#### **Securities Prospectus**

#### dated February 03, 2021

for the public offering in Germany

of

8,969,870 no-par registered shares

- each with a notional participation in the registered share capital of EUR 1,00 per no-par share and with dividend rights from 1 January 2020 on –

and

for the admission to the regulated market with simultaneous admission to the sub-segment of the regulated market with additional post-admission obligations ("Prime Standard") of the Frankfurt Stock Exchange and the regulated market of the Düsseldorf Stock Exchange

of

8,969,870 no-par registered shares

- each with a notional participation in the registered share capital of EUR 1,00 per no-par share and with dividend rights from 1 January 2020 on -

of

Biofrontera Aktiengesellschaft Leverkusen, Germany

International Securities Identification Number (ISIN): DE0006046113

German Securities Identification Number (WKN): 604611

Stock Ticker Symbol: B8F

European Bookrunner and Underwriter

Quirin Privatbank AG Berlin, Germany

This Prospectus is only valid until the entering of the New Shares into trading, in no case longer than March 05, 2021. The obligation to supplement this Prospectus in the event of significant new factors, material mistakes or material inaccuracies does no longer apply when the Offer Period has expired and the Prospectus has become invalid.

The New Shares and subscription rights are not and will not be registered in accordance with the provisions of the U.S. Securities Act 1933 as amended from time to time ("*Securities Act*") nor with the securities authorities of the states of the USA. They may not be offered or sold in the USA nor directly nor indirectly delivered there, except based on an exemption from the requirements of the Securities Act and the securities regulations of the individual US states and other applicable US regulations. In particular, this subscription offer is not a public offer nor a request for an offer to purchase the New Shares in the USA and may therefore not be disseminated there.

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# 1. Summary

## 1.1 <u>Section A – Introduction containing warnings</u>

This prospectus ("*Prospectus*") relates to the public offer and the admission to the regulated market with simultaneous admission to the sub-segment of the regulated market with additional post-admission obligations ("*Prime Standard*") of the Frankfurt Stock Exchange and the regulated market of the Düsseldorf Stock Exchange of 8,969,870 no-par registered shares each with a notional participation in the registered share capital of EUR 1,00 per no-par share and with dividend rights from January 01, 2020 on ("*New Shares*") of Biofrontera Aktiengesellschaft, Leverkusen, business address Hemmelrather Weg 201, 51377 Leverkusen, registered with the commercial register at the lower court of Cologne under HRB 49717, International Securities Identification Number (ISIN): DE0006046113, German Securities Identification Number (WKN): 604611 ("*Issuer*"). The Legal Identity Identifier (LEI) of the Issuer is 391200D6GFSVFGFQTL13.

The German Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistung-saufsicht*; "**BaFin**"), Marie-Curie-Straße 24-28, 60439 Frankfurt am Main, Germany (telephone: +49 228 4108 0; website: www.bafin.de), has approved this Prospectus as competent authority under Regulation (EU) 2017/1129 of the European Parliament and of the Council of June 14, 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC, on February 04, 2021.

This summary should be read as an introduction to this Prospectus. Any decision to invest in the shares of the Issuer should be based on a consideration of this Prospectus as a whole by an investor. Investors in the shares of the Issuer could lose all or part of their invested capital. Where a claim relating to the information contained in this Prospectus is brought before a court, the plaintiff investor might, under national law, have to bear the costs of translating this Prospectus before the legal proceedings are initiated. Civil liability attaches only to those persons who have tabled this summary, including any translation thereof, but only where this summary is misleading, inaccurate or inconsistent, when read together with the other parts of this Prospectus, key information in order to aid investors when considering whether to invest in the shares of the Issuer.

## 1.2 <u>Section B – Key information on the Issuer</u>

B.I Wh	o is the issuer of the securities?		
Issuer In-	The legal name of the issuer is "Biofrontera Aktiengesellschaft", it also operates under the		
formation	commercial name "Biofrontera". The domicile of the issuer is Leverkusen. The issuer is a		
	public stock corporation (Aktiengesellschaft, AG) operating under German law, which was		
	incorporated in Germany and registered at the lower court of Cologne under HRB 49717.		
	The Legal Identity Identifier (LEI) of the Issuer is 391200D6GFSVFGFQTL13.		
Principal	Biofrontera Group is an international biopharmaceutical enterprise specializing in the de-		
activities	velopment and commercialization of a platform of pharmaceutical products for the treat-		
	ment of dermatological conditions and diseases caused primarily by exposure to sunlight		
	that results in sun damage to the skin. Biofrontera Group's approved products focus on the		
treatment of actinic keratoses, which are skin lesions that can sometimes lead to			
	(also "AK"), in Europe and the United States, as well as the treatment of basal cell carci-		
	noma (also "BCC") in the EU. 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. Because of their		
	location and appearance, actinic keratoses are often cosmetically unappealing.		
	Biofrontera Group's principal product is Ameluz <sup>®</sup> , which is a prescription drug approved		
	for use in combination with photodynamic therapy, or PDT (also "PDT" and as PDT with		

	Ameluz <sup>®</sup> "Ameluz <sup>®</sup> PDT"). Ameluz <sup>®</sup> received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate sever- ity on the face and scalp. Since the initial centralized European approval of Ameluz <sup>®</sup> , the European Commission granted label extensions for the use of Ameluz <sup>®</sup> PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses, (ii) the treatment of superficial and/or nodular basal cell carcinoma un- suitable for surgical treatment due to possible treatment-related morbidity and/or poor cos- metic outcome, (iii) for treatment of actinic keratosis with Ameluz <sup>®</sup> in combination with daylight-PDT (i.e., using natural daylight to activate the drug), and (iv) for treatment of mild and moderate actinic keratosis on the extremities and trunk/neck with PDT. A major advantage of treating actinic keratosis and basal cell carcinoma with photodynamic therapy (as opposed to other common treatments such as surgery and cryotherapy) is that it is a non-invasive alternative that can have better cosmetic results, i.e., removal of tumors with- out leaving clearly visible scarring. In addition, Biofrontera Group has developed its own PDT lamp, BF-RhodoLED <sup>®</sup> , for use in combination with Ameluz <sup>®</sup> . The BF-RhodoLED <sup>®</sup> lamp was approved as a medical de- vice in the EU in November 2012 and is approved for sale in all EU countries, although the use of the BF-RhodoLED <sup>®</sup> lamp is not required to be used in combination with Ameluz <sup>®</sup> in the EU or Switzerland. In May 2016, Biofrontera Group received approval from the U.S. Food and Drug Admin- istration ("FDA"), for US marketing of Ameluz <sup>®</sup> in combination with photodynamic ther- apy using the BF-RhodoLED <sup>®</sup> lamp for lesion-directed and field-directed treatment of ac- tinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Group launched the commercialization of Ameluz <sup>®</sup> and BF-RhodoLED <sup>®</sup> for actinic keratosis in the US in Oc
	gree, other European countries.
Major Share- holders	Insofar as known to the issuer, the following persons hold, directly or indirectly, an interest in the issuer's capital or voting rights which is notifiable under German law: <i>Direct interest:</i>
	Maruho Deutschland GmbH, Düsseldorf, Germany: 28.1 %
	• DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Germany: 3% or
	more voting rights
	• Deutsche Balaton AG, Heidelberg, Germany: 3% or more voting rights
	• SPARTA AG, Heidelberg, Germany: 3% or more voting rights
	• Deutsche Balaton Biotech AG, Heidelberg, Germany: with 3% or more voting rights
	Note that due to limitation of mandatory information in voting rights disclosures, more detailed information regarding direct interest of shareholders is not available. Based on the disclosure requirements set out in the German Securities Trading Notification Regulation (Wertpapierhandelsanzeigeverordnung - WpAV), it is not possible to identify the number of voting rights directly held by one person if these voting rights are attributed to another person and the latter submits a so-called group voting rights notification. The above information regarding DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG is taken from a voting rights disclosure by Mr. Wilhelm K. T. Zours, to whom the voting rights held directly by DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG and Deutsche Balaton AG, SPARTA AG and Deutsche Balaton AG, SPARTA AG and Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG is taken from a voting rights disclosure by Mr. Wilhelm K. T. Zours, to whom the voting rights held directly by DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG are accordingly attributed. Indirect interest:

