (one-time payment) of EUR 6,000 thousand included in the prior-year figure, which are not offset by any directly attributable cost of sales.

Research and development costs

Research and development costs increased by EUR 532 thousand to EUR 2,921 thousand in the first half of 2021 (previous year: EUR 2,389 thousand), mainly due to the effects of the cost-cutting measures implemented in 2020 as a result of the COVID 19 pandemic. Research and development expenses include the costs for clinical trials, but also the expenses for regulatory affairs, i.e. for the granting, maintenance and extension of our approvals.

General and administrative costs

General and administrative expenses increased by EUR 1,141 thousand to EUR 5,553 thousand in the first half of 2021 (previous year: EUR 4,412 thousand), mainly due to the cost-cutting measures implemented in the previous year as a result of the COVID 19 pandemic and the increase in the provision for litigation costs for the DUSA litigation in the USA (see Legal and compliance section).

Sales and marketing costs

Selling expenses amounted to EUR 10,191 thousand in the first half of 2021, a decrease of EUR 1,960 thousand or 16% compared to the previous year (EUR 12,151 thousand). The decrease is mainly due to the impairment loss of EUR 2,001 thousand on the Xepi® license included in the prior-year figure. Selling expenses mainly include the costs for our own sales force in Germany, Spain, the United Kingdom, and the United States, as well as marketing expenses.

EBITDA and EBIT

In the 2021 financial year, EBITDA and EBIT are introduced as key performance indicators for management reporting. Both have become established internationally as key performance indicators and are replacing the previously reported figure of profit from operating activities.

Group EBITDA includes earnings before interest, taxes, depreciation of property, plant and equipment and amortization of intangible assets and decreased by EUR 5,070 thousand to EUR -5,768 thousand in the first half of 2021 compared with the first half of the previous year (EUR -697 thousand).

Group EBIT includes earnings before interest and taxes and decreased by EUR 2,872 thousand compared to the first half of the previous year to EUR -7,390 thousand (previous year: EUR -4,519 thousand).

Interest result

Net interest expense amounted to EUR -1,444 thousand in the first half of the year (previous year: EUR -715 thousand) and mainly includes the interest expense for the EIB loan (EUR 899 thousand, previous year: EUR 869 thousand) and the fair value changes of the purchase price liability for the acquisition of Cutanea Life Sciences, Inc. in the amount of EUR 279 thousand (previous year: income of EUR 16 thousand) and of the performance component of the EIB loan in the amount of EUR 126 thousand (previous year: income of EUR 516 thousand).

Income taxes

This item includes actual income taxes of EUR 38 thousand (prior-year period: EUR 19 thousand) and deferred tax expenses of EUR 0 thousand (previous year: EUR 319 thousand) from the utilization of tax loss carryforwards at Biofrontera Pharma GmbH.

Net assets of the Biofrontera Group

in EUR thousands	June 30, 2021	December 31, 2020
Non-current assets	29,459	30,264
Current financial assets	37,025	20,579
Other current assets	6,150	5,547
Total assets	**72,634**	**56,391**
Equity	21,574	7,375
Non-current liabilities	40,090	40,730
Current financial liabilities	5,456	2,852
Other current liabilities	5,515	5,434
Total equity and liabilities	**72,634**	**56,391**

Non-current assets

Non-current assets totaling EUR 29,459 thousand (December 31, 2020: EUR 30,264 thousand) include the recognized deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of EUR 7,525 thousand (December 31, 2020: EUR 7,525 thousand) and the acquired Xepi® license in the amount of EUR 16,382 thousand (December 31, 2020: EUR 16,720 thousand).

Current financial assets

Current financial assets amounted to a total of EUR 37,025 thousand as of June 30, 2021. This includes cash and cash equivalents of EUR 32,623 thousand (December 31, 2020: EUR 16,546 thousand), and trade receivables of EUR 3,329 thousand (December 31, 2020: EUR 3,501 thousand).

Other current assets

Other current assets mainly include inventories in the amount of EUR 3,887 thousand (previous year: EUR 4,673 thousand) and accounting deferrals in the amount of EUR 2,204 thousand (previous year: EUR 817 thousand).

Equity

The Group reports equity of EUR 21,574 thousand under IFRS (December 31, 2020: EUR 7,375 thousand). The equity ratio increased from 13% to 30%.

Non-current liabilities

Non-current liabilities include financial liabilities (EUR 21,042 thousand; December 31, 2020: EUR 22,736 thousand) and other non-current financial liabilities (EUR 19,047 thousand; December 31, 2020: EUR 17,994 thousand). This includes in particular the purchase price liability for Cutanea Life Sciences, Inc. (EUR 18,669 thousand; December 31, 2020: EUR 17,811 thousand).

Non-current financial liabilities include the EIB loan incl. performance component totaling EUR 18,838 thousand (December 31, 2020: EUR 18,076 thousand) and liabilities from leases to be recognized in accordance with IFRS 16 totaling EUR 2,204 thousand (December 31, 2020: EUR 2,657 thousand).

Current financial liabilities

Current financial liabilities include in particular trade payables of EUR 2,207 thousand (December 31, 2020: EUR 1,623 thousand), the unconverted shares of the convertible bond 2017/2022 in the amount of EUR 2,076 thousand, and current liabilities from leases in the amount of EUR 1,010 thousand (December 31, 2020: EUR 1,057 thousand).

