Biofrontera

Deep in dermatology

Biofrontera AG

Annual report 2020

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Biofrontera AG Annual Report 2020

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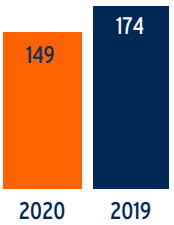
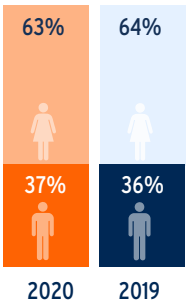
Key figures 2020

	Results and development 2020
Sales revenues	EUR 30.3 million
	compared to EUR 31.3 million in 2019
Loss from operations	EUR 7.6 million
	compared to EUR 23.4 million in 2019
Loss before income tax	EUR 12.7 million
	compared to EUR 4.8 million in 2019

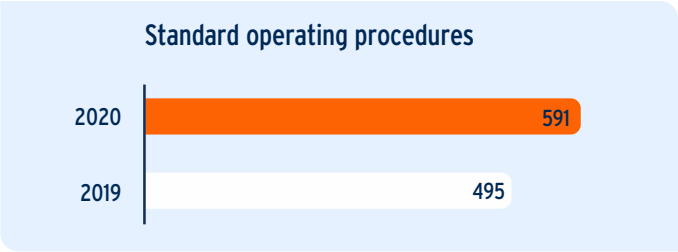
Non-finacial key performance indicators

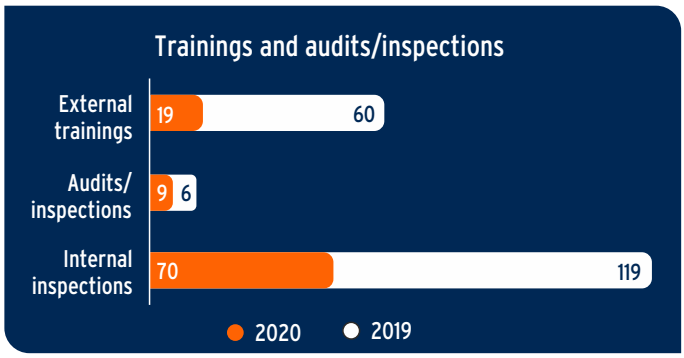
Employees





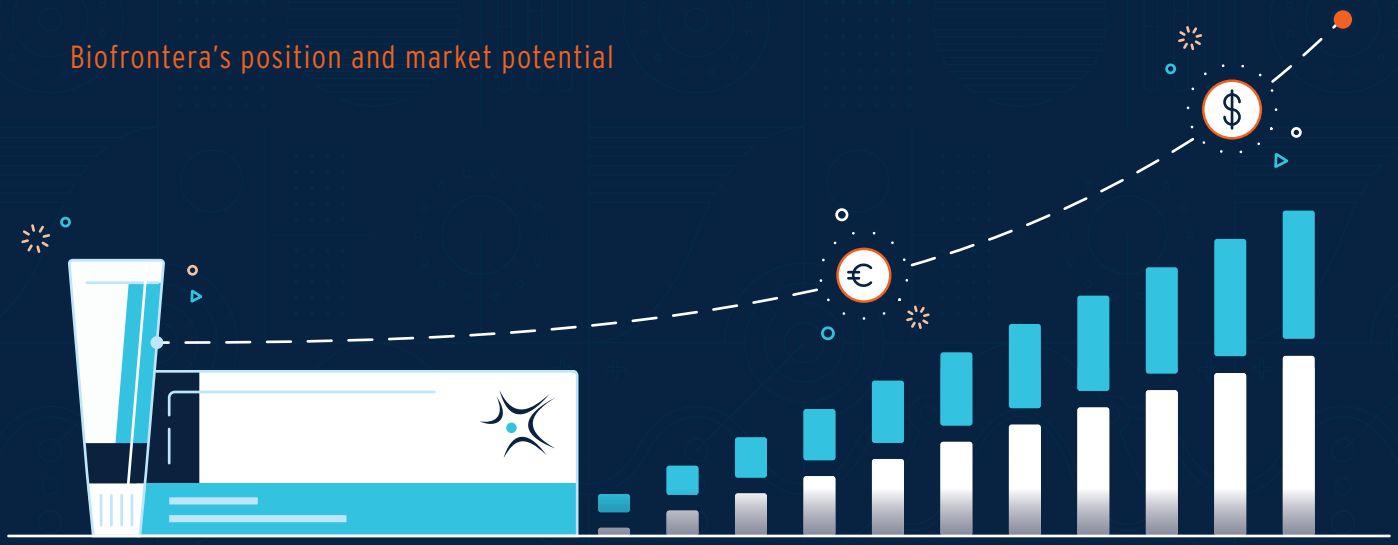
Quality management





The Opportunity for Ameluz®-PDT

Biofrontera's position and market potential



1 in 3 cancer diagnoses worldwide can be attributed to skin cancer[1]

Ameluz®-PDT describes is a light activated prescription drug for the lesion-directed and field-directed photodynamic therapy of mild to moderate actinic keratoses[2], premalignant lesions of the skin that can potentially develop into skin cancer if left untreated.[3]

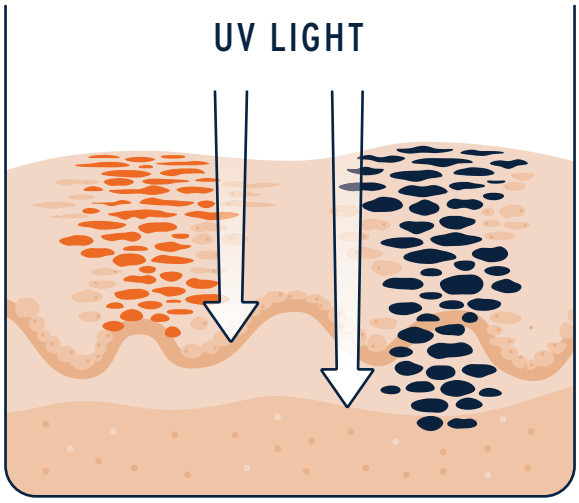
This unique therapy is well positioned for expansion.

[1]Zink, Hautarzt. 2017 Nov;68(11):919-928
[2]Ameluz SmPC (02/2021)
[3]www.awmf.org/leitlinien/detail/ll/032-022OL.html

ACTINIC KERATOSIS (AK)

- Most common precancerous skin condition[4]
- More prevalent in men, fair-skinned individuals, and those over age 40[3]

Since AK is caused by chronic sun damage, those with a history of tanning are more at risk, but even casual sun exposure can lead to AK when accumulated over time.[5]



Treating AK

Early and effective treatment is reasonable to reduce the risk of AK progression to skin cancer.

- One study found that approximately **10%** of AK lesions progressed to squamous cell carcinoma, the second most common skin cancer, within an average of two years.[6]
- AK treatment costs account for about **3.75%** of total skin disease medical cost.[7]

Treatment options include:

Cryotherapy/surgical procedures

Topicals

Photodynamic therapy (PDT): combination of prescription medication with illumination

[3]www.awmf.org/leitlinien/detail/ll/032-022OL.html; [4]Pinkus & Mehregan, Clin Plast Surg. 1980 Jul;7(3):289-300;
[5]Werner et al., J Eur Acad Dermatol Venereol. 2015 Nov;29(11):2069-79
[6]Fuchs & Marmur, Dermatol Surg. 2007 Sep; 33(9):1099-101; [7]Lim et al. 2017 J Am AcadDermatol 2017; 76 (5): 958-972

The potential for Ameluz®-PDT

Surgical procedures and cryotherapy for AK treatment are projected to lose market share.

- There's a need for therapies that don't physically destroy skin tissue or cause permanent scars.
- Additionally, surgery and cryotherapy lack a field-directed approach to treat AK lesions that aren't visible on the epidermis.[3]

Ameluz® has successfully increased market share in Germany and is poised for additional success in Biofrontera's major market, the U.S.

AMELUZ®-PDT HAS AN EFFICACY RATING OF MORE THAN 90% TOTAL CLEARANCE IN CLINICAL TRIALS.[8]

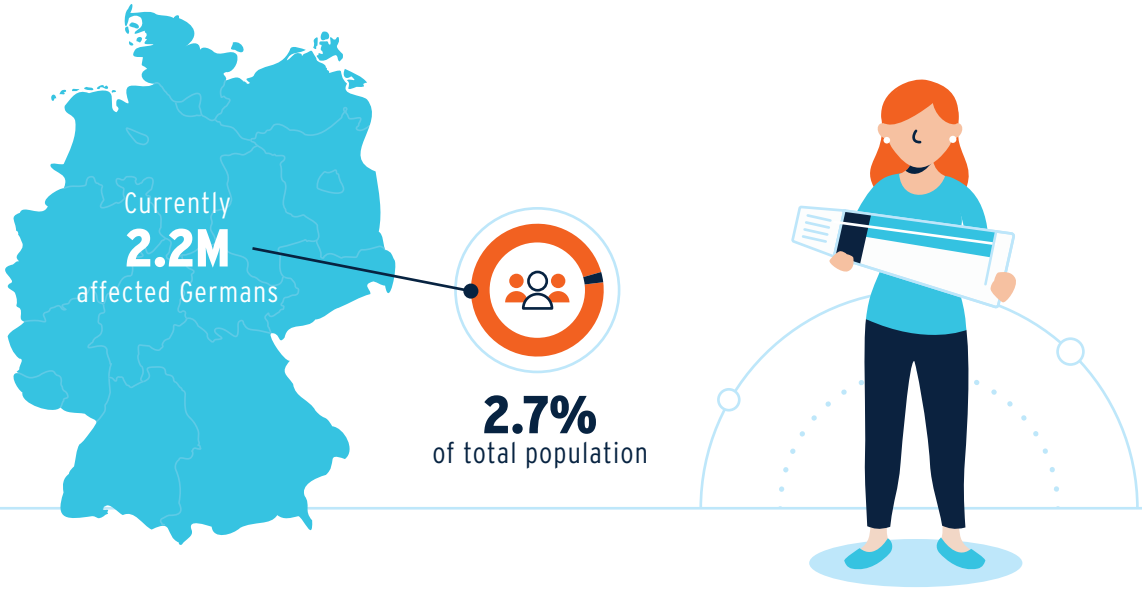
Strategic market expansion has made Ameluz® a leader in PDT in Biofrontera's domestic market Germany.

Ameluz®-dPDT (daylight PDT) is a more favorable option for European dermatologists and their patients than conventional PDT treatment.

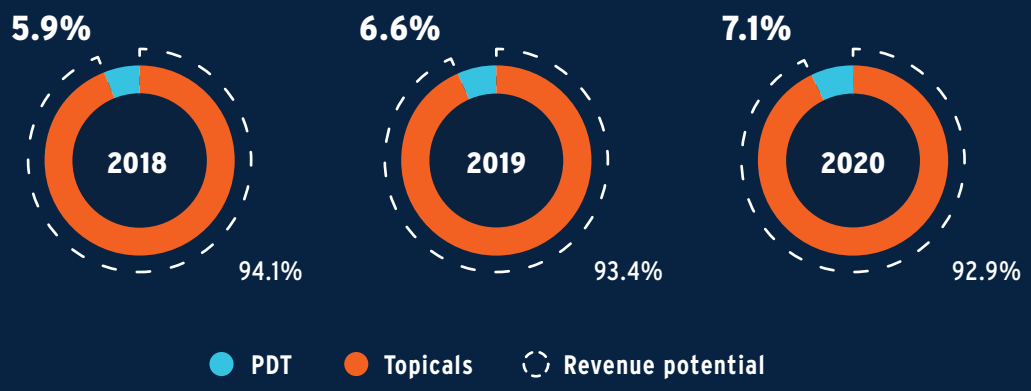
- Reimbursed & now available for all patients
- Simple application
- Less painful[9]

[3]www.awmf.org/leitlinien/detail/ll/032-022OL.html; [8]Reinhold et al., Br J Dermatol. 2016 Oct;175(4):696-705
[9]Dirschka et al., J Eur Acad Dermatol Venereol. 2019 Feb;33(2):288-297

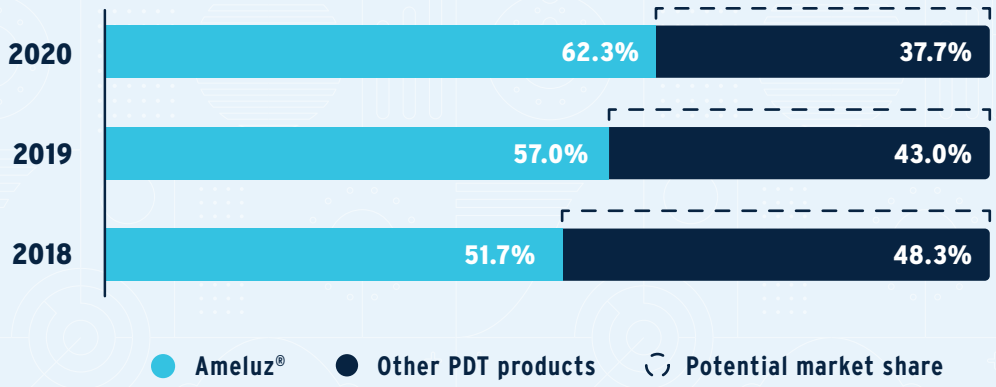
~1.7M AK patients treated annually[10]



German AK market by treatment option



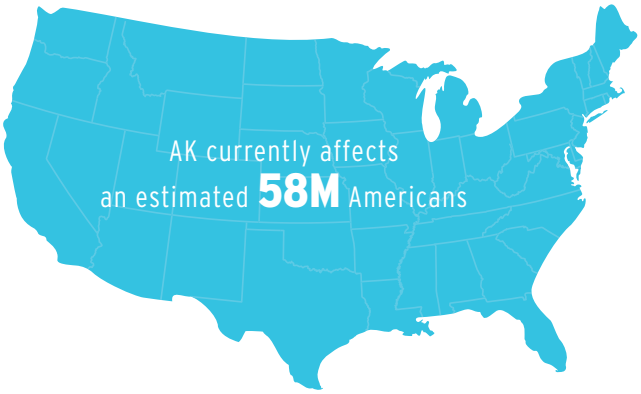
Share of Ameluz® in German PDT market

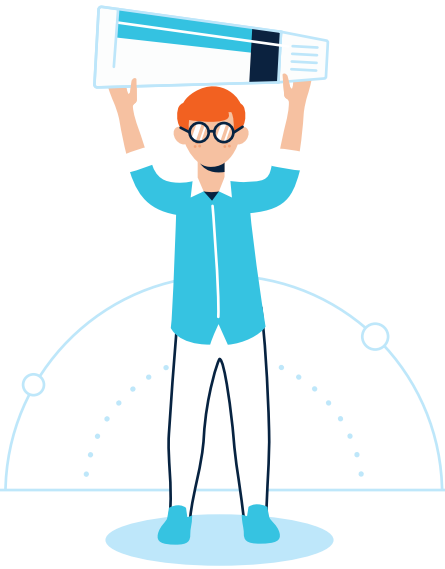


[10]Schäfer et al., J Eur Acad Dermatol Venereol. 2014 Mar;28(3):309-13.

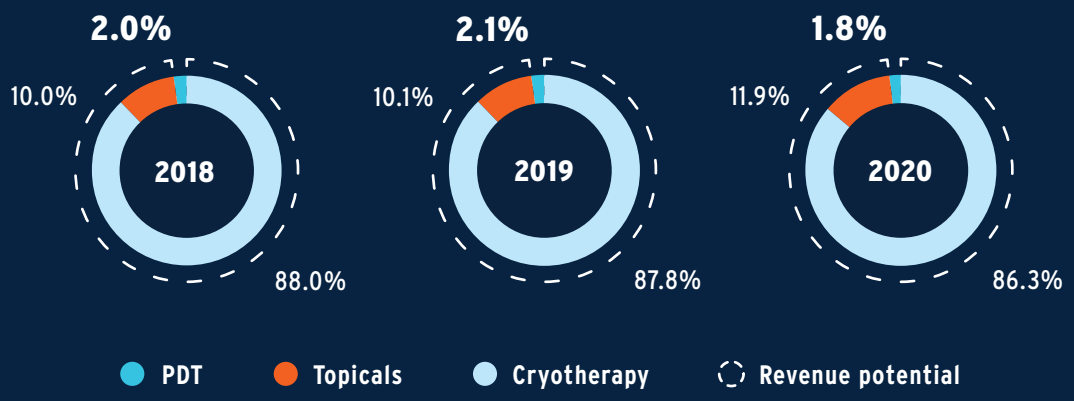
The U.S. has a tremendous market opportunity for Ameluz®-PDT

~13M AK patients treated annually

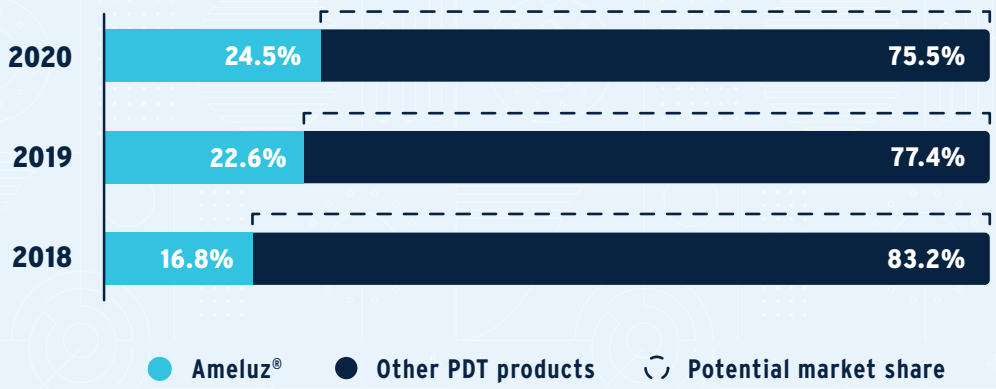




U.S. AK market by treatment option



Share of Ameluz® in U.S. PDT market



Our pipeline-in-a-product approach

Biofrontera follows a development strategy to optimize the U.S. market potential of Ameluz®.

BENEFITS OF A BROADER LABEL:

- Differentiation from other therapeutic options/competitors
- Greater overall awareness in the market

OUR GOAL IS TO OPTIMIZE THE AMELUZ® MARKET POTENTIAL BY SEEKING THE FOLLOWING LABEL EXPANSIONS IN THE U.S.

2H 2021

• LABEL EXPANSION •

Anticipated approval for the use of up to 3 tubes in one treatment

2H 2021

• PRODUCT DEVELOPMENT •

Anticipated approval of larger PDT-lamp: BF-RhodoLED® XL

2022/23

• LABEL EXPANSION •

Anticipated approval for the treatment of AK in the periphery

2022/23

• LABEL EXPANSION •

Indication: Superficial basal cell carcinoma

TBD

• LABEL EXPANSION •

Indication: Squamous cell carcinoma (SCC) *in situ*

2025/26

• LABEL EXPANSION •

Indications:
• severe acne
• wound healing

Broader label for non-melanoma skin cancer for Ameluz®

New indications

Letter to the Shareholders

Dear shareholders,

A challenging year lies behind us all. The impact of the global pandemic on society, politics and the world economy was immense and as such also had a significant impact on Biofrontera's business performance. We were able to respond promptly and flexibly to the crisis at our company sites by implementing a series of effective countermeasures. Protecting the health of our employees and business partners was our top priority. At the same time, we preserved the company's cash position by immediately introducing cost-saving measures and thus managed to navigate safely through the crisis without losing sight of our long-term strategic goals.

Clinical development processes are cost-intensive, complex and lengthy and require long-term strategic preparation, especially if they are to be initiated in a way that preserves cash. Despite the growing importance of Xepi® for the future, we continue to be a "pipeline in a product" company with our flagship product Ameluz® . This means that, as a product matures, it is necessary to plan precisely which indication expansions are feasible and financially viable in order to achieve the desired result, namely the best possible support for sales while expanding market share.

In Germany, this strategy has already led to clear successes. In particular, through the introduction of daylight PDT (photodynamic therapy), we have solidified our market leadership within the PDT sector in our home market and expanded the overall share of PDT among the available therapy options available for treatment of actinic keratosis. For years, sales in Germany have been showing an upward trend, even in the challenging year of 2020, without a slump. Ameluz®, which was launched in 2012 as a lesion-directed product for the treatment of actinic keratoses (AK) on the face and scalp with conventional PDT, has matured over the past 9 years into a product that is approved for the treatment of actinic keratoses, field cancerization, and superficial basal cell carcinoma that can be applied efficiently. The strategically important approval extension for the treatment with Ameluz® in combination with daylight PDT in Europe in 2018 finally led the product away from the reimbursement issue associated with conventional PDT. The label expansion of Ameluz® for the treatment of AK on the entire body in March 2020 has set Ameluz® even further apart from its competitor products. Now Ameluz® PDT is also on a par with topical medications in Germany in terms of handling and reimbursement, and the outstanding therapeutic results are convincing more and more physicians. The rise in German sales revenues in 2020, a year full of uncertainties and restrictions, by around 11% to EUR 5.1 million very clearly shows how well Ameluz® has now established itself on the market.

Surely we would have wished for one or the other progress earlier, but we have to remember that Biofrontera is a specialty pharmaceutical company that operates in a highly regulated market segment with limited financial flexibility by international standards. Human resources and financial constraints mean that development times can be delayed and studies are started later than desired. The difficult last 14 months should not, however, result in the company's chosen business strategy and development being abandoned due to uncontrollable external influences. Growth is the only way to create the corporate value that our shareholders desire. You have explicitly expressed your support for this growth strategy through your votes at the Annual General Meeting 2020.

This is particularly true for the USA. In our largest market, we have to use the same discipline to align our product with market requirements and patient needs as we do in Europe. The actinic keratosis market there is immense and the stronger the market positioning of our product, the faster the expansion can take place at the expense of the competitor product as well as the predominantly utilized treatment option of cryotherapy. After initially gaining a fairly rapid foothold in the U.S., we are now entering a slower growth phase. This also represents a certain analogy to our home market, where we reached a plateau after a successful launch and only then, driven by relevant approval extensions of Ameluz, we entered another strong growth phase. The strengthening of the independence of our subsidiary Biofrontera Inc. along with the resolution of the initial reimbursement challenges were the drivers for the first growth phase. Our ongoing clinical development process that is running in the background, the development of the larger PDT lamp and, concurrently, the reimbursement of up to three tubes of Ameluz® during one treatment are future-oriented enablers for the next growth phase.

In the U.S., treatment of AK with PDT is a therapy that requires an in-office setting. Being in the doctor's office during the application, occlusion time of the drug and the illumination of the treated areas challenged both doctors' offices and patients during coronavirus conditions. Due to the pandemic, many patients still shy away from the doctor's office and thus from PDT treatment. This has led to a decline in sales not only of Ameluz® PDT but also, to an even greater extent, of our direct competitor product. The annual stockpiling of Ameluz® in December due to the anticipated price increase was also less pronounced this year. As a result, we suffered a decline in sales of Ameluz® of around 29% in the USA in the year under review. It is not yet possible to estimate whether there

will be any catch-up effects in the coming months. However, the nature of the disease and its chronic course suggest that patients in the USA will again be increasingly visiting doctors' offices this year to undergo PDT.

Furthermore, the licensing agreement with Maruho Co., Ltd. in April of last year is another building block in the longer-term strategy of our corporate development. This means that the potential of Ameluz® can be tapped in other areas in addition to the already established markets of Europe and the USA, without Biofrontera having to bear the risk and costs of development and approval itself. The one-time payment of EUR 6 million made to Biofrontera in connection with the exclusive licensing agreement has provided us with an important cushion with respect to our cash position during the pandemic.

During the second half of the year, we were able to successfully place the offering of the mandatory convertible bond in August 2020. This brought additional liquidity into the company, so that we did not have to further reduce our cost-intensive but extremely important marketing expenses in the second half of the year, despite the lower sales. The significant oversubscription of the mandatory convertible as well as the capital increase successfully placed in February of this year shows both how attractive Biofrontera is to the capital market and the great potential that new investors recognize in Biofrontera.

Overall, we succeeded in navigating Biofrontera well through challenging times. Once again, I would like to express my sincere thanks to my colleagues for their tireless efforts, adaptability and strong team spirit.

Biofrontera set out early on with a great deal of courage, passion and responsibility to become an innovative player in dermatology. We are consistently pursuing this path and I would be delighted if you would continue to accompany us so that together we can make our company an indispensable supplier of innovative therapeutic solutions in dermatology.

Sincerely,

Prof. Dr. Hermann Lübbert

Ludwig Lutter

Investor Relations

The shares of Biofrontera AG, Leverkusen, have been traded in the Prime Standard segment of the Frankfurt Stock Exchange since June 3, 2014. They have been listed in the Regulated Market of the Düsseldorf Stock Exchange since 2006, and on the Regulated Market of the Frankfurt Stock Exchange since 2012. Since February 2018, Biofrontera shares are also traded in the form of American Depositary Shares (ADS) on the US Nasdaq Stock Market.

Key data on our financial instruments

Key data: ordinary shares (no par value)	
Stock exchange	Frankfurt Stock Exchange
Additional trading platforms	XETRA, Berlin, Düsseldorf, Munich, Stuttgart, Tradegate
Tier	Prime Standard
Shares issued as of Dec 31, 2020	47,747,515
Share capital as of Dec 31, 2020	EUR 47,747,515
ISIN	DE0006046113
WKN (German securities identification code)	604611
Ticker symbol	B8F
Designated Sponsor	ICF Bank AG
52-week high* (Aug 17, 2020)	EUR 5.44
52-week low* (Mar 20, .2020)	EUR 2.42
Market cap as of Dec 31, 2020	EUR 141 million
Avg. daily trading volume XETRA (Jan 2 to Dec 30, 2020)	41,493 shares

*based on XETRA closing price

Key data: American Depositary Shares (ADS)	
Stock exchange	NASDAQ
CUSIP	09075G105
ADS ISIN	US09075G1058
Ratio	1 ADS:2 ORDs (one ADS represents two ordinary shares)
Symbol	BFRA
Depositary	BNY Mellon
Additional trading platform	Stuttgart
WKN (German securities identification code)	A2JEEX
Ticker symbol	BFRA

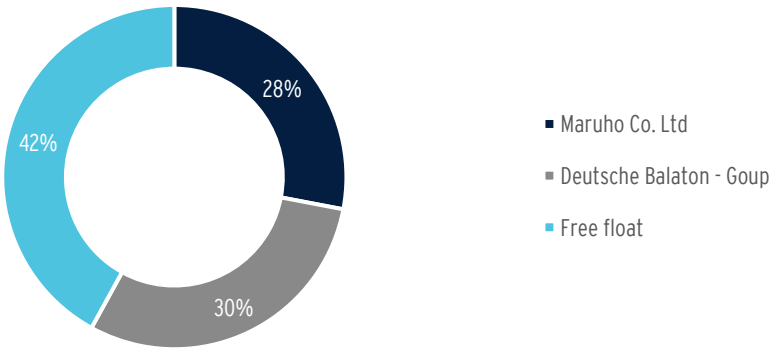
Key data: Convertible bond 2017/2022	
Stock exchange	Düsseldorf
WKN	A2BPDE
ISIN	DE000A2BPDE6
Date of maturity	December 31, 2021
Coupon	6 %
Nominal amount per bond	EUR 100.00
Total nominal amount	EUR 4,999,000
of which converted by Dec 31, 2020	EUR 2,030,800
Initial conversion price	EUR 3.50
Conversion price since March 2021	EUR 4.716

Share price performance

During the first half of the year, the stock markets were severely shaken by the COVID-19 pandemic, and in mid-March there were sharp declines in share prices in all sectors. After the crash, however, the stock markets recovered. By fall, the indices were already back at the previous year's level and recorded significant gains towards the end of the year. The performance of the Biofrontera share was similarly strongly influenced by the pandemic. In March 2020, the share price plummeted due to the global spread of the coronavirus crisis, reaching a low of EUR 2.28 on March 23, 2020. By mid-August, the share price then began a significant recovery, reaching its high for the year of EUR 5.67 on August 14, 2020. This substantial upward trend was due, among other things, to a rise in the price of ADSs on the Nasdaq. Due to an ongoing capital measure, the two financial instruments were decoupled, causing the price of the ordinary shares and the price of the ADSs to diverge significantly. On Nasdaq, ADSs traded at volumes many times higher than the number of shares outstanding. The enormous demand for ADSs during this period had a longer-lasting positive effect on the share price after the decoupling of the financial instruments was lifted once the subscription period was over. In the second half of the year, the share price then showed a decline again, leveling off at EUR 3.00. As of December 30, 2020, the stock was trading steadily around at EUR 3.05.

Shareholder structure

The shareholder structure* of Biofrontera AG as of December 31, 2020, based on the mandatory disclosures, is as follows:



*percentages are rounded

Annual general meeting 2020

The annual general meeting of Biofrontera took place on May 28, 2020. Pursuant to Section 1 of the COVID-19 Act, the Management Board, with the consent of the Supervisory Board, had decided to hold the annual general meeting as a virtual annual general meeting.

76.31% of the registered share capital of Biofrontera AG was represented, thus the attendance was approximately at the previous year's level. The shareholders approved the proposed resolutions 2 to 6 with a simple majority, the proposed resolution 7 for the creation of a new authorized capital, which required a three-quarters majority, as well as all supplementary requests of the Deutsche Balaton-Group did not receive the required majorities and were rejected by the annual general meeting. No vote was required on agenda items 1 and 10.