	<ul> <li>Maruho Co., Ltd., Osaka, Japan: 28.1 %</li> <li>Wilhelm K. T. Zours: 29.8 %</li> <li>DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Germany: 29.8 %</li> <li>Deutsche Balaton Aktiengesellschaft, Heidelberg, Germany: 29.8 %</li> <li>SPARTA AG, Heidelberg, Germany: 29.8 %</li> <li>Deutsche Balaton Biotech AG, Heidelberg, Germany: 29.8 %</li> <li>ABC Beteiligungen AG, Heidelberg, Germany: 29.8 %</li> <li>Heidelberger Beteiligungsholding AG, Heidelberg, Germany: 29.8 %</li> <li>Heidelberger Beteiligungsholding AG, Heidelberg, Germany: 29.8 %</li> <li>Note that DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton Aktiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG and Heidelberger Beteiligungsholding have entered into a voting pool agreement on January 28, 2020. Prisma Equity AG withdrew from this voting pool agreement as of December 21, 2020. The conclusion of the voting rights agreement has the effect that all voting rights held or attributable by the parties to the voting rights agreement are mutually attributable to the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement are in turn attributed to Mr. Wilhelm K. T. Zours</li> </ul>						
Control Manage- ment	Securities Acquisition and Takeover Act ( <i>Wertpapiererwerbs- und Übernahmegesetz</i> ) as none of them directly or indirectly holds more than 30% of the shares in the Issuer and none of them are attributed more than 30% of the voting rights in the Issuer. The Issuer's management board consists of Prof. Dr. Hermann Lübbert (CEO) and Thomas						
Board Statutory auditors	For the period covering & Klein Grant Thornto seldorf, Germany ("WI of the German Chambe	on AG Wirts <b>KGT</b> ") was a or of Public A	schaftsprüfur appointed as Auditors (W	ngsgesellscl auditor of irtschaftspr	haft, Johanr the Issuer.	nstr. 39, 40476 Düs- WKGT is a member	
The followi for the year	<b>B.II. What is the key financial information regarding the Issuer?</b> The following financial information are extracted from the audited group financial accounts of the Issuer for the year 2019 and the unaudited group financial accounts of the Issuer for the first half of 2020. Income statement for non-financial entities (equity securities)						
Period		2019	2018	H1 2020	H1 2019		
Sales revenue         31,265         21,107         16,116         13,904							
Loss from	operations	(23,377)	(18,478)	(4,327)	(12,864)		
Total loss	for period	(7,644)	(9,580)	(5,406)	8,557		

Basic earning per share (in EUR) $(0.16)$ $(0.20)$ $(0.12)$ $0.20$
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Balance sheet for non-financial entities (equity securities)

Date	31.12.2019	31.12.2018	30.06.2020	30.06.2019
Total assets	58,363	39,133	51,963	58,363
Total equity	9,955	16,356	4,737	9,955

Cash flow statement for non-financial entities (equity securities)

Period	2019	2018	H1 2020	H1 2019
Net cash flow used in operational activities	(32,894)	(13,434)	(1,246)	(21,873)
Net cash flow from (used in) investment activities	21,053	(511)	1,764	19,718
Net cash flows provided by financing activities	3,455	22,274	(1,079)	4,278

Without modifying the audit opinion, the auditors have drawn attention to the Risk and Opportunity Report. The y pointed out that a capital measure had to be cancelled in March 2020 due to the Corona crisis and that in order to finance its business operations for a further 12 months and beyond, Biofrontera Group is dependent on a capital measure of at least EUR 5 million. They pointed out that should the worldwide COVID-19 pandemic last longer than expected, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite the cost reduction measures that have been introduced, and also render further access to financing on the capital market impossible. These events or conditions indicate that material uncertainty exists that may cast significant doubt on the group's ability to continue as a going concern and that represents a going concern risk

## B.III What are the key risks that are specific to the Issuer?

- Biofrontera Group has a history of operating losses and anticipate that it will continue to incur operating losses in the future and that it may never sustain profitability.
- If Biofrontera Group fails to obtain additional financing, it may be unable to complete the development and commercialization of products and product candidates.
- Biofrontera Group's existing and any future indebtedness could adversely affect its ability to operate its business.

- Biofrontera's business depends substantially on the success of its principal product Ameluz<sup>®</sup>.
- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for products or product candidates, which could make it difficult for Biofrontera Group to sell products.
- Biofrontera Group depends on a single unaffiliated contract manufacturer to manufacture Ameluz<sup>®</sup>. If Biofrontera Group fails to maintain the relationship with this manufacturer or if that manufacturer is unable to continue to produce Ameluz<sup>®</sup> for Biofrontera Group, Biofrontera Group's business could be materially harmed.
- If Biofrontera fails to manufacture Ameluz<sup>®</sup>, BF-RhodoLED<sup>®</sup>, Xepi<sup>TM</sup> or other marketed products and product candidates in sufficient quantities and at acceptable quality and cost levels, Biofrontera may face adverse consequences.
- Biofrontera Group relies on third parties for the supply of raw materials and manufacture of its principal product.
- If Biofrontera Group's efforts to protect the proprietary nature of the intellectual property related to Biofrontera Group's technologies are not adequate, Biofrontera Group may not be able to compete effectively in its market.
- Third party claims of intellectual property infringement may affect Biofrontera's ability to sell its products and may also prevent or delay the product discovery and development efforts.

## **1.3** <u>Section C – Key information on the securities</u>

C.I. What are	the main features of the securities?		
Type, class,	Subject of the offering are new, no-par registered shares, representing a notional par-		
ISIN, par value	ticipation in the registered share capital of the Issuer of EUR 1.00 each, with the		
	German Securities Identification Number (WKN) 604611 and the International Se-		
	curities Identification Number (ISIN) DE0006046113 ("New Shares"). The sub-		
	scription rights have the German Securities Identification Number (WKN) A3H3LH		
	and the International Securities Identification Number (ISIN) DE000A3H3LH0.		
Number of secu-	8,969,870 New Shares		
rities			
Currency	The New Shares represent a notional participation denominated in EUR:		
Rights attached	Each New Share carries one vote at the Issuer's general shareholders' meeting. There		
	are no restrictions on voting rights. The New Shares carry full dividend rights as of		
	January 1, 2020.		
Seniority	The shares of the Issuer are subordinated to all other securities and claims in case of		
	an insolvency of the Issuer.		
Free transferabi-	The New Shares are freely transferable.		
lity			
Dividend policy	The Issuer has not made any dividend payments to date. Considering the substantial		
	loss carry-forward, no dividend payments are expected in the near future.		
C.II Where w	ill the securities be traded?		
The Issuer intends	s to have the shares admitted to the regulated market with simultaneous admission to		
the sub-segment of	of the regulated market with additional post-admission obligations ("Prime Standard")		
of the Frankfurt S	tock Exchange and the regulated market of the Düsseldorf Stock Exchange		

of the Frankfurt Stock Exchange and the regulated market of the Düsseldorf Stock Exchange. C.II What are the key risks that are specific to the securities?

- An investment in shares always bears the risk of a total loss of the invested capital.
- If the capital increase set out in this prospectus is not executed, buyers of subscription rights may lose the investment made into the subscription rights.
- An investment in the New Shares is not an appropriate investment for every investor.
- The stock price and the trade volume of the New Shares may be subject to high volatility.
- A large-scale disposal of shares would have detrimental effects on the stock price of the New Shares.

## 1.4 <u>Section D – Key information regarding the public offer of securities</u>

#### **D.I** Under which conditions and timetable can I invest in this security?

The offer is addressed to the shareholders of the Issuer, and, respectively, holders of subscription rights, to which the subscription offer is comunicated via Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin acting as European bookrunner and underwriter ("*QuirinBank*" or "**Underwriter**").

The statutory subscription right of the shareholders is granted by admitting QuirinBank to subscribe and take over up to 8,969,870 New Shares at an issue price of EUR 1.00 per New Share, together with the obligation to offer the New Shares to the shareholders for subscription ("*Subscription Offer*") in a quota of 5:1 against payment of a subscription price ("*Subscription Price*").

The Subscription Price will be published presumably on February 18, 2021 as an ad hoc release and on the same day in the German Federal Gazette. The Subscription Price is expected to be determined on February 18, 2021, by the management board with the approval of the supervisory board under consideration of the capital markets conditions and will not exceed EUR 3.50 ("*Maximum Subscription Price*").

The shareholders are requested to execute their subscription right to the New Shares, in order to avoid exclusion, within the period from February 08, 2021 to February 22, 2021 ("*Subscription Period*") at QuirinBank.

In order to execute their subscription rights, the Issuer requests shareholders or the holders of subscription rights, respectively, to instruct their depositary bank accordingly. For 5 old shares of the Issuer, 1 New Share may be subscribed to at the Subscription Price. For any fractions resulting from the subscription quota of 5:1 for the respective number of old shares held in each case, no New Shares may be subscribed to, only a subscription of 1 entire New Share or a multiple thereof is possible. The number of shares held at the end of February 09, 2021 shall be relevant for calculating the number of subscription rights allocated to each shareholder. At this time, the subscription rights (ISIN DE000A3H3LH0) are separated from the shares to the extent of the existing subscription rights and booked to the shareholders' securities accounts by their respective banks.

The Company will exercise reasonable efforts to allow a trade of subscription rights in the non-regulated market of a stock exchange in the Federal Republic of Germany. The Company explicitly makes no warranty that such trade will be possible. Subscription rights not executed are forfeit and will be booked out as invalid at the end of the subscription period.

From February 08, 2021 on, the old shares will be traded as "ex subscription rights".

Shareholders executing subscription rights shall pay the Subscription Price upon execution of the subscription right, but no later than the end of the Subscription Period on February 22, 2021. The subscription rights shall be proof that the shareholder is entitled to subscribe to New Shares.

The receipt of the subscription request and the Subscription Price at the agent referred to above is relevant for keeping the deadline. Shareholders / holders of subscription rights are charged the usual bank fee for the subscription.

Anyone who exercises subscription rights may submit further binding subscription orders over and above the subscription attributable to his or her holdings in accordance with the statutory subscription ratio ("*Additional Subscription*"). Shareholders or holders of subscription rights who wish to subscribe for additional New Shares at the subscription price in excess of their subscription right quota must submit their binding subscription order within the subscription period via their depositary bank to QuirinBank.