Other current liabilities

Other current liabilities amounted to EUR 5,515 thousand (December 31, 2020: EUR 5,434 thousand) and include in particular accruals of EUR 3,131 thousand (December 31, 2020: EUR 3,042 thousand) and other deferred liabilities of EUR 2,384 thousand (December 31, 2020: EUR 2,392 thousand).

Financial position of the Biofrontera Group

The Company's capital management regularly reviews the equity ratio of the Group and the publicly listed company. The aim is to ensure that equity is adequate in line with capital market expectations and creditworthiness towards national and international business partners. The Group's Management Board ensures that sufficient liquidity is available to all Group companies.

in EUR thousands	June 30, 2021	December 31, 2020
Cash flow from operating activities	(5,620)	(1,246)
Cash flow from investing activities	(287)	1,764
Cash flow from financing activities	21,764	(1,079)
Liquidity/Cash and cash equivalents	32,623	10,550
Non-current financial liabilities	21,042	22,305
Current financial debt	3,195	1,291
Net liquidity	8,386	(13,046)

Net cash flow from operating activities of EUR -5,620 thousand decreased by EUR 4,374 thousand compared to December 31, 2020 (EUR -1,246 thousand). This was mainly due to the cash inflow from non-recurring license payments of EUR 6,000 thousand in the prior-year period.

Net cash flow from investing activities amounted to EUR -287 thousand (December 31, 2020: EUR 1,764 thousand) and includes investments in property, plant and equipment and intangible assets of EUR 287 thousand (December 31, 2020: EUR 527 thousand).

The increased net cash flow from financing activities amounted to EUR 21,764 thousand (December 31, 2020: EUR -1,079 thousand) and mainly includes the proceeds from the capital increase carried out at the beginning of 2021.

The financial liabilities from the 2017/2022 convertible bond and the EIB loan have different maturities up to a maximum of 2024. The 2017/2022 convertible bond (EUR 2,076 thousand) and the first EIB tranche (EUR 13,033 thousand) mature in 2022. The second EIB tranche (EUR 5,805 thousand) matures in 2024. Annual purchase price payments for the Cutanea acquisition are expected from 2022 until 2030 depending on future profits from the sale of Xepi®.

The EIB loan is unsecured and guaranteed by our material subsidiaries. The loan has three different interest rate components. A variable interest component, which provides for quarterly interest payments on the outstanding amounts based on the 3-month EURIBOR rate plus a risk premium, a fixed component of 6% per annum, which is due at maturity, and a so-called performance component, which is also due at maturity and whose amount depends on the market capitalization of Biofrontera AG, but is limited to an interest rate of 4% per annum.

Cash and cash equivalents

Cash and cash equivalents amounted to EUR 32,623 thousand as of June 30, 2021 (Dec. 31, 2020: EUR 16,546 thousand).

Outlook and forecast of key financial indicators

Business environment and forecast

At the time of publication of this half-year report, the Company maintains its general outlook as published in the "Outlook" section of the Annual Report 2020 as well as the forecast of the key performance indicators for the fiscal year 2021. The Group continuous to expect revenue from product sales of EUR 25 to 32 million in fiscal year 2021. Our sales and thus business activities continue to depend on the infection trend and the general status of the pandemic in our sales markets.

EBITDA and EBIT have been introduced as key performance indicators in our reporting starting in 2021. Both have become established internationally as target metrics and replace the previously reported key performance indicator result from operating activities. Biofrontera Group expects EBITDA (loss) to be between EUR (11) million and EUR (14) million and EBIT (loss) between EUR (13) million and EUR (16) million in 2021.

From today's perspective, both Biofrontera Group and Biofrontera AG have sufficient liquidity available for the coming 12 months, given the earnings expectations as well as a level of cash and cash equivalents of EUR 32.6 million for the Group as of June 30, 2021. Taking into account the capital increase carried out in February 2021 and the expected earnings development in 2021, the level of liquidity at the end of the year is expected to be significantly above the 2020 level.

However, changes to the Group' s structure in connection with the planned IPO of Biofrontera Inc. (ad hoc announcement of July 6, 2021) may affect the full-year 2021 guidance of the Biofrontera Group.

Risk and opportunity report

A detailed description of the risks and opportunities for the Group can be found in the Risk and Opportunity Report in the Group Management Report as of December 31, 2020. As of June 30, 2021, no significant changes have occurred in relation to the risks and opportunities described there, 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 through globalization and digitalization can exert a negative impact on the achievement of Biofrontera's goals in the context of macroeconomic developments. In addition, political developments in our markets can influence the structures relevant for Biofrontera in the respective healthcare sector.

In addition to effects on individual markets, global crises may arise that could significantly affect Biofrontera.

The ongoing COVID-19 pandemic may continue to have a negative effect on the Biofrontera Group's business operations. For example, the maintenance of business processes may be impaired by, among other things, the imposition of certain (local) government measures that may prevent full business operations, or by employees of either our Group or relevant suppliers becoming infected with COVID-19. However, the Management Board believes that appropriate measures can be taken to counteract such potential adverse effects.

For information on the risks to the Group's ability to continue as a going concern, please refer to the section Liquidity, profitability, access to capital markets in the Risk and Opportunity Report 2020 and below.

Liquidity, profitability, capital markets access and risks to the going concern status

Liquidity risks may arise from the Company's current loss-making situation and uncertainties regarding future business trends or may consist in not being able to exploit market potential in accordance with Biofrontera's business strategy due to insufficient liquidity.