Capital raise 2020

For the purpose of securing liquidity in the short term, a resolution was passed at the end of July 2020 to issue a 1.0% qualified subordinated mandatory convertible bond 2020/2021 with a nominal amount of EUR 3.00 each and a total nominal amount of up to EUR 7.9 million. In mid-August, the issue was successfully placed and the Company received gross proceeds of EUR 7.9 million. In November, the Company exercised the right of mandatory conversion, whereby the mandatory convertible bond was converted into shares.

A capital measure initially announced in March 2020, also planned as a mandatory convertible bond issue, was called off due to the sudden economic downturn caused by the COVID- 19 pandemic.

Analyst coverage

The following analysts cover Biofrontera:

Institution	Analyst	Rating
The Benchmark Company, LLC	Bruce D. Jackson	Buy
Lake Street Capital Markets	Thomas Flaten	Buy
sc-consult GmbH	Dipl. Kfm. Holger Steffen	Buy

Conferences

Due to the COVID 19 pandemic, participation in conferences and the associated travel activities have been completely suspended since mid-March. Consequently, representatives of Biofrontera AG only attended the following capital market conferences in the reporting period, most of which were held virtually:

Date	Conference
January 13-17, 2020	JP Morgan 38th Annual Healthcare Conference
September 17, 2020	Lake Street Capital Markets 2020 Best Ideas Growth (BIG) Conference
September 25, 2020	Baader Investment Conference
November 16-17, 2020	Deutsches Eigenkapitalforum

Declaration of Biofrontera AG on Corporate Governance pursuant to sections 289f, 315d of the German Commercial Code (Corporate Governance Report) for the 2020 financial year

I. Declaration of the Management Board and the Supervisory Board of Biofrontera AG (Company) on the German Corporate Governance Code pursuant to section 161 of the German Stock Corporation Act (AktG)

Pursuant to Section 161 of the German Stock Corporation Act (AktG), the Management Board and Supervisory Board of Biofrontera AG are obliged to declare annually that the recommendations of the "Government Commission on the German Corporate Governance Code" ("Code") published by the Federal Ministry of Justice in the official section of the electronic Federal Gazette have been and are being complied with, or which recommendations have not been or are not being applied and why not ("Compliance Statement").

The Management Board and the Supervisory Board issue the following Compliance Statement:

Biofrontera AG has complied with the recommendations of the Code in the version cited therein, taking into account the exceptions therein, since issuing its annual Statement of Compliance in December 2019. The Management Board and the Supervisory Board further declare that the recommendations of the Code are complied with, subject to the following exceptions (the numbers listed below are those of the Code as amended on December 16, 2019):

Reporting (F. 2)

Financial reports, half-year reports and interim reports are published within the statutory deadlines and no earlier due to organizational circumstances.

Leverkusen, December 2020

Prof. Dr. Hermann Lübbert	Thomas Schaffer	Dr. Ulrich Granzer
CEO	CFO	Chairman of the Supervisory Board

II. Corporate governance report

The current corporate governance report is available on the Company's website at www.biofrontera.com in the section "Investors", sub-section "Corporate Governance".

Report of the Supervisory Board of Biofrontera AG for the 2020 financial year

Dear shareholders,

The 2020 financial year was dominated by the COVID-19 pandemic, which had a significant impact on Biofrontera Group's business. Following a healthy sales performance as well as positive regulatory and clinical developments at the beginning of the first quarter of 2020, we were confronted with a sharp decline in sales across all markets from March 2020 onwards as a result of the pandemic. As a result, Biofrontera Group was forced to implement company-wide cost reduction measures.

Although the situation improved in the further course of the year, we had to cope with a decline in revenue from product sales of around 29%, particularly in the USA, our main market. However, there were also some bright spots, with product sales in Germany increasing by 11% despite the challenging environment in general.

Overall, taking into account a one-time payment of EUR 6 million from Maruho Co., Ltd. under the license agreement concluded in April 2020, it was possible to keep Biofrontera Group's sales nearly stable. Although this falls short of the original expectations for the 2020 financial year, it nevertheless also shows that we were able to successfully steer Biofrontera Group through this unique global crisis.

For this, we would like to express our gratitude and appreciation to the employees and management of Biofrontera Group, especially insofar as they were directly affected by cost-cutting measures or voluntarily waived their salaries.

Monitoring and consultation

The Supervisory Board discharged the responsibilities incumbent upon it according to the law, the Company's articles of association, the German Corporate Governance Code (Deutscher Corporate Governance Kodex) and its rules of business procedure. The Supervisory Board's activities included monitoring and consulting with the Management Board concerning the management of the company and the Group. In the year under review, the Supervisory Board monitored the activities of the Management Board and engaged in discussions with it on forward-looking business decisions and planning.

The Management Board provided the Supervisory Board with regular, timely and comprehensive reports. The Supervisory Board was continuously informed about the Company's current performance by the Management Board, both during and outside of formal meetings. Based on the Management Board's written and verbal reports, the Supervisory Board was able to comprehensively discuss business developments and the state of the Company. Furthermore, there was a regular exchange of information and ideas between the Chief Executive Officer and the Chairman of the Supervisory Board. Particularly with regard to decisions of fundamental importance to the Company, the Supervisory Board was involved. The Supervisory Board also reviewed the legality, propriety and expediency of measures proposed by the Company's Management Board, as well as the economic feasibility of such measures. Deviations in business performance from the plans were explained and discussed with the Supervisory Board by the Management Board. Additionally, the Supervisory Board examined the extent to which its decisions, proposals and recommendations were subsequently taken into account and implemented by the Management Board in running the Company.

Where Management Board decisions required the approval of the Supervisory Board, or where the Management Board requested approval for measures, the Supervisory Board was informed in advance with the relevant information and documents for the decision. Approval was then granted following discussion at Supervisory Board meetings or by means of decisions taken by written correspondence or in telephone or video conferences held regularly by both the full Supervisory Board as well as the committees. In fulfilling its duties, the Supervisory Board and its committees may draw on resources of the Company it deems appropriate and may also engage external consultants as appropriate. The latter was done in the context of the license agreement concluded with Maruho for the distribution of Ameluz in East Asia and Oceania, for which the Supervisory Board selected an external subject matter expert and commissioned him to provide an independent opinion on the adequacy of the compensation.

At its meetings, the Supervisory Board also held regular discussions without the Management Board being present.

Consultation and areas of focus

In performing its duties, the Supervisory Board held seven meetings in the year under review. Due to the COVID-19 pandemic, these were held by phone or video conference to safeguard health, but also due to travel restrictions.
The Supervisory Board also passed resolutions outside formal meetings.

At the meeting held on March 27, 2020, the Management Board reported on the measures it had initiated with regard to the spreading COVID 19 pandemic and the response taken by governments. These corporate decisions included the introduction of short-time work in Germany and other countries and, unfortunately, also layoffs.

At the meeting held on April 8, 2020, the Management Board once again reported on the measures it had initiated with regard to the expanding COVID 19 pandemic and the governments' responses, as well as on the impact of the COVID 19 pandemic on business activities and clinical trials. In addition, the impact on the financial position was presented and possibilities for additional financing were discussed.

At the meeting on April 20, 2020, the auditor reported on the timing, structure and results of the audit for fiscal 2019. After discussing the 2019 annual financial statements, the consolidated financial statements and the combined management report, the Supervisory Board approved the auditor's reports, raised no objections following the final results of its own review, and approved the annual and consolidated financial statements. It thus followed the recommendation of its Audit Committee, which had previously held a meeting in the presence of the auditor to discuss the 2019 annual financial statements, the consolidated financial statements and the combined management report, as well as the audit reports. The annual financial statements of Biofrontera Aktiengesellschaft for the 2020 financial year were thus adopted. The Management Board also reported on the current sales and development of the market against the backdrop of the COVID 19 pandemic. This concerned in particular the challenging sales environment in the USA, the measures taken to reduce costs, as well as the financial situation and the proposal to the upcoming Annual General Meeting to resolve a capital increase. The agenda for the Annual General Meeting on May 28, 2020 was approved by the Supervisory Board. The Management Board's plan to hold a virtual Annual General Meeting was approved.

At the May 26, 2020 meeting, the measures initiated by the Management Board with regard to the COVID-19 pandemic and the countermeasures taken by governments were again discussed. Business continued to be significantly impacted, particularly in the USA. Against this background, the financial and liquidity situation was discussed.

At the meeting on September 01, 2020, the Management Board reported on the ongoing clinical trials and on the status of the newly developed BF-RhodoLED® XL lamp. In addition, the business development and the financial and liquidity situation were presented as well as the new marketing strategy for the US market. In addition, an overview of the ongoing legal proceedings was given.

At the November 02, 2020 meeting, the Management Board and Supervisory Board discussed the status of the mediation process agreed with Mr. Wilhelm K. T. Zours and with Deutsche Balaton AG and potential options for settling the disputes with the aforementioned.

At the meeting on December 09, 2020, the Management Board and Supervisory Board discussed current business developments and the Management Board provided an overview of the revenue, earnings and financial situation. The budget for 2021 and corporate targets for 2021 were discussed and approved. The Management Board reported on the status of the planned implementation of the ordinary capital increase resolved by the Annual General Meeting on May 28, 2020, and on the status of ongoing legal proceedings.

Activities other than regular meetings

In addition to meetings, the Supervisory Board adopted resolutions by written circulation on, among other things, the conclusion of the license agreement with Maruho Co., Ltd. and the issuance of a qualified subordinated mandatory convertible bond with the granting of statutory subscription rights.

Supervisory Board Committees

Currently, the Supervisory Board has established an Audit Committee, a Nominating Committee, as well as a Personnel Committee. The Supervisory Board appoints one Supervisory Board member to chair each committee.

The Chairman of the Supervisory Board or the Vice Chairman shall also chair the committees that deal with Management Board agreements and prepare the Supervisory Board meetings. The Chairman of the Supervisory Board should not chair the Audit Committee. These requirements were taken into account in the appointments. The committee chair(wo)men report to the Supervisory Board on the work of the committees.

Audit Committee

The Audit Committee is concerned in particular with monitoring the financial reporting process, the effectiveness of the internal control system, the risk management system and the internal auditing system, as well as the audit of the financial statements, here in particular the selection and independence of the auditor and the additional services provided by the auditor. The Audit Committee may make recommendations or proposals to ensure the integrity of the financial reporting process. In the case of companies within the meaning of Section 264d of the German Commercial Code, i.e. also in the case of Biofrontera Aktiengesellschaft, the proposal of the Supervisory Board for the election of the auditor shall be based on the recommendation of the Audit Committee. In the case of companies within the meaning of Section 264d of the German Commercial Code, at least one member of the Supervisory Board must also have expertise in the fields of accounting or auditing and be a member of the Audit Committee.

The Audit Committee comprised the following members in the reporting year: Mr. Jürgen Baumann, Mr. John Borer and Prof. Dr. Franca Ruhwedel. Prof. Dr. Ruhwedel is Chairwoman of the Audit Committee.

The committee met twice in the reporting year, namely with the auditor in preparation for the Supervisory Board's discussion of the financial statements on April 20, 2020 and November 19, 2020.

In addition to the regular meetings, the Chairwoman of the Audit Committee was in regular contact with the CFO of Biofrontera and with the auditors. She coordinated the audit planning and the focus of the audit with the auditor and was informed about the progress of the audit in regular virtual meetings.

Personnel Committee

The Personnel Committee prepares Supervisory Board decisions on the appointment and dismissal of Management Board members. Unlike in the past, the full Supervisory Board is now responsible for compensation decisions as a result of the changes introduced by the German Act on the Appropriateness of Management Board Compensation (VorstAG) which means the Personnel Committee is now only involved in preparatory work.

The Personnel Committee currently comprises the following members: Mr. Jürgen Baumann, Mr. John Borer and Dr. Ulrich Granzer. Mr. Baumann is currently Chairman.

The committee met on April 20, 2020, and dealt with the target achievement of the members of the Management Board in 2019 as well as the issuance of options to members of the Management Board. In addition, in several conference calls in June 2020 the Personnel Committee discussed the extension or restructuring of service contracts for members of the Management Board. In November and December 2020, the committee also addressed succession planning for the Management Board and in particular the search for a Chief Financial Officer to succeed Mr. Schaffer.

Nominating Committee

In addition to the Chairman, the Nominating Committee comprises two further members of the Supervisory Board who are to be elected. The task of the Nominating Committee is to propose suitable candidates to the Supervisory Board for recommendation to the Annual General Meeting. In doing so, the Nominating Committee takes into account the balance and diversity of expertise, skills and experience of all members of the Supervisory Board and prepares candidate profiles. In addition, the Nominating Committee shall make proposals to the Supervisory Board and communicate the results of a regular assessment of the expertise, skills and experience of both the individual members as well as the Supervisory Board as a whole. The Nominating Committee consulted by telephone during the reporting period.

The current members of the Nominating Committee are as follows: Mr. John Borer, Dr. Ulrich Granzer and Mr. Reinhard Eyring. Dr. Ulrich Granzer is currently Chairman of the Nominating Committee.

Disclosure of the participation of individual Supervisory Board members in Supervisory Board and committee meetings in the 2020 financial year

Supervisory Board member	Supervisory Board meetings/participation	Attendance	Committee meetings/ participation	Attendance
Jürgen Baumann	7/7	100%	3/3	100%
John Borer	7/7	100%	3/3	100%
Reinhard Eyring	7/7	100%		
Dr. Ulrich Granzer	7/7	100%	1/1	100%
Prof. Dr. Franca Ruhwedel	7/7	100%	2/2	100%
Kevin Weber	7/6	85,7%		

Annual and consolidated financial statements 2020

Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, Düsseldorf, (auditors) was appointed auditor and group auditor for the 2020 financial year by the Annual General Meeting on May 28, 2020 and was subsequently commissioned accordingly by the Supervisory Board. The auditors' declaration of independence was obtained. Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft audited the annual and consolidated financial statements of Biofrontera Aktiengesellschaft prepared by the Management Board and the combined management report for the 2020 financial year and issued the unconditional audit opinions. The auditor also found that the Management Board has set up an appropriate information and monitoring system, the design and operation of which are suitable for the early identification of developments that could jeopardize the going concern of the Company.

The consolidated financial statements were prepared on the basis of International Financial Reporting Standards (IFRS).

On April 12, 2021, the audit committee discussed the financial statement documents in the presence of the independent auditor. The Audit Committee dealt in particular with the key audit matters described in the respective audit opinion, including the audit procedures performed. At the subsequent Supervisory Board meeting on the same day at which the financial statements were approved, the documents relating to the financial statements were discussed in detail in the presence of and following a report by the independent auditors. All Supervisory Board members received the financial statement documents and the auditors' reports in good time before the financial statement meeting and dealt with these documents in detail. The annual financial statements and consolidated financial statements were discussed in detail with the Management Board at the financial statements meeting. The auditors reported on the scope, focus and main findings of their audit, addressing in particular the key audit matters and the audit procedures performed. The auditors were available to the Supervisory Board to answer questions and provide further information. All questions from the Supervisory Board were answered in full by the Management Board and the auditors. The auditors also provided information on their findings regarding internal controls and risk management in relation to the financial reporting process.

The Supervisory Board took note of and approved the audit reports, the annual financial statements, the consolidated financial statements and the combined management report. After discussing the annual financial statements, the consolidated financial statements and the combined management report, the Supervisory Board approved the auditors' reports and the results of the audit, raised no objections following the final results of its own review, and approved the annual and consolidated financial statements. The annual financial statements of Biofrontera Aktiengesellschaft are thus adopted.

The report of the Supervisory Board was adopted at the Audit Committee meeting on April 12, 2021.

Independent auditor and auditor in charge

Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, Düsseldorf, has been the independent auditor for Biofrontera AG and the Group since 2007. Mr. Michael Gottschalk has been the auditor in charge of the mandate for Biofrontera AG since fiscal year 2018 for the audit of the financial statements.

Corporate Governance and compliance statement pursuant to Section 161 of the German Stock Corporation Act (AktG)

Further information on corporate governance is provided in the Annual Report and at www.biofrontera.com in the section "Investors" / "Corporate Governance" as well as in the Corporate Governance Statement. Details of the Supervisory Board's objectives regarding its composition and the status of implementation are also disclosed there.

Training and continuing education activities

The Company supports the members of the Supervisory Board to an appropriate extent in their induction into office and in training and continuing education programs. For ongoing training and continuing education, the Company provides Supervisory Board members with access to a portal of a third-party provider (Arbeitskreis deutscher Aufsichtsrat e.V. (AdAR)) and covers the costs. Opportunities to attend congresses and expert events are also offered via this portal.

Conflicts of interest

Each member of the Supervisory Board is obliged to act in the best interests of the Company. In making decisions, they may neither act in their own personal interests nor exploit business opportunities available to the company for their own benefit without a resolution of the Supervisory Board. The Rules of Procedure of the Supervisory Board stipulate that each member of the Supervisory Board must disclose conflicts of interest to the Supervisory Board. This applies in particular to conflicts of interest that may arise as a result of a consultation or position with customers, suppliers, lenders or other business partners. Material and permanent conflicts of interest on the part of a Supervisory Board member shall result in the termination of his or her mandate.

No such conflicts of interest arose in the year under review.

Changes to the Supervisory Board

There were no changes to the Supervisory Board during the year under review.

Changes to the Management Board

At the end of January 2020, Mr. Christoph Dünwald resigned from the Management Board. Mr. Dünwald and Biofrontera AG have agreed that Mr. Dünwald's Management Board contract, which was due to expire on November 30, 2020, should not be extended. Mr. Dünwald resigned from his position as a member of the Management Board by mutual agreement in the course of a reorganization at the end of January 2020.

Effective March 1, 2021, Mr. Ludwig Lutter was appointed as the new Chief Financial Officer (CFO) of Biofrontera AG. As the successor to Thomas Schaffer, he is responsible for Finance, Administration, Controlling and Human Resources within the Company. Thomas Schaffer has left the Company by best mutual agreement as of February 28, 2021, in order to devote himself to new personal commitments outside the Company. The change in the finance department is part of the succession planning already announced by the Supervisory Board and Management Board.

Biofrontera AG expresses its appreciation to Mr. Dünwald and Mr. Schaffer for their many years of successful commitment.

In closing, we would like to thank you dear shareholders once again for your commitment and trust!

The Supervisory Board would also like to thank the Management Board and employees of Biofrontera Aktiengesellschaft and Biofrontera Group for their high level of commitment and for their outstanding performance in the past year.

Leverkusen, April 12, 2021

Dr. Ulrich Granzer
Vorsitzender des Aufsichtsrats

Consolidated management and group management report for the fiscal year 2020

Basis of the Group

Group structure

As of December 31, 2020, 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.

Effective March 25, 2019, all shares in Cutanea Life Sciences, Inc. and its subsidiaries Dermarc LLC and Dermapex LLC were acquired through the newly founded US-company Biofrontera Newderm LLC. The companies of Cutanea Life Sciences, Inc. as well as Biofrontera Newderm LLC were merged with Biofrontera Inc. at the end of 2019. While Biofrontera Inc. has assumed all commercial activities, Biofrontera Bioscience GmbH took over all regulatory tasks.

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, Massachussetts, USA.

Business model

The public 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®. 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 setup in order to commercialize Ameluz® 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.

To strengthen its commercial activities, the Biofrontera Group reorganized its sales structure in January 2020. Following the reorganization of the US subsidiary Biofrontera Inc., the sales organization in Europe was also restructured. Today, Biofrontera's global sales organization is based on two pillars: sales and marketing in the US, Biofrontera's largest market, and the combined management of all sales organizations in Europe.

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%) is a non-fluorinated quinolone that not only inhibits bacterial growth but also kills the bacteria directly. This results in an unusually fast effect of this new medication. 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 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

At the start of 2020, the Company completed organizational restructuring measures. Following the reorganization of the operational management of its subsidiary Biofrontera Inc. (published January 5, 2020), Biofrontera also announced an organizational restructuring of its sales organization in Europe. As a result of the 2020 changes, Biofrontera's global sales organization now stands on two pillars: sales and marketing in the U.S., Biofrontera's largest market, and unified management of all sales organizations in Europe.

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 to EUR 75 by decree of the Ministry, against which the Company filed an administrative complaint.

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 this context, the licensing agreements with Perrigo Israel for the commercialization of Ameluz® and BF-RhodoLED® in Israel and Desitin Arzneimittel GmbH for the commercialization of Ameluz® and BF-RhodoLED® in Scandinavia were terminated by mutual agreement during the reporting period.

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 are expected to commence in the second half of 2021.

In March 2020, Biofrontera announced that it had signed a non-binding term sheet for an exclusive license and supply agreement with medac GmbH Sp. z o.o., Warsaw, the Polish branch of medac Gesellschaft für klinische Spezialpräparate mbH, for the commercialization of Ameluz® and BF-RhodoLED® in Poland. The Company expects the final agreement to be concluded in 2021.

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.

Under the agreement, Maruho will receive exclusive development and marketing rights, including permission to sublicense Ameluz® in Japan, China, Korea, India, Pakistan, Vietnam, the Philippines, Australia, New Zealand and surrounding countries and islands (Territory). Maruho is entitled, with the consent of Biofrontera, to conduct its own research and development under the terms and conditions of the licensing agreement. Maruho will grant the Company a free and unlimited license for all results of such research and development activities performed by Maruho for commercialization outside the Territory. Under the terms of the license agreement, Biofrontera will supply Ameluz® to Maruho at cost plus 25%, while Maruho has the obligation to make commercially reasonable efforts to develop, register and market Ameluz® in all countries within the Territory.

Under the agreement, Maruho has made a one-time payment of EUR 6 million to Biofrontera AG. Further future payments will be due upon achievement of certain regulatory and commercial milestones. Maruho will also pay royalties of initially 6% of net sales in the countries of the Territory, which may increase to 12% depending on sales volume and will decrease in case of the introduction of generic products in these countries.

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, since 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 the previous year. 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, 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 the previous year. We were thus able to improve our market positioning vis-à-vis the competing PDT product despite the corona crisis. 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, particularly in patients with more than 15 lesions.

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 antibiotic-resistant bacteria.

The U.S. market for topical antibiotics is dominated by generic products containing the active ingredient mupirucin. American dermatologists write about one 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

Management Board

As of December 31, 2020, the Management Board consisted of Prof. Dr. Hermann Lübbert (Chairman and CEO) and Mr. Thomas Schaffer* (CFO).

Name	Nationality	Age	Position	Date of first appointment	Term
Prof. Dr. Hermann Lübbert	German	65	Chairman and CEO	2000	December 31, 2022
Thomas Schaffer*	German	58	CFO	2013	February 28, 2021

*Mr. Thomas Schaffer resigned from his position as Chief Financial Officer effective February 28, 2021. Effective March 1, 2021, Mr. Ludwig Lutter was appointed new Chief Financial Officer of Biofrontera AG. Mr. Dünwald resigned from his position as Chief Commercial Officer at the end of January 2020.

Employees

As of December 31, 2020, the Biofrontera Group had 149 employees (previous year: 174) who were distributed as follows:

	December 31, 2020	December 31, 2019
Total number of employees	149	174
Full-time	127	147
With academic degree	22	27
By business segments	149	174
Production	16	15
Research and development	5	6
Clinical and regulatory tasks	16	16
Marketing and sales	60	73
Quality management	7	9
Management, business development, finance, HR and administration	45	55
By countries	149	174
Germany	81	89
USA	56	73
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.

Supervisory Board

In 2020, the Supervisory Board comprised the following members as representatives of the shareholders:

Name	Nationality	Age	Position	Date of first appointment	Term
Dr. Ulrich Granzer	German	60	Chairman	May 12, 2006	2021
Jürgen Baumann	German	66	Vice Chair	May 24, 2007	2021
John Borer	USA	63	Member	May 31, 2016	2021
Reinhard Eyring	German	62	Member	February 7, 2018	2021
Prof. Dr. Franca Ruhwedel	German	48	Member	July 10, 2019	2021
Kevin Weber	USA	63	Member	May 31, 2016	2021

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 BF-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 BF-RhodoLED® XL red light lamp, are recognized as expenses in the period in which they are incurred. In the year under review, 21 people were employed in research and development as well as regulatory affairs (previous year: 22).

Research cooperation with Maruho Co., Ltd.

On March 19, 2019, the Company signed an agreement to continue its research collaboration with Maruho Co., Ltd. of Osaka, Japan (Maruho) for the development of branded generics. As part of the new project phase, Biofrontera has prepared the formulation of one of four active ingredients investigated in an earlier project phase (phase 1) using Biofrontera's nanoemulsion for entry into the clinical phase. During the reporting period, the agreement on this phase of the research collaboration expired as planned and is currently not being continued. Biofrontera has a right to use all research results.

Phase II trial for the treatment of mild to severe acne

With regard to the possible label extension of Ameluz® for acne in the USA, Biofrontera has prepared a corresponding development plan for the indication extension and received feedback from the US Food and Drug Administration (FDA) on the design of the necessary clinical trials. The study program is expected to start with a Phase IIb trial in the second half of 2021.

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

Based on the positive assessment of the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) in February 2020, the European Commission granted the formal extension of approval in March 2020. The extended approval of Ameluz® now also includes the treatment of mild and moderate actinic keratoses (AK) on the extremities and trunk/neck with photodynamic therapy (PDT).

Based on the data for the European label extension, Biofrontera has also held discussions with the FDA about expanding the label for Ameluz® in the USA to include the treatment of AK in the extremities and trunk/neck. The FDA proposed an additional clinical trial to approve the label extension of Ameluz® to include additional body regions. The study protocol will be coordinated with the FDA prior to the start of the clinical trial. Patient recruitment is expected to start prior to the end of 2021.

Phase I trial / 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.

The maximum use PK study included 32 patients with actinic keratoses on larger or multiple areas who received PDT treatment with a total of three tubes of Ameluz® on either the face/scalp or extremities/torso/neck. Ameluz® was applied in accordance with the currently approved treatment protocol, except that 60 cm^2 of skin area was treated with three tubes of the drug. Illumination was performed after 3 hours of occlusion time, using either one or two BF-RhodoLED® lamps simultaneously, depending on the number and location of the treatment area(s). The study was conducted at a specialized Phase I dermatology facility in Texas/USA.

The objective of the study was to investigate the amount of the active ingredient that enters the blood after three complete tubes of Ameluz® have been applied to the skin, in order to evaluate safety in this regard. In addition, other parameters relating to the safety of patients undergoing this treatment were investigated. These results will enable Biofrontera as well as the regulatory authority to assess whether simultaneous treatment with three tubes could result in risks for patients.

Development of the BF-RhodoLED® XL lamp

The future use of the BF-RhodoLED® XL will allow the application of Ameluz® on larger areas as well as the simultaneous illumination of several interspersed lesions. Furthermore, the BF-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. Following delays in the Company's first production batch of the lamp due to supply delays of parts caused by the coronavirus crisis, the application for approval was submitted to the FDA in March 2021.

Phase III trial for the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our red-light lamp BF-RhodoLED® 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. However, due to the extremely demanding study protocol mandated by the FDA, the recruitment process will likely take a considerable amount of time. Patient recruitment is expected to be completed at the beginning of 2022. Following successful FDA approval, Ameluz® would be the only drug in the United States for the treatment of superficial BCC with PDT.

Patent development

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

The patent families refer to our technologies related to our nanoemulsion, photodynamic therapy (PDT) and migraine prophylaxis.

Nanoemulsion

We have been issued patents 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. Patent applications have been filed and are pending in the United States. Patent applications in the United Arab Emirates were discontinued in 2020.

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 US 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, including regulatory hurdles. As part of Biofrontera's patent strategy to further protect Ameluz®, additional patent applications have been submitted (see below).

Photodynamic therapy

A new international patent application " Photodynamic therapy comprising two light exposures at different wave lengths" was filed with the European Patent Office (EPO) on August 23, 2018. All countries that were members of the PCT (Patent Cooperation Treaty) on the filing date (including the USA) were designated in the application. The international publication of the application was published on February 27, 2020. Entry into the regional/national phase is initiated for the EU, USA, Japan, Australia, China, Hong Kong, New Zealand and Singapore.

Another international patent application titled "Illumination for photodynamic therapy" was filed with the EPO on June 5, 2019. Again, all states which were contracting states of the PCT at the date of filing of the PCT application were designated in the application.

On November 17, 2020, the national phase was initiated in the US. On December 10, 2020, the international application was published.

Additionally, 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 US on October 15, 2020.

Migraine prophylaxis BF-1

An international patent application regarding anti-migraine compounds and their use was submitted the EPA, the European Patent Office. Patents were granted to the Group in Europe (nationalized for Germany, Spain, France, United Kingdom, Italy) and 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 composition of Xepi® until January 29, 2032 and for the treatment of impetigo, for which it is approved, until December 15, 2029 (for more information see section "Products").

Internal controls

Biofrontera AG is managed by its Management Board. The Management Board is responsible for and supervises the operational business. To this end, the Management Board regularly receives and reviews internal management reports.

Key performance indicators are compiled on a monthly basis, while the budget planning for the current financial year is revised and updated quarterly. In addition, medium-term planning is prepared once a year. An in-depth cost analysis is performed on an ongoing basis.

Key financial performance indicators

Until and including 2020, the key financial performance indicators for the Group's operating performance were revenue and liquidity as well as the result from operating activities.

In the context of internal reporting, the Group's sales revenues are the key performance indicator, which are reported by region and by product. On a consolidated basis, revenue includes sales to wholesalers as well as to physicians and hospitals, sales to our licensing partners, and revenue from research contracts.

In addition, liquidity trends are used as a key performance and management metric for the Group as well as for Biofrontera AG. These are monitored on a daily basis. Liquidity is defined as the sum of cash and cash balances in bank accounts and is described as cash and cash equivalents.