Based on the assumed subscription price of EUR 3.50, the offer would result in an increase of the net carrying value of Biofrontera Group as of December 31, 2019, by approximately EUR 0.50 per share to EUR 0.72 per share for existing shareholders. This would amount to an increase by approximately 225.2 %. There would be an immediate dilution of EUR 2.78 per share or approximately 79.4 % for the purchasers of the New Shares since the subscription price of EUR 3.50 per share would be above the calculated net carrying value per share of approximately EUR 0.72.

In the case of a full placement, the Issuer expects costs of EUR 2,500,000.

No costs or taxes will be charged to subscribers; however, usual banking fees will be applied by the subscribers' depositary banks.

D.II Why is	s this prospectus being produced?
The use and	Under the assumption of full placement at an expected subscription price of EUR 3.50
estimated net	per New Share, the Issuer expects gross proceeds of EUR 31,394,545, and assuming
amount of the	costs of EUR 2,500,000, net proceeds of EUR 28,894,545. Of this net amount, up to
proceeds	EUR 20 million will be used for clinical studies aimed at improving the market posi-
	tioning of Biofrontera's products, in particular for the extension of the indication in the
	USA to basal cell carcinoma, acne and actinic keratoses on body areas other than the
	face and scalp. Up to EUR 4 million will be used to complete the development of a
	larger BF-RhodoLED <sup>®</sup> lamp, invest in the procurement the necessary materials and the
	launch of the new lamp. The remaining amount of EUR 4,894,545 will be used to finance
	the business operations of the Issuer.
Indication of	The Offer is coordinated by QuirinBank. The role of QuirinBank is limited to subscrib-
whether the	ing and taking over New Shares pursuant to the provision of sec. 186 German Stock
offer is sub-	Corporation Code, with the obligation to offer the New Shares to the shareholders for
ject to an un-	subscription and to place them in the context of Additional Subscriptions and the Private
derwriting	Placement. The final placing agreement between the Issuer and QuirinBank is expected
agreement on	to be entered into on February 1, 2021. The underwriting role of QuirinBank will be
a firm com-	limited to these coordination efforts; no "hard underwriting" will take place, meaning
mitment ba-	that QuirinBank will not acquire New Shares for distribution on their own risk.
sis	
Any interest that is mate-	QuirinBank will receive, in addition to a fixed base fee, a performance-based placement
rial to the is-	fee and commission for its services in connection with the Offer. Accordingly,
sue/offer, in-	QuirinBank has an interest in the successful implementation of the Offer. In the opinion of the Issuer, this does not constitute a conflict of interest, since the personal interest of
cluding con-	QuirinBank is not contrary to the Issuer's interests.
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flicting inter- ests	Members of the management and supervisory boards hold shares of the Issuer as well as option rights to the acquisition of shares of the Issuer. They have an own interest regarding the development of the stock market price of the Issuer's shares. In the opin- ion of the Issuer, this does not constitute a conflict of interest, since the private interest of the members of the management and supervisory boards are not contrary to the com- pany's interests. The Issuer is not aware of any further interests, conflicts of interest or potential conflicts of interest of natural or legal persons which might be relevant for the Offer.

# 2. German Translation of the Summary of the Prospectus – Zusammenfassung des Prospekts

## 2.1 <u>Abschnitt A – Einleitung mit Warnhinweisen</u>

Dieser Wertpapierprospekt ("*Prospekt*") betrifft das öffentliche Angebot und die Zulassung zum regulierten Markt mit gleichzeitiger Zulassung zum Segment des regulierten Markts der Frankfurter Wertpapierbörse mit zusätzlichen Folgepflichten und dem Regulierten Markt an der Börse Düsseldorf von 8.969.870 nennbetragslosen auf den Namen lautenden Aktien, die jeweils eine wirtschaftliche Beteiligung am Grundkapital von EUR 1,00 der Biofrontera Aktiengesellschaft, Leverkusen, Geschäftsanschrift Hemmelrather Weg 201, 51377 Leverkusen, eingetragen beim Handelsregister beim Amtsgericht Köln unter der Registernummer HRB 49717 ("*Emittentin*") verbriefen, mit Dividendenanspruch ab dem 1. Januar 2020 und International Securities Identification Number (ISIN): DE0006046113, sowie Wertpapierkennnummer (WKN): 604611 ("*Neue Aktien*"). Der Legal Identity Identifier (LEI) der Emittentin ist 391200D6GFSVFGFQTL13.

Die Bundesanstalt für Finanzdienstleistungsaufsicht ("**BaFin**"), Marie-Curie-Straße 24-28, 60439 Frankfurt am Main, Germany (Telefon: +49 228 4108 0; website: <u>www.bafin.de</u>), hat diesen Prospekt als zuständige Behörde gemäß der Verordnung (EU) 2017/1129 des Europäischen Parlaments und des Rats vom 14. Juni 2017 über den Prospekt, der beim öffentlichen Angebot von Wertpapieren oder bei deren Zulassung zum Handel an einem geregelten Markt zu veröffentlichen ist und zur Aufhebung der Richtlinie 2003/71/EG am 04. Februar 2021 gebilligt.

Diese Zusammenfassung sollte als Prospekteinleitung verstanden werden. Der Anleger sollte sich bei der Entscheidung, in die Wertpapiere zu investieren, auf den Prospekt als Ganzes stützen. Anleger könnten bei einer Anlage in die Neuen Aktien das gesamte angelegte Kapital oder einen Teil davon verlieren. Für den Fall, dass vor einem Gericht Ansprüche aufgrund der in diesem Prospekt enthaltenen Informationen geltend gemacht werden, könnte der als Kläger auftretende Anleger nach nationalem Recht die Kosten für die Übersetzung des Prospekts vor Prozessbeginn zu tragen haben. Zivilrechtlich haften nur diejenigen Personen, die die Zusammenfassung samt etwaiger Übersetzungen vorgelegt und übermittelt haben, und dies auch nur für den Fall, dass die Zusammenfassung, wenn sie zusammen mit den anderen Teilen des Prospekts gelesen wird, irreführend, unrichtig oder widersprüchlich ist oder dass sie, wenn sie zusammen mit den anderen Teilen des Prospekts gelesen wird, nicht die Basisinformationen vermittelt, die in Bezug auf Anlagen in die betreffenden Wertpapiere für die Anleger eine Entscheidungshilfe darstellen würden.

## 2.2 Abschnitt B - Basisinformationen über den Emittenten

B.I Wer is	t der Emittent der Wertpapiere?
Information	Der Firmenname der Emittentin ist "Biofrontera Aktiengesellschaft"; sie tritt auch
über den	unter der kommerziellen Bezeichnung "Biofrontera" auf. Sitz der Emittentin ist Le-
Emittenten	verkusen. Die Emittentin ist eine Aktiengesellschaft nach deutschem Recht, die in
	Deutschland gegründet wurde und beim Handelsregister beim Amtsgericht Köln un-
	ter der Registernummer 49717 eingetragen ist. Die Rechtsträgerkennung (LEI) der
	Emittentin ist 391200D6GFSVFGFQTL13.
Hauptätig-	Die Biofrontera-Gruppe ist ein internationales biopharmazeutisches Unternehmen,
keiten des	das auf die Entwicklung und Kommerzialisierung einer Plattform pharmazeutischer
Emittenten	Produkte für die Behandlung dermatologischer Erkrankungen spezialisiert ist, die im
	wesentlichen durch die Aussetzung der Haut an Sonneneinstrahlung verursacht wer-
	den. Die zugelassenen Produkte der Biofrontera Gruppe fokussieren sich auf die Be-
	handlung der Aktinischen Keratose, bei der es sich um Hautläsionen handelt, die
	manchmal zu Hautkrebs führen können (auch "AK"), in Europa und den USA, sowie
	der Behandlung von Basalzellkarzinomen ("BCC") in Europa. Aktinische Keratose
	entsteht typischerweise in Hautpartien, die der Sonne ausgesetzt sind, wie Gesicht,