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

Biofrontera Group may not be able to meet existing or future payment obligations due to insufficient availability of cash and cash equivalents. To date, Biofrontera Group has been able to meet its payment obligations at all times and has always succeeded in providing the necessary financing for its business operations through equity or debt funding. As a result of the drawdown of several tranches from the European Investment Bank loan, the down payment received under the license agreement with Maruho, the issuance of a convertible bond in August 2020 as well as the capital raise completed in February 2021, the Company has had sufficient liquidity at its disposal throughout the reporting period. On July 6, 2021, the Company announced plans for a potential initial public offering (IPO) of Biofrontera Inc in the United States. The main objectives of an IPO of Biofrontera Inc are to raise additional capital to finance the growth of its business, to create a public market for its shares and to facilitate future access to the capital market.

Legal and compliance

Biofrontera Group may be subjected to litigation or legal proceedings in the future. In particular, this includes risks arising from product liability, antitrust law, competition law, patent law, tax law and environmental protection. Risks may also arise in connection with publication and information obligations on the capital market. Inquiries and investigations on grounds of possible infringements of statutory or regulatory provisions may result in criminal and civil sanctions, including considerable fines or other financial disadvantages and these may harm the Company's reputation and ultimately have a negative effect on the Company's success and performance or our access to the capital market.

In the trial of DUSA Pharmaceuticals, Inc. (DUSA) filed in March 2018 with the District Court of Massachusetts against the Biofrontera Group, in October the further proceedings were referred to the decision by a jury. A trial date has been set for November 29, 2021. The lawsuit includes the alleged infringement of the since expired DUSA Patents No. 9,723,991 and No. 8,216,289 through the sale of BF-RhodoLED® in the USA, claims based on unauthorized use of alleged trade secrets as well as tortious interference with contractual relations and deceptive and unfair trade practices. DUSA has asserted considerable claims for damages in these proceedings. However, the Company considers these to be unfounded and unsubstantiated.
On June 11, 2018, Biofrontera Group filed a complaint in the United States District Court for the Southern District of New York against Deutsche Balaton AG, Wilhelm Konrad Thomas Zours, Delphi Unternehmensberatung AG, VV Beteiligungen AG, ABC Beteiligungen AG, Deutsche Balaton Biotech AG, and Axxion S.A., alleging violations of U.S. federal securities law and state common law in connection with actions taken by the defendants during a tender offer for Biofrontera AG's shares that were designed to defame Biofrontera Group and negatively impact its share price. On October 1, 2018, Axxion was voluntarily dismissed from the litigation. On December 6, 2018, the remaining defendants filed a motion to dismiss. The motion to dismiss was fully briefed to court on February 11, 2019. On July 8, 2019, prior to the court issuing a decision on the motion to dismiss, Biofrontera Group amended its complaint to include additional allegations regarding the defendants' tender offer that was the subject of the original complaint and allegations regarding a subsequent tender offer made by certain of the defendants in 2019, including that defendants have committed continuing and new violations of U.S. federal securities law. On August 19, 2019, defendants moved to dismiss the amended complaint. The motion was fully briefed on November 8, 2019. On March 27, 2020, the court issued a ruling granting in part and denying in part defendants' motion to dismiss, permitting certain of Biofrontera Group's U.S. federal securities law claims to move forward. The court also ordered that the parties conduct jurisdictional discovery in connection with all of the remaining claims and submit supplemental briefing on Biofrontera Group's common law claims. On June 10, 2020, at the parties' request, the court stayed the litigation until November 10, 2020, so that the parties could mediate the issues raised in the complaint as well as certain other disputes. In order to have sufficient time for the complex negotiations, the parties mutually agreed to extend the original deadline of November 11, 2020 until February 28, 2022. Deutsche Balaton AG, Wilhelm Konrad Thomas Zours and DELPHI Unternehmensberatung AG are among our shareholders.

Condensed interim consolidated financial statements as of June 30, 2021

Consolidated balance sheet as of June 30, 2021

Assets

in EUR thousands	June 30, 2021	December 31, 2020
Non-current assets		
Tangible assets	4,457	5,051
Intangible assets	17,478	17,688
Deferred tax	7,525	7,525
Total non-current assets	**29,459**	**30,264**
Current assets		
Financial assets		
Trade receivables	3,329	3,501
Other financial assets	1,073	531
Cash and cash equivalents	32,623	16,546
Total financial assets	37,025	20,579
Other assets		
Inventories	3,887	4,673
Income tax	0	5
Other assets	2,263	869
Total other assets	6,150	5,547
Total current assets	**43,175**	**26,126**
Total assets	**72,634**	**56,391**

Equity and liabilities

in EUR thousands	June 30, 2021	December 31, 2020
Equity		
Subscribed capital	56,717	47,748
Capital reserve	137,310	123,493
Capital reserve from foreign currency conversion adjustments	2,151	1,866
Loss carried forward	(165,732)	(152,709)
Loss for the period	(8,872)	(13,023)
Total equity	**21,574**	**7,375**
Non-current liabilities		
Financial debt	21,042	22,736
Other financial liabilities	19,047	17,994
Total non-current liabilities	**40,090**	**40,730**
Current liabilities		
Financial liabilities		
Trade payables	2,207	1,623
Current financial debt	3,195	1,139
Other financial liabilities	53	90
Total financial liabilities	5,456	2,852
Other liabilities		
Other provisions	3,131	3,042
Other current liabilities	2,384	2,392
Total other liabilities	5,515	5,434
Total current liabilities	**10,971**	**8,286**
Total equity and liabilities	**72,634**	**56,391**