Starting in fiscal year 2021, EBITDA and EBIT will be introduced as key performance indicators in our reporting. Both have become established internationally as key performance indicators and will replace the previously reported result from operating activities.

Group EBITDA includes earnings before interest, taxes, depreciation of tangible assets and amortization of intangible assets. EBIT includes earnings before interest and taxes. These key performance indicators are suitable for describing and comparing operating performance, as they do not include non-operating fluctuation variables such as valuation adjustments and amortization of acquired assets.

The key financial performance indicators are calculated as follows:

Result from operating activities
+ Depreciation and amortization
+ /- Other expenses and income
EBITDA
- Depreciation and amortization
EBIT
+/- Interest expense and interest income
Earnings before income taxes

Non-financial performance indicators

The maintenance and further development of our regulatory approvals is essential to secure and strengthen Biofrontera's market positioning and is, among other things, reflected in research and development costs. As a consequence, both the maintenance of our regulatory approvals and the expansion of our labels as well as the number of external and internal audits are important non-financial control parameters for the Company.

The employees of Biofrontera are an important success factor and therefore also represent a central control parameter. With respect to personnel, particular emphasis is placed on the qualifications and the necessary know-how of the employees in order to achieve the set goals in the operational and administrative areas. We therefore measure the annual expenditure on training and professional development as well as the number of training activities. Personnel costs are always assessed in line with the salary levels customary in the industry.

Economic and business report for the fiscal year 2020

Business performance

The year under review 2020 was characterized by the impact of the coronavirus pandemic. In the reporting period from January 1 to December 31, 2020, Biofrontera was directly affected by the global coronavirus crisis starting in mid-March and as a result suffered from reduced sales especially in the USA. However, the down payment by the Japanese company Maruho Co., Ltd. (Maruho), the fully placed convertible bond 2020/2021 in August 2020, as well as cost reduction measures introduced at an early stage of the pandemic, the Company was able to successfully mitigate the negative impact on the revenue side.

Key figures in accordance with IFRS

in EUR thousands	2020		2019	
Results of operations				
Sales revenue	30,346	100,00%	31,265	100,00%
Gross profit on sales	26,810	88,35%	26,390	84,41%
Profit/loss on operations	(7,611)	(25,08)%	(23,377)	(74,77)%
EBITDA	(4,696)	(15,47)%	964	3,08%
EBIT	(10,029)	(33,05)%	(2,192)	(7,01)%
Profit/loss before income tax	(12,697)	(41,84)%	(4,777)	(15,25)%
Profit/loss for the period	(13,023)	(42,92)%	(7.358)	(23,54)%

in EUR thousands	December 31, 2020	December 31, 2019
Net assets		
Total assets	56,391	58,363
Non-current assets	30,264	35,873
Cash and cash equivalents	16,546	11,119
Other current assets	9,580	11,372
Non-current liabilites	40,730	36,830
Current liabilities	8,286	11,579
Equity	7,375	9,955

	December 31, 2020	December 31, 2019
Number of employees	149	174
Biofrontera Shares		
Number of shares outstanding	47,747,515	44,849,365
Share price (Xetra closing price in EUR)	3.05	4.60

Commercialization of Ameluz® in the USA

Revenues generated from sales in the U.S.A. were EUR 16.6 million, compared to EUR 23.3 million in 2019, representing a decrease of 29% year-on-year. Revenues include EUR 0.3 million from product sales of Xepi® (previous year: EUR 0.6 million).

As reported above, Biofrontera was directly affected by the global coronavirus crisis from mid-March 2020. From that point on, rising infection rates and the official recommendation of the American Academy of Dermatology to provide patients with remote diagnosis and treatment whenever possible led to significantly declining patient numbers and extensive, albeit temporary, practice closures. In the wake of this, our U.S. sales in particular declined sharply. As a result, Biofrontera Inc. the wholly owned subsidiary in the U.S.A., initiated extensive cost-cutting measures, including headcount reductions. After sales of our products initially fell to almost zero in April 2020, we observed a slow recovery of our U.S. business again in the summer and later the first signs of stabilization in line with the usual seasonality. In many parts of the U.S., doctors' offices reopened during the second half of the year, at least in part, and patients showed increasing willingness to undergo treatment for actinic keratosis. In the fourth quarter of 2020, we again saw a

seasonally strong increase in sales, but overall sales in this quarter also remained below the level of the previous year, in part due to the so-called second wave of coronavirus infections.

Commercialization of Ameluz® in Europe

Revenue from product sales in Germany increased by approximately 11% to EUR 5.1 million in fiscal 2020 compared to EUR 4.6 million in 2019, despite Corona-related restrictions. In the rest of Europe, the pandemic led to a decline in sales, with product sales of EUR 2.1 million compared to EUR 2.6 million in the prior-year period.

In Germany, our sales team successfully leveraged an approval extension granted in March 2020 to include the treatment of actinic keratoses on the body and extremities, as well as recent study results, even during the crisis, promoting the benefits of Ameluz® to dermatologists. In this context, the advantages of daylight PDT, which could be performed in good weather without immediate contact with doctors, became particularly evident during the summer months. In Spain, we saw very positive sales development at the beginning of the year prior to the outbreak of the pandemic, after which business declined sharply due to the strict lockdown regulations there. In the United Kingdom, sales remained at a low level for almost the entire year due to the pandemic.

Sales generated by distribution partners in other European countries contributed only a small share to total sales.

Regional expansion of the commercialization of Ameluz®

On March 13, 2020, the Company announced that it had signed a non-binding term sheet for an exclusive license agreement with medac GmbH Sp. z o.o., Warsaw, the Polish subsidiary of medac Gesellschaft für klinische Spezialpräparate mbH, for the commercialization of Ameluz® and BF-RhodoLED® in Poland. The term sheet contains terms and conditions regarding the amount of the one-time license fee of about EUR 200,000, the expected term of 5 years, the transfer price for Ameluz® and BF-RhodoLED® as well as the local regulatory responsibilities in Poland.

On April 20, 2020, Biofrontera concluded 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 sales in the countries covered by the agreement. This partnership gives us the opportunity to generate long-term revenues at low cost and low business risk in markets that we are unlikely to be able to serve with our own resources. We will continue to focus on the USA and Europe, which are already well established and key markets for us. As part of the licensing agreement, Maruho has made a one-time payment of EUR 6.0 million to Biofrontera AG. In addition, further future payments are dependent on the achievement of certain regulatory and sales milestones as well as royalties on sales.

On December 7, 2020, the Company announced that its wholly owned subsidiary Biofrontera Pharma GmbH and Galenica AB, Malmö, Sweden, signed an exclusive license and supply agreement for the marketing of both Ameluz® and BF-RhodoLED® in Sweden, Norway, Denmark, Finland and Iceland. According to the agreement, Galenica AB of Malmö, Sweden, receives exclusive distribution rights for the Nordic regions, whereby Biofrontera will supply Ameluz® to Galenica at a transfer price of 50% of the expected net revenues. Furthermore, Biofrontera will be responsible for the marketing authorization as well as manufacturing and quality control, while Galenica will handle all aspects of commercialization, local registration and reimbursement in the Scandinavian countries. Both companies will collaborate on regulatory compliance regarding drug safety (pharmacovigilance). After the amicable termination of the agreement between Biofrontera and the former distribution partner for some of these regions, Galenica is now working towards the reintroduction of the products in Denmark, Sweden and Norway and their initial launch in Finland and Iceland by the middle of next year. In addition, Galenica has a right of first refusal for commercialization in the Baltic States.

Consequences of the COVID-19 pandemic

As a result of the coronavirus crisis, the number of treatments 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.

As such, short-time work was introduced for all employees in Germany until the end of July 2020. Similar measures were implemented for the subsidiaries in Spain and the UK. The US subsidiary Biofrontera Inc. had also introduced significant cost-cutting measures. As described above, the headcount there was significantly reduced and a furlough program was introduced, under which all employees were required to take temporary unpaid leave. In addition, the members of the Supervisory Board as well as the Management Board of Biofrontera AG and the management of Biofrontera Inc. voluntarily waived part of their salaries. In addition, costs for training and continuing education, among other things, were reduced in the year under review.

While these cost reduction measures were in effect, the Company was able to ensure full compliance with all legal requirements from a medical and capital markets perspective at all times as well as comply with all continuous disclosure obligations.

Due to the COVID-19 crisis, the continued challenging business environment has impacted the valuation of some of the Company's assets and liabilities. During the crisis, the sales strategy in the U.S. market has focused on our flagship product Ameluz® and the targeted re-launch to improve the positioning of our in-licensed product Xepi® had to be delayed. The reduced sales of Xepi® led to a reassessment of the medium-term business and earnings prospects for Xepi® and thus to an impairment of the Xepi® license in the first quarter of 2020. To a minor extent, inventories were written down as of December 31, 2020 due to an anticipated expiration of shelf life. Beyond this, no significant risks have arisen in relation to financial instruments, particularly regarding unusual receivables.

Reorganization of the sales structure and the US business

In January, following the reorganization of the US subsidiary Biofrontera Inc., we also restructured the sales and marketing structure in Europe. In the course of this restructuring, Christoph Dünwald resigned from his position as Chief Commercial Officer (CCO) in order to devote himself to new tasks. Biofrontera's worldwide sales organization now stands on two pillars: sales and marketing in the USA, Biofrontera's largest market, and the joint management of all sales organizations in Europe.

Regulatory and clinical progress

Based on a positive assessment by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on February 3, 2020, the European Commission granted the formal label extension for Ameluz® on March 10, 2020, which now also covers the treatment of mild and moderate actinic keratoses (AK) on the extremities and trunk/neck with photodynamic therapy (PDT).

In addition, the results of the follow-up phase of the clinical comparative study on daylight PDT with Ameluz® and Metvix® were included in the product information (SmPC). Ameluz® showed significantly lower recurrence rates after 12 months at 19.5% compared to Metvix® at 31.2%.

Based on a positive assessment by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) on February 3, 2020, the European Commission granted the formal label extension for Ameluz® on March 10, 2020, which now also covers the treatment of mild and moderate actinic keratoses (AK) on the extremities and trunk/neck with photodynamic therapy (PDT).

In addition, the results of the follow-up phase of the clinical comparative study on daylight PDT with Ameluz® and Metvix® were included in the product information (SmPC). Ameluz® showed significantly lower recurrence rates after 12 months at 19.5% compared to Metvix® at 31.2%.

In October 2020, the clinical phase of the pharmacokinetics study (PK study) in the USA, which had been underway since the beginning of the reporting year, was concluded with the so-called "last subject last visit". The PK study tested the safety of photodynamic therapy (PDT) for the treatment of actinic keratoses on larger or multiple areas with the simultaneous use of up to three tubes of Ameluz®. This represents a prerequisite for the treatment of larger body surfaces with multiple tubes of Ameluz® , as well as for the alignment of reimbursement modalities vis-à-vis competing products, and thus an increase in the competitiveness of Ameluz® in all our markets, particularly in the USA. The study report was submitted to the FDA in February 2021 with the objective of removing a restriction in the product information to the use of only one tube per treatment.

In addition, we were able to bring the development of the new BF-RhodoLED® XL lamp, which enables Ameluz® to be used on larger surfaces, to near completion. However, due to pandemic-related delays in the supply of parts for the production of the first production batch, it was not possible to submit the approval application to the FDA until March 2021.

In 2020, we also continued to pursue patient recruitment for the Phase III trial for the treatment of basal cell carcinoma (BCC) with Ameluz® in the USA.

Despite the COVID-19 pandemic and the associated measures, the Company was able to maintain full compliance with all regulatory requirements in the year under review. Although there were fewer (internal and external) employee training activities, we met the high-quality standards for ensuring drug quality with a higher number of audits and inspections in our quality management system compared with the previous year.

Subscription offers for mandatory convertible bonds

On February 26, 2020, the Management Board, with the approval of the Supervisory Board, resolved to issue up to 1,600,000 units of the 0.5% qualified subordinated mandatory convertible bond 2020/2024 and up to 1,600,000 units of the 1.00% qualified subordinated mandatory convertible bond 2020/2026. In March 2020, the subscription offer was withdrawn and not implemented due to the disruptions on the capital markets caused by the coronavirus crisis.

To ensure short-term liquidity, Biofrontera issued a 1.0% qualified subordinated mandatory convertible bond 2020/21 in August. The bond issue was fully placed with gross proceeds of EUR 7.9 million. On November 12, 2020, the Company announced that it would exercise its right of mandatory conversion pursuant to Section 8 (2) of the bond terms and conditions, which was then implemented in the year under review.

Exchange rate differences

As a result of the internationalization of the Company, the Company is exposed to currency risks in its sales and procurement markets. The exchange rate development in 2020 had a negative impact on the financial result.

The development of the USD exchange rate in the 2020 financial year resulted in losses from currency translation adjustments totaling EUR 3,601 thousand (previous year: income of EUR 324 thousand).

Evaluation of the business performance of the Biofrontera Group

Comparison of actual and forecast business performance

Due to the coronavirus pandemic and the resulting planning uncertainty, the Company's forecasting ability was severely impaired in the previous year. In April 2020, Biofrontera had assumed that the effects would lead to a noticeable decline in sales compared to earlier planning or even compared to the 2019 financial year. With the expected reduced sales, Biofrontera assumed that the profitability of the Group as well as the cash position of Biofrontera AG and the Group in the 2020 financial year would also be negatively impacted, as the shortfall in sales may not be fully offset by cost reduction measures. Steps to secure liquidity and strengthen cash flow had high priority.

Evaluation of the business performance by the Management Board

In total, the Group generated sales of more than EUR 30 million in the 2020 financial year. As forecast, the COVID 19 pandemic led to a significant slump in commercial activities from mid-March 2020 onwards. This led to lower product sales, especially in our largest sales market, the USA. In 2020, we recorded a 29% year-on-year decline in sales in this market. The decline in US sales was partially offset by cost reductions and the positive sales performance in Germany, where sales increased by a pleasing 11% year-on-year. The existing approval extension for daylight PDT in particular had a positive impact on sales development here.

Additionally, the Group received a one-time payment (down payment) of EUR 6 million from Maruho. As a result, the Group's total revenue was only slightly below the prior-year result.

Group EBITDA (loss) decreased to EUR (4,696) thousand in the 2020 financial year (previous year: earnings of EUR 964 thousand). This still includes the one-off effects from the receipt of the down payment from Maruho in 2020 in the amount of EUR 6,000 thousand) and from the badwill of EUR 14,812 thousand resulting from the acquisition of Cutanea in the previous year. Adjusted for these effects, the development of EBITDA is as follows:

in EUR thousands	2020	2019
EBITDA	(4,697)	964
One-off effects	(6,000)	(14,812)
Adjusted EBITDA (loss)	**(10,697)**	**(13,848)**

At EUR 5,333 thousand, depreciation and amortization in the 2020 financial year was higher than the previous year's amount of EUR 3,156 thousand, resulting from the unscheduled write-down due to the Xepi® impairment in the amount of EUR 2,001 thousand. Accordingly, EBIT (loss) in the reporting year amounts to EUR (10,029) thousand compared to EUR (2,192) thousand in the prior year.

Biofrontera reports consolidated earnings (loss) before income taxes of EUR (12,697) thousand (previous year: loss of EUR 4,777 thousand). In the single-entity financial statements, a net loss of EUR 3,196 thousand is reported, compared to a loss of EUR 2,034 thousand in 2019.

Due to the fully placed convertible bond 2020/2021 in August 2020 and the down payment received from Maruho, the negative impact of the COVID-19 pandemic on the financial position was compensated. In addition, the cost reduction measures introduced successfully mitigated the negative impact on the sales side. Although the overall business performance of the Biofrontera Group in the 2020 fell short of initial expectations, we were able to overcome the coronavirus crisis comparatively well. As a result, and also due to the capital measure resolved in May 2020 and successfully implemented in February 2021, Biofrontera is financially well-equipped for the future.

Biofrontera Group financial position and performance

Results of operations of the Biofrontera Group

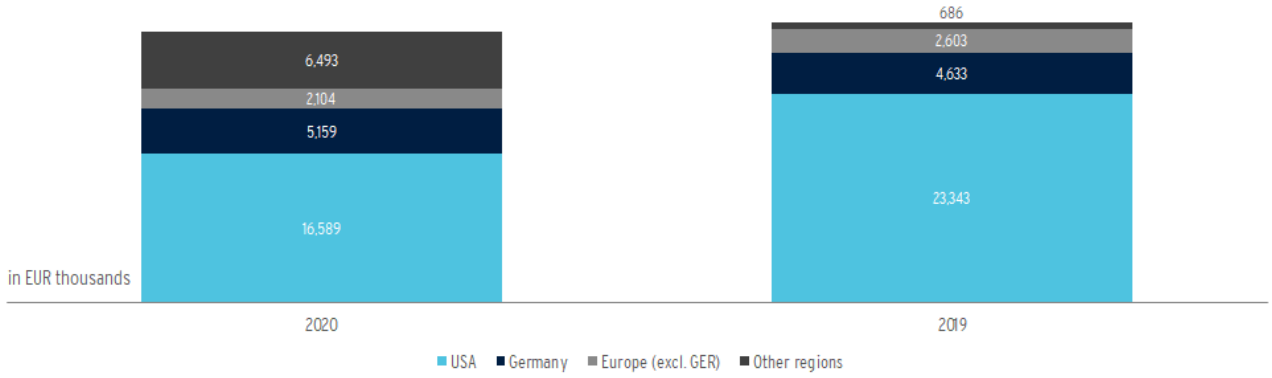
The results of operations as of December 31, 2020 are as follows:

in EUR thousands	2020	2019
Sales revenue	30,346	31,265
Gross profit on sales	26,810	26,390
Research and development costs	(4,789)	(4,636)
General administrative costs	(9,150)	(16,275)
Sales and marketing costs	(20,482)	(28,856)
Loss from operations	(7,611)	(23,377)
Other expenses and income	(2,418)	21,184
EBIT	(10,029)	(2,192)
Interest result	(2,668)	(2,584)
Loss before income tax	(12,697)	(4,777)
Loss after income tax	(13,023)	(7,358)

Sales revenue

The Biofrontera Group generated total revenues of EUR 30,346 thousand in 2020, a decrease of 3% compared to the amount generated last year (previous year: EUR 31,265 thousand). Revenues from product sales decreased by almost 22% year-on-year to EUR 23,853 thousand (previous year: EUR 30,579 thousand). The greatest impact of the coronavirus pandemic was felt in the USA, where sales fell by 29% to a total of EUR 16,589 thousand (previous year: EUR 23,343 thousand). This includes EUR 279 thousand in sales of the new product Xepi® (previous year: EUR 566 thousand).

Sales in Germany improved by 11% year-on-year to EUR 5,159 thousand (previous year: EUR 4,633 thousand). In other European countries, total sales decreased by 19% to EUR 2,104 thousand (previous year: EUR 2,603 thousand). Revenues from other regions amounted to EUR 6,493 thousand (previous year: EUR 686 thousand) and include EUR 6,000 thousand in revenue from a down payment from Maruho.



Gross profit on sale

Gross profit increased only slightly by EUR 420 thousand in 2020 to EUR 26,810 thousand compared to EUR 26,390 thousand in the prior-year period. The gross margin improved from 84% in 2019 to 88% in fiscal year 2020 due to the down payment of EUR 6,000 thousand.

Research and development costs

In the year under review, research and development costs of EUR 4,789 thousand were slightly above the previous year's level of EUR 4,636 thousand. They include costs for clinical trials as well as regulatory expenses, i.e., for the granting, maintenance, and extension of our regulatory approvals.

General and administrative costs

General and administrative costs amounted to EUR 9,150 thousand in 2020 (previous year: EUR 16,275 thousand) and thus decreased by a total of EUR 7,125 thousand compared to the previous year. This was mainly due to the cost-saving measures introduced in response to the COVID-19 pandemic and lower legal and consulting expenses in the amount of EUR 1,976 thousand (previous year: EUR 6,929 thousand).

Sales and marketing costs

In fiscal year 2020, sales and marketing expenses amounted to EUR 20,482 thousand, a significant reduction of EUR 8,374 thousand compared to the previous year of EUR 28,856 thousand. In this context, the effects of the cost-saving measures that were implemented are offset by the non-cash impairment of the Xepi® license in the amount of EUR 2,001 thousand. Sales and marketing costs include the expenses for our sales forces in Germany, Spain, the United Kingdom, and the United States, as well as marketing expenses.

Result of operations

Loss from operating activities improved by EUR 15,766 thousand compared with the previous year loss in the amount of EUR 23,377 thousand to a loss of EUR 7,611 thousand, mainly as a result of the cost-saving measures implemented in the reporting period and the effects of the first-time consolidation of Cutanea included in the previous year's figure.

Interest result

Interest expenses amounted to EUR 3,079 thousand (previous year: EUR 2,712 thousand) and mainly comprise interest expenses for the EIB loan in the amount of EUR 1,765 thousand (previous year: EUR 1,716 thousand) as well as the fair value change of the purchase price liability for Cutanea in the amount of EUR 750 thousand (previous year: EUR 650 thousand).

Other income and expenses

Other expenses and income totaled EUR (2,418) thousand in the reporting period (previous year: EUR 21,184 thousand), with the previous year's amount including non-recurring effects from the acquisition of Cutanea Life Sciences, Inc. amounting to EUR 21,027 thousand. In addition, expenses and income from currency translation amounting to EUR (3,601) thousand (previous year: EUR 324 thousand) are reflected here.

Income taxes

This item includes actual income taxes of EUR 56 thousand (previous year: income of EUR 26 thousand) and deferred tax expense of EUR 269 thousand (previous year: EUR 256 thousand) from the utilization of tax loss carryforwards at Biofrontera Pharma GmbH. In the previous year, deferred income tax expense was also recognized from the reduction in the trade tax assessment rate of the city of Leverkusen in the amount of EUR 2,350 thousand.

Net assets of the Biofrontera Group

Net assets

in EUR thousands	December 31, 2020	December 31, 2019
Non-current assets	30,264	35,872
Current financial assets	20,579	17,227
Other current assets	5,547	5,264

in EUR thousands	December 31, 2020	December 31, 2019
Total assets	**56,391**	**58,363**
Equity	7,375	9,955
Non-current liabilities	40,730	36,830
Current financial liabilities	2,852	5,507
Other current liabilities	5,434	6,071
Total equity and liabilities	**56,391**	**58,363**

Non-current assets

The non-current assets as of December 31, 2020 in the amount of EUR 30,264 thousand (previous year: EUR 35,872 thousand) include the recognized deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of EUR 7,525 thousand, tangible assets in the amount of EUR 5,051 thousand (previous year: EUR 5,230 thousand) and intangible assets of EUR 17,688 thousand (previous year: EUR 22,848 thousand). This includes the acquired Xepi® license in the amount of EUR 16,720 thousand (previous year: EUR 22,078 thousand). The valuation of the balance sheet item was assessed by means of an impairment test, which also took into account the current market situation influenced by the COVID 19 pandemic and the resulting shifts in the timing of the market penetration of Xepi®. As a result, this led to a non-cash impairment loss of EUR 2,001 thousand.

Current financial assets

Current financial assets amounted to a total of EUR 20,579 thousand as of December 31, 2020 (previous year: EUR 17,227 thousand). This includes cash and cash equivalents of EUR 16,546 thousand (previous year: EUR 11,119 thousand), trade receivables of EUR 3,501 thousand (previous year: EUR 5,031 thousand) and other current financial assets of EUR 531 thousand (previous year: EUR 1,077 thousand).

Other current assets

Other current assets mainly comprise inventories. This increased to EUR 4,673 thousand (previous year: EUR 4,065 thousand) due to higher inventories of raw materials and supplies as a result of the initial provisioning of an additional contract manufacturer. Impairment losses of EUR 414 thousand (previous year: EUR 24 thousand) were recognized in the reporting year due to an expected expiry of the shelf life of inventories.

Equity

The Group reports equity of EUR 7,375 thousand in accordance with IFRS accounting principles (previous year: EUR 9,955 thousand). The equity ratio decreased slightly from 17% to 13%.

Non-current liabilities

Non-current liabilities include financial liabilities of EUR 22,736 thousand (previous year: EUR 22,110 thousand) and other non-current financial liabilities in the amount of EUR 17,994 thousand (previous year: EUR 14,720 thousand). This includes in particular the purchase price liability for Cutanea Life Sciences, Inc. in the amount of EUR 17,811 thousand (previous year: EUR 14,720 thousand). The increase in the purchase price liability measured at fair value is due in particular to the provision of further start-up costs by Maruho in the amount of EUR 3,547 thousand.

Non-current financial liabilities include the EIB loan incl. performance component totaling EUR 18,076 thousand (previous year: EUR 17,146 thousand), the unconverted shares of the convertible bond 2017/2022 in the amount of EUR 2,003 thousand (previous year: EUR 1,977 thousand), and liabilities from leases to recognized in accordance with IFRS 16 in the amount of EUR 2,657 thousand (previous year: EUR 2,987 thousand).

Current financial liabilities

Current financial liabilities include in particular trade payables of EUR 1,623 thousand (previous year: EUR 4,196 thousand) as well as current liabilities from leases of EUR 1,057 thousand (previous year: EUR 1,038 thousand).

Other current liabilities

Other current liabilities amounted to EUR 5,434 thousand (previous year: EUR 6,071 thousand) and include in particular accruals of EUR 3,042 thousand (previous year: EUR 3,495 thousand) and other deferred liabilities of EUR 2,392 thousand (previous year: EUR 2,565 thousand).

Financial position of the Biofrontera Group

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

in EUR thousands	2020	2019
Cash flow from operating activities	(2,849)	(32,894)
Cash flow from investing activities	2,873	21,053
Cash flow from financing activities	5,948	3,455
Cash and cash equivalents	16,546	11,119
Non-current financial liabilities	22,736	22,110
Current financial debt	1,139	1,212
Net liquidity	(7,328)	(12,203)

Net cash flow from operating activities of EUR (2,849) thousand (previous year: EUR (32,894) thousand) decreased mainly due to the effects from the acquisition and restructuring of Cutanea included in the previous year's figure.

Net cash flow from investing activities decreased by EUR 18,180 thousand from EUR 21,053 thousand to EUR 2,873 thousand in the 2020 financial year. The previous year's figure includes EUR 22,814 thousand in liquidity taken over as part of the Cutanea acquisition as well as start-up costs from Maruho. Investments in property, plant and equipment and intangible assets amounted to EUR 774 thousand (previous year: EUR 1,854 thousand).

The increased net cash flow from financing activities amounted to EUR 5,948 thousand (previous year: EUR 3,455 thousand) and mainly includes the proceeds from the mandatory convertible bond 2020/2021. In the previous year, cash inflows resulted from the further utilization of a tranche of the EIB loan (EUR 5,000 thousand). At EUR 2,145 thousand, cash outflows for lease payments and interest paid were slightly higher than in the previous year at EUR 1,847 thousand.

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 of EUR 2,003 thousand and the first EIB tranche of EUR 12,474 thousand mature in 2022. The second EIB tranche in the amount of EUR 5,591 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 major subsidiaries. The loan has three different interest 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% p.a., which is due at the end of the term, and a so-called performance component, which is also due at the end of the term and which depends on the market capitalization of Biofrontera AG, but is capped at an interest rate of 4% p.a.

Cash and cash equivalents

Cash and cash equivalents in the Group amount to EUR 16,546 thousand as of December 31, 2020 (previous year: EUR 11,119 thousand).

From the present perspective, also due to the capital measure carried out in February 2021, Biofrontera AG and the Biofrontera Group have sufficient liquidity available to implement the Group strategy.

Biofrontera AG financial position and performance

Results of operations of Biofrontera AG

in EUR thousands	2020	2019
Sales revenue	4,220	7,919
Other operating income	1,409	498
Personnel costs	(3,008)	(3,395)
Depreciation and amortization	(23)	(29)
Other operating expenses	(8,142)	(8,474)
Other interest and similar income	3,943	3,435
Interest and similar expenses	(1,594)	(1,987)
Other taxes	(1)	(1)
Net loss	(3,196)	(2,034)

The sales revenues reported in the single-entity financial statements are prepared in accordance with German commercial law and include revenues from intragroup services and from the remuneration for initiating and concluding the license agreement with Maruho Co, Ltd. to the subsidiary Biofrontera Pharma GmbH. The prior-year amount also included income from intercompany charges, which will be reported under other operating income in 2020.

In the wake of the COVID-9 pandemic, short-time work was introduced for all employees, resulting in lower personnel costs.

Other operating expenses decreased in particular due to the decrease in costs for legal advice by EUR 3,612 thousand to EUR 1,071 thousand. On the other hand, significant exchange losses of EUR 3,636 thousand (previous year: EUR 49 thousand) were incurred in connection with the loan granted to the subsidiary Biofrontera Inc.

The increase in interest and similar income is due to the further granting of loans to Group companies. Interest expenses decreased in particular due to lower interest expenses on the loan provided by the EIB.

The net loss for the year amounts to EUR 3,196 thousand (previous year: loss of EUR 2,034 thousand).

Net assets of Biofrontera AG

in EUR thousands	December 31, 2020	December 31, 2019
Non-current assets	70,690	32,262
Receivables due from affiliated companies	59,000	97,165
Cash and cash balances with banks	9,201	3,926
Other assets	187	285
Total assets	**139,078**	**133,638**
Equity	115,200	109,604
Provisions	3,572	4,026
Bonds	2,031	2,031
Liabilities to banks	17,722	16,900
Other liabilities	553	1,077
Total equity and liabilities	**139,078**	**133,638**

As in the previous year, non-current assets relate almost exclusively to shares held in affiliated companies. The addition of shares in affiliated companies in the amount of EUR 38,425 thousand and the associated reduction in receivables from affiliated companies result from the conversion of the loan granted between Biofrontera AG and the US subsidiary Biofrontera Inc. into equity.