	kahle Kopfhaut, Arme oder Handrücken, und zeigt sich oft als hervorgehoben, schup-
	pig und rauh, und erscheint auf der Haut als hyperpigmentierter Fleck. Wegen des
	Orts des Auftretens und des Erscheinungsbilds werden aktinische Keratosen oft als
	kosmetisch unattraktiv wahrgenommen.
	Das wichtigste Produkt der Biofrontera-Gruppe ist Ameluz <sup>®</sup> , ein verschreibungs-
	pflichtiges Medikament, das für die Verwendung in der photodynamischen Therapie
	zugelassen ist (" <i>PDT</i> " bzw. in Verbindung mit Ameluz " <i>Ameluz</i> <sup>®</sup> <i>PDT</i> "). Die A-
	meluz <sup>®</sup> PDT hat 2011 eine zentrale europäische Zulassung von der Europäischen Kommission erhalten, für die Behandlung von leichten bis mittelschweren aktini-
	schen Keratosen auf Gesicht und Kopfhaut. Seit der erstmaligen zentralen europäi-
	schen Zulassung der Ameluz <sup>®</sup> PDT hat die Europäische Kommission Erweiterungen
	der Zulassung der Ameluz <sup>®</sup> PDT gewährt für (i) die Behandlung von Feldkanzerisie-
	rung, d.h. großflächiger Hautarealen im Gesicht und auf der Kopfhaut mit multiplen
	aktinischen Keratosen, (ii) die Behandlung von oberflächlichen und/oder nodularen
	Basalzellkarzinomen, bei denen eine operative Entfernung aufgrunf möglicher Mor-
	bidität oder wegen des unvorteilhaven kosmetischen Ergebnisses ausscheidet, (iii) für
	die Behandlung von aktinischer Keratose mit Ameluz® in Kombination mit Tages-
	licht-PDT (i. e., unter Verwendung von natürlichem Tageslicht zur Aktivierung des
	Medikaments) und (iv) zur Behandlung von leichter und mittelschwerer aktinischer
	Keratose an den Extremitäten und am Rumpf/Hals mit PDT.
	Ein wesentlicher Vorteil der Behandlung von aktinischer Keratose und Basalzellkar-
	zinom mit photodynamischer Therapie (im Gegensatz zu anderen verbreiteten Be-
	handlungsarten wie operativer Entfernung und Cryotherapie), ist, dass es sich um eine
	nicht-invasive Alternative handelt, die bessere kosmetische Ergebnisse haben kann,
	d.h. die Entfernung von Tumoren ohne Hinterlassung klar sichtbarer Narben. Zusätzlich hat die Biofrontera-Gruppe ihre eigene PDT-Lampe entwickelt, BF-Rho-
	doLED <sup>®</sup> , zur Verwendung mit Ameluz <sup>®</sup> . Die BF-RhodoLED <sup>®</sup> -Lampe wurde als Me-
	dizingerät in der EU im November 2012 zugelassen und ist zum Vertrieb in allen EU-
	Mitgliedsstaaten zugelassen, obwohl die Verwendung der BF-RhodoLED®-Lampe
	nicht zwingend in Kombination mit Ameluz <sup>®</sup> in der EU oder der Schweiz erfolgen
	muss.
	Im Mai 2016 hat die Biofrontera-Gruppe die Zulassung von der US-Food and Drug
	Administration ("FDA") für den US-Vertrieb von Ameluz® in Kombination mit pho-
	todynamischer Therapie unter Verwendung der BF-RhodoLED <sup>®</sup> -Lampe für läsions-
	und feldbezogene Behandlung von aktinischen Keratosen milder bis mittlerer
	Schwere auf Gesicht und Kopfhaut erhalten. Die Biofrontera-Gruppe hat den Vertrieb
	von Ameluz <sup>®</sup> und BF-RhodoLED <sup>®</sup> für die Behandlung der aktinischen Keratose in den USA im Oktober 2016 aufgenommen.
	Durch die Akquisition der Cutanea Life Sciences, Inc. im März 2019 konnte Biofron-
	tera das Produktportfolio in den USA mit dem FDA-zugelassenen Medikament Xepi <sup>*</sup>
	erweitern. Xepi <sup>®</sup> ist das erste topische Antibiotikum, das von der FDA in den letzten
	10 Jahren zugelassen wurde. Xepi <sup>®</sup> ist zugelassen für die Behandlung von Impetigo.
	Die Zulassung beinhaltet auch die Behandlung von Infektionen mit Antibiotika-re-
	sistenten Bakterienstämmen.
	Die wichtigsten Märkte der Biofrontera-Gruppe sind die USA, Deutschland, und, in
	geringerem Umfang, andere europäische Länder.
Hauptanteils-	Soweit der Emittentin bekannt, halten die folgenden Personen direkt oder indirekt
eigner des	eine Beteiligung am Kapital der Emittentin, die nach deutschem Recht meldepflichtig
Emittenten	ist:
	Direkte Beteiligung:
	• Maruho Deutschland GmbH, Düsseldorf, Germany: 28,1 %
	• DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Deutsch-
	land: 3% oder mehr Stimmrechte

<ul> <li>Deutsche Balaton AG, Heidelberg, Deutschland: 3% oder mehr Stimmrechte</li> <li>SPARTA AG, Heidelberg, Deutschland: 3% oder mehr Stimmrechte</li> <li>Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 3% oder mehr Stimmrechte</li> <li>Wir weisen darauf hin, dass aufgrund der Beschränkung verpflichtender Informationen betreffend die direkte Beteiligung von Aktionären verfligbar sind. Gestützt auf die Offenleungszerenflichtungen der Wertpapierhandlesknazeigeverordnung (WpAV) ist es nicht mögzikch die Zahl der Stimmrechte, die durch eine bestimmte Person gehalten werden, zu identifizieren, wenn diese Stimmrechte siner anderen Person zugerschnet werden und letztere eine sogenannte Gruppenstimmtechtsmitteilung einreicht. Die vorstehende Information AG, SPARTA AG and Deutsche Balaton Biotech AG istammt aus einer Stimmrechtsmitteilung von Herm Wilhelm K. T. Zours, dem die Stimmrechte der DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG, stammt aus einer Stimmrechte Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG, stammt aus einer Stimmrechte Balaton Biotech AG, and Deutsche Balaton Biotech AG, stammt aus einer Stimmter Beteiligung:</li> <li>Maruho Co, Lid., Osaka, Japan: 28,1 %</li> <li>Wilhelm K. T. Zours: 29,8 %</li> <li>DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %</li> <li>Deutsche Balaton Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %</li> <li>Deutsche Balaton AG, BARTA AG, Deutschland: 29,8 %</li> <li>Methel Balaton AG, BARTA AG, AD eutschland: 29,8 %</li> <li>Methel Balaton AG, BARTA AG, Deutschland: 29,8 %</li> <li>Metsche Balaton AKtiengesellschaft, SPARTA AG, Deutschland: 29,8 %</li> <li>Metsche Balaton AKtiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 29,8 %</li> <li>Metsche Balaton AKtiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG, Heidelberg, Deutschl</li></ul>		
• Maruho Co., Ltd., Osaka, Japan: 28,1 %• Wilhelm K. T. Zours: 29,8 %• DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %• Deutsche Balaton Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %• Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 29,8 %• Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 29,8 %• ABC Beteiligungen AG, Heidelberg, Deutschland: 29,8 %• Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %• Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %• Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %• Wir weisen darauf hin, dass DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton Aktiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG und Heidelberger Beteiligungsholding eine Stimmbindungsvereinbarung zum 28. Januar 2020 geschlossen haben. Prisma Equity AG hat die Stimmbindungsvereinbarung gehalten oder diesen zugerech- net werden, allen Beteiligten wechselseitig zugerechnet werden. Im Ergebnis besteht daher nur eine mittelbare Beteiligung von 29,8 %, die den Parteien der Stimmrechts- vereinbarung wechselseitig zuzurechnen ist. Alle Stimmrechte der Parteien der Stimmbindungsvereinbarung werden wiederum Herrn Wilhelm K. T. Zours zuge- rechnet.Beherr- schungKein Aktionär kontrolliert die Emittentin im Sinne von § 29 Abs. 2, 30 WpÜG, da kein Aktionär direkt oder indirekt mehr als 30 % der Aktien der Emittentin hält und keinem Aktionär direkt oder indirekt mehr als 30 % der Aktien der Emittentin hält und keinem Aktionär direkt oder indirekt mehr als 30 % der Aktien der Emittentin hält und keinem Aktionär mehr als 30 % der Stimmrechte der Emittentin bistert (CEO) und Thomas Schaffe		<ul> <li>SPARTA AG, Heidelberg, Deutschland: 3% oder mehr Stimmrechte</li> <li>Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 3% oder mehr Stimmrechte</li> <li>Wir weisen darauf hin, dass aufgrund der Beschränkung verpflichtender Informationen in Stimmrechtsmitteilungen keine weitergehenden Informationen betreffend die direkte Beteiligung von Aktionären verfügbar sind. Gestützt auf die Offenlegungsverpflichtungen der Wertpapierhandelsanzeigeverordnung (WpAV) ist es nicht möglich die Zahl der Stimmrechte, die durch eine bestimmte Person gehalten werden, zu identifizieren, wenn diese Stimmrechte einer anderen Person zugerechnet werden und letztere eine sogenannte Gruppenstimmrechtsmitteilung einreicht. Die vorstehende Information betreffend DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG stammt aus einer Stimmrechte and Deutsche Balaton Biotech AG, SPARTA AG and Deutsche Balaton Biotech AG stammt aus einer Stimmrechte and Deutsche Balaton Biotech AG augerechnet werden.</li> </ul>
<ul> <li>Wilhelm K. T. Zours: 29,8 %</li> <li>DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %</li> <li>Deutsche Balaton Aktiengesellschaft, Heidelberg, Deutschland: 29,8 %</li> <li>SPARTA AG, Heidelberg, Deutschland: 29,8 %</li> <li>Deutsche Balaton Biotech AG, Heidelberg, Deutschland: 29,8 %</li> <li>ABC Beteiligungen AG, Heidelberg, Deutschland: 29,8 %</li> <li>Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %</li> <li>Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %</li> <li>Heidelberger Beteiligungsholding AG, Heidelberg, Deutschland: 29,8 %</li> <li>Wir weisen darauf hin, dass DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton Aktiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG und Heidelberger Beteiligungsholding eine Stimmbindungsvereinbarung zum 28. Januar 2020 geschlossen haben. Prisma Equity AG hat die Stimmbindungsvereinbarung zum 21 Dezember 2020 verlassen. Der Abschluss der Stimmbindungsvereinbarung gehalten oder diesen zugerechnet werden, allen Beteiligten wechselseitig zugerechnet werden. Im Ergebnis besteht daher nur eine mittelbare Beteiligung von 29,8 %, die den Parteien der Stimmrechts vereinbarung wechselseitig zuzurechnen ist. Alle Stimmrechte der Parteien der Stimmbindungsvereinbarung werden wiederum Herrn Wilhelm K. T. Zours zugerechnet.</li> <li>Kein Aktionär kontrolliert die Emittentin im Sinne von § 29 Abs. 2, 30 WpÜG, da kein Aktionär direkt oder indirekt mehr als 30 % der Aktien der Emittentin hält und keinem Aktionär mehr als 30 % der Stimmrechte der Emittentin hält und Keinem Aktionär mehr als 30 % der Stimmrechte der Emittentin zugerechnet werden.</li> <li>Vorstand Der Vorstand der Emittentin besteht aus Prof. Dr. Hermann Lübbert (CEO) und Thomas Schaffer (CFO).</li> <li>Abschluss- prüfer der von den historischen Finanzinformationen abgedeckten Zeitraum (d.h. das Geschäftsjahr 2019), war Warth &amp; Klei</li></ul>		
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	<b>B.II.</b> Welches	

Die nachfolgenden Finanzinformationen sind dem geprüften Konzernabschluss der Emittentin für das Geschäftsjahr 2019 sowie dem ungeprüften Zwischenabschluss für das erste Halbjahr 2020 entnommen.