Consolidated statement of comprehensive income for the first six months of the fiscal years 2021 and 2020

in EUR thousands	6M 2021	6M 2020
Sales revenue	13,094	16,117
Cost of sales	(2,012)	(1,491)
Gross profit from sales	**11,082**	**14,625**
Operating expenses		
Research and development costs	2,921	2,389
General and administrative costs	5,553	4,413
Sales and marketing costs	10,191	12,151
Result from operations	(7,583)	(4,327)
Amortization and depreciation	1,623	3,822
Other Expenses	(142)	(301)
Other Income	334	110
EBITDA	**(5,768)**	**(697)**
Amortization and depreciation	(1,623)	(3,822)
EBIT	**(7,391)**	**(4,519)**
Effective interest expenses	(197)	(807)
Interest expenses	(1,255)	(439)
Interest income	8	531
Result before tax	**(8,835)**	**(5,233)**
Income tax	38	338
Result for the period	**(8,872)**	**(5,572)**
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	285	166
Total result for the period	**(8,587)**	**(5,406)**
Basic/diluted earnings per share	(0.16)	(0.12)

Both the net result for the year and the consolidated result are fully attributable to the shareholders of Biofrontera AG.

Consolidated statement of changes in equity for the first six months of the fiscal year 2021 and fiscal year 2020

	Number of ordinary shares	Subscribed capital	Capital reserve	Capital from foreign currency conversion	Accumulated loss	Total
		EUR thousands	EUR thousands	EUR thousands	EUR thousands	EUR thousands
Balance as of Januuary 1, 2020	**44,849,365**	**44,849**	**118,103**	**(288)**	**(152,709)**	**9,955**
Loss for the period	-	-	-	-	(5,571)	(5,571)
Foreign currency conversion	-	-	-	165	-	165
Consolidated result	**-**	**-**	**-**	**(123)**	**(5,571)**	**(5,406)**
Increase in capital reserve from the stock option	-	-	188	-	-	188
Balance as of June 30, 2020	**44,849,365**	**44,849**	**118,291**	**(123)**	**(158,280)**	**4,737**
Loss for the period	-	-	-	-	(7,452)	(7,452)
Foreign currency conversion	-	-	-	1,990	-	1,990
Consolidated result	**-**	**-**	**-**	**1,990**	**(7,452)**	**(5,462)**
Conversion from convertible bond 2020/2021	2,638,150	2,638	5,179	-	-	7,817
Conversion of stock options from the stock option	260,000	260	325	-	-	585
Costs of equity procurement	-	-	(407)	-	-	(407)
Increase in capital reserve from the stock option	-	-	105	-	-	105
Balance as of December 31, 2020	47,747,515	47,747	123,493	1,867	(165,732)	7,375
Balance as of January 1, 2021	**47,747,515**	**47,747**	**123,493**	**1,867**	**(165,732)**	**7,375**
Loss for the period	-	-	-	-	(8,872)	(8,872)
Foreign currency conversion	-	-	-	284	-	284
Consolidated result	**-**	**-**	**-**	**284**	**(8,872)**	**(8,588)**
Capital increase	8,969,870	8,970	15,697	-	-	24,667
Costs of capital procurement	-	-	(2,000)	-	-	(2,000)
Increase in capital reserve from the stock option	-	-	120	-	-	120
Balance as of June 30, 2021	**56,717,385**	**56,717**	**137,310**	**2,151**	**(174,604)**	**21,574**

Consolidated cash flow statements for the first six months of the fiscal years 2021 and 2020

in EUR thousands	6M 2021	6M 2020
Cash flows from operations		
Loss before income tax	(8,835)	(5,233)
Adjustments to reconcile loss before income tax to cash flow into operations		
Income tax	(38)	(19)
Financial result	1,444	731
Depreciation	1,623	3,822
Losses from disposal of assets	3	(13)
Non-cash (income) and expenses	333	(117)
Changes in operating assets and liabilities		
Trade receivables	172	2,840
Other assets and income tax assets	(1,931)	537
Inventories	787	(319)
Trade payables	584	(1,956)
Provisions	89	(416)
Other liabilities	149	(1,103)
Net cash flow used in operational activities	**(5,620)**	**(1,246)**
Cash flows from investment activities		
Purchase of intangible and tangible assets	(287)	(527)
Business combinations (including cash and cash equivalents)	-	2,264
Proceeds from sale of intangible and tangible assets	-	27
Net cash flow from investment activities	**(287)**	**1,764**
Cash flows from financing activities		
Proceeds from capital increase	24,667	-
Costs of equity procurement	(2,000)	-
Leasing payments	(668)	(744)
Interest paid	(235)	(335)
Net cash flows from (used in) financing activities	**21,764**	**(1,079)**
Net increase/(decrease) in cash and cash equivalents	15,857	(561)
Changes from exchange rate differences	220	(8)
Cash and cash equivalents at the beginning of the period	16,546	11,119
Cash and cash equivalents at the end of the period	**32,623**	**10,550**

Select explanatory notes to the interim consolidated financial statements as of June 30, 2021

Information about the company

Biofrontera AG (www.biofrontera.com), registered in the commercial register of Cologne District Court, Department B under No. 49717, together with its wholly owned subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, all with head office at Hemmelrather Weg 201, 51377 Leverkusen, Germany, as well as the Spanish branch operation Biofrontera Pharma GmbH sucursal en España based in Cornellá de Llobregat, and Biofrontera Inc., which is based in Woburn, Massachusetts, U.S., research, develop and market dermatological products.