Cash on hand and bank balances increased from EUR 3,926 thousand in the previous year to EUR 9,201 thousand in 2020. For further details on the financial position, please refer to the presentation of the consolidated financial position.

As of December 31, 2020, Biofrontera AG holds equity of EUR 115,200 thousand in accordance with commercial law (previous year: EUR 109,604 thousand). In particular, the issue and conversion of the mandatory convertible bond 2020/2021 increased equity by EUR 7,915 thousand.

Provisions mainly include provisions for litigation costs in the amount of EUR 1,979 thousand (previous year: EUR 2,523 thousand) and provisions for the performance component of the EIB loan in the amount of EUR 768 thousand (previous year: EUR 838 thousand).

The bonds include the convertible bond 2017/22. Liabilities to banks increased by EUR 823 thousand, in particular due to interest payable at maturity on the loan provided by the EIB.

Assessment of the financial position of Biofrontera AG and the Group

In the single-entity financial statements of Biofrontera AG, liquidity amounts to EUR 9,201 thousand, compared to EUR 3,926 thousand in the previous year. The Group's liquidity increased by EUR 5,427 thousand to EUR 16,546 thousand in the 2020 financial year. Key factors influencing liquidity in the 2020 were the successful capital increase in August 2020 and the one-off payment received from Maruho. Together with the cost-saving measures introduced in 2020, liquidity developed positively in 2020.

Taking into account the capital measure carried out in February 2021 with gross proceeds of EUR 24,667 thousand, the Biofrontera Group currently has sufficient liquidity to continue to finance business operations for at least 12 months.

Outlook

Business environment

We expect the global economy to grow again in 2021 following the recession in the previous year. However, the first months of the year are likely to be dominated by the containment of the COVID-19 pandemic. With the anticipated distribution of effective vaccines among the population, we expect the situation to improve starting in the second half of 2021. In this context, the recovery of the economy will continue to depend heavily on the course of the pandemic and the measures taken by governments to contain it.

The German government's (Federal Ministry for Economic Affairs and Energy) Annual Economic Report 2021, published on February 2, 2021, indicates a 5.0% decline in German gross domestic product (GDP) in 2020, due to the impact of the COVID-19 pandemic. To date, both the German government and the German Council of Economic Experts have assumed a significant recovery in economic activity in 2021, with GDP rising by 3.0% and 3.7%, respectively. However, both the German government and the Council of Economic Experts conceded that the German economy would not reach its pre-crisis level seen in the fourth quarter of 2019 before the middle or beginning of 2022.

According to a February 1, 2021 release from the U.S. Congressional Budget Office (CBO), U.S. gross domestic product fell 3.5% in 2020 due to the pandemic. For the current year, it is expected that vaccination will cause a sharp decline in the number of infections. In its new economic forecast, which covers the period from 2021 to 2031, the CBO therefore projects that the positive economic trend that began in mid-2020 will continue, with GDP expected to return to pre-pandemic levels by mid-2021. For 2021, CBO projects that GDP will increase by 4.6%.

Our key markets, the U.S. and Germany, experienced fewer actinic keratosis treatments in 2020. We saw a 17% decline in the AK market in the U.S. and a 2% decline in Germany. While the option for daylight PDT in Germany continued to establish PDT treatment as a "contact-free" treatment for patients, the PDT market in the U.S. completely collapsed at the onset of the pandemic. As previously reported by us, due to the pandemic-related restrictions as well as the treatment recommendation (telehealth) of the American Academy of Dermatology (AAD), our largest sales market has still not been able to recover to pre-crisis levels.

Guidance

The Biofrontera Group provides the following guidance for the full year 2021, which reflects the Group's assessment regarding the timing and speed of recovery from the pandemic. We expect that due to the vaccination programs, the pandemic will slowly subside in our key sales markets, resulting in a growth momentum in the second half of 2021.

Forecast of key financial indicators

The Group expects revenue from product sales of EUR 25 to 32 million in fiscal year 2021. Our sales and thus business activities largely depend on the further infection trend and the associated easing of containment measures.

Particularly in the U.S.A., our primary sales market for our flagship product Ameluz®, we expect demand to remain subdued as fewer face-to-face patient visits to physicians continue to occur, resulting in fewer prescriptions and lower demand for drugs that must be administered in a physician's office. Treatment of skin diseases in a physician's office has generally been less attractive to patients during the ongoing pandemic. As Ameluz® is sold directly to physicians in the U.S., the impact of restrictions on travel as well as on visits to doctors' offices, also factors into our sales team's work. For our second product in the U.S. portfolio, Xepi®, we are planning a re-launch in the dermatology market to increase awareness and accelerate the use and prescribing of the drug by dermatologists. However, due to the strong market penetration of generic topical antibiotics, we continue to expect relatively low sales in the 2021 re-launch phase.

In Germany, our key European sales market, we expect to continue the steady expansion of the PDT market by gaining market share. Daylight PDT approved in Europe is expected to remain a growth driver in 2021. In Europe, we expect first sales from the licensing agreement with Galenica AB in Scandinavia starting in the second half of the year.

We also anticipate that the FDA's amendment to the product information for Ameluz® in the USA to allow the simultaneous use of three tubes will be issued before the end of the year. Biofrontera also expects approval of the larger BF-RhodoLED® XL lamp in the U.S. by year-end (see " Planned regulatory progress" section below) as well as plans for extensive marketing activities to support product sales across the U.S. portfolio. While it is difficult to quantify the outcome of the marketing activities, they do lead us to expect increased growth momentum in the second half of the year. However, as mentioned earlier, this is heavily dependent on the course of the pandemic. Consequently, there is still considerable uncertainty with regard to the sales revenues that may be

generated in 2021. Furthermore, following the successful completion of the capital increase in February 2021, we are increasing our R&D activities (see "Planned regulatory progress" section below).

As described in the section "Internal controls," EBITDA and EBIT will be introduced as key performance indicators in our reporting starting in 2021. Both have become established internationally as target metrics and will replace the previously reported key performance indicator result from operating activities.

Group EBITDA includes earnings before interest, taxes, depreciation of tangible assets and amortization of intangible assets. EBIT includes earnings before interest and taxes. These key performance indicators are suitable for describing and comparing operating performance, as non-operating fluctuation variables, for example valuation adjustments and amortization of acquired assets, are not included here.

Based on the above assumptions, the 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 the 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 16.5 million for the Group as of December 31, 2020. 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.

For the single-entity financial statements of Biofrontera AG, we continue to expect a loss in 2021, which will, however, be slightly lower than in 2020.

Forecast of other key performance indicators

To adequately continue to drive and support the Company's growth, Biofrontera expects a slight increase in headcount in 2021, following a reduction in headcount in 2020 to a total of 149 as of December 31, 2020, from 174 as of December 31, 2019, due to pandemic-related cost saving measures. Based on the slight increase in headcount as well as the necessary easing of cost saving measures, we expect annual training and development expenses as well as the number of training sessions to increase in 2021 compared to 2020.

The maintenance and further development of our approvals are essential for securing and strengthening Biofrontera's market position and as such are reflected in our quality management, among other things. Accordingly, the number of external and internal audits, for instance, are important non-financial performance indicators for the Company. We expect the number of audits in 2021 to be higher compared to the number in 2020.

Planned regulatory progress

We are currently conducting a phase III- 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. However, due to the extremely demanding study protocol mandated by the FDA, the recruitment process will likely take a considerable amount of time. Patient recruitment is expected to be completed in the beginning of 2022.

Based on the March 2020 approval for the European label extension, Biofrontera has also held discussions with the FDA about expanding the label for Ameluz® in the USA to include the treatment of AK on the extremities and trunk/neck. The FDA expects additional clinical trials in order to approve the label extension of Ameluz® to include additional body regions. The study protocol will be coordinated with the FDA prior to the start of the clinical trials. Patient recruitment is expected to start prior to the end of 2021.

Following consultation with the FDA, Biofrontera initiated a phase I pharmacokinetics study (PK study) to test the safety of PDT using three tubes of Ameluz®. This will ensure reimbursement of multiple tubes for the treatment of larger body regions in the periphery in the USA in the future. The Company was able to complete this study in October 2020. After analyzing the study data and preparing the study report, the results and safety argumentation were incorporated into the registration dossier (NDA). In February 2021, the Company announced the submission of an application to the FDA to amend the product information, which currently limits use to one tube of Ameluz® per treatment. We expect feedback regarding the change to the product information by the end of the year.

To complement this progress with an optimized illumination source, Biofrontera has developed a new lamp, the BF-RhodoLED® XL, which can be used to illuminate larger areas of skin. After the Company experienced delays in manufacturing the initial batch due to delays in the supply of parts caused by the coronavirus crisis, the application for approval was submitted to the FDA in March 2021. We expect the approval process to take until the end of 2021.

With regard to the possible label extension of Ameluz® for acne in the USA, Biofrontera has prepared a corresponding development plan for the indication extension and received feedback from the FDA on the design of the necessary clinical trials. The study program is expected to start with a Phase IIb trial in the second half of 2021.

Risk and opportunity report

Each industry has its own specific characteristics that give rise to specific risks. The health industry, in particular, is in a state of constant change, with the ensuing risks and opportunities being shaped by a wide variety of influences.

As an internationally biopharmaceutical company, the Biofrontera Group is exposed to a large number of risks arising from its business activities, which can have a significant impact on the achievement of the targets. Deviations from the plan are to be understood as opportunities (positive deviations) and risks (negative deviations).

Risk management system

Biofrontera's management deploys a comprehensive risk management system to counter risks within the Biofrontera Group. The risk management system for the Biofrontera Group applies equally to Biofrontera AG. By virtue of its holding company function, Biofrontera AG controls all the legally independent entities within the Biofrontera Group. For this reason, risks and opportunities must be assessed on a standard basis across the entire group of companies.

The Biofrontera Group's primary objective is to achieve sustainable and long-term growth while continuously increasing the Company's value. Risk management plays a major role in achieving this objective. Risk management at Biofrontera involves the identification of risks that could lead to lasting or significant harm to the Group's financial position and performance, as well as the responsible analysis and monitoring of such risks and initiation of suitable countermeasures. This requires the establishment of guidelines, organizational structures and measuring and monitoring processes that are specifically geared to the Biofrontera Group's activities.

Correspondingly detailed risk prevention measures are essential to fully exploit the opportunities arising from Biofrontera's business activities. Biofrontera's existing risk management structures are continuously being further developed to reflect the quality management system required for pharmaceutical manufacturers and businesses, as well as medical device manufacturers. This system incorporates sales and marketing activities, as well as the international responsibilities of license holders with regard to the manufacture and sale of drugs, medical devices and cosmetics.

The Biofrontera Group's risk management system is integrated into its corporate processes and decision-making processes, thereby forming an integral element of planning and controlling processes Group-wide. Risk management and control mechanisms are coordinated with each other. These ensure that risks of relevance the Company are identified and evaluated at an early stage. They also serve to rapidly seize potential opportunities.

Risk management at Biofrontera is organized both locally and centrally. The Management Board exercises overall responsibility in this regard. The coordinated subsystems are the specialist departments' responsibility. Opportunities and risks are regularly identified and evaluated at all hierarchical levels. All Biofrontera Group management staff as well as the audit committee are involved in Group-wide risk monitoring and associated reporting. This includes the Management Board, the companies' managing directors, and process and project managers.

The Risk Management Team headed by the Chief Executive Officer is responsible for the risk management system. It coordinates the individual management bodies and ensures they receive their information continuously and promptly. The team is also responsible for the continuous monitoring of risk profiles, for initiating risk prevention measures, and for corresponding monitoring instruments. The Biofrontera Group management holds regular meetings at which the Group's central and operational departments exchange and evaluate information relevant to risk management at all levels.

The Risk Management Officer, who is also a member of the Risk Management Team, is the first point of contact Group-wide. If unexpected risks arise, he/she immediately initiates the necessary steps to counteract them. The Risk Management Officer is responsible for developing the risk management system, and for ensuring that it is properly documented. Furthermore, the Risk Management Officer sets uniform standards and ensures that similar types of risk management processes are implemented throughout the Biofrontera Group. Regular analysis of key business performance indicators helps to ensure that any possible discrepancies from expected performance levels in terms of potential opportunities and risks can be identified and assessed at an early stage, allowing necessary measures to be adopted in a reasonable time. The relevant control variables and business processes are monitored as a whole. Risk planning and identification in this area are performed in collaboration with the relevant unit managers.

Accounting risk management system and internal controls

The Group financial accounting process at Biofrontera AG aims to ensure that the figures and information provided in external accounting instruments (bookkeeping, components of the separate and consolidated financial statements as well as the management report) are accurate and complete, and comply with the relevant legal requirements and bylaw provisions. The related existing structures and processes include detailed internal control measures integrated into the financial accounting process. In connection with the growing business activities, the internal accounting control system is subject to an ongoing monitoring and improvement process.

The internal control system aims to identify, assess and manage all the risks that could prevent the proper preparation of the separate and consolidated financial statements. Any risks identified must be assessed with regard to their influence on the separate and consolidated financial statements. The purpose of the internal accounting control system is to ensure that the process of compiling financial statements complies with all the relevant laws and regulations, by implementing appropriate guidelines, processes and controls to this end. The internal control system covers all the areas that are essential for the separate and consolidated financial statements and all the processes relevant to the preparation of the financial statements.

Significant aspects of accounting risk management and control include the clear assignment of responsibilities and controls for the compilation of financial statements, as well as transparent accounting standards. The two sets of eyes principle and separation of roles are also important control principles in financial accounting processes.

Risk reporting concerning financial instruments

In the ordinary course of business, the Group is exposed to risks that may have an impact on its net assets, financial position and results of operations.

Market risk

In general, Biofrontera's market risk consists of foreign currency and changes in interest rates.

- Foreign currency risk: As of the balance sheet date, the Biofrontera Group was exposed to foreign currency risks, in particular as a result of the intercompany loan granted to the subsidiary Biofrontera Inc. Trade receivables arise to a greater extent than in the past due to the business expansion in the USA and are regularly reviewed with regard to a potential default risk. Trade payables denominated in foreign currencies are insignificant. The Company does not enter into any specific currency hedging transactions. Exchange rate fluctuations are recognized in profit or loss.

- Interest rate risk: Interest rate risks exist for the purchase price liability for Cutanea to Maruho and the performance component of the EIB loan. Otherwise, the interest rate risk is considered negligible, as the existing interest rate modalities for the relevant financing of the Biofrontera Group can generally be adjusted to market conditions in the short to medium term. For the performance component, a limit of 4% mitigates the market price risk.

Purchase price risk

The purchase price risk relates to the earn-out agreement in connection with the acquisition of Cutanea. For instance, the current uncertain business outlook due to the COVID-19 pandemic may also affect the future valuation of certain assets and liabilities of the Company. Reduced sales of Xepi® may thus lead to a different assessment of the medium-term business and earnings outlook for Xepi® and subsequently to a revaluation of the balance sheet value of the earn-out agreement.

Credit risk

The Group incurs a credit risk if transaction partners are unable to meet their obligations within the ordinary payment periods. The maximum default risk on the balance sheet is represented by the book value of the respective financial asset. The development of receivables is monitored in order to identify possible default risks at an early stage and initiate appropriate measures. Biofrontera's financial instruments bear minimal risk of default.

Liquidity risk

Liquidity risk refers to the inability to meet existing or future payment obligations as they become due. To ensure the ability to pay at all times and to avoid financial shortages, Biofrontera has established a central cash management system that monitors liquidity requirements in the short, medium and long term. Refinancing for all Group companies is mainly provided by Biofrontera AG.

Liquidity is monitored and managed on the basis of short- and long-term corporate planning. Liquidity risks are identified at an early stage by simulating various scenarios. Current cash and cash equivalents are recorded and monitored on a daily basis.

For further information, please refer to the section "Liquidity, profitability and capital markets access".

Risks and opportunities relating to future business development and growth

The business strategy of Biofrontera AG is based to a large extent on establishing the current products, in particular the drug Ameluz®, on the relevant sales markets in the long term. In order to exploit market potential, it is necessary to obtain and expand the existing approvals in the USA and Europe. In addition, the aim is to broaden the product pipeline. The protection of our intellectual property is to be secured by a suitable patent strategy. The prerequisite for achieving these targets is ensuring sustained profitability and sufficient liquidity.

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® is the next innovation for the American dermatology market to be commercialized by Biofrontera. Increasing resistance to known antibiotics is a concern that is taken very seriously by American doctors. We are convinced that with Xepi® our portfolio now includes an innovative, promising product with a large market potential. Risks exist in a slower than projected market penetration of Xepi®.

Risks may arise from deviations from targets in the form of negative developments, the insufficient realization of targeted and already recognized opportunities or potentials, or the failure to take advantage of new opportunities. Biofrontera's risk management takes this into account through continuous analysis of relevant influencing factors.

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.

Since the beginning of 2020, for instance, COVID-19 has become a global pandemic. As a result of the measures implemented by governments worldwide, Biofrontera's business operations are directly affected. In particular, demand for Biofrontera's products in the U.S. has declined significantly due to different priorities for medical treatments that have emerged during the COVID-19 pandemic, delaying actinic keratosis treatment for most patients along with diagnosis. If the COVID-19 pandemic persists, we could experience adverse effects that could severely impact our business, operations, sales and marketing, and clinical trials. The immediate and indirect effects of the pandemic may ultimately have a corresponding negative impact on the Company's cash position as the pandemic continues. In addition, the success of the Company's financing measures could be compromised.

To this end, in 2020, the Company had successfully implemented immediate steps to mitigate these risks and to safeguard business processes by implementing comprehensive cost reductions, emergency plans to maintain central processes and activities to protect employees. If necessary, these could be implemented again.

For further information on the risks related to the ongoing COVID-19 pandemic, please refer to the section "Liquidity, profitability and capital markets access".

On February 1, 2020, the United Kingdom has left the European Union. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from European Union directives and regulations, this could impact the future regulatory regime which applies to products and the approval of product candidates in the United Kingdom. It remains to be seen how, if at all, the UK's exit of the EU will impact regulatory requirements for products in the United Kingdom. Due to the insignificant amount of revenues from product sales in the United Kingdom, the Company considers this risk to be very low.

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

Liquidity, profitability and capital markets access

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.

The Biofrontera Group may not be able to meet existing or future payment obligations due to insufficient availability of cash and cash equivalents. To date, the 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 totaling EUR 15 million from the European Investment Bank loan, the down payment of EUR 6 million received under the license agreement with Maruho concluded in April 2020, as well as the issuance of the convertible bond in August 2020, the Company has had sufficient liquidity at its disposal throughout the year under review. Therefore, and also due to the capital measure carried out in February 2021, the Group is well positioned for the future.

However, should the worldwide COVID-19 pandemic continue to last, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite possible cost reduction measures and might require further financing via the capital market. However, the Management Board currently assumes that despite the current crisis, appropriate capital measures could be implemented successfully.

Law and compliance

The 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 not yet been set. The lawsuit includes the alleged infringement of 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.

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

Regulatory approvals

Restrictions on existing approvals in Europe and the USA would call the Company's ability to market its products into question. In addition, the risk exists that strategically relevant extensions to approvals could not be approved, could be delayed or only approved to a limited extent, thereby impairing the Company's competitiveness vis-à-vis its competitors.

The Company compensates for such risks through consistent compliance with regulatory requirements and an effective quality management system.

Research and development

The Company is also exposed to risks in connection with product development processes or the expansion of indications. No guarantee exists that a product will be launched on the market at the end of a project's clinical development period, which is 6 to 10 years on average. Due to lack of success in individual study phases, for example in study design, patient recruitment, possible quality defects or documentation of study results, studies can prove more cost-intensive than planned, can be delayed or even come to a complete standstill. It is possible that none, or only some, of the funds invested will be recouped in sales revenue.

The Company tries to mitigate these risks, to some extent, by selecting projects with relatively attractive risk profiles, by setting up a project control and reporting system, and by drawing on the Supervisory Board members' professional expertise. The project control system represents the entire development process in detail right up to approval, making it possible to analyze the effects that even small changes or delays – with clinical trials, for example – can have on the development process and on its costs. This makes it possible to precisely observe the risk associated with individual projects and take the steps necessary to minimize the development risk.

Product portfolio

The Company's product portfolio currently contains two approved drugs, Ameluz® and Xepi®. While Ameluz® is being marketed in some European countries as well as the USA, Xepi® is only being sold by the Company in the US market and is still in its launch phase. A risk exists that neither Ameluz® nor Xepi® may not be established sufficiently or sustainably on the market. The consolidated financial statements are subject to the risk of impairment for the acquired Xepi® license in the event that it is not sufficiently or sustainably established on the market.

Disadvantages over our competitors are also possible due to advantages regarding the indication spectrum of competing products. Additional label expansions, for example, are initiated in order to gain competitive advantages.

A further risk is that the Company's own product pipeline cannot be broadened, and that successor or supplementary products cannot be made ready for market launch.

Biofrontera counters these risks by permanently observing the market with regard to the activities of known competitors or the entry of new competitors and leads the way in the market for its products and development activities in order to broaden the indication base. In addition, cooperation opportunities for expanding the product portfolio are being evaluated. In 2019, the integration of Xepi® in the product portfolio has already made a contribution to mitigating this risk.

Patent protection

The Company may be subject to patent protection risks. If our products are marketed successfully, the resulting profits can be deployed for sustainable ongoing investment in research and development activities. Due to the long time gap between the patent application and the launch of a product, Biofrontera generally has only a few years to earn a suitable income from its intellectual work. If a patent expires or cannot be successfully defended, increased competition is usually to be expected. A lack of patents can jeopardize the market position of the Company's products and facilitate the market entry of competitors. In order to avoid these risks, Biofrontera's patent portfolio is continuously reviewed and its patent strategy adjusted. Further information on individual patents can be found in the section on patent and trademark development.

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

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

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

Products and product stewardship

As an international biopharmaceutical company, Biofrontera is subject to the highest requirements and associated risks in the quality and safety areas. Biofrontera assesses potential environmental and health risks associated with a product along the entire value chain. This includes every stage from research and development to disposal, including production, marketing and customer use. Despite extensive studies, the possibility exists of previously unknown and unexpected side effects from Biofrontera products.

The Company may be exposed to a cost risk due to product safety deficiencies if, for example, our products are recalled voluntarily or as a result of legal or regulatory action. Possible payments of damages associated with the aforementioned risks could exert a considerable negative effect on the Company's financial results. These risks are offset by established pharmacovigilance processes in the Company and ensure that potential side effects or other product-related problems are quickly identified. As no previously unknown side effects of our drugs have appeared, we consider it highly improbable that risks of this kind will arise.

Both regulatory requirements and standards applied beyond them are guaranteed by a wide variety of processes integrated into the Company. The Company's product-related risks are countered with a functioning quality management system. Biofrontera's focus on Good Manufacturing Practice (GMP) guidelines and Standard Operation Procedures (SOPs), which are mandatory in the pharmaceutical industry, ensures the quality and safety requirements for products and processes. Regular internal audits of standards at suppliers and subcontractors contribute in this context. Regular checks and inspections are also carried out by regulators.

Markets

Biofrontera operates in regulated competitive markets. The Company's sales and revenue targets could be jeopardized by sales and revenue-related measures taken by competitors with respect to the indications treated with their products, pricing strategy or marketing strategy, as well as by new products introduced by competitors. If sales targets are not met, this could also have a negative impact on the Company's earnings and cash flow targets as well as impairments on already produced product inventories or the Xepi® license.

Changes in the respective healthcare systems and changes in the reimbursement behavior of payors as well as market barriers in the relevant markets may result in the risk of insufficient or unsustainable market penetration. The competitive position of our products may also be adversely affected by product characteristics that are not optimally perceived in the respective market in comparison with competing products. In addition, our products compete with other therapies. In the case of PDT with Ameluz®, we compete with treatments such as simple curettage and, particularly in the United States, cryotherapy, which do not require the use of a drug but have achieved significant market acceptance.

To avoid these risks, Biofrontera's sales and marketing organization carries out intensive market observation and regular market analyses. The marketing instruments deployed and communication with our customers are subject to constant further development in order to identify opportunities and risks and to strengthen the Company's competitive position.

Procurement and production

As a pharmaceutical manufacturer, the Company is exposed to various risks in connection with the procurement and production of its products. Biofrontera relies on individual manufacturers or suppliers for the production of its finished products as well as raw materials, whose exchange would entail lengthy regulatory approval processes. Difficulties regarding procurement prices, quality, delivery reliability or quantity at or with these suppliers may affect the Company's revenue and results targets. By establishing alternative suppliers, changing production sizes and actively managing contracts and inventories, Biofrontera seeks to minimize these dependencies and ensure the supply of the required goods and services.

Risks associated with the manufacturing, bottling, storage and transportation of products may result in personal injury or material or environmental damage and may give rise to an obligation to pay damages. Using our own audit and monitoring system, Biofrontera regularly ensures that the manufacturing conditions at its most important suppliers meet the required standard. This enables us to avoid such risks and damages. We have also established our own production facilities for in-house production quality control of the BF-RhodoLED® lamp to reduce our dependence on suppliers in this area, too.

Business strategy

Due to changing framework conditions, the strategy chosen by the Company to guarantee its sales, growth and profitability targets may not be sufficiently effective in the future. As part of the risk management process, management uses ongoing analyses to counteract current and potentially future influencing variables or developments in order to initiate suitable measures if necessary.

Staff

The recruitment of qualified and dedicated staff is a key prerequisite for the Company's success. A high staff turnover rate could jeopardize the achievement of corporate goals and the safeguarding of the Company's know-how. In order to counter these risks, motivate employees and retain key personnel, the Company offers competitive compensation, participation in option programs and extensive training and professional development opportunities for employees. Furthermore, the Group pursues a diversity-

orientated personnel policy in order to leverage the labor market's full potential. To date, Biofrontera has always succeeded in recruiting the qualified staff the Company requires. For this reason, the Company regards this risk as low. However, this assessment could change significantly in the case of a change of control.

Information technology and data protection

The Group's business processes and internal and external communication are increasingly based on global IT systems. A significant technical malfunction or total failure of IT systems could result in severe impairment of our business processes. It is of fundamental importance to us that both internal and external data remain confidential. If the confidentiality, integrity or authenticity of data or information were to be lost, the manipulation and/or uncontrolled outflow of data and know-how could arise. We have adopted appropriate measures to mitigate this risk, such as an authorization concept. However, while we have IT security measures and disaster recovery plans in place, they may prove to be inadequate or ineffective. Our IT systems may be vulnerable to cyberattacks, unauthorized access, computer viruses, system failures, human error, natural disasters, fire, power failure, communication disruptions or acts of sabotage. The measures adopted by the Company have always proven adequate to date, so such risk is to be regarded as low.

As a pharmaceutical company, Biofrontera is exposed to additional risks in the area of data protection. A large volume of person-related data is generated, particularly in the area of clinical trials and drug safety reports and must be protected in particular under the new Basic Data Protection Regulation (EU-DSGVO). Violations or violations of these regulations may result in severe penalties against the Company. Biofrontera counteracts these risks with continuous data protection processes and the implementation of legal guidelines.

Insurance coverage

The Company may be subject to the risk of insufficient insurance coverage for the continuation of business operations in the event of damage, for events affecting the Company's assets or claims for damages due to product defects as well as actions by the Company and its employees. Biofrontera mitigates these risks as part of its risk analysis with regular reviews of the adequacy of the relevant insurance coverage.

Taxes

The future use of the tax loss carryforwards accrued to date in the consolidated group of companies may not be realized or may not be optimized due to the organizational structure of the Company. To this end, Biofrontera carries out regular analyses to make appropriate adjustments, if necessary.

However, the Company cannot influence the risk of limited use of the tax loss carryforwards due to changes in tax law or as a result of a tax-relevant change in the shareholder structure.

Opportunities

In addition to identifying risks, the Biofrontera Group's risk management system also includes opportunities that are to be seen as positive deviations from corporate planning.

The Company identifies opportunities in the expansion of the indications for its products, particularly in the approval expansion of Ameluz® in our key sales markets, especially in the USA, in order to expand and exploit market potential. At the time of publication of this annual report, for example, a phase III trial is in preparation for the approval expansion of Ameluz® for the treatment of AK also on the extremities and trunk/neck, as well as a phase IIb trial for the approval expansion of Ameluz® for moderate to severe acne in the USA. In order to ensure future reimbursement of multiple tubes in the USA for the treatment of larger body areas in the periphery, Biofrontera submitted an application to the FDA in February 2021 to amend the product information, which currently limits use to one tube of Ameluz® per treatment. To accompany this progress with an optimized light source, the Group has also completed the development of a larger BF-RhodoLED® XL lamp and submitted the corresponding application for approval to the FDA. In order to further increase our growth opportunities in the US market in the medium term, we are also currently conducting a clinical trial for the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our BF-RhodoLED® lamp in the US. Upon successful FDA approval, Ameluz® would be the only drug in the US for the treatment of superficial BCC with PDT. There is also an opportunity for portfolio expansion in the medium and long term through the development of new products based on our nanoemulsion technology.

In addition, we see further long-term revenue opportunities in the form of milestone and royalty payments from the license and supply agreement concluded with Maruho in April 2020 for the commercialization of Ameluz® in East Asia and Oceania.

Overall opportunity and risk situation at Biofrontera

The Biofrontera Management Board believes that the current COVID-19 crisis still significantly impairs the ability of Biofrontera AG to provide reliable guidance at this time. We currently assume that the general economic conditions will normalize again during the second half of 2021.