Gewinn- und Verlustrechnung — Nichtfinanzunternehmen (Dividendenwerte)

Jahr	2019	2018	H1 2020	H1 2019
Umsatzerlöse	31.265	21.107	16.116	13.904
Verlust aus der betrieblichen Tätigkeit	-23.377	-18.478	-4.327	-12.864
Gesamtergebnis	-7.644	-9.580	-5.406	8.557
Unverwässertes Ergebnis je Aktie	-0,16	-0.20	-0.12	0.20

Bilanz — Nichtfinanzunternehmen (Dividendenwerte)

	31.12.2019	31.12.2018	30.06.2020	30.06.2019
Summe Aktiva	58.363	39.133	51.963	58.363
Summe Eigenkapital	9.955	16.356	4.737	9.955

Kapitalflussrechnung — Nichtfinanzunternehmen (Dividendenwerte)

	31.12.2019	31.12.2018	30.06.2020	30.06.2019
Netto-Cashflow aus der betriebli- chen Tätigkeit	-32.894	-13.434	-1.246	-21.873

Netto-Cashflow aus der (in die) In- vestitionstätigkeit	21.053	-511	1.764	19.718
Netto-Cashflow aus der Finanzie- rungstätigkeit	3.455	22.274	-1.079	4.278

Ohne das Testat einzuschränken, haben die Abschlussprüfer auf den Bericht zu Risiken und Chancen hingewiesen. Sie weisen darauf hin, dass eine Kapitalmaßnahme im März 2020 wegen der Corona-Krise abgebrochen werden muss und dass zur Finanzierung des operativen Geschäfts über einen Zeitraum von 12 Monaten hinaus die Biofrontera-Gruppe auf eine Kapitalmaßnahme von mindestens EUR 5 Mio. angewiesen ist. Sie haben darauf hingewiesen, dass eine längere als erwartete Dauer der weltweiten COVID-19-Pandemie zu einem drastischen Abfall in der Liquidität der Biofrontera-Gruppe aufgrund wesentlich reduzierter Umsätze führen kann, trotz der eingeführten Kosteneinsparungen, und Zugang zu weiteren Kapitalmarktfinanzierungen unmöglich machen könnte. Diese Ereignisse bzw. Bedingungen indizieren, dass eine wesentliche Unsicherheit existiert, die wesentlichen Zweifel auf die Fähigkeit der Gruppe zur Fortführung des operativen Geschäfts wirft, und die ein bestandsgefährdendes Risiko darstellen kann.

### B.III Welches sind die zentralen Risiken, die für den Emittenten spezifisch sind?

- Die Biofrontera-Gruppe hat in der Vergangenheit bislang nur Verluste erzielt, und geht davon aus, dass sie in absehbarer Zeit Verluste erzielen wird, und möglicherweise nie profitabel wird.
- Wenn die Biofrontera-Gruppe keine zusätzliche Finanzierung erlangt, könnte sie außerstande sein, die Entwicklung und Kommerzialisierung von Produkten und Produktkandidaten abzuschließen.
- Die bestehende und künftige Verschuldung der Biofrontera-Gruppe könnte ihre Fähigkeit zur Führung ihrer Geschäfte nachteilig beeinflussen.
- Das Geschäft der Biofrontera-Gruppe hängt wesentlich vom Erfolg des Hauptproduktes Ameluz<sup>®</sup> ab.
- Die Abdeckung durch Versicherungen und die Erstattung von Kosten für Medikamente kann in bestimmten Marktsegmenten für Produkte oder Produktkandidaten nicht verfügbar sein, was den Vertrieb durch die Biofrontera-Gruppe erschweren kann.
- Die Biofrontera-Gruppe hängt für die Herstellung von Ameluz<sup>®</sup> von einem einzelnen unabhängigen Vertragshersteller ab. Wenn es der Biofrontera-Gruppe nicht gelingt, die Vertragsbeziehung mit diesem Hersteller aufrechtzuerhalten, oder wenn dieser Hersteller nicht in der Lage ist, Ameluz<sup>®</sup> für die Biofrontera-Gruppe zu produzieren, könnte dies die Biofrontera-Gruppe nachhaltig schädigen.
- Gelingt es der Biofrontera-Gruppe nicht, Ameluz<sup>®</sup>, BF-RhodoLED<sup>®</sup>, Xepi<sup>TM</sup> oder andere vermarktete Produkte und Produktkandidaten in ausreichenden Mengen und zu akzeptablen Qualitäts- und Kostenniveaus herzustellen, kann sich die Biofrontera-Gruppe nachteiligen Folgen ausgesetzt sehen.
- Bei der Lieferung von Rohstoffen und der Herstellung des Hauptprodukts ist die Biofrontera-Gruppe auf Dritte angewiesen.
- Wenn die Bemühungen der Biofrontera-Gruppe, ihre gewerblichen Schutzrechte zu schützen nicht hinreichend sind, könnte die Biofrontera-Gruppe Wettbewerbsnachteile erleiden.
- Ansprüche Dritter wegen Verletzung von geistigem Eigentum können die Fähigkeit des Emittenten, seine Produkte zu verkaufen, beeinträchtigen und auch die Produktentwicklung und -forschung verhindern oder verzögern.

## 2.3 Abschnitt C – Basisinformationen über die Wertpapiere

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	es sind die wichtigsten Merkmale der Wertpapiere?
Art, Gattung	Gegenstand des Angebots sind neue Aktien ohne Nennbetrag, die eine wirtschaftli-
und ISIN der	che Beteiligung am Grundkapital der Emittentin von je EUR 1,00 repräsentieren, mit
Wertpapiere	der Wertpapierkennnummer (WKN) 604611 und der International Securities Identi-
	fication Number (ISIN) DE0006046113 ("Neue Aktien"). Die Bezugsrechte haben
	die Wertpapierkennnummer (WKN) A3H3LH und die International Securities Iden-
	tification Number (ISIN) DE000A3H3LH0.
Anzahl der	8,969,870 Neue Aktien
begebenen	
Wertpapiere	
Währung	Die neuen Aktien repräsentieren eine wirtschaftliche Beteiligung in EUR.
Mit den	Jede Neue Aktie gewährt eine Stimme in der Hauptversammlung der Emittentin. Es
Wertpapieren	bestehen keine Beschränkungen der Stimmrechte. Die Neuen Aktien sind mit Ge-
verbundene	winnbezugsrecht ab dem 1. Januar 2020 ausgestattet.
Rechte	
Rang	Die Neuen Aktien sind in der Insolvenz der Emittentin nachrangig gegenüber allen
	anderen Wertpapieren und Forderungen.
Freie Handel-	Die Neuen Aktien sind frei handelbar.
barkeit	
Dividenden-	Die Emittentin hat bislang keine Dividendenzahlungen vorgenommen. Angesichts
politik	des hohen Verlustvortrags ist auch in der nahen Zukunft nicht von Dividendenzah-
	lungen auszugehen.
	erden die Wertpapiere gehandelt?
	beabsichtigt, die Neuen Aktien zum Handel am regulierten Markt der Frankfurter se (Prime Standard) und am regulierten Markt der Börse Düsseldorf zuzulassen.
C.II Welch	es sind die zentralen Risiken, die für die Wertpapiere spezifisch sind?
• Eine Invest	ition in Aktien birgt stets das Risiko eines Verlusts des eingesetzten Kapitals.
	diesem Prospekt beschriebene Kapitalerhöhung nicht durchgeführt, so können Erwer-
	zugsrechten einen Verlust in Höhe der für die Bezugsrechte getätigten Aufwendungen
erleiden.	
	e in die Neuen Aktien ist nicht für jeden Anleger zweckmäßig.
• Der Kurs un	nd das Handelsvolumen der Aktien der Biofrontera Aktiengesellschaft können starken
	gen unterliegen.
• Die Veräuß	erung von Aktien in großem Umfang kann negative Auswirkungen auf den Börsenkurs
der Emitten	itin haben.

## 2.4 Abschnitt D – Basisinformationen über das öffentliche Angebot von Wertpapieren

# **D.I** Zu welchen Konditionen und nach welchem Zeitplan kann ich in dieses Wertpapier investieren?

Das Angebot richtet sich ausschließlich an die Aktionäre der Emittentin bzw. an die Inhaber von Bezugsrechten, denen das Bezugsangebot über die Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin als European Bookrunner und Underwriter ("*QuirinBank*" oder "*Underwriter*") übermittelt wird.