Summary of significant accounting policies

Basis for the preparation of the consolidated interim financial statements

In accordance with the provisions of section 115 of the Wertpapierhandelsgesetz (WpHG - German Securities Trading Act) in conjunction with section 117 of the WpHG, the half-year financial report as of June 30, 2021 comprises condensed interim consolidated financial statements, an interim Group management report and a responsibility statement by the legal representatives in accordance with the provisions of section 264 (2) sentence 3 and section 289 (1) sentence 5 of the German Commercial Code (HGB).

The interim consolidated financial statements are prepared on a going concern basis. If the improvement of the COVID-19 pandemic - particularly in the USA - and the associated sales recovery fail to materialize or are even less pronounced, the financing requirement would increase and would have to be implemented sooner, even taking into account the expected lower cost burden. However, if coverage of this further financing requirement is not possible in a timely manner, this would result in a threat to the going concern status of the Biofrontera Group. For further details regarding this significant uncertainty in connection with the going concern, we refer to the risk report of the interim group management report.

The condensed consolidated interim financial statements of Biofrontera AG as of June 30, 2021 were prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) for "Interim Financial Reporting" according to IAS 34, as they are to be applied in the European Union. Accordingly, they do not contain all the information and disclosures required for consolidated financial statements and should therefore be read in conjunction with the consolidated financial statements for the year ended December 31, 2019.

On August 19, 2021, the Management Board approved the half-year financial report of Biofrontera AG for publication.

Due to commercial rounding, rounding differences in the tables can arise.

The interim report as of June 30, 2021 does not contain separate segment reporting, as the activities of the Biofrontera Group are limited to one business segment as defined by IFRS 8. The entire operating activity is focused on the sale of dermatological products, in particular Ameluz® including the complementary products BF-RhodoLED® (PDT-lamp) and Belixos® as well as Xepi™, and is therefore uniformly monitored and controlled internally.

Changes in accounting standards

For the preparation of the condensed consolidated interim financial statements, the same accounting policies have been applied as for the consolidated financial statements as of December 31, 2020. The new IFRS rules to be applied for the first time as of January 1, 2021 have no material effect on the interim consolidated financial statements.

Basis of consolidation

The interim condensed financial statements as of June 30, 2021 include, as in the prior-year period, the interim 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 were included in the consolidated financial statements:

1. Biofrontera Bioscience GmbH, Leverkusen, Germany, with a direct interest of 100%
2. Biofrontera Pharma GmbH, Leverkusen, Germany, with a direct interest of 100%
3. Biofrontera Development GmbH, Leverkusen, Germany, with a direct interest of 100%
4. Biofrontera Neuroscience GmbH, Leverkusen, Germany, with a direct interest of 100%
5. Biofrontera Inc., Woburn, Massachusetts, U.S., with a direct interest of 100%.

The basis for the consolidation of the companies included in the consolidated financial statements were the interim financial statements of these companies as of June 30, 2021, prepared in accordance with uniform principles (or "Handelsbilanz II" according to IFRS). The financial statements as of June 30, 2021 were prepared on the basis of uniform 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 gained control of these subsidiaries. Subsidiaries are included in the consolidated financial statements until such time as the parent company no longer controls these companies.

All intercompany receivables and liabilities as well as income and expenses were eliminated in the course of consolidation. Interim results were eliminated.

Impact of the COVID-19-pandemic

The coronavirus crisis led to a declining number of treatments and thus to strong sales declines in our most important sales market, the U.S.A., especially in the last fiscal year, i.e. the comparative year 2020. On March 20, 2020, the Company announced that it was taking comprehensive measures to reduce and control costs during the COVID-19-pandemic.

The uncertain business outlook due to the pandemic had also impacted the valuation of certain assets and liabilities of the Company in 2020. Reduced sales of Xepi® led to a different assessment of the medium-term business and profit outlook for Xepi® and thus to a revaluation of both the balance sheet value of the Xepi® license and the purchase price liability to Maruho in the first quarter of 2020.

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

Sales revenue

in EUR thousands	6M 2021 Product revenue	6M 2021 Development revenue	6M 2021 Other	6M 2020 Product revenue	6M 2020 Development revenue	6M 2020 Other
Germany	2,718	0	0	2,364	0	0
Europe	1,719	0	0	965	0	0
U.S.	8,657	0	0	6,347	0	0
Other regions	0	0	0	0	441	6,000
Total	13,094	0	0	9,676	441	6,000

Revenue from product revenues generated in the U.S. includes revenue from finance and operating lease agreements concerning the BF-RhodoLED® lamps.

In the first six months of 2021, we generated EUR 22 thousand of income from operating leases (previous year period: EUR 31 thousand). We generated income of EUR 14 thousand from finance leases (previous year period: EUR 75 thousand).

Personnel costs

in EUR thousands	June 30, 2021	June 30, 2020
Wages and salaries	8,637	6,530
Social security charges	1,337	1,148
Costs for pension schemes	137	161
Total	**10,112**	**7,838**

Intangible assets

Intangible assets include the marketing license for Xepi® acquired as part of the acquisition of Cutanea Life Sciences, Inc. on March 25, 2019 in the amount of EUR 16,720 thousand. The acquisition costs of the license amounted to EUR 23,604 thousand translated at the acquisition date and will be amortized over a useful life of 139 months corresponding to the term of the license agreement.