The Management Board considers the overall risks that are not related to the current crisis to be manageable. The Management Board trusts the effectiveness of the risk management system with regard to the positive and negative changes of the business environment and the requirements of its current business. The assessment is based on various factors, which are summarized below:

- Since March 2020, the Company has been directly affected by the global COVID-19 crisis. The Company has taken immediate steps to safeguard its business processes through comprehensive cost reductions, emergency plans to maintain central processes and measures to protect its employees.
- To date, the Group has been able to meet its payment obligations at all times. The cash position is currently adequate due to the EIB loans, the received down payment of EUR 6 million under the license agreement with Maruho concluded in April 2020, as well as the capital increases successfully completed in August 2020 and February 2021. As a result, at present there is no longer a potential threat to the Company's going-concern status.

  According to current estimates, capital requirements should therefore be covered up to the operating break-even point. However, the Company will have payment obligations, among other things from the repayment of the EIB loan in 2022 and 2024. For the settlement of the liability due in 2024 and also for the unlikely but possible negative outcome of the DUSA Pharmaceuticals Inc. lawsuit, which could lead to a further payment obligation, the Company will have to make accruals in the next 24 months, as the gross proceeds of the capital measure completed in February 2021 were lower than expected. This was due to the lower than expected stock market price of the Biofrontera share to which the subscription price of the shares to be issued in the capital measure was linked.
- With the approval of daylight PDT with Ameluz® in the EU in 2018, Biofrontera's market position was further strengthened. We hope to further increase the market potential of Ameluz® from the obtained EU label expansion for photodynamic therapy of actinic keratoses on the extremities as well as the trunk and neck.
- To further increase our growth opportunities in the U.S. market, we are currently conducting a study for the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our red-light lamp BF-RhodoLED®, for which we started patient recruitment in September 2018.
- In the U.S., Biofrontera is also working diligently to improve reimbursement arrangements, as well as to expand approval to include the treatment of actinic keratoses to extremities, as well as trunk and neck. In order to ensure future reimbursement of multiple tubes for the treatment of larger body areas in the periphery, Biofrontera has submitted an application for a change in the product information to the FDA.
- To further strengthen its competitive position, Biofrontera has completed the development of the new lamp "BF-RhodoLED® XL", which will allow Ameluz® to be used on larger surfaces, and has submitted the application for approval to the FDA. With the market launch of this new medical device, the Group expects a further increase in sales of Ameluz®, especially in the US market.
- As a result of the restructuring of the US subsidiary Biofrontera Inc. at the beginning of 2020 with local operational management as well as the reorganization of the European sales structure under unified management, the Company sees – once the pandemic has subsided - an opportunity for future increased sales growth both in the USA and in Europe.
- Biofrontera sees further opportunities in the expansion of the US-product portfolio with the FDA-approved drug Xepi®, which was launched in November 2018 and complements the Company's existing core business. It was added as part of Biofrontera's acquisition of Cutanea Life Sciences, Inc. The expansion of the US-product portfolio represents an opportunity for continued long term corporate growth and strengthening of the US-market presence.
- Biofrontera considers itself well positioned with regard to the legal disputes. Provisions are in place for future legal costs, which include the estimated costs for legal disputes with DUSA Pharmaceuticals, Inc. and the Deutsche Balaton Group until a ruling is issued in the next instance. While we assume that the claims of DUSA Pharmaceuticals, Inc. in particular are unjustified, we are unable to guarantee a successful outcome in court.

Litigation

DUSA v. Biofrontera

In March 2018, DUSA Pharmaceuticals, Inc. ("DUSA") brought a lawsuit against Biofrontera AG and its subsidiaries before the District Court of Massachusetts due to alleged infringement of its patents No. 9,723,991 and No. 8,216,289 by sales of BF-RhodoLED® in the U.S. In July 2018, DUSA amended its complaint to add claims of trade secret misappropriation, tortious interference with contractual relations, and deceptive and unfair trade practices. For these claims, DUSA has asserted damages for profits allegedly lost by DUSA or alleged unjust enrichment for profits gained by Biofrontera from sales of the BF-RhodoLED® and Ameluz® in the United States.

Biofrontera Group's responses to the patent claims include that it does not infringe the DUSA patents and that the patents are invalid. With regard to the non-patent claims, Biofrontera Group's responses include that the information does not constitute trade secrets and that Biofrontera Group's actions do not constitute any violation of trade practices. With regard to DUSA's claims for damages, Biofrontera Group's responses include that DUSA has not proven it is entitled to lost profits or unjust enrichment. Submission of expert reports and related discovery regarding these claims finished in early December 2019. The parties filed motions for summary judgment and motions to exclude certain expert testimony closing on February 18, 2020. The Court issued decisions on the motions on October 9, 2020, sending most issues to trial.

The Court has tentatively scheduled a jury trial starting in late November 2021. The Issuer expects the trial to proceed through December 2021. The Issuer believes that these claims lack merit and Biofrontera Group intends to defend against them vigorously; however, Biofrontera Group cannot guarantee that it will be successful. The Court largely denied a motion by DUSA for a preliminary injunction, but did order Biofrontera Group not to use any documents, or documents derived from documents, that originated at DUSA.

In addition, Biofrontera Group submitted petitions for inter partes review to the Patent Trial and Appeal Board (PTAB) seeking to have the patents declared invalid. The PTAB issued decisions on February 26, 2019, finding a reasonable likelihood of success on invalidity arguments for some claims, but nonetheless denying institution of the review petitions because the PTAB disagreed on the remainder of claims.

Biofrontera may incur considerable expenses from defending its legal position, as it has hired attorneys in the U.S. in addition to internal resources for defense. Due to the practices of the U.S. legal system, the costs incurred by Biofrontera would not be reimbursed by the plaintiff even if Biofrontera were to achieve a positive outcome of the proceedings.

Biofrontera v. DUSA

In 2018, Biofrontera Inc. brought a lawsuit against DUSA in California Superior Court. Biofrontera Group's complaint alleges that DUSA engaged in unfair competition by providing excessive product samples to physicians and by using its distributor Foundation Care to inflate product prices. After filing the lawsuit, DUSA stopped distributing its pharmaceutical products through this distributor (Foundation Care), which was a key objective of Biofrontera when this lawsuit was filed. Biofrontera Group's complaint also alleges that DUSA engaged in tortious interference by making statements to third parties regarding the off-label use of its products. The court has allowed Biofrontera Group's tortious interference claims to proceed to discovery. Given the unprecedented and unforeseen economic circumstances caused by the spread of COVID-19, Biofrontera has reevaluated its litigation strategy. Because Biofrontera was successful in stopping DUSA from using Foundation Care, it decided at this time to stop prosecuting the case against DUSA in California state court and dismissed those claims.

Biofrontera v. Deutsche Balaton et. al.

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 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 the end of February 2021. Subsequently, a further extension until August 31, 2021 was agreed. Deutsche Balaton AG, Wilhelm Konrad Thomas Zours and DELPHI Unternehmensberatung AG are among our shareholders.

In June 2017, the Company was served with legal action for rescission and annulment by the shareholder Deutsche Balaton AG, claiming the invalidity of certain resolutions of the annual general meeting of May 24, 2017. The claim was dismissed by the Cologne Regional Court in December 2017. Following an appeal by Deutsche Balaton AG, the Cologne Higher Regional Court granted the appeal in November 2018. In its ruling of September 22, 2020, the Federal Supreme Court of Germany overturned the judgment of the Cologne Higher Regional Court and referred the case back to the Cologne Higher Regional Court for a new hearing and decision.

Deutsche Balaton AG has further brought a claim for rescission and annulment against the negative resolutions of the annual general meeting of July 11, 2018 regarding the proposed resolutions under agenda item 8 (conducting a special audit on the circumstances of the cooperation with the (indirect) major shareholder Maruho Co. Ltd. and its affiliated companies), agenda item 9 (decision on the assertion of claims for damages against the members of the Management Board Prof. Dr. Lübbert and Schaffer as well as against Maruho Deutschland GmbH and Maruho Co. Ltd. pursuant to Section 147 (1) AktG as well as the appointment of a Special Representative for the assertion of these claims pursuant to Section 147 (2) AktG), Agenda Item 10 (conducting of a special audit on the circumstances of the capital increase at the beginning of 2018 and the associated US listing) and Agenda Item 11 (Decision on the assertion of compensation claims against the Management Board members Prof. Dr. Lübbert and Schaffer, against the Supervisory Board member Dr. John Borer as well as against Maruho Deutschland GmbH and Maruho Co., Ltd pursuant to Section 147 (1) AktG and the appointment of a Special Representative for the assertion of these claims pursuant to Section 147 (2) AktG due to the circumstances of the capital increase in February 2018 (including the US listing and the US share placement). With regard to the above-mentioned agenda items 8 to 11, Deutsche Balaton AG also filed a positive claim for a resolution to declare that it is to be recognized that the Annual General Meeting adopted the resolutions in accordance with the resolution proposals published for this purpose. Furthermore, under agenda item 4 (Elections to the Supervisory Board), a positive action for resolution was filed with the motion to declare that Mr. Mark Sippel had been elected to the Supervisory Board as successor to Mr. Mark Reeth with effect from the end of the annual general meeting on July 11, 2018. An action for rescission and nullity was filed against the resolution to reject the election of Mr. Sippel adopted at the annual general meeting. Deutsche Balaton AG withdrew the claims with regard to the latter two matters in dispute.

DELPHI Unternehmensberatung AG, Heidelberg, filed an action for rescission and annulment against resolutions of the annual general meeting of Biofrontera AG on July 1, 2019. The complaint is filed against the election of Prof. Dr. Franca Ruhwedel to the supervisory board and against the resolution of the annual general meeting not to elect Wilhelm K.T. Zours to the supervisory board (agenda item 4 of the annual general meeting). In addition, a positive action for a resolution was filed, according to which the court is to declare that Mr. Wilhelm K.T. Zours was elected to the supervisory board. The lawsuit is also directed against the rejecting resolutions of the annual general meeting under the Agenda item 7 (Resolution to conduct a special audit regarding the circumstances of the acquisition of Cutanea Life Sciences, Inc. from Maruho), 8 (Resolution to conduct a special audit regarding the circumstances of the cooperation agreement dated March 19, 2019 with the (indirect) major shareholder Maruho Co. Ltd. regarding branded generics and regarding the extension of indications and distribution of Ameluz®), 9 (Resolution on the assertion of claims for damages against the Management Board members Prof. Dr. Lübbert and Schaffer and the appointment of a Special Representative to assert these claims in accordance with section 147 (2) AktG), 10 (Dismissal of the supervisory board member Dr. Ulrich Granzer, election of a new supervisory board member and election of a substitute member for the newly elected supervisory board member), 11 (Dismissal of the supervisory board member Dr. John Borer, election of a new supervisory board member and election of a substitute member for the newly elected supervisory board member) 12 (Amendment of Article 13 of the Articles of Association (resignation from the supervisory board / dismissal from office)), 13 (Resolution on the assertion of claims for damages against the Management Board members Prof. Dr. Lübbert and Schaffer and against Maruho Deutschland GmbH and Maruho Co. Ltd. in accordance with section 147 (1) of the AktG and the appointment of a Special Representative for the assertion of these claims in accordance with section 147 (2) of the AktG) and 14 (Cancellation of the resolution passed under agenda item 6 of the annual general meeting held on 24 May 2017 (creation of authorised capital in the amount of EUR 4,000,000 with the option to exclude shareholders' subscription rights), creation of new authorised capital 2019 and amendment of the Articles of Association). With regard to agenda items 7 to 14, the complaint was also filed for a positive decision by the court, according to which it should be stated that the annual general meeting adopted the resolutions in accordance with the resolution proposals of Deutsche Balaton AG, partly in the form of countermotions to these proposals submitted at the annual general meeting. The lawsuit is currently pending at Cologne Regional Court under file number 82 O 75/19.

A legal action for rescission and annulment was brought by ABC Beteiligungen AG, Heidelberg, against resolutions of the annual general meeting of Biofrontera AG on May 28, 2020. The action for rescission and nullification is directed against the resolutions under agenda items 6 (resolution on the increase of share capital against cash contributions with the granting of an indirect subscription right), 9 (removal of a Supervisory Board member and election of a new Supervisory Board member), 11 (Resolution on the performance of a special audit on the circumstances of the lawsuit filed in the USA by the Company against Deutsche Balaton AG and other defendants), 12 (Resolution on the performance of a special audit on the circumstances of the withdrawal of the subscription offer for mandatory convertible bonds) and 13 (Resolution on the authorization to issue mandatory convertible bonds and the creation of conditional capital with a corresponding amendment to the Articles of Association). With regard to agenda items 9, 11, 12 and 13, a positive action for the adoption of a resolution was also filed, according to which it should be recognized that the annual general meeting adopted the resolutions in accordance with the resolution proposals published in this regard in the supplementary request of Deutsche Balaton AG. The lawsuit is pending before the Cologne Regional Court under file number 82 O 53/20.With regard to agenda item 6 (resolution on the increase in capital stock against cash contributions with granting of an indirect subscription right), an application for release was filed with the Cologne Higher Regional Court on October 20, 2020. The Cologne Higher Regional Court granted the application for release on January 7, 2021. Subsequently, ABC Beteiligungen AG and the Company declared the legal action for rescission and annulment to be settled to that extent.

Biofrontera v. Automattic Inc.

Biofrontera AG has applied for and obtained various preliminary injunctions against Automattic Inc, San Francisco, USA, at the Hamburg Regional Court. Automattic Inc. is the operator of the portal WordPress.com, on which a (so far) unknown person has published false and defamatory allegations about Biofrontera AG and its management in a blog. Automattic Inc. has appealed the obtained preliminary injunctions. The Hamburg Regional Court has now ruled on this appeal by Automattic Inc. in oral proceedings and confirmed the injunctions obtained almost without exception. Automattic Inc. appealed against these rulings of the Regional Court. These appeal proceedings are currently pending before the Hanseatic Higher Regional Court.

Compensation report

The remuneration of the members of the Management Board consist of fixed compensation paid in twelve equal monthly installments. In addition, an annual performance-related bonus payment is provided for the Management Board members, which must be linked to the long-term performance of the Company in accordance with the German Act on the Appropriateness of Management Board Compensation. Furthermore, a long-term compensation component is in place through participation in the Company's stock option program and stock appreciation rights (SAR) program.

The total Management Board compensation in fiscal 2020 as well as the total number of stock options issued to the members of the Management Board as of December 31, 2020 are as follows:

	Prof. Dr. Hermann Lübbert		Thomas Schaffer		Christoph Dünwald	
	CEO		CFO		CCO	
Term	Feb 1, 1998	incumbent	June 1, 2013	Feb 28, 2021	Nov 16, 2015	Jan 31, 2020
in EUR thousands (unless otherwise indicated)	2020	2019	2020	2019	2020	2019
Fixed component of compensation	322	350	244	257	23	275
Compensation in kind	9	16	13	12	1	16
Total fixed compensation	331	366	257	269	24	291
Short-term incentive (variable, STI)	-	167	-	154	50	140
Long-term incentive (variable, LTI), thereof from						
Stock options (maturity May 13, 2025)						
Fair value of options granted	-	37	-	25	-	25
Income from exercising stock options	86	149	54	-	72	-
Stock Appreciation Rights (SARs) (maturity May 3, 2030)						
Fair value of SARs	290	-	218	-	-	-
Income from exercising SARs	-	-	-	-	-	-
Total LTI	376	186	271,5	25	72	25
Total performance-based compensation	376	353	271,5	179	122	165
Total compensation	707	719	529	448	146	456
Number of stock options (Dec 31)	164,495	244,495	100,000	150,000	-	150,000
Number of stock options granted	-	14,495	-	10,000	-	10,000
Fair value when granted	-	414	-	255	-	255
Number of SARs (Dec 31)	200,000	-	150,000	-	-	-
Number of SARs granted	200,000	-	150,000	-	-	-
Fair value when granted	290	-	218	-	-	-

After his departure from the Management Board, Mr. Christoph Dünwald received remuneration as a former executive member in the amount of EUR 137 thousand for the period from February to November.

The fixed component of Prof. Dr. Lübbert's compensation amounts to 47% (previous year: 51%) and that of Mr. Schaffer to around 49% (previous year: 60%) of total compensation. The fixed compensation of Mr. Dünwald amounts to approximately 16% (previous year: 64%).

The Management Board members are also provided with company cars for private use. In addition, the Company contributes to the costs of private health, pension and long-term care insurance up to the maximum amount of the respective employer's contribution limit, insofar as corresponding insurance policies actually exist and corresponding costs are incurred. The existing service

agreements provide that - depending on the achievement of defined targets - an annual bonus is to be granted. If targets are exceeded, the maximum amount of the annual bonus is limited (cap). If targets are missed by up to 70%, the bonus payment is reduced on a straight-line basis; if targets are missed by more, the bonus payment is not paid at all. The assessment factors (2019: revenue (30%), earnings after tax (20%), achievement of break-even in Q4-2019 (20%), completion of patient recruitment in the BCC study (20%), completion of the clinical phase of the peripheral study (10%)) are mutually agreed at the end of each fiscal year for the following fiscal year in a performance target agreement. The aforementioned performance criteria set for 2019 were not achieved and thus no bonus payment was granted in fiscal year 2020.

Severance payments in the event of premature termination of a Management Board member's contract without serious cause are limited to a total of two annual salaries, but not more than the total compensation entitlement for the remaining term of the contract at the time of departure ("severance payment cap").

The maximum compensation of the Management Board members from the fixed and one-year performance-related compensation (bonus) amounts to EUR 520 thousand for Prof. Dr. Lübbert and EUR 390 thousand for Thomas Schaffer. With regard to the maximum compensation under the multi-year variable compensation, we refer to the following explanations on the stock option program and SAR program.

In order to further increase the long-term incentive effect of the variable compensation and consequently its focus on sustainable corporate development, the members of the Management Board have committed themselves to holding ordinary shares in the Company as private assets for stock options granted under the 2015 stock option program. This commitment is for a period of three years beginning one month after the issue date of the options ("blocked shares"). The amount of the personal commitment varies for the individual Management Board members. If restricted shares are sold prematurely, which must be reported to the Chairman of the Supervisory Board without delay, the Company may demand the retransfer of a corresponding number of stock options free of charge within one month of notification of the sale, whereby the options granted last are always to be retransferred (last in first out). A retransfer is not possible if the Management Board member can demonstrate that the sale of the restricted shares was necessary to meet urgent financial obligations. The range of exercise prices for outstanding options is between EUR 2.25 and EUR 6.708, the range of fair value of outstanding options is between EUR 1.00 and EUR 2.55. After expiry of the respective vesting period, the option rights may be exercised up to the end of six years after the respective issue date (exclusive).

As a long-term performance component, members of the Management Board are granted stock appreciation rights ("SARs") under their service agreements, starting in the 2020 financial year (long-term incentive, "LTI"). An annual target amount of 150% of the STI ("short-term incentive") target amount ("LTI target amount") has been agreed. The number of SARs granted each year is equal to the LTI target amount divided by the economic value of the SARs at the time they are granted. SARs subject to vesting requirements may not be exercised if and to the extent that the gross proceeds from all exercised SARs granted to the Management Board Chairman would exceed the gross fixed compensation actually received by the Management Board member since the first grant of SARs by more than 300% without this limit.

To the extent that terms and conditions of the SAR program provide for a personal investment, it is agreed, in deviation from any SAR terms and conditions, that the personal investment must be made without fail within six months of the exercise date in the amount of 25% of the payout amount (gross) and that the acquired shares in the Company may not be sold for at least four years after the granting of the SARs.

For the purpose of further increasing the long-term incentive effect of the variable compensation and thus its focus on sustainable corporate development, members of the Management Board undertake to acquire up to 100,000 shares in the Company and to hold them until the end of their service agreement (share ownership guideline). However, the total acquisition cost (including incidental acquisition costs) to be borne by the Management Board member is limited per fiscal year to an amount equivalent to 25% of the target achievement bonus granted to him for the previous fiscal year.

Takeover information

Trading platforms

Biofrontera shares are traded under ticker symbol B8F and ISIN DE0006046113 in the Prime Standard segment of the Frankfurt Stock Exchange and on all other German stock exchanges. In the USA, shares of Biofrontera AG are traded as American Depositary Shares (ADS) on the U.S. Nasdaq Stock Exchange under the ticker symbol BFRA. One ADS securitizes the right to two ordinary shares of Biofrontera AG.

Shareholder structure

The detailed presentation of the positions held by the shareholders as of December 31, 2020 on the basis of the mandatory disclosures by the shareholders can be found in the notes to the consolidated financial statements under 9 Equity and in the notes to the individual financial statements of Biofrontera AG under item "III. Information on the balance sheet and income statement" under "5 Subscribed capital, capital reserve, conditional capital".

Share capital and existing capital

The detailed presentation of share capital as of December 31, 2020, is included in the notes to the consolidated financial statements under 9 Equity and in the notes to the single-entity financial statements of Biofrontera AG under "III. Information on the balance sheet and income statement" under "5 Subscribed capital, capital reserves, conditional capital".

Articles of association

The Articles of Association of Biofrontera comply with the applicable statutory requirements. There are no stipulations beyond Sections 84, 85 and Sections 133, 179 of the German Stock Corporation Act regarding the appointment and dismissal of members of the Management Board.

Corporate governance declaration pursuant to sections 289f and 315d HGB including the statement pursuant to the German Corporate Governance Code required by Section 161 AktG.

Pursuant to sections 289f and 315d HGB, listed stock corporations are required to issue a declaration relating to their corporate governance. This must either be included in the combined management and Group management report or be published on the Company's website. The current corporate governance declaration by Biofrontera AG and the corporate governance report are available on the Company's website at www.biofrontera.com in the section "Investors", subsection "Corporate Governance".

Leverkusen, April 12, 2021
Biofrontera AG

Prof. Dr. Hermann Lübbert
CEO and Chairman

Ludwig Lutter
CFO

Consolidated financial statements as of December 31, 2020

Consolidated balance sheet as of December 31, 2020

Assets

in EUR thousands		December 31, 2020	December 31, 2019
Non-current assets			
Tangible assets	(1)	5,051	5,231
Intangible assets	(1)	17,688	22,848
Deferred tax	(8)	7,525	7,794
Total non-current assets		**30,264**	**35,873**
Current assets			
Financial assets			
Trade receivables	(3)	3,501	5,031
Other financial assets	(4)	531	1,077
Cash and cash equivalents	(7)	16,546	11,119
Total financial assets		**20,579**	**17,227**
Other assets			
Inventories	(2)	4,673	4,065
Income tax	(6)	5	4
Other assets	(5)	869	1,195
Total other assets		**5,547**	**5,264**
Total current assets		**26,126**	**22,491**
Total assets		**56,391**	**58,363**

Equity and liabilities

in EUR thousands		December 31, 2020	December 31, 2019
Equity	(9)		
Subscribed capital		47,748	44,849
Capital reserve		123,493	118,103
Capital reserve from foreign currency conversion adjustments		1,866	(289)
Loss carried forward		(152,709)	(145,351)
Loss for the period		(13,023)	(7,358)
Total equity		**7,375**	**9,955**
Non-current liabilities			
Financial debt	(10)	22,736	22,110
Other financial liabilities	(11)	17,994	14,721
Total non-current liabilities		**40,730**	**36,830**
Current liabilities			
Financial liabilities			
Trade payables	(12)	1,623	4,196
Current financial debt	(10)	1,139	1,212
Other financial liabilities	(11)	90	99
Total financial liabilities		**2,852**	**5,508**
Other liabilities			
Income Tax	(6)	0	11
Other provisions	(13)	3,042	3,495
Other liabilities	(14)	2,392	2,565
Total other liabilities		**5,434**	**6,071**
Total current liabilities		**8,286**	**11,579**
Total equity and liabilities		**56,391**	**58,363**

Consolidated statement of comprehensive income for the fiscal year 2020

in EUR thousands		2020	2019
Sales revenue	(16)	30,346	31,265
Cost of sales	(17)	(3,536)	(4,875)
Gross profit from sales		**26,810**	**26,390**
Operating expenses			
Research and development costs	(18)	(4,789)	(4,636)
General administrative costs	(19)	(9,150)	(16,275)
Sales costs	(20)	(20,482)	(28,856)
Result from operations		**(7,611)**	**(23,377)**
Effective interest expenses	(21)	(546)	(245)
Interest expenses	(21)	(2,534)	(2,466)
Interest Income	(21)	411	127
Other Expenses	(22)	(3,836)	(799)
Other Income	(22)	1,417	7,171
Other income from the PPA (Badwill)	(22)	-	(14,812)
Profit/loss before income tax		**(12,697)**	**(4,777)**
Income tax	(23)	(326)	(2,581)
Profit/loss for the period		**(13,023)**	**(7,358)**
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		2,155	(286)
Total profit/loss for the period		**(10,868)**	**(7,644)**
Basic/diluted earnings per share	(24)	(0.24)	(0.16)

The accompanying notes are an integral part of these consolidated financial statements.
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 fiscal year 2020

		Ordinary shares	Subscribed capital	Capital reserve	Reserve from foreign currency conversion adjustment (OCI)	Loss carried forward Loss for the period	Total
		Number of shares	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands
Balance as of December 31, 2018		**44,632,674**	**44,633**	**117,109**	**(2)**	**(145,384)**	**16,356**
First time application of IFRS 16		-	-	-	-	33	33
Balance as of January 01, 2019		44,632,674	44,633	117,109	(2)	(145,351)	16,389
Loss for the period		-	-	-	-	(7,358)	(7,358)
Foreign currency conversion		-	-	-	(286)	-	(286)
Total loss for the period		**-**	**-**	**-**	**(286)**	**(7,358)**	**(7,645)**
Conversion from convertible bond 2017/2022		118,841	119	429	-	-	548
Conversion of stock options from the stock option program		97,850	98	207	-	-	305
Cost of equity procurement		-	-	(2)	-	-	(2)
Increase in capital reserve from the stock option program		-	-	360	-	-	360
Balance as of December 31, 2019	**(9)**	**44.849.365**	**44,849**	**118,103**	**(289)**	**(152,709)**	**9,955**

		Ordinary shares	Subscribed capital	Capital reserve	Reserve from foreign currency conversion adjustments (OCI)	Loss carried forward Loss for the period	Total
		number	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands	in EUR thousands
Balance as of December 31, 2019	**(9)**	**44,849,365**	**44,849**	**118,103**	**(288)**	**(152,709)**	**9,955**
Loss for the period		-	-	-	-	(13,023)	(13,023)
Foreign currency conversion		-	-	-	2,155	-	2,155
Total loss for the period		**-**	**-**	**-**	**2,155**	**(13,023)**	**(10,868)**
Conversion from convertible bond 2020/2021		2,638,150	2,638	5,179	-	-	7,817
Conversion of stock options from the stock option program		260,000	260	325	-	-	585
Cost of equity procurement		-	-	(407)	-	-	(407)
Increase in capital reserve from the stock option program		-	-	293	-	-	293
Balance as of December 31, 2020	**(9)**	**47,747,515**	**47,748**	**123,493**	**1,867**	**(165,732)**	**7,375**

Consolidated cash flow statement for the fiscal year 2020

in EUR thousands		2020	2019
Cashflows from operations			
Loss before income tax		(12,697)	(4,777)
Adjustments to reconcile loss before income tax to cash flow into operations			
Income tax		(57)	36
Financial result		2,669	2,658
Depreciation		5,333	3,156
Other non-current provisions		-	(1,545)
Losses from disposal of assets		(85)	386
Non-cash (income) and expenses		3,771	(15,334)
Changes in operating assets and liabilities			
Trade receivables		1,514	(673)
Other assets and income tax assets		871	3,044
Inventories		(1,023)	(148)
Trade payables		(2,573)	596
Provisions		(563)	710
Other liabilities		(9)	(21,003)
Net cash flow used in operational activities		**(2,849)**	**(32,894)**
Cash flow from investment activities			
Purchase of intangible and tangible assets		(774)	(1,854)
Business combination (incl. cash and start-up costs)		3,547	22,814
Proceeds from sale of intangible and tangible assets		100	93
Net cash flow from investment activities		**2,873**	**21,053**
Cashflows from financing activities			
Proceeds from the issue of shares		7,914	-
Costs of equity procurement		(406)	(3)
Proceeds from draw down of EIB loan		-	5,000
Proceeds from exercise of employee stock options		585	305
Leasing payments		(1,363)	(1,183)
Interest paid		(782)	(664)
		5,948	**3,455**
Net increase/(decrease) in cash and cash equivalents		5,972	(8,386)
Changes from exchange rate differences		(545)	54
Cash and cash equivalents at the beginning of the period		11,119	19,451
Cash and cash equivalents at the end of the period	**(28)**	**16,546**	**11,119**

Notes to the consolidated financial statements as of December 31, 2020

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 preparation of the consolidated financial statements

The consolidated financial statements for Biofrontera AG for the financial year from January 1, 2020 to December 31, 2020 have been prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC), which are endorsed by the European Union (EU) and applicable on the balance sheet date. In addition, statutory provisions pursuant to Section 315a (1) of the German Commercial Code (HGB) have been complied with.

The consolidated financial statements are prepared on a going concern basis.

Biofrontera AG is the parent company, which prepares consolidated financial statements for the group companies.
The consolidated financial statements as of December 31, 2020 are presented in euros (EUR) or thousands of euros. Rounding differences can arise in the tables due to commercial rounding.

On April 12, 2021, the Management Board approved the consolidated financial statements for the financial year ending December 31, 2020 for publication and forwarding to the Supervisory Board.