Den Aktionären wird das gesetzliche Bezugsrecht auf die Neuen Aktien als mittelbares Bezugsrecht in der Weise gewährt, dass die QuirinBank als Emissionsbank zur Zeichnung und Übernahme der 8.969.870 Neuen Aktien zu einem Bezugspreis von EUR 1,00 zugelassen wird mit der Verpflichtung, die Neuen Aktien den Aktionären der Gesellschaft im Verhältnis 5 : 1 entsprechend der Ausübung von Bezugsrechten zum Bezugspreis ("*Bezugspreis*") zu übertragen ("*Bezugsangebot*").

Der Bezugspreis wird voraussichtlich am 18. Februar 2021 als ad-hoc-Mitteilung und am selben Tag im Bundesanzeiger veröffentlicht. Der Bezugspreis wird voraussichtlich am 18. Februar 2021 durch den Vorstand mit Zustimmung des Aufsichtsrats unter Berücksichtigung der aktuellen Kapitalmarktbedingungen festgelegt und wird EUR 3,50 nicht überschreiten ("*Maximaler Bezugspreis*").

Zur Vermeidung des Ausschlusses müssten Aktionäre ihre Bezugsrechte im Zeitraum vom 08. Februar 2021 bis zum 22. Februar 2021 ("*Bezugsfrist*") bei der QuirinBank ausüben.

Zur Ausübung des Bezugsrechts bittet die Emittentin die Aktionäre bzw. Inhaber von Bezugsrechten, ihrer Depotbank eine entsprechende Weisung zu erteilen. Für 5 alte Stückaktien der Gesellschaft kann eine 1 Neue Aktie zum Bezugspreis bezogen werden. Für sich aus dem individuellen Aktienbestand aufgrund des Bezugsverhältnisses rechnerisch ergebende Bruchteile von Neuen Aktien können keine Neuen Aktien bezogen werden, sondern es ist nur der Bezug von einer Neuen Aktie oder einem Vielfachen davon möglich. Die zum Ablauf des 09. Februar 2021 gehaltene Zahl der Aktien ist maßgeblich für die Berechnung der jedem Aktionär zugeordnete Zahl von Bezugsrechten. Die Bezugsrechte (ISIN DE000A3H3LH0) werden von den Aktienbeständen im Umfang des bestehenden Bezugsrechts abgetrennt und den Aktionären von ihren Depotbanken eingebucht.

Die Emittentin wird sich bemühen, einen börslichen Bezugsrechtshandel für die Bezugsrechte im Freiverkehr an einer Börse in der Bundesrepublik Deutschland herbeizuführen. Eine Zusage, dass eine solche Notierung erfolgen wird, wird ausdrücklich nicht erteilt. Nicht ausgeübte Bezugsrechte verfallen und werden nach Ablauf der Bezugsfrist wertlos ausgebucht.

Vom 08. Februar 2021 werden die alten Aktien "ex Bezugsrecht" gehandelt.

Aktionäre, die Bezugsrechte ausüben, haben den Bezugspreis spätestens zum Ende der Bezugsfrist am 22. Februar 2021 zu entrichten. Die Bezugsrechte gelten als Nachweis für die Berechtigung des Inhabers zum Bezug von Neuen Aktien.

Für die Einhaltung der Bezugsfrist ist der Eingang des Zeichnungsantrags und des Bezugspreises bei der o.g. Stelle maßgeblich. Aktionären bzw. Inhabern von Bezugsrechten werden die üblichen Bankspesen für den Bezug berechnet.

Jeder, der Bezugsrechte ausübt, kann über den auf seinen Bestand nach Maßgabe des gesetzlichen Bezugsverhältnisses entfallenden Bezug hinaus weitere verbindliche Bezugsorders abgeben ("*Mehr-bezug*"). Aktionäre bzw. Inhaber von Bezugsrechten, die über ihre Bezugsrechtsquote hinaus weitere Neue Aktien zum Bezugspreis beziehen möchten, müssen ihren verbindlichen Bezugsauftrag innerhalb der Bezugsfrist über ihre Depotbank der QuirinBank übermitteln.

Auf der Grundlage eines erwarteten Bezugspreises von EUR 3,50, würde die Durchführung des Angebots zu einer Erhöhung des Nettobuchwerts der Biofrontera-Gruppe zum Stand 31. Dezember 2019 um ca. EUR 0,50 je Aktie auf EUR 0,72 je Aktie für bestehende Aktionäre führen. Dies entspricht einer prozentualen Erhöhung um ca. 225,2 %. Für Erwerber Neuer Aktien ergäbe sich eine sofortige Verwässerung von ca. EUR 2,78 je Aktie oder ca. 79,4 %, da der Bezugspreis von EUR 3,50 je Aktie über dem berechneten Nettobuchwert je Aktie von ca. EUR 0,72 liegt.

Im Fall einer vollständigen Platzierung erwartet die Emittentin Kosten von EUR 2.500.000.

Den Anlegern werden keine Kosten oder Steuern in Rechnung gestellt; allerdings fallen die üblichen Bankspesen der Depotbanken der Anleger an.

D.II Weshalb wird dieser Prospekt erstellt?

Dill Weshald	while dieser 110spekt erstent.
Zweckbestim-	Unter der Annahme einer vollständigen Platzierung zum erwarteten Bezugspreis
mung der Erlöse	von EUR 3,50, erwartet die Emittentin Bruttoerlöse von EUR 31.394.545, und un-
und die ge-	ter der Annahme von Kosten der Emission im Umfang von EUR 2.500.000, Net-
schätzten Netto-	toerlöse von EUR 28.894.545. Von diesen Nettoerlösen werden bis zu EUR 20
erlöse	Mio. für klinische Studien zur Verbesserung der Marktpositionierung von
	Biofronteras Produkten verwendet, insbesondere für die Erweiterung der Indika-
	tion in den USA auf die Behandlung von Basalzellkarzinom, Akne und aktini-
	schen Keratosen auf anderen Körperteilen als dem Kopf, bis zu EUR 4 Mio. wer-
	den verwendet, um die Entwicklung eines größeren Nachfolgemodells der BF-
	RhodoLED <sup>®</sup> -Lampe abzuschließen und in die Beschaffung der notwendigen Ma-
	terialien und in die Markteinführung der neuen Lampe zu investieren. Der verblei-
	bende Betrag von EUR 4.894.545 wird für die allgemeine Finanzierung der Ge-
	schäftstätigkeit der Emittentin verwendet.
Angabe, ob das	Das Angebot wird durch die QuirinBank koordiniert. Die Funktion der Quirin-

Angabe, ob das | Das Angebot wird durch die QuirinBank koordiniert. Die Funktion der Quirin-Angebot einem | Bank beschränkt sich auf die Übernahme der Neuen Aktien gemäß der Regelung

Übernahmever- trag mit fester Übernahmever- pflichtung unter- liegt	des § 186 AktG, mit der Verpflichtung, die Neuen Aktien den Aktionären zum Bezug anzubieten und sie im Private Placement zu platzieren. Der endgültige Plat- zierungsvertrag zwischen der Emittentin und QuirinBank wird während der Be- zugsfrist abgeschlossen. Die Funktion der QuirinBank beschränkt sich auf diese koordinierende Tätigkeit; es erfolgt kein "hartes Underwriting", d.h. die Quirin- Bank unterliegt keiner festen Übernahmeverpflichtung zur Platzierung der Neuen Aktien auf eigenes Risiko.
Angabe der we- sentlichsten In- teressenkon- flikte in Bezug auf das Angebot	QuirinBank erhält neben einer fixen Basisvergütung eine erfolgsabhängige Plat- zierungsprovision für ihre Leistungen im Zusammenhang mit dem Angebot. Sie hat daher ein Interesse an der erfolgreichen Durchführung des Angebots. Auf- grund des Gleichlaufs der eigenen Interessen der QuirinBank mit den Interessen der Emittentin erwartet die Emittentin insoweit keine Interessenkonflikte. Mitglieder von Vorstand und Aufsichtsrat halten Aktien an der Emittentin als auch Optionen auf den Erwerb von Aktien der Emittentin. Sie haben insoweit ein eige- nes Interesse an der Entwicklung des Kurses der Aktien der Emittentin. Nach Ein- schätzung der Emittentin stellt dies keinen Interessenkonflikt dar, da die privaten Interessen der Mitglieder von Vorstand und Aufsichtsrat den Interessen der Emit- tentin nicht entgegenstehen. Der Emittentin sind keine weiteren Interessen, Interessenkonflikte oder potentiel- len Interessenkonflikte von natürlichen oder juristischen Personen bekannt, die für das Angebot relevant sein könnten.

## 3. Risk Factors

Investing in the shares of Biofrontera Aktiengesellschaft with registered seat in Leverkusen, business address Hemmelrather Weg 201, 51377 Leverkusen (also "*Issuer*" and together with its subsidiaries "*Biofrontera Group*" or "*Biofrontera*"), in particular the 8,969,870 registered no-par shares of the Issuer with a notional participation in the registered share capital of EUR 1.00 per no-par share, WKN 604611, ISIN DE0006046113 subject to this prospectus (also "*New Shares*") is subject to risks.