Biofrontera uses external and internal sources of information to assess at each reporting date whether there are any indications of impairment or a reversal of impairment.

As of March 31, 2020, an impairment loss of EUR 2,001 thousand was recognized on the value in use of the license of EUR 21,981 thousand. Within the framework of the impairment in fiscal year 2020, term-specific cost of capital rates in the range of 8.87% to 9.07% were used. A change in the expected profits from the sale of Xepi® of +5% (-5%) would result in a change in the impairment of EUR 1,151 thousand; an increase or decrease in the weighted average cost of capital of 1% would result in a decrease in the impairment of EUR 1,550 thousand and an increase in the impairment of EUR 1,696 thousand, respectively.

Due to the COVID-19 pandemic, the planned re-launch to better position Xepi® was prevented. The resulting reduced sales of Xepi® have led to a reassessment of the medium-term business and earnings outlook.

As of June 30, 2021, Biofrontera has not identified any indication for impairment or reversal of impairment.

Trade receivables

Trade accounts receivable are mainly attributable to the sale of Ameluz®, the PDT lamp BF- RhodoLED®, Xepi® and the medical cosmetic product Belixos®. It is expected that all trade receivables will be settled within twelve months of the reporting date.

Allowances for doubtful accounts were made in the amount of EUR 62 thousand (previous year: EUR 36 thousand). As in the previous year, there were no overdue, non-value-adjusted receivables in a significant amount as of the reporting date.

Of the receivables, EUR 64 thousand (previous year: EUR 100 thousand) relate to finance leases of PDT lamps.

Inventories

in EUR thousands	June 30, 2021	December 31, 2020
Raw materials	1,436	1,557
Unfinished goods	325	390
Finished goods and products	2,126	2,727
Total	**3,887**	**4,673**

During the reporting period, impairment losses of EUR 28 thousand (previous year: EUR 414 thousand) were recognized on inventories.

Deferred Tax

As of June 30, 2021, deferred taxes on loss carryforwards amounting to EUR 7,525 thousand are recognized, unchanged from December 31, 2020. These are capitalized to the extent that they can probably be offset against future tax profits. This is based on a planning period of five years. These relate to the deferred tax assets to be recognized on loss carryforwards for Biofrontera Pharma GmbH. For the full fiscal year 2021 and also in the future, it can still be assumed that Biofrontera Pharma GmbH will generate positive results and thus utilize its tax loss carryforwards.

Equity

In accordance with IFRS, the Group reported equity of EUR 56,717,385 (December 31, 2020: EUR 47,747,515). It consisted of 56,717,385 registered shares with a notional value of EUR 1.00 each.

The fully paid-in share capital of the company amounts to EUR 56,717,385 as of June 30, 2021.

In 2006, the shares of Biofrontera AG were listed on the Regulated Market of the Düsseldorf Stock Exchange. In August 2012, upon application by 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.

The shareholder structure as of June 30, 2021, based on the respective latest mandatory shareholder disclosures, is as follows:

	June 30, 2021	December 31, 2020
Maruho Deutschland Co., Ltd., Osaka Japan All voting rights are attributed to Maruho Co., Ltd. through Maruho Deutschland GmbH,Düsseldorf, which is controlled by Maruho Co., Ltd.	13,399,965	13,399,965
Wilhelm Konrad Thomas Zours The voting rights are allocated to Mr. Zours through the chain of subsidiaries listed below according to voting rights disclosure: • DELPHI Unternehmensberatung AG • VV Beteiligungen AG • Deutsche Balaton AG • Deutsche Balaton Biotech AG • Sparta AG	16,990,199	14,218,773

	June 30, 2021	December 31, 2020
• ABC Beteiligungen AG • Heidelberger Beteiligungsholding AG • Altech Advanced Materials AG • Ming Le Sports AG • Strawtec Group AG		
Free float	26,327,221	20,128,777
Total	**56,717,385**	**47,747,515**

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 submitted a corresponding report. 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 by the respective shareholders; since then, they may have changed their holdings within the respective reporting limits without notifying the Company.

Financial liabilities

in EUR thousands	June 30, 2021	December 31, 2020
Non-current financial liabilities		
Convertible bond 2017/2022	-	2,003
EIB loan 2017	13,033	12,484
EIB loan 2019	5,805	5,591
Leasing liabilities	2,204	2,657
Total non-current financial liabilities	**21,042**	**22,736**
Current financial liabilities		
Convertible bond 2017/2022	2,076	-
Leasing liabilities	1,010	1,057
Other current liabilities	109	82
Total current financial liabilities	**1,119**	**1,139**

Other financial liabilities

in EUR thousands	June 30, 2021	December 31, 2020
Non-current other financial liabilities		
Purchase price liability (earn-out and start-up costs)	18,669	17,811
Liability from SAR program	378	183
Total non-current other financial liabilities	**19,047**	**17,994**
Current financial liabilities	**53**	**90**

Purchase price liability (earn-out and start-up costs)

The purchase price liability of EUR 18,669 thousand (previous year: EUR 17,811 thousand) resulting from the Cutanea acquisition, which took place in 2019, was discounted on the basis of the expected annual purchase price payments. The expected annual purchase price payments will be due from 2022 to 2030 depending on future profits generated from the sale of Xepi®. The expected profits from the sale of Xepi® and, consequently, the expected annual purchase price payments have been re-estimated in 2020 due to the current market situation influenced by the COVID 19 pandemic and the resulting delays in the market penetration of Xepi®. The purchase price liability in the nominal amount of USD 26.4 million / EUR 22.3 million (previous year USD 26.4 million / EUR 21.6 million) remains unchanged as of December 31, 2020. The start-up costs received in the nominal amount of USD 7.3 million (EUR 6.1 million) are to be repaid in approximately equal parts in 2022 and 2023.