Special events in the 2020 financial year

Impact of the COVID-19 pandemic

The reporting year 2020 was defined by the impact of the coronavirus pandemic. In the reporting period from January 1 to December 31, 2020, Biofrontera was directly affected by the global coronavirus crisis from mid-March and had to accept lower sales figures as a result, especially in the USA. Due to the down payment of the Japanese Maruho Co., Ltd. (Maruho), the fully placed convertible bond 2020/2021 in August 2020, and cost-saving measures introduced at an early stage, the Company was able to successfully counteract the negative effects on the sales side.

The coronavirus crisis has led to a declining number of treatments and thus to sharp declines 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 preventive measures to reduce and control costs.

While these cost reduction measures were in place, the Company was able to ensure full compliance with all medical and capital regulatory requirements without interruption, as well as meeting all disclosure obligations at all times.

The continued difficult business outlook due to the COVID-19 crisis has affected the valuation of certain assets and liabilities of the Company. During the crisis, the sales strategy in the U.S. market has focused on our flagship product Ameluz® and the envisioned re-launch to better position our in-licensed product Xepi® had to be delayed. The reduced sales of Xepi® have led to a reassessment of the medium-term business and earnings prospects for Xepi® and thus to an impairment of the Xepi® license in the first quarter of 2020. To a minor extent, inventories were written down as of December 31, 2020 due to an expected expiration of shelf life. Beyond this, no significant risks have arisen in relation to financial instruments, in particular no unusual bad debt events.

Subscription offers for mandatory convertible bonds

The issuance of up to 1,600,000 units of a 0.5% qualified subordinated mandatory convertible bond 2020/2024 and the issuance of up to 1,600,000 units of a 1.00% qualified subordinated mandatory convertible bond 2020/2026, which were resolved on February 26, 2020, were withdrawn in March 2020 due to the turmoil on the capital markets caused by the coronavirus crisis and were not executed.

To ensure liquidity in the short term, Biofrontera issued a 1.0% qualified subordinated mandatory convertible bond 2020/2021 in August 2020. The issuance was fully placed with gross proceeds of EUR 7.9 million. On November 12, 2020, the Company announced that it would exercise its right to mandatory conversion in accordance with section 8 (2) of the bond terms and conditions, which was subsequently implemented in the reporting year.

Taking into account the capital measure carried out in February 2021 with gross issue proceeds of EUR 24.7 million, the Biofrontera Group currently has sufficient liquidity to continue financing its business operations for at least 12 months.

Changes in accounting standards

The accounting policies applied are consistent with those applied on December 31, 2019, with the exception of the new and revised standards and interpretations described below that were applied for the first time starting with the 2020 financial year.

Standard	Description	Mandatory application	Expected effects
Amendment to IAS 1	"Presentation of financial statements"	January 1, 2020	No effects
Amendment to IAS 8	"Accounting policies, changes in accounting estimates and errors" "Definition of material"	January 1, 2020	No effects
Amendment to IFRS 3	"Business combinations"	January 1, 2020	No effects
Amendment to IFRS 9	"Financial instruments"	January 1, 2020	No effects
Amendment to IFRS 7	"Financial instruments: Disclosures"	January 1, 2020	No effects
Amendment to IAS 39	"Financial instruments: Recognition and measurement"	January 1, 2020	No effects
Amendment to IFRS 16	"Leases"	June 1, 2020	No effects
Amendments to References to the Conceptual Framework	References to the Conceptual Framework	January 1, 2020	No effects

Future changes in accounting standards

Biofrontera has not implemented early adoption or does not intend to implement early adoption of the following standards, interpretations and amendments to the set of regulations approved by the IASB:

Standard	Description	Mandatory application	Expected effects
Amendment to IFRS 3*	"Business combinations" References to the Conceptual Framework	January 1, 2022*	No effects
Amendment to IFRS 17*	Insurance contracts	January 1, 2023*	No effects
Amendment to IFRS 4 and IFRS 9	IFRS 4 "Insurance contracts" : postponement of the application of IFRS 9	January 1, 2021	No effects

Standard	Description	Mandatory application	Expected effects
Amendment to IFRS 4,7,9,16 and IAS 39	IFRS 9 "Financial instruments", IFRS 4 "insurance contracts" IFRS 7 "Financial instruments: Disclosures", IFRS 16 "Leases", IAS 39 "Financial instruments: Recognition and measurement" Interest rate benchmark reform (phase 2)	January 1, 2021	No effects
Amendment to IAS 16	"Property, plant and equipment": Revenues before the intended use	January 1, 2022*	No effects
Amendment to IAS 1	"Presentation of financial statements" Classification of liabilities as current or non-current; disclosure of accounting policies	January 1, 2023*	No effects
Amendment to IAS 37	"Provisions, contingent liabilities and contingent assets": Adverse contracts - costs of contract fulfillment	January 1, 2022*	No effects
Amendment to IAS 8	"Accounting Policies, Changes in Accounting Estimates and Errors": Definition of accounting estimates	January 1, 2022*	No effects
Annual Improvements to IFRSs	Annual improvements to IFRSs Cycle 2018-2020	January 1, 2022*	No effects

* Adoption by the EU still pending

Basis of consolidation

The consolidated financial statements for the financial year ending December 31, 2020 include the financial statements of the parent company, Biofrontera AG, and the subsidiary companies in which the parent has a direct majority of the voting rights. The following companies have been included in the consolidated financial statements. The shareholdings are unchanged from the previous year:

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 are the financial statements (or HBII pursuant to IFRS) of these companies prepared for December 31, 2020 pursuant to uniform principles. The consolidated financial statements as of December 31, 2020 have been prepared on the basis of uniform accounting policies (IFRS).

The subsidiaries have been fully consolidated from the date of acquisition. The date of acquisition is the date when the parent company obtained control of these subsidiaries. The subsidiaries are included in the consolidated financial statements until control over these companies no longer exists.

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

Translation of amounts in foreign currencies

The consolidated financial statements as of December 31, 2020 have been prepared in EUR (or thousands of EUR), which is the functional currency of all the German companies included in the consolidated financial statements and is the Group's reporting currency.

For subsidiaries with a functional currency that is the local currency of the country in which they have their registered office, the assets and liabilities that are recognized in the foreign currency on the balance sheets of the foreign, economically independent subsidiaries, are converted to euros applying the relevant period-end exchange rate (2020: 1.2230 USD/EUR, previous year 1.1227 USD/EUR). Income and expense items are translated applying the average exchange rates applicable to the relevant period (2020: 1.1410 USD/EUR, previous year: 1.1194 USD/EUR). The differences resulting from the valuation of equity at historical rates and applying the period-end exchange rates are reported as a change not affecting profit or loss and carried directly to equity within the other equity components (2020: EUR 2,155 thousand, previous year: EUR (286) thousand).

Transactions realized in currencies other than EUR are reported using the exchange rate on the date of the transaction. Assets and liabilities are translated applying the closing exchange rate for each balance sheet date. Gains and losses resulting from such translation are recognized in the income statement as a loss in the amount of EUR (3,601) thousand (previous year: gain of EUR 324 thousand).

Application of estimates

The preparation of the consolidated financial statements for December 31, 2020 in accordance with IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities as reported on the balance sheet date, and revenues and expenses arising during the financial year.

Main areas of application for significant assumptions, estimates and the exercise of discretion arise for the following matters:

- Fair value measurement under IFRS 13 in relation to the determination of the fair value of the purchase price liability for Cutanea.
  According to the earn-out agreement of the purchase agreement for the acquisition of the shares in Cutanea Life Sciences, Inc. the profits from the sale of the Cutanea products will be split equally between Maruho and Biofrontera until 2030. The expected annual purchase price payments will be due depending on future profits generated from the sale of Xepi®. In determining the future purchase price payments, management has to make assumptions and estimates about the future expected profits from the sale of Xepi® as well as a determination of the cost of capital.

- Assessment of the recoverability of non-current assets
  Biofrontera is required to assess external and internal sources of information for non-current assets that are subject to amortization, based on which possible indications of impairment or reversal of impairment can be identified. When assessing whether there are indications of impairment or a reversal of impairment losses and - if such indications exist - when determining the fair values required in this case as part of an impairment test, management must make assumptions and estimates about the expected future cash flows from the use of the non-current assets and a determination of the cost of capital.

- Income taxes
  Biofrontera is required to calculate the expected current income tax for each group company, as well as to assess temporary differences arising from the different treatment of certain balance sheet items between the IFRS consolidated financial statements and the financial statements prepared for tax purposes. Where temporary differences exist, these generally result in the recognition of deferred tax assets and liabilities in the consolidated financial statements. Management must make assumptions and estimates when calculating actual and deferred taxes. The recognition of deferred tax assets of Biofrontera AG is subject to higher requirements due to the loss history. Deferred tax assets are only recognized if it can be substantiated that taxable profits will be generated in the future and that it is then probable that the deferred tax item to be capitalized can be offset against future taxable profits. In order to assess the probability of the future utilization of deferred tax assets, various factors have to be taken into account, such as the earnings situation in the past and operational planning. If actual results differ from these estimates, or if these estimates have to be adjusted in future periods, this could have an adverse effect on the Group's net assets, financial position and results of operations. If there is a change in the assessment of the recoverability of deferred tax assets, the recognized deferred tax assets - in accordance with the original recognition - are to be written down through profit or loss or recognized directly in equity, or impaired deferred tax assets are to be recognized through profit or loss or directly in equity.

- Provisions for litigation risks
  Provisions are recognized for pending legal proceedings on the basis of current estimates. The outcome of the legal proceedings cannot be determined or is subject to uncertainties. In assessing the risks arising from litigation, management

must make assumptions and estimates as to whether and to what extent provisions for litigation risks should be recognized. Actual claims arising from legal proceedings may therefore differ from the amounts accrued.

- Estimates in connection with financial instruments
  Estimates are made to determine fair values in connection with the measurement of the performance component of the EIB loans and the liabilities from the stock appreciation program. The determination requires management to make assumptions regarding the valuation models used as well as a determination of the cost of capital.

- Development costs
  At Biofrontera, research and development costs include expenses for clinical trials as well as for the granting, maintenance and extension of approvals. For the approved drug Ameluz® as well as for the other research and development projects, with the exception of the further development of the new BF-RhodoLED® XL red light lamp, research and development costs are recognized as expenses in the period in which they are incurred. In the opinion of management, the criteria prescribed by IAS 38.57 for the recognition of development costs as assets are not met due to the uncertainties associated with the development of new products by the Biofrontera Group until approval in the target markets has been obtained and it is probable that future economic benefits will flow to the Company.
  The BF-RhodoLED® XL red light lamp is a further development of the existing lamp, from which Biofrontera expects a future economic benefit.

Estimates are based on experience and other assumptions that are believed to be reasonable under the circumstances. They are reviewed on an ongoing basis, but may differ from actual values.

Changes in previous estimates due to the impact of the COVID-19 pandemic have occurred with regard to the valuation of the Xepi® license, the purchase price payment from the earn-out agreement with Maruho and the EIB loan.

The expected income from the sale of Xepi® and, consequently, the expected annual purchase price payments were reestimated as of March 30, 2020, due to the current market situation influenced by the COVID-19 pandemic and resulting time shifts in the market penetration of Xepi®. This resulted in an impairment of the Xepi® license and a reduction of the nominal amount of the expected purchase price payment. As a result of the significant decrease in market capitalization in 2020, there was a reduction in the performance component of the EIB loan recognized in income.

The carrying amounts of the items affected by estimates can be found in the respective explanations of the items in the notes to the consolidated financial statements.

Tangible assets and leases

Pursuant to IAS 16, tangible assets are recognized on the balance sheet at historical acquisition and production cost less scheduled depreciation. Depreciation of tangible assets is generally applied straight-line over the estimated useful life of assets (generally three to thirteen years). The main useful lives are unchanged:

- IT equipment 3 years, straight-line
- Other Fixtures and equipment 4 years, straight-line
- Office and laboratory facilities 10 years, straight-line
- Laboratory devices 13 years, straight-line

Low value assets with purchase costs of between EUR 250 and EUR 1,000 have been booked to the year of acquisition as a single item for the relevant year and are fully depreciated over five years.

Biofrontera is a lessee mainly for buildings and vehicles used for operational and administrative purposes. The leasing liability to be carried as a liability is calculated as the present value of the payments that are highly likely to be made to the lessee. They are updated using the so-called effective interest method. The right of use of the underlying asset to be recognized in return is measured at cost at the beginning of the lease. In addition to the lease payments, any initial direct costs of the lessee and dismantling costs are included in the calculation. Incentive payments made by the lessor are deducted. The activated right of use is to be depreciated on a scheduled basis and tested for impairment if there is any indication of impairment.

The main useful lives of leases are determined by the term of the agreement and are as follows

- Motor vehicles 3 years, straight-line
- Buildings 6 years, linear

Future lease payments are to be discounted at the lessor's imputed interest rate or, if this is not available, at the marginal interest rate on the date of first application.

For expenses from leases with a remaining term of no more than one year and from leases with a low value, Biofrontera has decided to make use of the simplification of IFRS 16.6 and to treat the monthly leasing instalments unchanged compared with the accounting according to IAS 17 immediately as income.

Intangible assets

Purchased software is recognized at cost less amortization applied straight-line over a three-year useful life.

Purchased intangible assets consist of licenses and other rights. They are recognized at cost less accumulated amortization. These intangible assets are capitalized as assets and generally amortized straight-line over an estimated useful life of between 4 and 12 years.

Intangible assets under development relate to the further development of the BF-RhodoLED®. Furthermore, no development costs are capitalized, as the requirements for the recognition of internally generated intangible assets are not met.

No intangible assets exist with indefinite useful lives.

Borrowing costs are not recognized as part of the purchase cost of the acquired assets but are instead expensed in the period in which they arise, as the Group has no material qualifying assets in the meaning of IAS 23.5.

Impairment of assets

The Company tests non-current tangible and intangible assets for impairment when indications exist that the carrying amount of an asset exceeds its recoverable amount. A possible impairment loss on assets held for use is determined by comparing its carrying amount with the future cash flows expected to be generated by the asset. An impairment loss to be recognized is measured by Biofrontera at the amount by which the carrying amount of the asset exceeds its recoverable amount.

Financial assets

Financial assets are recognized as assets in the event that Biofrontera has a contractual right to receive cash or other financial assets from another party. Customary purchases and sales of financial assets are generally recognized on the settlement date. Financial assets are allocated to the category "Held" and are valued at amortized cost. Non-interest-bearing or low-interest receivables are recognized at cash value.

Impairment of financial assets

Biofrontera calculates the credit risk of trade receivables as the probability-weighted amount of the expected shortfall in payments compared to the contractual payment claims. In addition to individual factors, the basis for estimating expected credit losses is the general experience of collecting receivables in the past. The Company adjusts the fixed allowance rates derived from them, based on the extent of aged receivables, in the event of significant changes in the economic environment.

Trade receivables

Trade receivables are reported at their nominal value. Any value adjustments are booked directly against the relevant receivable.

Cash and cash equivalents

Cash and cash equivalents include cash in hand, cheques and bank deposits with a term of up to three months at the time of acquisition, as well as current financial assets. These are valued at amortized cost.

Non-financial assets

Non-financial assets are valued at cost.

Inventories

Raw materials and supplies, as well as finished and unfinished goods, are recognized at the lower of cost or net realizable value. Borrowing costs are not capitalized. Cost is calculated applying the first-in-first-out method (FIFO). A value adjustment is made to the inventories on the balance sheet date if the net realizable value is lower than the carrying amount. BF-RhodoLED®, which are carried for sales activities in the Company's own inventory are recognized at a fixed value.

Financial liabilities

Financial liabilities include original liabilities, with the exception of the embedded derivative that was separated from the EIB loan (the so-called performance component). Original liabilities are recognized if there is a contractual obligation to transfer cash or other assets to another party. The initial recognition of original financial liability is at fair value. In subsequent valuations of financial liabilities valued at amortized cost, any discounts between the amount received and the repayment amount are spread over the term using the effective interest method.

The financial liabilities of the performance component measured at fair value and the purchase price liability (earn-out) included in other financial liabilities are allocated to the category "Financial liabilities at fair value through profit or loss".

The valuation of the purchase price liability from the earn-out agreement was based on term-specific cost of capital rates ranging from 8.27% to 8.74% (previous year: from 9.39% to 9.53%).

Trade payables

Trade payables, as well as liabilities from current accounts and other liabilities are recognized at their redemption amount. Due to their short-term nature, the reported carrying amount reflects the fair value.

Convertible bonds

The convertible bond is a so-called compound financial instrument, which must be divided into the components debt (bond) and equity (conversion right) on initial recognition. The liability component (bond) must be recognized at its fair value at the time the contract is concluded. The fair value is determined by discounting the contractually agreed future payments at an interest rate customary for a comparable bond without conversion right. In this context, the default risk of the issuer must also be taken into account. The equity component (conversion right) is calculated as the difference between the proceeds of the issue and the present value of the liability (equity derivative, residual value method).

In subsequent accounting for the convertible bond, a distinction is made as follows: The liability component is subsequently valued at amortized cost using the effective interest method. The equity component is not subject to subsequent valuation.

EIB loan with an embedded derivative requiring separation

The loan contains three different interest components: 1) a variable interest component, entailing quarterly interest payments on the outstanding amounts based on 3-month EURIBOR plus a risk premium; 2) a fixed component at 6% per annum which is due at term-end, and 3) a performance component which is due at the term-end, and whose level is derived from the market capitalization of Biofrontera AG but limited to a 4% per annum interest rate.

The loan is carried forward at amortized purchase cost applying the effective interest method.

The performance component represents a separable financial instrument in the form of an embedded derivative, which is measured at fair value on each reporting date and is to be classified to a fair value hierarchy of level 3. The market capitalization at maturity is the same as that of the measurement cut-off date, which is based on the 90 trade days preceding the measurement cut-off date. The performance-based interest payment for the tranches received is calculated based on a notional participation rate in the market capitalization (the so-called notional equity proportion). This is discounted to the valuation date applying a market interest rate of 2.93% (previous year: 12.33%) for the 2017 EIB loan and 3.26% (previous year: 10.63%) for the 2019 EIB loan. The overall valuation effect on the performance component resulting from the change in interest rates is immaterial.

Non-financial liabilities

Non-financial liabilities are carried at the repayment amount.

Provisions

Provisions are formed if an obligation to third parties resulting from a past event exists and is likely to result in an outflow of assets in the future, and if the effect on assets can be reliably estimated.

Stock options

Stock options (equity-settled share-based payments) are valued at the fair value on the date of granting. The fair value of the obligation is capitalized as a personnel expense over the retention period. Obligations relating to cash-settled share-based payment transactions are recognized as liabilities and are measured at the fair value on the balance sheet date. In the event that Biofrontera AG has the right to choose between payment in cash or payment using shares when a right is exercised, an increase in the capital reserve is initially performed pursuant to IFRS 2.41 and IFRS 2.43. The costs are recognized over the vesting period. The fair value of both cash-settled and equity-settled share-based payment transactions is generally determined using a generally accepted valuation model.

Stock Appreciation Rights

The obligations under Biofrontera's stock appreciation rights program are cash-settled share-based payments that are recognized at fair value. Changes in fair value during the term are recognized in profit or loss. The fair value is determined using internationally recognized valuation techniques.

Income tax

In accordance with IAS 12, Biofrontera recognizes deferred taxes for valuation differences between IFRS valuation and tax law valuation. Deferred tax liabilities are generally recognized for all taxable temporary differences.

The recognition of deferred tax assets is subject to higher requirements due to the loss history. Deferred tax assets are only recognized if there are substantial indications that future taxable profits will be generated and that the deferred tax item to be recognized can be expected to be offset against future taxable profits.

The carrying amount of deferred income tax assets is reviewed on each balance sheet date and reduced to the extent that it is not probable that sufficient taxable profit will be available against which the deferred tax claim can be at least partially utilized. Previously unrecognized deferred income tax assets are reassessed on each balance sheet date and are recognized to the extent that it is probable from a current perspective that sufficient future taxable profit will be available to realize the deferred tax asset.

Deferred tax liabilities and deferred tax assets are offset if a right to offset exists, and if they are levied by the same tax authority.

Current taxes are calculated on the basis of the Company's taxable earnings for the period. The tax rates applicable to the respective companies on the balance sheet date are used for this purpose.

Earnings per share

In accordance with IAS 33 "Earnings per Share", earnings per share are calculated by dividing net consolidated income by the weighted average number of outstanding shares during the year.

Revenue recognition

The Company recognizes as revenue all income from product sales and the granting of licenses. The completed customer contracts contain only one performance obligation each. The Company is entitled to a fixed consideration for the products sold and licenses granted. To the extent that obligations to take back expired goods have been agreed with customers, Biofrontera only recognizes revenue to the extent that it is highly probable that it will be possible to realize this amount, taking into account the proportion of products to be taken back as based on historical experience. The timing and amount of the revenues to be reported in the consolidated income statement are determined by the extent to which Biofrontera transfers control of the products to be supplied or the rights to be granted to the customers.

Most of the revenues are generated by product sales. In accordance with respective local legislation concerning the marketing of pharmaceuticals and medical products, Ameluz® is sold exclusively through pharmaceutical wholesalers or directly to hospitals in Germany, as well as directly to pharmacies and hospitals in other European countries. In the U.S., Ameluz® is reimbursed as a so-called "buy-and-bill drug" and consequently marketed directly to physicians.

Xepi® is sold directly to specialty pharmacies in the USA. Sales are recognized net of sales deductions when ownership and control are transferred to the customer. Sales deductions include expected returns, discounts and incentives such as payments made under patient assistance programs. These rebates are estimated at the time of sale based on the amounts incurred or expected to be received for the related sales.

Revenue is recognized when the products are delivered to the respective customers.

In addition, Biofrontera generates sales revenues within the framework of the research and development cooperation with Maruho Co Ltd. Revenue is recognized over a specific period of time.

Down payments received by Biofrontera for the conclusion of license agreements granting customers a right of use are realized on a point-in-time basis.

In the case of direct sales of BF-RhodoLED®, the delivered products and services on which amounts are owed are settled only after complete installation has taken place. The installation service represents a pure ancillary service, as for legal reasons the lamp may only be used by the customer once it has been installed. In the U.S., some lamps are made available to physicians in return for a fee for an up to six-month evaluation period. A final decision to purchase does not need to be made until the end of this period. The Company generated revenues from the monthly fees during the evaluation period, and from the sale of lamps.

Belixos® is predominantly distributed through Amazon and pharmaceutical wholesalers. Revenue from Amazon sales is recognized after transfer of control and payment by the customer. For sales to pharmaceutical wholesalers, revenue is recognized upon transfer of control. Based on experience, return rights granted with the sale through Amazon are exercised by customers only in very few cases.

Revenue is recognized net of sales-related taxes and sales deductions. For expected sales deductions, such as rebates and discounts, estimated amounts are taken into account accordingly at the time of revenue recognition. The payment terms for Ameluz® include short-term payment terms with the possibility of cash discounts.

Cost of sales

The cost of sales includes material costs for sold products, payments to third parties for services directly attributable to revenue generation and product manufacturing, as well as directly attributable personnel expenses and depreciation, as well as proportional overhead expenditures.

Research and development expenses

Pursuant to IAS 38, development costs are recognized as "intangible assets" under certain conditions. Research costs are recognized as costs as they are incurred. Development costs are capitalized if the criteria of IAS 38.57 are fulfilled depending on the possible outcome of development activities.

Research and development costs relating to the drug Ameluz®, which has been approved in Europe and the U.S., and to the Company's other research and development projects, are consequently expensed in the period in which they are incurred. Intangible assets under development relate to the further development of BF-RhodoLED®, as the recognition criteria of IAS 38.57 are fulfilled.

Notes to the consolidated balance sheet

1. Intangible and tangible assets

In the 2020 financial year, impairment losses on tangible assets were recognized in the amount of EUR 0 thousand (previous year: EUR 527 thousand) and on intangible assets in the amount of EUR 2,001 thousand (previous year: EUR 0 thousand). The impairment losses on property, plant and equipment in the previous year were included in the cost of sales, and those on intangible assets are also included in the cost of sales.

The cost of short-term and low-value leases amounts to EUR 374 thousand (previous year: EUR 386 thousand). The income from a sublease agreement amounts to EUR 33 thousand (previous year: EUR 34 thousand).

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 evaluate 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 EUR 21,981 thousand on the license. 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 December 31, 2020, Biofrontera has not identified any indication for impairment or reversal of impairment.

Tangible and intangible assets are composed as follows:

Statement of changes in non-current assets for 2020

in EUR thousands	Purchase and production cost					Accumulated depreciation and amortization					Carrying amounts	
	Jan. 01,2020	Currency translation	Additions	Disposals	Dec. 31,2020	Jan. 01,2020	Currency translation	Additions	Disposals	Dec. 31,2020	Dec. 31,2020	Jan. 01, 2020
Tangible assets and leases												
Operating and business equipment	3,647	(46)	548	(191)	3,958	(2,492)	18	(276)	176	(2,574)	1,385	1,155
Right-of-use leasing properties	3,560	-	653	-	4,213	(505)	-	(722)	-	(1,227)	2,986	3,055
Right-of-use leasing tangible assets	1,612	-	166	-	1,778	(592)	-	(505)	-	(1,098)	681	1,020
	8,819	(46)	1,367	(191)	9,949	(3,589)	18	(1,503)	176	(4,898)	5,051	5,230
Intangible assets												
Software and licenses	206	(2)	25	(1)	227	(190)	2	(14)	1	(201)	27	16
Right-of-use assets	24,474	(2,138)	-	-	22,336	(2,356)	582	(3,816)	-	(5,590)	16,746	22,118
Intangible assets under development	715	-	201	-	916	-	-	-	-	-	916	715
	25,395	(2,140)	226	(1)	23,480	(2,546)	584	(3,830)	1	(5,791)	17,689	22,849
	34,214	(2,185)	1,593	(193)	33,429	(6,135)	601	(5,333)	177	(10,689)	22,740	28,079

Statement of changes in non-current assets for 2019

in EUR thousands	Purchase and production cost						Accumulated depreciation and amortization					Carrying amounts	
	Jan 01, 2019	Currency translation	Additions	Change of consolidation group	Disposals	Dec. 31, 2019	Jan. 01, 2019	Currency translation	Additions	Disposals	Dec. 31, 2019	Dec. 31, 2019	Jan. 01, 2019
Tangible assets and leases													
Operating and business equipment	4,104	2	1,294	1,340	(3,093)	3,647	(3,309)	(1)	(482)	1,300	(2,492)	1,155	795
Right-of-use leasing properties	1,768	-	1,792	-	-	3,560	-	-	(505)	-	(505)	3,055	1,768
Right-of-use leasing tangible assets	567	-	1,045	-	-	1,612	-	-	(592)	-	(592)	1,020	567
	6,439	2	4,131	1,340	(3,093)	8,819	(3,309)	(1)	(1,579)	1,300	(3,589)	5,230	3,130
Intangible assets													
Software and licenses	446	-	20	-	(260)	206	(427)	-	(21)	258	(190)	16	19
Right-of-use-assets	1,101	(69)	92	23,604	(254)	24,474	(1,035)	5	(1,556)	230	(2,356)	22,118	66
Intangible asset under development	267	-	448	-	-	715	-	-	-	-	-	715	267
	1,814	(69)	560	23,604	(514)	25,395	(1,462)	5	(1,577)	488	(2,546)	22,849	352
	8,253	(67)	4,691	24,944	(3,607)	34,214	(4,771)	4	(3,156)	1,788	(6,135)	28,079	3,482

2. Inventories

in EUR thousands	December 31, 2020	December 31, 2019
Raw materials	1,557	893
Unfinished goods	390	201
Finished goods and products	2,727	2,971
Total	**4,673**	**4,065**

In 2020, inventories were written down by EUR 414 thousand (previous year: EUR 24 thousand).

The finished goods and products include PDT lamps that are made available to doctors for a fee within the framework of a 6-month evaluation phase of EUR 145 thousand (previous year: EUR 89 thousand).

3. Trade receivables

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

Allowances for doubtful accounts were made in the amount of EUR 36 thousand (previous year: EUR 43 thousand). As in the previous year, there were no outstanding receivables on the balance sheet closing date that were not value-adjusted.

Of the receivables, EUR 100 thousand (previous year: EUR 178 thousand) are attributable to finance leases for PDT-lamps.

4. Other financial assets

Other financial assets comprise mainly prepayments rendered for studies (EUR 220 thousand; previous year: EUR 359 thousand) and the depositing of collateral, mainly for leasing property, credit cards and leasing vehicles in the amount of EUR 267 thousand (previous year: EUR 300 thousand). As in the previous year, no individual value impairments were applied during the reporting year.

5. Other assets

Other assets mainly comprise of accruals and deferrals (EUR 817 thousand; previous year: EUR 1,113 thousand).

As in the previous year, no individual value impairments were applied during the reporting year.

6. Income tax

Income tax reimbursement claims consist of claims for tax refunds relating to withheld capital gains tax, plus the Solidarity Surcharge of EUR 5 thousand (previous year: EUR 4 thousand). Income tax liabilities relate to current income tax liabilities for fiscal year 2020 in the amount of EUR 0 thousand (previous year: 11 thousand).

7. Cash and cash equivalents

Cash and cash equivalents relate to cash in hand, cheques, bank deposits and money deposits with a term of up to three months at the time of acquisition amounting to a total of EUR 16,546 thousand (previous year: EUR 11,119 thousand).

8. Deferred income tax

Deferred tax assets amount to EUR 7,525 thousand (previous year: EUR 7,794 thousand) and relate to the deferred tax assets on losses carried forward for Biofrontera Pharma GmbH.