The Issuer considers the following risks to be specific to it and to the New Shares as well as material for taking an informed investment decision. The risk factors are separated into risk factors specific to the Issuer (3.1) and risk factors relating to the New Shares (3.2), and further sorted into categories and subcategories.

The Issuer has assessed the materiality of each risk factor as of the date of this prospectus ("*Prospectus*"), considering (i) the magnitude of its negative impact on the Issuer and the New Shares and (ii) its probability of occurrence. All risk factors in each category are presented in order of their significance, as assessed by the Issuer.

With regard to the magnitude of the negative effects, the Issuer determines in particular whether, in its opinion, a risk can cause the insolvency of the Issuer (and therefore potentially a total loss of the investment in the New Shares), or only a decrease of earnings and therefore a decline in the price of the shares, or if other disadvantages to the investor may occur, such as the shares not being able to be sold at the desired time or at the desired price. The Issuer also takes options to mitigate risk factors into account.

The first two risk factors listed first in each respective category or subcategory are - according to the current assessment of the Issuer - the most significant risk factors in such category or subcategory (in accordance with the methodology for determining materiality set out above). The other risk factors in each category or subcategory are also listed in order of materiality.

The order of the categories and subcategories does not reflect the materiality of the risk factors included in the categories and subcategories.

At the end of each risk factor, the Issuer includes a statement as of the date of this Prospectus, whether the risk in case of its materialization would have an "adverse effect", a "material adverse effect" or a "highly adverse effect". For this statement, both the magnitude and the probability of realization were taken into account when determining the potential influence; therefore, a risk with a comparatively higher probability of occurrence, but a comparatively lower impact may be considered to have a more substantial adverse effect. The following description and ranking of the risks relating to the Issuer and the New Shares is based the Issuer's assessment as of the date of this Prospectus, which may prove to be incorrect in retrospect. Various risks can also interact and reinforce each other. Investors are advised to refer to the entire Prospectus for each investment decision in the New Shares.

#### 3.1 <u>Risk factors specific to the Issuer and its industry</u>

#### 3.1.1 <u>Risks relating to the Issuer's financial position</u>

# 3.1.1.1 <u>Biofrontera Group has a history of operating losses and anticipate that</u> it will continue to incur operating losses in the future and that it may never <u>sustain profitability.</u>

Biofrontera Group has incurred losses in each year since its incorporation. The net loss for the fiscal years ended December 31, 2019 was EUR 7.358 million.

Biofrontera Group's ability to become profitable depends on the ability to further commercialize the principal product Ameluz<sup>®</sup>. Even if Biofrontera Group is successful in increasing product sales, Biofrontera Group may never achieve or sustain profitability. Biofrontera Group anticipates substantially increasing sales and marketing expense as Biofrontera Group attempts to exploit the recent regulatory approvals Biofrontera Group has received to market Ameluz<sup>®</sup> in the U.S. for the photodynamic therapy treatment of actinic keratoses of mild-to-moderate severity on the face and scalp and in the EU for the treatment of field cancerization and basal cell carcinoma. There can be no assurance that sales and marketing efforts will generate sufficient sales to allow Biofrontera Group to become profitable. Moreover, of the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, the Issuer is unable to predict the extent of any future losses or when Biofrontera Group will become profitable, if ever.

The Issuer therefore cannot exclude the possibility of implementing further capital measures for financing purposes which could dilute the voting rights of shareholders and the value of their shareholding. If Biofrontera Group is unable to achieve profitability over time or to obtain additional equity or debt financing in such a scenario, this would have a highly adverse effect on its financial condition. In the worst case, the Issuer could become insolvent and the shareholders' investments in its shares would be lost.

# 3.1.1.2 <u>If Biofrontera Group fails to obtain additional financing, it may be un-</u> able to complete the development and commercialization of products and product candidates.

Biofrontera Group's operations have consumed substantial amounts of cash since inception. The Issuer expects to continue to spend substantial amounts to pursue additional indications for which products and product candidates may be commercialized, and to continue the clinical development of product candidates, including further Phase III clinical trials and to defend and/or prosecute lawsuits, including Biofrontera's patent litigation with DUSA. Biofrontera Group also requires significant additional funds in order to commercialize both Biofrontera's drugs Ameluz<sup>®</sup> and Xepi<sup>®</sup> in the U.S.

Biofrontera Group believes that existing cash and cash equivalents will be sufficient to fund operations for the next 12 months at least. However, changing circumstances may cause Biofrontera Group to consume capital significantly faster than currently anticipated, and Biofrontera Group may need to spend more money than currently expected because of circumstances beyond the control of the Issuer.

The Issuer cannot be certain that additional funding will be available on acceptable terms, or at all. If the Issuer is unable to raise additional capital in sufficient amounts and on acceptable terms, Biofrontera Group may have to significantly delay, scale back or discontinue the commercialization of products or development of product candidates. Biofrontera Group also could be required to license rights to products and product candidates to third parties on unfavorable terms. In addition, any equity financing would likely result in dilution to existing holders of shares and ADSs, and any debt financing would likely involve significant cash payment obligations and include restrictive covenants that may restrict Biofrontera Group's ability to operate its business.

Any inability to raise capital as needed going forward could harm Biofrontera Group's financial position and, therefore, business, prevent it from realizing business opportunities, prevent it from growing its business or responding to competitive pressures, and could, thus, have a material adverse effect on the Issuer's financial condition and business.

# 3.1.1.3 <u>Biofrontera Group's existing and any future indebtedness could ad</u>versely affect its ability to operate its business.

In May 2017, Biofrontera Group entered into a finance contract with the European Investment Bank ("*EIB*"), under which EIB agreed to provide Biofrontera Group with loans of up to EUR 20 million in the aggregate. The finance contract with EIB ("*EIB Credit Facility*"), is unsecured, guaranteed by certain of the company's subsidiaries, and was available to be drawn in tranches through May 19, 2020. The drawdown of each tranche required the achievement of certain milestones and must be repaid five years after drawdown. The EIB Credit Facility contains undertakings by Biofrontera Group regarding the use of proceeds and limitations on debt, liens, mergers, acquisitions, asset sales, dividends and other

restrictive covenants. As of the date of this prospectus, Biofrontera Group has borrowed EUR 15 million under the EIB Credit Facility. On July 6, 2022, Biofrontera Group will be required to repay this EUR 10 million principal amount, plus EUR 3 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in market capitalization between disbursement and maturity of the loan. On February 4, 2024, Biofrontera will be required to repay another principal amount of  $\notin$ 5.0 million, plus  $\notin$ 1.5 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in Biofrontera's market capitalization between disbursement and maturity of the loan. Under the EIB Credit Facility, Biofrontera Group is not permitted to incur additional third-party debt in excess of EUR 1 million without the prior consent of the EIB (subject to certain exceptions, such as for ordinary course deferred purchase arrangements and, subject to maximum amounts, various types of leases).

In addition to Biofrontera's required payments under the EIB credit facility, the Share Purchase and Transfer Agreement dated March 25, 2019 (as amended, the "Share Purchase Agreement"), by and among Biofrontera Newderm LLC, Biofrontera AG, Maruho Co., Ltd. and Cutanea Life Sciences, Inc., pursuant to which Biofrontera acquired Cutanea Life Sciences, Inc. ("Cutanea") from Maruho Co., Ltd.,("Maruho") requires Biofrontera to repay to Maruho up to \$3.6 million on December 31, 2022 and up to \$3.7 million on December 31, 2023 in start-up costs that Maruho agreed to pay to Biofrontera in connection with such acquisition (not to exceed \$7.3 million in the aggregate).

In January 2017, Biofrontera Group issued convertible bonds maturing on January 1, 2022 in the aggregate initial principal amount of EUR 5.0 million of which EUR 3.0 million has already been converted into shares. The convertible bonds Biofrontera issued in January 2017 provide the holders of those bonds with the right to convert them, at any time, in whole but not in part, into Biofrontera's ordinary shares, at a conversion price per share equal to  $\notin$ 5.00 per share from January 1, 2018 until maturity. In March 2018 the conversion rate was changed from  $\notin$ 5.00 to  $\notin$ 4.75 in accordance with section 11 of the bond terms and conditions. If all of the remaining bonds were converted, Biofrontera would be required to issue up to 427,642 additional ordinary shares, which would result in additional dilution to shareholders.

Biofrontera Group may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under existing debt obligations, in particular the minimum EUR 13 million payment that must be made on July 6, 2022 and the minimum €6.5 million payment due under the EIB credit facility on February 4, 2024 as well as the repayments of start-up costs to Maruho of up to \$3.6 million on December 31, 2022 and up to \$3.7 million on December 31, 2023. The latter are not to exceed \$7.3 million in the aggregate, which Maruho agreed to provide to Biofrontera under the terms of the Share Purchase Agreement pursuant to which Biofrontera acquired Cutanea, and which must be repaid by the Biofrontera Group if certain profits from the sale of Cutanea products Biofrontera agreed to share with Maruho are less than the amount of such start-up costs. Failure to make payments or comply with other covenants under existing debt could result in an event of default and acceleration of amounts due.

If an event of default occurs and the lender or lenders accelerate the amounts due, Biofrontera Group may not be able to make accelerated payments, and such lenders could file suit to collect the amounts due under such obligations or pursue other remedies. In addition, the covenants under existing debt obligations could limit the ability to obtain additional debt financing. The impending payment obligation should be considered a potential material adverse effect.