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, 2021	December 31, 2020
Outstanding at the beginning of the period	727,750	0
Granted during the period	429,529	755,750
Forfeited during the period	211,000	28,000
Exercised during the period	-	-
Outstanding at the end of the period	946,279	727,750
Exercisable at the end of the period	-	-
Fair value at the end of the period	EUR 378,000	EUR 183,000
Cost during the period	EUR 195,000	EUR 183,000

The fair value of an SAR 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.

Reporting on financial instruments

The financial instruments held by the Biofrontera Group on the balance sheet date primarily consist of cash and cash equivalents, trade payables and receivables, other non-current financial liabilities as well as financial debt. Biofrontera does not deploy any financial derivatives, apart from the derivative embedded within the EIB loan (so-called performance component).

Financial assets

in EUR thousands	Fair Value as of June 30, 2021	Carrying amount as of June 30, 2021	Fair Value as of December 31, 2020	Carrying amount as of December 31, 2020
Financial assets at amortized cost				
Cash and cash equivalents	32,623	32,623	16,546	16,546
Trade receivables	3,329	3,329	3,501	3,501
Other financial assets	1,073	1,073	531	531
Total	**37,025**	**37,025**	**20,579**	**20,579**

Financial liabilities

in EUR thousands	Fair Value as of June 30,2021	Carrying amount as of June 30, 2021	Fair Value as of December 31, 2020	Carrying amount as of December 31, 2020
Financial liabilities at amortized cost				
Financial liabilities, current	(3,195)	(3,195)	(1,139)	(1,139)
Trade payables	(2,207)	(2,207)	(1,623)	(1,623)
Other financial liabilities	(53)	(53)	(90)	(90)
Financial liabilities, non-current	(19,742)	(19,742)	(21,561)	(21,561)
Total	**(25,198)**	**(25,198)**	**(24,413)**	**(24,413)**
Financial liabilities at fair value through profit or loss				
Financial liabilities, non-current	(1,300)	(1,300)	(1,174)	(1,174)
Other financial liabilities, non-current	(19,047)	(19,047)	(17,994)	(17,994)
Total	**(20,347)**	**(20,347)**	**(19,169)**	**(19,169)**

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

The performance component of the EIB loans (financial instrument at level 3 of the fair value hierarchy) as a further variable interest component and, at the same time, embedded derivative requiring separation, is subsequently measured at fair value at each reporting date and is allocated to the category "Financial liabilities at fair value through profit or loss". To simplify matters, the market capitalization at the end of the term is initially determined on the basis of the market capitalization at the respective valuation date (market capitalization based on the valuation date 90 previous trading days).

The performance-based interest payment for the respective tranches is determined on the basis of a notional equity ratio of 0.64% (EIB tranche 2017) and 0.20% (EIB tranche 2019) of the market capitalization (notional equity ratio). These are then discounted to the measurement cut-off date applying a market interest rate.

As of June 30, 2021, the discounted interest payment (carrying amount) or the fair value of the performance component of the EIB loan tranche 2017 amounted to EUR 996 thousand (previous year: EUR 908 thousand) and of the EIB loan tranche 2019 to EUR 304 thousand (previous year: EUR 266 thousand). The net losses of the performance component amounted to EUR 126 thousand (previous year: EUR -516 thousand).

The net losses on the purchase price liability reported under non-current financial liabilities amounted to EUR 279 thousand (previous year: EUR -16 thousand), with the net gains in the previous year being based on the revaluation, in particular the adjusted estimate of the purchase price liability.

The fair values of the performance component of the EIB loan would be EUR 130 thousand higher or lower if the market capitalization increased or decreased by 10%. The fair value of the purchase price liability would be EUR 797 thousand higher or lower, respectively, if the cash flows increased or decreased by 5% and EUR 915 thousand lower or higher, respectively, if the weighted average cost of capital increased or decreased by 1%.

The other financial liabilities continue to be allocated to the category "Financial liabilities measured at amortized cost". The carrying amounts correspond to the fair values to be reported.

Provisions

The companies included in the consolidated financial statements of Biofrontera AG face several threatened or pending legal proceedings, the outcome of which either cannot be determined or cannot be predicted due to the uncertainty associated with such legal proceedings. No provisions have been recognized for the claims asserted against Biofrontera, as the Executive Board does not believe that any claims will be enforceable.

As of the reporting date, provisions for litigation costs totaled EUR 2,200 thousand (previous year: EUR 1,940 thousand) for the pending proceedings in the USA and Germany. In the first half of 2021, EUR 129 thousand were utilized. Based on a current estimate of the outstanding litigation costs, further amounts of EUR 389 thousand were accrued.

Biofrontera assumes that the claims are unjustified and will defend itself vigorously against the claims, but cannot guarantee that it will be successful in doing so.