The reduction in deferred tax assets results from the use of the tax loss carryforwards of Biofrontera Pharma GmbH in the amount of EUR 269 thousand (previous year: EUR 256 thousand). In the previous year, there was also a reduction in the trade tax rate of the city of Leverkusen with effect of January 1, 2020 in the amount of EUR 2,350 thousand.

The subsidiary Biofrontera Pharma GmbH has generated profits in the fiscal years 2019 and 2020 and it can be assumed that Biofrontera Pharma GmbH will continue to generate positive results in the future and thereby utilize its tax loss carryforwards.

Further deferred income tax on loss carryforwards incurred at Biofrontera AG in the amount of EUR 74 thousand (previous year: EUR 153 thousand) and at Biofrontera Inc. in the amount of EUR 0 (previous year: EUR 533 thousand) were capitalized to the extent that they are offset by deferred tax liabilities in the same amount.

The following table explains the generally existing deferred tax assets from tax loss carryforwards that have developed within the Group:

in EUR thousands	December 31, 2020		December 31, 2019	
	Loss carried forward	Deferred tax assets	Loss carried forward	Deferred tax assets
Corporation tax including Solidarity Surcharge	134,606	21,301	135,415	21,436
Business tax	118,599	10,377	120,692	10,561
U.S. corporation tax	32,172	8,365	23,616	6,140
Total		**40,044**		**38,137**

These loss carryforwards have an unlimited carryforward period under current German law. In the USA, tax loss carryforwards can be carried forward for 20 years when occurred until December 31, 2017 in the amount of EUR 8,595 thousand, and indefinitely when occurred from January 1, 2018 in the amount of EUR 23,577 thousand (previous year: EUR 15,021 thousand).

in EUR thousands	December 31, 2020		December 31, 2019	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Loss carried forward	7,824	-	8,568	-
Non-current assets				
- Intangible assets	789	(656)	-	(620)
- Tangible assets	-	(980)	-	(1,002)
Current assets				
- Receivables and other assets	15	-	43	-
Non-current and current financial liabilities	812	-	859	-
Current liabilities				
- Liabilities and other	-	(279)	-	(54)
Total	9,440	(1,915)	9,470	(1,676)
Netting of deferred tax assets and liabilities	(1,915)	1,915	(1,676)	1,676
As recognized on balance sheet	**7,525**	**-**	**7,794**	**-**

Deferred taxes on losses carried forward are capitalized to the extent that there is substantial evidence that it is probable that future taxable profit will be available against which the loss carryforwards can be utilized or if there is an equivalent level of deferred tax liabilities. Due to the lack of predictability regarding future taxable profits with consideration of the loss history, the remaining deferred tax assets deriving from loss carryforwards in the amount of EUR 32,220 thousand (previous year: EUR 29,569 thousand) and deferred tax assets in the amount of EUR 1,812 thousand (previous year: EUR 2,000 thousand) were not recognized on the balance sheet, in accordance with IAS 12.34.

The following provides a reconciliation between expected and actual reported income tax expense, with the output value being based on the income tax rate of 24,575% (previous year: 32,45%) currently applicable to the Biofrontera Group.

in EUR thousands	December 31, 2020	December 31, 2019
Consolidated loss before tax	(12,697)	(4,777)
Expected income tax reimbursement	3,120	1,550

in EUR thousands	December 31, 2020	December 31, 2019
Differences arising from different tax rates	146	(839)
Effects of changes in trade tax rates		
- from temporary differences	-	16
- from loss carryforwards	-	(2,350)
Tax increases due to non-deductible expenses	(982)	(538)
Changes in unrecognized deferred tax assets		
- from active temporary differences	188	(1,217)
- from loss carryforwards	(2,627)	(4,251)
Tax-free income (badwill)	-	4,807
Other effects	(170)	241
Income taxes as per statement of comprehensive income	**(325)**	**(2,581)**

9. Equity

Share capital

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 47,747,515 on December 31, 2020. It was divided into 47,747,515 registered shares with a nominal value of EUR 1.00 each. On December 31, 2019, the share capital amounted to EUR 44,849,365.

The Biofrontera AG shares were listed on the Regulated Market of the Düsseldorf Stock Exchange in 2006. In August 2012, the Company's shares were also admitted to trading on the Regulated Market of the Frankfurt Stock Exchange in response to an application by the Company. The Company's shares are also traded on the Xetra computer trading system and all other German stock exchanges. On June 3, 2014, the share was included in the Prime Standard of the Frankfurt Stock Exchange.

The introduction on the NASDAQ Stock Market in the U.S. occurred on February 14, 2018. Shares in Biofrontera AG are traded there as American Depositary Shares (ADS) under the ticker symbol BFRA. One ADS securitizes the right to two ordinary shares of Biofrontera AG.

The numbers of shares held by the shareholders on December 31, 2020, based on the most recent mandatory disclosures, are as follows:

	December 31, 2020	December 31, 2019
Maruho Deutschland Co., Ltd., Osaka Japan The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.	13,399,965	13,047,754
Wilhelm Konrad Thomas Zours The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours: • DELPHI Unternehmensberatung AG • VV Beteiligungen AG • Deutsche Balaton AG • Deutsche Balaton Biotech AG • Prisma Equity AG • Sparta AG • ABC Beteiligungen AG • AEE Ahaus-Enscheder AG • MARNA Beteiligungen AG • Youbisheng Green Paper AG • Strawtec Group AG	14,218,773	13,300,694
Free float	20,128,777	18,500,917
Total	**47,747,515**	**44,849,365**

Only those shareholders are listed who are subject to reporting requirements under the German Securities Trading Act (WpHG) and the Securities and Exchange Commission (SEC) and have made a corresponding notification. This includes all shareholders who hold at least 3% of the outstanding shares or voting rights. The number of shares listed here refers to the last notification of the

respective shareholders, since then they may have changed their holdings within the respective notification thresholds without informing the Company.

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

Authorized/conditional capital

The Company had no authorized capital as of the reporting date.

The conditional capital consisted of three share capital amounts.

The conditional increase in the share capital (Conditional Capital I) of EUR 6,434,646 was approved on August 28, 2015, of which is EUR 1,359,864 available as at December 31, 2020. Conditional Capital I serves to secure the granting of option rights and the agreement of option obligations in accordance with the bond terms and conditions.

The conditional increase in the share capital (Conditional Capital III) of EUR 542,400 was approved on February 28, 2015, of which is EUR 249,050 available as of December 31, 2020, and serves exclusively to fulfill option rights (2010 share option program) granted on July 1, 2015 on the basis of the annual general meeting ("AGM") of July 2, 2010.

The conditional increase in the share capital (Conditional Capital V) of EUR 1,814,984 approved on February 28, 2015. of which is EUR 1,554,984 available as at December 31, 2020 and serves exclusively to fulfill option rights (2015 share option program) granted until August 27, 2020 on the basis of the AGM on August 28, 2015.

Convertible bond 2017/2022

On December 23, 2016, the Company's Management Board approved the issue of a convertible bond, which was placed in full in an amount of EUR 5.0 million in January 2017. The individual bonds will bear interest of 6% per year from February 1, 2017 on their nominal amount. The interest is payable semi-annually in arrears on January 1 of each year, for the first time on July 1, 2017. The fair value of the convertible bond was calculated on the basis of an interest rate of 7.6% in the initial valuation. The term of the 2017/2022 convertible bond begins on the day of its initial issue ("issue date") and ends on December 31, 2021 and is due for repayment on January 01, 2022.

As of December 31, 2020, bonds in a nominal amount of EUR 2,030,800 were converted into the Company's shares. In 2020, no bonds were converted (previous year: nominal amount EUR 564,500; 118,841 shares).

Convertible bond 2020/2021

In August 2020, Biofrontera issued a qualified subordinated mandatory convertible bond 2020/2021 from Conditional Capital I. The bond was divided into 2,638,150 bearer bonds with a nominal value of EUR 3.00 each ("bonds"). The term of the bonds began on August 20, 2020 and ends on December 20, 2021. However, in accordance with section 8 (2) of the terms and conditions of the bonds, the Company is entitled to make a mandatory conversion at any time for an unlimited period after the price of the Company's shares has exceeded EUR 4.50 ("mandatory conversion trigger price").

On November 12, 2020, Biofrontera decided to exercise the right to mandatory conversion in accordance with §8 (2) of the bond terms and conditions.

Accordingly, shares with a nominal value of EUR 2,638,150.00 Biofrontera AG were converted from the mandatory convertible bond 2020/2021. In this context, EUR 5,179 thousand was allocated to the capital reserve. With the early exercise of the conversion option by Biofrontera, the debt portion outstanding at the conversion date in the amount of EUR 98 thousand was recognized in profit or loss. The capital procurement costs incurred in the amount of EUR 378 thousand were deducted from the capital reserve.

2010 stock option program

The exercise period for the last tranche of the 2010 stock option program ended on April 02, 2020. The options still exercisable as of December 31, 2019 (23,000 options) expired in the reporting period.

2015 stock option program

At the AGM on August 28, 2015, the Management Board and Supervisory Board proposed a new share option program for employees to the AGM, which approved the initiative. Accordingly, the Management Board or, to the extent that the beneficiaries are Management Board members, the Supervisory Board, are entitled until August 27, 2020 to issue up to 1,814,984 subscription rights to up to EUR 1,814,984 of the Company's ordinary registered shares, whose exercise is tied to certain targets.

The program has a total nominal value of EUR 1,814,984 and a term of five years from the issue date, in other words, until August 27, 2020. Eligibility for the 2015 share option program was granted to members of the Management Board and employees of the Company as well as to members of management bodies and employees of affiliates of Biofrontera AG. The granting of options is made without any payment being provided in return.

In accordance with the associated conditions, each subscription right that is granted entitles the beneficiary to acquire one new registered no par value unit share in the Company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices on the Frankfurt Stock Exchange in floor trading and in Xetra trading for the Company's shares on the ten trading days prior to the issuing of the share. However, the minimum exercise price shall amount to the proportionate share of the Company's share capital allocated to each individual no par value unit share, pursuant to Section 9 (1) of the German Stock Corporation Act (AktG).

The options granted can only be exercised after expiry of a vesting period. The vesting period is four years from the respective date of issue. A prerequisite for the whole or partial exercising of the options is that the following performance target is achieved:

Exercising the options from a tranche is possible, if at the beginning of the respective exercise period, the price (hereinafter referred to as the "reference price") of a share in Biofrontera Aktiengesellschaft exceeds the exercise price by at least 20%, and a minimum reference price of EUR 5.00 is reached (hereinafter referred to as the "minimum reference price"). The reference price is equal to the arithmetical average (unweighted) of the closing prices on the Frankfurt Stock Exchange in floor trading and Xetra trading for the Company's shares between the 15th and the 5th stock market day (in each case inclusive) before the start of the respective exercise window. The minimum reference price is adjusted in the following cases to align the specified performance target with changed circumstances:

- In the event of a capital increase from company funds being implemented by issuing shares, the minimum reference price is reduced by the same ratio as new shares issued compared to existing shares. If the capital increase is implemented from company funds without issuing new shares (Section 207 (2) Clause 2 of the German Stock Corporation Act [AktG]), the minimum reference price is not changed.
- In the case of a capital reduction, no adjustment of the minimum reference price is implemented, provided that the total number of shares is not changed by the capital reduction, or if the capital reduction is connected to a capital repayment or purchase of treasury shares. In the case of a capital reduction performed by consolidating shares without capital repayment and in the case of increasing the number of shares with no associated change in capital (share split), the minimum reference rate increases in line with the capital reduction or share split.

Other adjustments to the minimum reference price are not implemented.

The exercising of options is limited to the following time periods (hereinafter "exercise windows"), in other words, only declarations of exercising of rights submitted to the Company within an exercise window will be considered:

a) on the 6th and subsequent 20 banking days after the date of the AGM (exclusive),
b) on the 6th and subsequent 20 banking days after the date of submission of the semi-annual or quarterly report or an interim statement by Biofrontera AG (exclusive)
c) in the period between the 15th and 5th banking day prior to the expiration of the option rights of the respective expiration day (exclusively).

After the vesting period, the options can be exercised up until the expiry of six years from the date of issue (exclusive). For the valuation of the employee share options, we have assumed an average holding period of 5 years.

Any claim by the beneficiaries to receive a cash settlement in the event of non-exercise of the options is invalid even in the event of the existence of the above exercise prerequisites. An option may only be exercised if the holder has a current service or

employment contract with the Company or another Company affiliated with the Company or if the holder is a member of the Management Board or the management team of another company affiliated with the Company.

In the event of the exercising of a subscription right, the Company is generally and in specific cases permitted to choose between granting the registered share in exchange for payment of the exercise price, or fulfilling its debt by paying a cash settlement to the holder of the subscription right. The cash settlement per subscription right is equal to the difference between the exercise price per share and the share price on the exercise date, minus due taxes and fees.

As this stock option scheme entails share-based payment transactions in which the terms of the arrangement provide the Company with a choice of settlement, the Company has decided, in accordance with IFRS 2.41 and IFRS 2.43, to recognize the transactions pursuant to the provisions for equity-settled share-based payments (IFRS 2.10-29).

	Tranche 1	Tranche 2	Tranche 3	Tranche 4	Tranche 5	Tranche 6
Number of options issued	425,000	130,500	329,000	300,500	180,000	333,485
Date of issue	18.04.2016	01.12.2016	28.04.2017	28.11.2017	07.05.2018	14.05.2019
Exercise price	EUR 2.49	EUR 3.28	EUR 4.02	EUR 3.33	EUR 5.73	EUR 6.708
Adjusted exercise price March 2018	EUR 2.25	EUR 3.04	EUR 3.78	EUR 3.09	-	-
End of vesting period	18.04.2020	01.12.2020	28.04.2021	28.11.2021	07.05.2022	14.05.2023
End of exercise window	18.04.2022	01.12.2022	28.04.2023	28.11.2023	07.05.2024	14.05.2025
Fair value per option	EUR 1.00	EUR 1.30	EUR 1.56	EUR 1.48	EUR 2.35	EUR 2.55
Share price volatility	50.59%	49.00%	47.00%	46.00%	47.00%	47.30%
Dividend yield	0%	0%	0%	0%	0%	0%
Share price yield	2,31%	7,00%	7,50%	7,60%	7,60%	7,60%
Risk-based interest rate	5.92%	13.26%	13.94%	14.05%	14.03%	13.35%
Fluctuation rate	12%	12%	12%	12%	9%	9%

The fair value of a stock option under this option program is determined on the basis of a Monte Carlo risk simulation. The pro rata amounts are recognized ratably over the vesting period as personnel expenses and an increase in the capital reserves.

2015 stock option program	December 31, 2020	December 31, 2019
Outstanding at the beginning of the period	1,496,985	1,252,000
Granted during the period	-	333,485
Forfeited during the period	215,500	88,500
Exercised during the period	260,000	-
Expired during the period	-	-
Outstanding at the end of the period	1,021,485	1,496,985
Exercisable at the end of the period	-	-
Range of exercise prices for outstanding options	EUR 2.25 – 6.708	EUR 2.25 - 6.708
Weighted average of remaining contractual life	35 months	44 months
Cost during the period	EUR 293,000	EUR 360,000

Due to the non-fulfillment of the exercise conditions, no options were exercisable as of December 31, 2020.

Capital reserves

The capital reserves shown on the balance sheet comprise the capital reserve, the reserves from currency translation, the loss carried forward and the result of the period. The statement of changes in equity provides further information about the development of equity.

In accordance with IAS 32.37, equity procurement costs in connection with capital increases are deducted from the capital reserve in an amount of EUR 407 thousand (previous year: EUR 2 thousand) for the year ended December 31, 2020.

Capital management

The Group's equity calculated in accordance with IFRS is managed as capital. The Company's capital management regularly reviews the Group's level of liquidity and equity. Objective is to ensure that the Group's financing is adequate within the expectations of the capital market and to ensure creditworthiness with respect to national and international business partners to secure the Group's business operations for at least 12 months. The Company's Management Board ensures that all Group companies have sufficient capital available in the form of equity and debt.

10. Financial liabilities

in EUR thousands	December 31, 2020	December 31, 2019
Non-current financial liabilities		
Convertible bond 2017/2022	2,003	1,977
EIB loan 2017	12,484	11,845
EIB loan 2019	5,591	5,301
Leasing liabilities	2,657	2,987
Total non-current financial liabilities	**22,736**	**22,110**
Current financial liabilities		
Leasing liabilities	1,057	1,038
Other current liabilities	82	174
Total current financial liabilities	**1,139**	**1,212**

The contractual interest and repayment obligations relating to convertible bonds and the EIB loan are composed on the balance sheet date as follows:

in EUR thousands	December 31, 2020					
	2021	2022	2023	2024	2025	Total
Convertible bond 2017/2022:						
Principal repayment		2,031				2,031
Interest payment	122	61				183
EIB loan 2017						
Principal repayment		10,000				10,000
Interest payment	461	4,354				4,815
EIB loan 2019						
Principal repayment				5,000		5,000
Interest payment	204	214	227	1,874		2,519
Leasing liabilities						
Principal repayment	1,138	577	603	630	459	3,407
Interest payment	148	85	59	33	6	331

in EUR thousands	December 31, 2019						
	2020	2021	2022	2023	2024	2025	Total
Convertible bond 2017/2022:							
Principal repayment			2,031				2,031
Interest payment	122	122	61				305
EIB loan 2017							
Principal repayment			10,000				10,000
Interest payment	433	461	4,949				5,843
EIB loan 2019							

Principal repayment					5,000		5,000
Interest payment	194	204	214	227	2,058		2,897
Leasing liabilities							
Principal repayment	1,033	1,098	484	503	523	384	4,025
Interest payment	146	114	64	44	24	4	396

Loan agreement with the European Investment Bank

The liability component of the financial instrument is subsequently measured at amortized cost applying the effective interest method. As of December 31, 2020, the carrying amount of the liability component on this basis was EUR 16,901 thousand (previous year: EUR 15,684 thousand).

As a variable interest component and also as a separable financial instrument in the form of an embedded derivative, the performance component is subsequently measured at fair value. As of December 31, 2020, the discounted interest payment or fair value of the performance component amounted to EUR 1,174 thousand (previous year: EUR 1,462 thousand). The undiscounted interest payment of the performance component amounts to EUR 1,244 thousand (previous year: EUR 2,023 thousand).

For further details, please refer to the section on significant accounting policies.

Leasing liabilities

The carrying amount of the current and non-current leasing liabilities amounts to EUR 3,715 thousand (previous year: EUR 4,025 thousand). Future lease payments are discounted at the lessor's imputed interest rate or, if this is not available, at the marginal borrowing rate.

For further details, please refer to the section on significant accounting policies.

11. Other financial liabilities

in EUR thousands	December 31, 2020	December 31, 2019
Non-current other financial liabilities		
Purchase price liability (earn-out and start-up costs)	17,811	14,720
Liability from SAR program	183	-
Total non-current other financial liabilities	**17,994**	**14,720**
Current financial liabilities	**90**	**99**

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

The purchase price liability was discounted based on 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 revaluated in 2020 due to the current market situation influenced by the COVID 19 pandemic and the resulting postponement of the market penetration of Xepi®. In total, excluding the repayment of start-up costs, this results in a purchase price liability of nominally USD 26.4 million / EUR 21.6 million (previous year USD 28.9 million / EUR 25.8 million). The start-up costs received in the nominal amount of USD 7.3 million (EUR 6.0 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	December 31, 2020
Granted during the period	755,750
Forfeited during the period	28,000
Exercised during the period	-
Expired during the period	-
Outstanding at the end of the period	727,750
Exercisable at the end of the period	-
Fair value at the end of the period	EUR 183,000
Cost during the period	EUR 183,000

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

12. Trade payables

As of December 31, 2020, trade payables amounted to EUR 1,623 thousand (previous year: EUR 4,196 thousand).

13. Other provisions

in EUR thousands	01.01.2020	Utilized	Released	Added	Translation difference	31.12.2020
Outstanding invoices	393	(339)	(17)	274	0	311
Auditing costs	323	(314)	(8)	501	(1)	501
Provision for litigation costs	2,305	(672)	0	307	0	1,940
Other provisions	474	(357)	(83)	286	(30)	290
Total	**3,495**	**(1,682)**	**(109)**	**1,368**	**(31)**	**3,042**

Other provisions relate to various identifiable individual risks and uncertain obligations. The provisions classified as current are expected to result in an outflow of economic benefits within the subsequent financial year.

The companies included in the consolidated financial statements of Biofrontera AG are exposed to several anticipated 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. The claims asserted against Biofrontera in connection with the patent litigation have not been recognized as liabilities, as the Executive Board continues to believe that the claims are unjustified.

Provisions were recognized in the reporting year for future litigation costs, which include the estimated costs for legal disputes with DUSA Pharmaceuticals, Inc. and the Deutsche Balaton Group in each case until a decision is reached in the next instance. We assume that the lawsuits of DUSA Pharmaceuticals, Inc. in particular are unjustified, but we cannot guarantee that we will be successful in court with them.

For the pending proceedings in the USA and Germany, there are provisions for litigation costs totaling EUR 1,940 thousand in 2020 (previous year: EUR 2,305 thousand). In the 2020 financial year, further amounts of EUR 306 thousand (previous year: EUR 1,035 thousand) were added.

14. Other current liabilities

in EUR thousands	December 31, 20200	December 31, 2019
Accrual for employee bonuses	1,350	1,731
Accrual for outstanding vacation	372	403
Payroll tax	395	135
Wages and salaries	196	212
Social security	37	21
Other	41	63
Total	**2,392**	**2,565**

15. Reporting on financial instruments

Financial assets

in EUR thousands	Fair value as of Dec 31, 2020	Carrying amount as of Dec 31, 2020	Fair value as of Dec 31, 2019	Carrying amount as of Dec 31, 2019	Net gains or (losses) Dec31, 2020	Net gains or (losses) Dec 31, 2019
Category: Held						
Cash and cash equivalents	16,546	16,546	11,119	11,119	(125)	(15)
Trade receivables	3,501	3,501	5,031	5,031	(53)	(33)
Other financial assets	531	531	1,077	1,077	-	-
Total	**20,579**	**20,579**	**17,227**	**17,227**	**(178)**	**(48)**

Financial liabilities

in EUR thousands	Fair value as of Dec 31, 2020	Carrying amount as of Dec 31, 2020	Fair value as of Dec 31, 2019	Carrying amount as of Dec 31, 2019	Net gains or (losses) Dec 31, 2020	Net gains or (losses) Dec 31, 2019
Financial liabilities at amortized cost						
Financial liabilities, current	1,139	1,139	1,212	1,212	-	-
Trade payables	1,623	1,623	4,196	4,196	53	(2)
Other financial liabilities	90	90	99	99	-	-
Financial liabilities, non-current	21,561	21,561	20,647	20,647	-	-
Total	**24,413**	**24,413**	**26,155**	**26,155**	**53**	**(2)**
Financial liabilities at fair value through profit or loss						
Financial liabilities, non-current	1,174	1,174	1,462	1,462	288	(82)
Other financial liabilities, non-current	17,994	17,994	14,721	14,721	(750)	(650)
Total	**19,169**	**19,169**	**16,183**	**16,183**	**(462)**	**(732)**

Under other operating expenses, Biofrontera reports value adjustments to trade receivables and miscellaneous financial obligations allocable to the "held" category.

The net gains and losses generally include currency translation effects as well as impairments and write-ups. Fair value changes of liabilities recognized at fair value are included in interest expense. Interest income is not included in net income.

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

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

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

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

Biofrontera has level 3 financial instruments. These relate to the performance component of the EIB loan (EUR 1,174 thousand; previous year: EUR 1,462 thousand) included under non-current financial liabilities and the purchase price liability arising in 2019 from the acquisition of Cutanea (EUR 17,811 thousand; previous year: EUR 14,720 thousand). No reclassifications were made between the individual levels of the fair value category during the 2020 fiscal year.

For further details, please refer to the disclosures in the general accounting policies and the notes to the statement of financial position and statement of comprehensive income (Notes 10 and 11). The gains and losses included in the statement of net income are presented in interest income and interest expense.

Principles on risk management

In the ordinary course of business, the Group is exposed to risks that may have an impact on its net assets, financial position and results of operations.

In general, Biofrontera's market risk consists of foreign currency and changes in interest rates.

- Foreign currency risk: As of the balance sheet date, the Biofrontera Group was exposed to foreign currency risks, in particular as a result of the intercompany loan granted to the subsidiary Biofrontera Inc. Trade receivables arise to a greater extent than in the past due to the business expansion in the USA and are regularly reviewed with regard to a potential default risk. Trade payables denominated in foreign currencies are insignificant. The Company does not enter into any specific currency hedging transactions. Exchange rate fluctuations are recognized in profit or loss.

  Financial assets and liabilities in foreign currencies amount to EUR 7.8 million (previous year: EUR 29.1 million). An exchange rate-related change in the value of financial assets and financial liabilities denominated in foreign currencies of +5%

would result in a change in earnings of EUR 0.4 million (previous year: EUR 1.5 million) in the income statement item "Other income and expenses".

- Interest rate risk: Interest rate risks exist for the purchase price liability for Cutanea to Maruho and the performance component of the EIB loan. Otherwise, the interest rate risk is considered negligible, as the existing interest rate modalities for the relevant financing of the Biofrontera Group can generally be adjusted to market conditions in the short to medium term. For the performance component, a limit of 4% mitigates the market price risk. An interest rate-related change in the value of the purchase price liability of 1% would result in a change in interest expense of EUR 1.0 million (previous year: EUR 1.0 million).

The purchase price risk relates to the earn-out agreement in connection with the acquisition of Cutanea. For instance, the current uncertain business outlook due to the COVID-19 pandemic may also affect the future valuation of certain assets and liabilities of the Company. Reduced sales of Xepi® may thus lead to a different assessment of the medium-term business and earnings outlook for Xepi® and subsequently to a revaluation of the balance sheet value of the earn-out agreement. A change in the expected gains from the sale of Xepi® of +5% (-5%) would result in a change in the purchase price liability of EUR +0.8 million (EUR -0.8 million).

The Group incurs a credit risk if transaction partners are unable to meet their obligations within the ordinary payment periods. The maximum default risk on the balance sheet is represented by the book value of the respective financial asset. The development of receivables is monitored in order to identify possible default risks at an early stage and initiate appropriate measures. Biofrontera's financial instruments bear minimal risk of default. No specific bad debt allowances were recognized on trade receivables in fiscal year 2020 (previous year: EUR 43 thousand). Cash and cash equivalents assets are invested with banks and insurance companies with adequate deposit protection. All financial assets are due in the short term. As in the previous year, there are no material overdue financial assets.

Liquidity risk refers to the inability to meet existing or future payment obligations as they become due. To ensure the ability to pay at all times and to avoid financial shortages, Biofrontera has established a central cash management system that monitors liquidity requirements in the short, medium and long term. Refinancing for all Group companies is mainly provided by Biofrontera AG.

Liquidity is monitored and managed on the basis of short- and long-term corporate planning. Liquidity risks are identified at an early stage by simulating various scenarios. Current cash and cash equivalents are recorded and monitored on a daily basis.

For information on the (undiscounted) payments from financial debt due in the next few years and other financial liabilities, please refer to the corresponding notes on this balance sheet item. All other financial liabilities are current and are expected to be settled within one year.

Notes to the consolidated statement of comprehensive income

16. Sales revenue

in EUR thousands	2020 Product revenues	2020 Development revenues	2020 Licensing revenues	2019 Product revenue	2019 Development revenues	2019 Licensing revenues
Germany	5,159	-	-	4,633	-	-
Europe	2,104	-	-	2,603	-	-
U.S.	16,589	-	-	23,343	-	-
Other regions	-	493	6,000	-	686	-
Total	**23,853**	**493**	**6,000**	**30,579**	**686**	**-**

Licensing revenues include EUR 6,000 thousand in down payments received from Maruho under the license agreement.

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

In the 2020 financial year, we generated EUR 75 thousand of income from operating leases (previous year: EUR 72 thousand). We generated income of EUR 91 thousand from finance leases (previous year: EUR 126 thousand).

17. Cost of sales, gross profit

The cost of materials included in the cost of sales amounted to EUR 2,927 thousand for the 2020 financial year (previous year: EUR 3,827 thousand).

The gross profit on sales increased slightly by EUR 420 thousand in the 2020 reporting year, to reach EUR 26,810 thousand, compared with EUR 26,390 thousand in the prior-year period.

18. Research and development costs

Research and development costs amounted to EUR 4,789 thousand (previous year: EUR 4,636 thousand) and include costs for clinical studies as well as expenses for regulatory activities, i.e. the granting, maintenance and expansion of our approvals.

19. General administrative costs

General administrative costs amounted to EUR 9,150 thousand in the 2020 financial year (previous year: EUR 16,275 thousand) and thus decreased by a total of EUR 7,125 thousand compared to the previous year, in particular due to the cost-cutting measures introduced as a result of the COVID-19 pandemic Legal and consulting costs amounted to EUR 1,976 thousand (previous year: EUR 6,929 thousand).

20. Sales and marketing costs

Sales and marketing costs amounted to EUR 20,482 thousand in the 2020 financial year (previous year: EUR 28,856 thousand). Sales and marketing costs include costs for our own sales force in Germany, Spain, the UK and the U.S., marketing expenses as well as the depreciation of the Xepi® license amounting to EUR 3,802 thousand (previous year: EUR 1,533 thousand).