Biofrontera may incur further substantial costs in defending its legal position in the future, as in addition to internal resources, lawyers in the USA have also been mandated to defend the company. The costs incurred by Biofrontera as a result of this would not be reimbursed by the plaintiff due to the customs of the U.S. legal system, even in the event of a positive outcome of the proceedings.

Related party disclosures

Maruho Col., Ltd.

As a result of the acquisition of Cutanea, the research and development cooperation as well as a sublease agreement, the following relationships with the Maruho Group are in place:

in EUR thousands	June 30, 2021	December 31, 2020
Revenue from research collaborations	-	493
Revenue from license agreements	-	6,000
Income from the reimbursement of costs by Maruho	-	659
Income from subleases	17	33
Accounts receivables	-	-
Purchase price liability Cutanea (earn-out and start-up costs)	18,669	17,811
Other liabilties	-	-

Subsequent events

Biofrontera enters into license and supply agreement with Medac for the marketing of Ameluz in Poland

On July 23, 2021, the Company announced that Biofrontera Pharma GmbH, a wholly owned subsidiary of Biofrontera AG (NASDAQ: BFRA; Frankfurt Stock Exchange: B8F), and Medac Gesellschaft für klinische Spezialpräparate mbH. (Medac), signed an exclusive license and supply agreement for the marketing of both Ameluz® and BF-RhodoLED® in Poland. The agreement has a term of 5 years commencing with the start of sales in Poland.

Under the terms of the agreement, Medac will make an immediate one-time upfront payment of EUR 50,000 to the Company, plus an additional one-time payment of EUR 150,000 following receipt of the drug's reimbursement eligibility from the Polish health insurance providers. According to the agreement, Medac receives exclusive distribution rights for Poland. Once reimbursement eligibility has been granted in Poland, Biofrontera will supply Ameluz® to Medac at a fixed transfer price based on the expected net revenues. As it is custom

for the Company's other licensing agreements, Biofrontera will be responsible for regulatory affairs as well as manufacturing and quality control, while Medac will handle all aspects of commercialization and local regulatory and reimbursement in Poland.

Biofrontera Inc. seeks IPO in the USA

On July 6, 2021, the Company announced that its currently wholly owned U.S. subsidiary Biofrontera Inc.is seeking a separate initial public offering (IPO) in the United States.

The main objectives of an IPO of Biofrontera Inc. are to raise additional capital to finance the growth of its business, to create a public market for its shares and to facilitate future access to the capital markets. A registration statement relating to the securities to be offered in the IPO has been filed with the Securities and Exchange Commission but has not yet become effective.

Leverkusen, August 19, 2021

Prof. Dr. Hermann Lübbert
CEO and Chairman

Ludwig Lutter
CFO

Review report

To Biofrontera AG, Leverkusen

We have reviewed the condensed interim consolidated financial statements – comprising the condensed statement of financial position, the condensed statement of profit or loss and other comprehensive income for the period, the condensed statement of changes in equity, the condensed statement of cash flows and selected explanatory notes – and the interim group management report of Biofrontera AG, Lerverkusen, for the period from 1 January 2021 to 30 June 2021 which form part of the half-year financial reporting in accordance with section 115 German Securities Trading Act (Wertpapierhandelsgesetz – WpHG). The preparation of the condensed interim consolidated financial statements in accordance with those IFRS applicable to interim financial reporting as adopted by the EU, and of the interim group management report in accordance with the requirements of the German Securities Trading Act applicable to interim group management reports, is the responsibility of the Company's management. Our responsibility is to issue a report on the condensed interim consolidated financial statements and on the interim group management report based on our review.

We conducted our review of the condensed interim consolidated financial statements and the interim group management report in accordance with the German generally accepted standards for the review of financial statements promulgated by the Institut der Wirtschaftsprüfer (IDW). Those standards require that we plan and perform the review so that we can preclude through critical evaluation, with moderate assurance, that the condensed interim consolidated financial statements have not been prepared, in material aspects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU, and that the interim group management report has not been prepared, in material aspects, in accordance with the regulations of the German Securities Trading Act applicable to interim group management reports. A review is limited primarily to inquiries of Company employees and analytical assessments and therefore does not provide the assurance attainable in a financial statement audit. Since, in accordance with our engagement, we have not performed a financial statements audit, we cannot issue an auditor's report.

Based on our review no matters have come to our attention that cause us to believe that the condensed interim consolidated financial statements of Biofrontera AG, Leverkusen, for the period from 1 January 2021 to 30 June 2021 have not been prepared, in material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU, or that the interim group management report has not been prepared, in material respects, in accordance with the regulations of the German Securities Trading Act applicable to interim group management reports."

On publication or further submission of the condensed interim consolidated financial statements and or the interim group management report in a form other than that reviewed by us (including translations into other languages), a further statement will be required from us if our review report is cited or reference is made to our review.

Frankfurt am Main, den 19. August 2021

Warth & Klein Grant Thornton AG
Wirtschaftsprüfungsgesellschaft

Eckhard Lewe
Wirtschaftsprüfer

Maximilian Meyer zu Schwabedissen
Wirtschaftsprüfer

Responsibility statement

Affirmation of the legal representatives

To the best of our knowledge, and in accordance with the applicable reporting principles for interim financial reporting, the interim consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the Group, and the interim management report of the Group includes a fair review of the development and performance of the business and the position of the Biofrontera Group, together with a description of the principal opportunities and risks associated with the expected development of the Biofrontera Group for the remaining months of the financial year.

Leverkusen, August 19, 2021
Biofrontera AG

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