21. Interest expenses and income

in EUR thousands	2020 Effective interest expenses	2020 Interest espenses	2019 Effective interest expenses	2019 Interest expenses
Convertible bond 2017/2022	26	122	32	136
EIB loan 2017	269	975	202	1.046
EIB loan 2019	33	488	11	457
Purchase price liability (earn-out and start-up costs)	-	750	-	650

in EUR thousands	2020 Effective interest expenses	2020 Interest espenses	2019 Effective interest expenses	2019 Interest expenses
Leasing	-	179	-	124
Other	218	20	-	53
Total	**546**	**2.534**	**245**	**2.466**

Interest income amounted to EUR 411 thousand (previous year: EUR 127 thousand) and resulted mainly from the fair value valuation of the performance component of the EIB loan in the amount of EUR 288 thousand (previous year: EUR 0 thousand) and from the recognition in the income statement of the debt component upon early conversion of the mandatory convertible bond 2020/2021 in the amount of EUR 98 thousand.

22. Other expenses and income

Other expenses and income totaled EUR (2,418) thousand in the fiscal year 2020 (previous year: income of EUR 21,184 thousand), with the previous year's figure including non-recurring effects from the acquisition of Cutanea Life Sciences Inc. amounting to EUR 21,027 thousand. In addition, the items include expenses and income from currency translation amounting to EUR (3,601) thousand (previous year: income of EUR 324 thousand).

23. Income tax

in EUR thousands	2020	2019
Deferred taxes	(269)	(2,606)
Actual income taxes	(56)	25
Total income taxes	**(325)**	**(2,581)**

The deferred tax expense results from the use of the tax loss carryforwards of Biofrontera Pharma GmbH of EUR 269 thousand (previous year: EUR 256 thousand) and, in the previous year, also from changes in tax rates.

24. Earnings per share (EPS)

Earnings per share are calculated on the basis of the net loss for the year of the Biofrontera Group and the average ordinary shares in circulation in the financial year, in accordance with IAS 33.

	December 31, 2020	December 31, 2019
Number of weighted ordinary shares in circulation (on average)	54,179,685	44,690,009
Net loss for the year in EUR	(13,023,030)	(7,358,285)
Basic/diluted earnings per share in EUR	**(0.24)**	**(0.16)**

As part of the capital increase in February 2021, Biofrontera issued 8,969,870 new ordinary shares with subscription rights from January 1, 2020. After registration of the capital increase in the commercial register, the number of shares outstanding increased to 56,717,385. The capital increase has therefore been included in the calculation of the weighted average number of ordinary shares outstanding.

In principle, there are dilutive instruments. However, due to the loss situation, the diluted EPS corresponds to the undiluted EPS.

At the balance sheet date, there are options to convert the convertible bond into shares and stock options. Based on the conversion price of EUR 4.74 (previous year EUR 4.75), 428,710 shares (previous year: 427,536 options) and 1,019,485 stock options (previous year: 1,519,985) can be exercised.

25. Additional information to the consolidated statement of comprehensive income

Other comprehensive income only includes exchange differences from the conversion of foreign currency from our foreign operations into the Group currency.

Depreciation and amortization expense

The amortization of intangible assets and depreciation of tangible assets are included in the following items of the statement of comprehensive income:

in EUR thousands	2020	2019
Research and development costs	37	72
General administrative costs	1,352	383
Cost of sales	91	17
Sales and marketing	3,854	2,684
Depreciation and amortization expense	**5,333**	**3,156**

Personnel costs

in EUR thousands	2020	2019
Wages and salaries	14,067	19,894
Social security charges	2,016	2,958
Cost for pension schemes	257	391
Total	**16,340**	**23,243**

26. Staff

In 2020, the Biofrontera Group had an average of 157 salaried employees (previous year: 180).

27. Other information

In the USA, BF-RhodoLED® lamps are also available under leasing agreements. These agreements are accounted for as operating leases in the first six months. After six months, the customer has the option of either returning the lamp or purchasing it. The agreed purchase price can then be paid immediately in full or over an additional 24 months. If payment is made over an additional 24 months, the agreements are accounted for as financing leases. In financial year 2020, the Company generated income of EUR 75 thousand (previous year: EUR 71 thousand) from operating lease agreements. Income of EUR 91 thousand (previous year: EUR 126 thousand) was generated from finance lease agreements.

Notes to the consolidated cash flow statement

28. Composition and change

The cash flow statement is presented in accordance IAS 7. The net loss for the year is adjusted for effects of non-cash transactions, deferrals or accruals of past or future operational deposits or disbursements, and income and expense items attributable to investment or financing activities.

In the consolidated cash flow statement, cash and cash equivalents include cash in hand, checks, bank deposits and money deposits with a maturity of up to three months. Current account liabilities are incorporated into the cash fund where applicable.

Interest paid out amounted to EUR 782 thousand (previous year: EUR 664 thousand). Taxes paid amounted to EUR 57 thousand (previous year: EUR 36 thousand). Interest received amounted to EUR 26 thousand (previous year: EUR 127 thousand).

The changes are comprised as follows:

in EUR thousands	Changes in financial liabilities				
	January 1, 2020	Cash effective	Addition/ retirement	Fair value change	December 31, 2020
Convertible bond 2017/2022	1,977	-	26	-	2,003
EIB loan 2017	11,845	-	879	(240)	12,484

in EUR thousands	Changes in financial liabilities				
	January 1, 2020	Cash effective	Addition/ retirement	Fair value change	December 31, 2020
EIB loan 2019	5,301	-	338	(48)	5,591
Interest convertible Bond 2017/2022, Convertible Bond 2017/22	61	(122)	122	-	61
Interest EIB loan 2017	84	(456)	365	-	(8)
Interest EIB loan 2019	29	(184)	183	-	28
Leasing liabilities	4,025	(1,363)	1,053	-	3,715
Total financial liabilities	**23,322**	**(2,125)**	**2,965**	**(288)**	**23,874**

The mandatory convertible bond 2020/2021 issued and converted in 2020 resulted in cash interest expenses of EUR 20 thousand.

Other explanatory notes

29. Members of the Management Board

The Executive Board in 2020 consisted of Prof. Dr. Hermann Lübbert, biologist, (Chairman), Mr. Thomas Schaffer, businessman, (Chief Financial Officer, until February 28, 2021, and Mr. Christoph Dünwald, businessman, (Chief Commercial Officer, until January 31, 2020).

Mr. Ludwig Lutter, businessman, was appointed to the Executive Board with effect from March 1, 2021.

Management Board compensation

in EUR thousands	2020	2019
Short-term benefits	662	1,387
Performance-based compensation	508	87
Total compensation	**1,170**	**1,474**

After leaving the Management Board, Mr. Christoph Dünwald received short-term remuneration due as a former board member in the amount of EUR 137 thousand for the period from February to November.
Further information on individualized compensation of the Management Board can be found in the "Compensation Report" in the Management Report.

The Management Board members held the following supervisory board positions and positions on comparable domestic and foreign boards during the reporting period:

Name	Company	Board	Position
Thomas Schaffer	Industrial Tracking Systems AG, Fürstenfeldbruck	Supervisory Board	Chair

30. Members of the Supervisory Board

Name	Nationality	Age	Position	Date of first appointment	Term until
Dr. Ulrich Granzer	German	60	Chair	May 12, 2006	2021
Curriculum vitae	Dr. Ulrich Granzer, Supervisory Board Chairman, is a founder and owner of Granzer Regulatory Consulting & Services and has been a Supervisory Board member since 2006. Previously, he was Head of Regulatory Affairs at Glaxo, and VP Global Regulatory Centers BASF Pharma and VP Global Regulatory Affairs at Bayer Pharma. He is a proven expert in the drug approval area. He studied pharmaceuticals at Phillips University Marburg before receiving his doctorate from Tübingen University.				

Name	Nationality	Age	Position	Date of first appointment	Term until
Jürgen Baumann	German	66	Deputy Chair	May 24, 2007	2021
Curriculum vitae	Mr. Jürgen Baumann, Deputy Supervisory Board Chairman, is an independent management consultant. He has held various management positions, including on the Management Board of Schwarz Pharma AG, where he was responsible for sales and marketing in Europe. Mr. Baumann studied economic sciences at Wuppertal University.				
John Borer	U.S.	63	Member	May 31, .2016	2021
Curriculum vitae	Dr. John Borer is Senior Managing Director and Head of Investment Banking at The Benchmark Company, LLC. He was previously CEO and Head of Investment Banking at Rodman & Renshaw and held management positions at Pacific Business Credit as well as at Barclays American Business Credit. His law doctorate was awarded by the Loyola Law School in Los Angeles.				
Reinhard Eyring	German	62	Member	February 7, .2018	2021
Curriculum vitae	Reinhard Eyring is a partner and Head of Germany at Ashurst LLP. He studied law at the University of Freiburg/Breisgau. Prior to joining Ashurst in 2000, Mr. Eyring was a partner at another internationally active law firm. From 2008 until 2015 he was a member of Ashurst's international board. He has had seats on the supervisory board of various German companies.				
Prof. Dr. Franca Ruhwedel	German	48	Member	July 10, 2019	2021
Curriculum vitae	Franca Ruhwedel is Professor of Finance & Accounting at the Rhein-Waal University of Applied Sciences in Kamp-Lintfort. At the same time, she has many years of experience as a supervisory board member and member of audit committees. After a banking apprenticeship and studies in Münster, she completed her doctorate in Bochum and then worked in the Mergers & Acquisitions department of the thyssenkrupp Group. She has been a university professor since 2007; her research focuses on the capital market and corporate governance.				
Kevin Weber	USA	63	Member	May 31, 2016	2021
Curriculum vitae	Mr. Kevin Weber is a principal at Skysis, LLC. He was previously CEO at Paraffin International Inc., and has extensive experience in pharmaceutical marketing as well as worldwide commercialization strategies. He previously held senior roles at Depomed, Hyperion Therapeutics and Medicis Pharmaceuticals.He holds a degree in management and marketing from Western Michigan University.				

Supervisory Board compensation

in EUR thousands	2020	2019
Dr. Ulrich Granzer	35	30
Jürgen Baumann	23	23
John Borer	15	15
Reinhard Eyring	19	15
Hansjörg Plaggemars	-	3
Prof. Dr. Franca Ruhwedel	21	7
Kevin Weber	15	15
Total	128	108

The payments are short-term payments within the meaning of IAS 24.17 (a).

The Supervisory Board members held the following other supervisory board positions and positions on comparable domestic and foreign boards during the reporting period:

Name	Company	Board	Position
Reinhard Eyring	DESTAG Deutsche Steinindustrie AG	Supervisory Board	Chair
Prof. Dr. Franca Ruhwedel	NATIONAL-BANK AG, Essen	Supervisory Board	Member
	VTG AG, Hamburg	Supervisory Board	Member

31. Related party disclosures

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	December 31, 2020	December 31, 2019
Revenue from research collaborations	493	686
Revenue from license agreements	6,000	-
Income from the reimbursement of costs by Maruho	659	6,215
Income from subleases	33	34
Accounts receivables	-	149
Purchase price liability Cutanea (earn-out and start-up costs)	17,811	14,720
Other liabilties	-	72

Under the earn-out agreement with Maruho in connection with the acquisition of Cutanea Life Sciences, Inc. in March 2019, profits from the sale of Cutanea products will be shared equally between Maruho and Biofrontera until 2030. For further details, please refer to the presentation under Note 11 "Other financial liabilities". Furthermore, Maruho had agreed to provide an amount of up to USD 7.3 million as start-up financing for Cutanea's redesigned business activities ("Start-up Costs"). The outstanding Start-Up Costs were drawn down in full in fiscal 2020 and are repayable to Maruho by 2023. Furthermore, Maruho reimbursed restructuring costs resulting from pre-contract obligations in the current fiscal year.

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

The agreement concluded on March 19, 2019 to continue the research collaboration with Maruho in the field of branded generics expired as planned during the reporting period and is currently not being continued. Under this agreement, Biofrontera has prepared the formulation of one of four compounds investigated in an earlier project phase (phase 1) in Biofrontera's nanoemulsion for entry into the clinical phase, and Biofrontera has a right to use all research results.

During 2020, we received no additional advisory services from supervisory board member Dr. Ulrich Granzer. In the previous year Dr. Granzer assisted the Company with key issues relating to the preparation of the applications for approval submitted to the regulatory authorities in Europe and the U.S. During the fiscal year ending December 31, 2020, advisory services in the amount of EUR 0 were provided by Granzer Regulatory Consulting & Services (previous year: 1 thousand). The amounts stated here do not include statutory value added tax at the current rate of 19%. The underlying consultancy agreement was approved with due consideration of the applicable legal and regulatory framework.

In the 2020 financial year, there were no further reportable transactions or relationships with related parties beyond those described above or in sections 29 and 30.

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

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

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

32. Auditor's fees and services

The total fee invoiced by the auditor Warth & Klein Grant Thornton AG for the 2020 financial years consist of:

in EUR thousands	2020	2019
Auditing services	530	571
[of which for the previous year]	[54]	[102]
Other audit services	-	-
	530	**571**

The auditing services includes, in addition to the mandatory audit of the annual and consolidated financial statements of Biofrontera AG, the review of the condensed interim financial statements and interim management report, as well as the audit of the consolidated financial statements according to PCAOB standards.

As in the previous year, no other audit services were provided.

33. Subsequent events

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 takes 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 made as part of the succession planning by the Supervisory Board and the Management Board already announced in summer 2020.

Successful completion of the capital increase resolved on May 28, 2020

On February 26, 2021, the Company announced the successful 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.

No other subsequent events subject to mandatory reporting occurred after the balance sheet date.

Leverkusen, April 12, 2021

Prof. Dr. Hermann Lübbert
CEO and Chairman

Ludwig Lutter
CFO

The independent auditor's report reproduced below also includes a "Report on the Assurance in Accordance with Section 317 Paragraph 3b HGB on the Electronic Reproduction of the Annual Financial Statements and the Management Report Prepared for Publication Purposes" ("ESEF Report"). The subject matter of the ESEF Report (ESEF documents to be audited) is not attached. The audited ESEF documents can be viewed in or retrieved from the German Federal Gazette [Bundesanzeiger].

INDEPENDENT AUDITOR'S REPORT

To Biofrontera AG, Leverkusen

Report on the Audit of the Consolidated Financial Statements and the Combined Management Report

We have audited the consolidated financial statements of Biofrontera AG, Leverkusen, and its subsidiary (the Group), which comprise the consolidated balance sheet as at 31 December 2020, and the consolidated statement of comprehensive income, the consolidated statement of changes in equity and the consolidated cash flow statement for the financial year from 1 January 2020 to 31 December 2020, and notes to the consolidated financial statements, including a summary of significant accounting policies. In addition, we have audited the group management report which is combined with the management report (referred to subsequently as "combined management report") of Biofrontera AG for the financial year from 1 January 2020 to 31 December 2020. In accordance with the German legal requirements, we have not audited the content of the Corporate Governance Declaration pursuant to section 289f and section 315d HGB [Handelsgesetzbuch: German Commercial Code] which is referred to in the combined management report.

In our opinion, on the basis of the knowledge obtained in our audit,

- the accompanying consolidated financial statements comply, in all material respects, with the IFRSs as adopted by the EU, and the additional requirements of German commercial law pursuant to section 315e paragraph 1 HGB and, in compliance with these requirements, give a true and fair view of the assets, liabilities, and financial position of the Group as at 31 December 2020 and of its financial performance for the financial year from 1 January 2020 to 31 December 2020, and

- the accompanying combined management report as a whole provides an appropriate view of the Group's position. In all material respects, this combined management report is consistent with the consolidated financial statements, complies with German legal requirements and appropriately presents the opportunities and risks of future development. Our audit opinion on the combined management report does not cover the content of the above-mentioned Corporate Governance Declaration pursuant to section 289f and section 315d HGB.

Pursuant to section 322 paragraph 3 sentence 1 HGB, we declare that our audit has not led to any reservations relating to the legal compliance of the consolidated financial statements and of the combined management report.

Basis for the Audit Opinions

We conducted our audit of the consolidated financial statements and of the combined management report in accordance with section 317 HGB and the EU Audit Regulation (No. 537/2014, referred to subsequently as "EU Audit Regulation") and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Our responsibilities under those requirements and principles are further described in the "Auditor's Responsibilities for the Audit of the Consolidated

Financial Statements and of the Combined Management Report" section of our auditor's report. We are independent of the group entities in accordance with the requirements of European law and German commercial and professional law, and we have fulfilled our other German professional responsibilities in accordance with these requirements. In addition, in accordance with Article 10 (2) point (f) of the EU Audit Regulation, we declare that we have not provided non-audit services prohibited under Article 5 (1) of the EU Audit Regulation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions on the consolidated financial statements and on the combined management report.

Key Audit Matters in the Audit of the Consolidated Financial Statements

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements for the financial year from 1 January 2020 to 31 December 2020. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our audit opinion thereon, we do not provide a separate audit opinion on these matters.

Our presentation of the key audit matters has been structured as follows:

① Financial Statement Risk
② Audit Approach
③ Reference to Related Disclosures

Evaluation of the financial liabilities from the variable purchase price for shares in Cutanea Life Sciences acquired in 2019 and the recoverability of the Xepi license

① Financial Statement Risk

In the consolidated balance sheet of Biofrontera AG as at 31 December 2020, the item other long-term financial obligations includes the financial liability measured at fair value from the variable purchase price of EUR 17,811 thousand for the shares in Cutanea Life Sciences acquired in 2019. The book value of the Xepi license, reported under intangible fixed assets, amounts to EUR 16,720 thousand as at 31 December 2020, after an impairment loss of EUR 2,001 thousand recognized as of 31 March 2020.

The measurement of the fair value of the purchase price liability and the assessment of the recoverability of the Xepi license is based on material assumptions and estimates by the executive directors. Particular risks relating to the measurement of the purchase price liability and the recoverability of the Xepi license are arising from the subjective discretionary assumptions of the executive directors regarding the future profits from the Xepi product sales.

In consideration of the foregoing, the measurement of the financial liability and the recoverability of the Xepi license on the balance-sheet date was of particular importance.

② Audit Approach

Our audit procedures included, without limitation, the audit of management process to determine the fair value of the purchase price liability, the audit of the completeness, accuracy and relevance of the underlying data used in the models and the evaluation of the appropriateness of the assumptions used, including revenue from Xepi sales, the applied discount rates and other factors. Furthermore, we evaluated the assessment by management whether there were indications for a repeated verification of the recoverable amount of the Xepi license as at the balance sheet date.

Our audit procedures also included the design and implementation of the relevant controls in relation to the measurement of the financial liability referred to above including controls of the development of the assumptions used by management to estimate the expected profits from the Xepi product sales and the assessment whether there were indications for a verification of the recoverable amount of the Xepi license in particular.

We evaluated the appropriateness of the assumptions by management in relation to the profits from the Xepi product sales, in particular, whether the assumptions used were appropriate to the subject in consideration of the particularities of introducing a new product in the market and whether the assumptions coincide with the findings obtained in the other fields of audit. We also evaluated the appropriateness of the assumptions in relation to the existence of indications for a verification of the recoverable amount of the Xepi license as at the balance sheet date.

We evaluated the competence, capability and objectivity of the external expert engaged by Biofrontera AG to determine the discount rates. In consultation with our internal valuation experts, we furthermore evaluated the determination of the discount rates in connection with the measurement of the financial liability, on the basis of which the executive directors of Biofrontera AG derived their fair value estimates, and compared them with the relevant book values, and verified the information on the underlying estimates of the measurement of the financial liability and the information on the verification of the recoverable amount.

③ Reference to Related Disclosures

The information relating to the measurement of the financial liability and the variable purchase price resulting from the earn out agreement and to the verification of the recoverable amount are included in the "Summary of significant accounting policies" section, "Use of estimate" subsection of the notes to the consolidated financial statements, and the notes to the consolidated balance sheet in sections "1. Fixed assets, intangible fixed assets" and "11. Other financial liabilities".

Other information

The executive directors and the supervisory board are responsible for the statement under section 161 Stock Corporations Act [Aktiengesetz - AktG], which is part of the Corporate Governance Declaration included in the management report. Save as aforesaid, the executive directors are responsible for the other information provided. The other information comprises

- the Corporate Governance Declaration pursuant to section 289f and section 315d HGB (Corporate Governance Report),
- the Responsibility Statement pursuant to section 264 para. 2 sentence 3 HGB and pursuant to section 289 para. 1 sentence 5 HGB,
- but not the notes to the consolidated financial statements, not the information in the combined management report, whose content is unaudited, and not our auditor's report.

Our audit opinions on the consolidated financial statements and on the combined management report do not cover the other information, and consequently we do not express an audit opinion or any other form of assurance conclusion thereon.

In connection with our group audit, our responsibility is to read the other information referred to above, and, in so doing, to consider whether the other information

- is materially inconsistent with the consolidated financial statements, the audited information in the combined management report or our knowledge obtained in the audit, or

- otherwise appears to be materially misstated.

If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact. We have nothing to report in this regard.

Responsibilities of the Executive Directors and the Supervisory Board for the Consolidated Financial Statements and the Combined Management Report

The executive directors are responsible for the preparation of the consolidated financial statements that comply, in all material respects, with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to section 315e paragraph 1 HGB and that the consolidated financial statements, in compliance with these requirements, give a true and fair view of the assets, liabilities, financial position, and financial performance of the Group. In addition, the executive directors are responsible for such internal control as they have determined necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the executive directors are responsible for assessing the Group's ability to continue as a going concern. They also have the responsibility for disclosing, as applicable, matters related to going concern. In addition, they are responsible for financial reporting based on the going concern basis of accounting unless there is an intention to liquidate the Group or to cease operations, or there is no realistic alternative but to do so.

Furthermore, the executive directors are responsible for the preparation of the combined management report that, as a whole, provides an appropriate view of the Group's position and is, in all material respects, consistent with the consolidated financial statements, complies with German legal requirements, and appropriately presents the opportunities and risks of future development. In addition, the executive directors are responsible for such arrangements and measures (systems) as they have considered necessary to enable the preparation of a combined management report that is in accordance with the applicable German legal requirements, and to be able to provide sufficient appropriate evidence for the assertions in the combined management report.

The supervisory board is responsible for overseeing the Group's financial reporting process for the preparation of the consolidated financial statements and of the combined management report.

Auditor's Responsibilities for the Audit of the Consolidated Financial Statements and of the Group Management Report

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and whether the combined management report as a whole provides an appropriate view of the Group's position and, in all material respects, is consistent with the consolidated financial statements and the knowledge obtained in the audit, complies with the German legal requirements and appropriately presents the opportunities and risks of future development, as well as to issue an auditor's report that includes our audit opinions on the consolidated financial statements and on the combined management report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with section 317 HGB and the EU Audit Regulation and in compliance with German Generally Accepted Standards for Finan-

cial Statement Audits promulgated by the Institut der Wirtschaftsprüfer (IDW) will always detect a material misstatement. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements and this combined management report.

We exercise professional judgment and maintain professional skepticism throughout the audit. We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements and of the combined management report, whether due to fraud or error, design and perform audit procedures responsive to those risks, and obtain audit evidence that is sufficient and appropriate to provide a basis for our audit opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit of the consolidated financial statements and of arrangements and measures (systems) relevant to the audit of the combined management report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an audit opinion on the effectiveness of these systems.

- Evaluate the appropriateness of accounting policies used by the executive directors and the reasonableness of estimates made by the executive directors and related disclosures.

- Conclude on the appropriateness of the executive directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in the auditor's report to the related disclosures in the consolidated financial statements and in the combined management report or, if such disclosures are inadequate, to modify our respective audit opinions. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to be able to continue as a going concern.

- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements present the underlying transactions and events in a manner that the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Group in compliance with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to section 315e paragraph 1 HGB.

- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities within the Group to express audit opinions on the consolidated financial statements and on the combined management report. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinions.

- Evaluate the consistency of the combined management report with the consolidated financial statements, its conformity with German law, and the view of the Group's position it provides.

- Perform audit procedures on the prospective information presented by the executive directors in the combined management report. On the basis of sufficient appropriate audit evidence we evaluate, in particular, the significant assumptions used by the executive directors as a basis for the prospective information, and evaluate the proper derivation of the prospective information from these assumptions. We do not express

a separate audit opinion on the prospective information and on the assumptions used as a basis. There is a substantial unavoidable risk that future events will differ materially from the prospective information.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with the relevant independence requirements, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence, and where applicable, the related safeguards.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

Other Legal and Regulatory Requirements

Report on the Assurance in Accordance with Section 317 Paragraph 3b HGB on the Electronic Reproduction of the Annual Financial Statements and the Management Report Prepared for Publication Purposes

Audit opinion

We have performed assurance work in accordance with section 317 paragraph 3b HGB to obtain reasonable assurance about whether the reproduction of the annual financial statements and the management report (hereinafter the "ESEF documents") contained in the attached electronic file biofronteraag-2020-12-31.zip, with a hash-value C582E43C23FCC8C2FE8601E0B8D22B95B8F93DC231 B424BD61B5B 5110AB7CB06 and prepared for publication purposes complies in all material respects with the requirements of section 328 paragraph 1 HGB for the electronic reporting format ("ESEF format"). In accordance with German legal requirements, this assurance only extends to the conversion of the information contained in the annual financial statements and the management report into the ESEF format and therefore relates neither to the information contained within this reproduction nor to any other information contained in the above-mentioned electronic file.

In our opinion, the reproduction of the annual financial statements and the management report contained in the above-mentioned attached electronic file and prepared for publication purposes complies in all material respects with the requirements of section 328 paragraph 1 HGB for the electronic reporting format. We do not express any opinion on the information contained in this reproduction nor on any other information contained in the above-mentioned file beyond this reasonable assurance opinion and our audit opinion on the accompanying annual financial statements and the accompanying management report for the financial year from 1 January 2020 to 31 December 2020 contained in the "Report on the Audit of the Annual Financial Statements and of the Management Report" above.

Basis for the Reasonable Assurance Opinion

We conducted our assurance work on the reproduction of the annual financial statements and the management report contained in the above-mentioned attached electronic file in accordance with section 317 paragraph 3b HGB and the Exposure Draft of IDW Assurance Standard "Assurance in Accordance with section 317 Paragraph 3b HGB on the Electronic Reproduction of Financial Statements and Management Reports Prepared for Publication Purposes"

(ED IDW AsS 410). Accordingly, our responsibilities are further described below in the "Auditor's Responsibilities for the Assurance Work on the ESEF Documents" section. Our audit firm has applied the IDW Standard on Quality Management 1 "Requirements for Quality Management in the Audit Firm" (IDW QS 1).

Responsibilities of the Executive Directors and the Supervisory Board for the ESEF Documents

The executive directors of the company are responsible for the preparation of the ESEF documents including the electronic reproduction of the annual financial statements and the management report in accordance with section 328 paragraph 1 sentence 4 no. 1 HGB.

In addition, the executive directors of the company are responsible for such internal control as they have considered necessary to enable the preparation of ESEF documents that are free from material intentional or unintentional non-compliance with the requirements of section 328 paragraph 1 HGB for the electronic reporting format.

The executive directors of the company are also responsible for the submission of the ESEF documents together with the auditor's report and the attached audited annual financial statements and audited management report as well as other documents to be published to the operator of the Federal Gazette.

The supervisory board is responsible for overseeing the preparation of the ESEF documents as part of the financial reporting process.

Auditor's Responsibilities for the Assurance Work on the ESEF Documents

Our objective is to obtain reasonable assurance that the ESEF documents are free from material intentional or unintentional non-compliance with the requirements of section 328 paragraph 1 HGB. We exercise professional judgment and maintain professional skepticism throughout the assurance work. We also:

- Identify and assess the risks of material intentional or unintentional non-compliance with the requirements of section 328 paragraph 1 HGB, design and perform assurance procedures responsive to those risks, and obtain assurance evidence that is sufficient and appropriate to provide a basis for our assurance opinion.

- Obtain an understanding of internal control relevant to the assurance on the ESEF documents in order to design assurance procedures that are appropriate in the circumstances, but not for the purpose of expressing an assurance opinion on the effectiveness of these controls.

- Evaluate the technical validity of the ESEF documents, i.e., whether the electronic file containing the ESEF documents meets the requirements of the Delegated Regulation (EU) 2019/815 on the technical specification for this electronic file.

- Evaluate whether the ESEF documents enables a XHTML reproduction with content equivalent to the audited annual financial statements and to the audited management report.

- Evaluate whether the mark-up of the ESEF document with XBRL technology (iXBRL) enables an appropriate and complete machine-readable XBRL copy of the XHTML reproduction.

Further Information pursuant to Article 10 of the EU Audit Regulation

We were elected as group auditor by the annual general meeting on 28 May 2020. We were engaged by the supervisory board on 29 October 2020. We have been the group auditor of Biofrontera AG, Leverkusen, without interruption since the financial year 2007.

We declare that the audit opinions expressed in this auditor's report are consistent with the additional report to the supervisory board pursuant to Article 11 of the EU Audit Regulation (long-form audit report).

German Public Auditor Responsible for the Engagement

The German Public Auditor responsible for the engagement is Michael Gottschalk

Düsseldorf, 12 April 2021

Warth & Klein Grant Thornton AG
Wirtschaftsprüfungsgesellschaft

Eckhard Lewe

Wirtschaftsprüfer
[German Public Auditor]

Michael Gottschalk

Wirtschaftsprüfer
[German Public Auditor]

Responsibility statement

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

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

Leverkusen, April 12, 2021
Biofrontera AG

Prof. Dr. Hermann Lübbert

Ludwig Lutter

Biofrontera AG
Hemmelrather Weg 201
51377 Leverkusen, Germany

Telephone: + 49 (0) 214 87 63 2 0
Fax: + 49 (0) 214 87 63 2 90
E-mail: info@biofrontera.com

www.biofrontera.com