# 3.1.1.4 <u>The future financing of the Issuer could be adversely impacted by legal</u> disputes with a shareholder, as well as by a lack of majority for resolutions at the shareholders' meeting

Since 2017, various legal actions have been filed against resolutions of the issuer's shareholders' meetings (see 9.13). Inter alia, actions for annulment and rescission were filed against resolutions of the shareholders' meetings which concerned the further financing of the Issuer. The filing of such actions for rescission and annulment may lead to financing measures being defeated in court, or even if the Issuer is successful in such litigation, may lead to a situation where the litigation process takes so long that the resolutions expire. In addition, proposed resolutions at the shareholders' meeting on further financing have failed to receive the necessary majority on several occasions since 2017. If this were to continue in the future, the Issuer might not be able to secure its future financing at the capital markets. This would have adverse effects on the Issuer.

### 3.1.2 <u>Regulatory Risks</u>

# 3.1.2.1 <u>Biofrontera's business depends substantially on the success of its prin-</u> <u>cipal product Ameluz<sup>®</sup>.</u>

Biofrontera has invested a significant portion of its efforts and financial resources in the development of Ameluz<sup>®</sup>, which has received marketing approval in the U.S. for lesion- and field-directed treatment of actinic keratosis and in the EU for actinic keratosis, field cancerization and basal cell carcinoma. Although Biofrontera has received these approvals, there remains a significant risk that Biofrontera will fail to generate sufficient revenue or otherwise successfully commercialize these products in the EU or the U.S. The success of Biofrontera's products will depend on several factors, including:

- successful completion of further clinical trials;
- receipt of further regulatory approvals, including for the marketing of Ameluz<sup>®</sup> for additional indications and/or in additional countries;
- obtaining adequate reimbursement from governments and other third-party payors for Ameluz<sup>®</sup>;
- maintaining regulatory compliance for Biofrontera's contract manufacturing facility and sales force;

- manufacturing sufficient quantities in acceptable quality;
- achieving meaningful commercial sales of Biofrontera's products;
- sourcing sufficient quantities of raw materials used to manufacture Biofrontera's products;
- successfully competing with other products;
- continued acceptable safety and effectiveness profiles for Biofrontera's products following regulatory approval and marketing;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting Biofrontera's intellectual property rights.

If Biofrontera does not achieve one or more of these factors in a timely manner, or at all, it could experience significant delays or an inability to successfully commercialize Biofrontera's products, which would affect Biofrontera's business in a highly adverse way.

# 3.1.2.2 <u>Insurance coverage and medical expense reimbursement may be limited</u> or unavailable in certain market segments for products or product candidates, which could make it difficult for Biofrontera Group to sell products.

Government authorities and third-party payors, such as private health insurers and health maintenance organizations or, in some jurisdictions such as Germany, statutory health insurance, decide which products they will cover and the amount of reimbursement. Reimbursement by a third-party payor may depend upon a number of factors, including the government or third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- reasonable and appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

Obtaining coverage and reimbursement approval for a product from a government or other third-party payor is a time-consuming and costly process that could require Biofrontera Group to provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of products. Biofrontera Group may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or a particular reimbursement amount. If reimbursement of future products or extended indications for existing products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Biofrontera Group may be unable to achieve or sustain profitability.

The pricing of prescription pharmaceuticals is subject to governmental control in some of the countries in which Biofrontera Group has received and/or seek to receive approval to commercialize certain of products. Biofrontera Group is approved to market certain products in the EU and the U.S., and intends to seek approval to market product candidates in selected other jurisdictions. If Biofrontera Group obtains approval in one or more foreign jurisdictions for product candidates, Biofrontera Group will be subject to rules and regulations in those jurisdictions. In some countries, particularly those in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a product candidate. Furthermore, reference pricing measures and parallel import between EU countries may render selling in certain EU markets poisonous for the pricing in other EU markets and force Biofrontera to withdraw its products from the market in EU countries with low drug prices. In addition, market acceptance and sales of product candidates will depend significantly on the availability of adequate coverage and reimbursement from government or other third-party payors for product candidates and may be affected by existing and future health care reform measures. Without adequate levels of reimbursement by government health care programs and private health insurers, the market for products will be limited. While Biofrontera Group continues to support efforts to improve reimbursement levels to physicians and plan to work to improve coverage for its products, if such efforts are not successful, a broader adoption of products and sales of products could be negatively impacted.

Furthermore, in the U.S. and certain other countries, there have been a number of legislative and regulatory changes to the health care system that could impact Biofrontera Group's ability to sell products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the U.S., which has resulted in lower rates of reimbursement. In 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the Affordable Care Act. There is no guarantee whether the Affordable Care Act will remain in effect or be repealed/replaced. There is significant uncertainty about the future of the Affordable Care Act in particular and healthcare laws generally in the United States. This expansion of the government's role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. Biofrontera Group is unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact its profitability.

The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. This law revises the definition of

"average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require Biofrontera to modify Biofrontera's business practices with healthcare practitioners.

Some of the provisions of the Affordable Care Act have yet to be fully implemented, while certain provisions have been subject to judicial and Congressional challenges. Thus, the full impact of the Affordable Care Act, any law replacing elements of it, or the political uncertainty surrounding its repeal or replacement on Biofrontera's business remains unclear. Such developments may materially adversely affect the prices Biofrontera is able to receive for Biofrontera's products or otherwise materially adversely affect Biofrontera's ability to profitably commercialize its products in the United States.

Depending on the jurisdiction in question, a lack of reimbursement would cause a material adverse effect.

# 3.1.2.3 <u>Clinical drug development is expensive and involves uncertain out-</u> comes, and results of earlier studies and trials may not be predictive of future <u>trial results.</u>

If the results of clinical trials for Biofrontera Group's current products or product candidates or clinical trials for any future product candidates do not achieve their primary efficacy endpoints or raise unexpected safety issues, the prospects for approval of product candidates or the extension of indications for products will be materially adversely affected. Moreover, preclinical and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, or have ultimately failed to obtain regulatory approval of their product candidates. Many products that initially showed promise in clinical trials or earlier stage testing have later been found to cause undesirable or unexpected adverse effects that have prevented their further development and regulatory approval. Biofrontera Group's ongoing trials for the extension of the approval to treatment of trunk and neck areas may not produce the results that Biofrontera Group expects or that are required to achieve FDA approval. This would have an adverse effect on the Issuer.

# 3.1.2.4 <u>Biofrontera Group will be subject to ongoing regulatory requirements</u> in every market where its engages in business and may face future development, manufacturing and regulatory difficulties.

Ameluz<sup>®</sup> and any other drug products Biofrontera Group develops will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping, submission of safety and other post-market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and the requirements of other similar regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP requirements.

Accordingly, Biofrontera Group will be required to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. Biofrontera Group will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar regulatory authorities and to comply with certain requirements concerning advertising and promotion for potential products.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated or unacceptable severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions, including requiring withdrawal of the product from the market. This could have adverse effects on the Issuer.

# 3.1.2.5 <u>A recall of Biofrontera Group's drug or medical device products, or the</u> <u>discovery of serious safety issues with Biofrontera Group's drug or medical</u> <u>device products, could have a significant negative impact on Biofrontera</u> <u>Group.</u>

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and European and other foreign governmental agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit Biofrontera Group's ability to carry on or expand its operations or result in higher than anticipated costs or lower than anticipated sales.

The FDA, the EMA and other relevant regulatory agencies have the authority to require or request the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product. A government-mandated or voluntary recall by Biofrontera or one of Biofrontera Group's distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of

Biofrontera Group's products would divert managerial and financial resources and have an adverse effect on Biofrontera Group's reputation, financial condition and operating results, which could impair Biofrontera Group's ability to produce its products in a cost-effective and timely manner.

Before Biofrontera Group can offer its device products to any of the 31 nations within the EU and the European Free Trade Association, Biofrontera Group must first satisfy the requirements for CE Mark clearance, a conformity mark that signifies a product has met all criteria of the relevant EU directives, especially in the areas of safety and performance. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and Biofrontera Group may not be able to obtain these clearances or approvals on a timely basis, or at all for Biofrontera Group's products or proposed products. Biofrontera Group obtained CE Mark clearance for its BF-RhodoLED<sup>®</sup> lamp in November 2012 and FDA approval for it, to be used in connection with Ameluz<sup>®</sup> gel, in May 2016.

Biofrontera is also working to develop a new lamp, the "BF-RhodoLED<sup>®</sup> XL," which would allow use of Ameluz<sup>®</sup> on larger surfaces. Management believes that this new lamp, if it is developed and approved, could provide new business growth opportunities for Biofrontera Group. In the United States, according to FDA guidance, products for PDT, such as Ameluz<sup>®</sup> gel and its corresponding lamp(s), must be approved as combination products that cover both the drug and the lamp. In May 2016, the Issuer received approval from the FDA to market in the U.S. Ameluz<sup>®</sup> in combination with photodynamic therapy using Biofrontera's BF-RhodoLED<sup>®</sup> lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. The applicable office of the FDA has determined that if Biofrontera Group develops a new lamp to be used with Ameluz<sup>®</sup>, it must seek a new approval utilizing the "New Drug Application" procedure. As part of a drug/device combination, the lamp is by definition classified as a class III medical device and as such requires a premarket approval by the FDA. A new lamp will also require changes in the "Prescribing Information" of the drug. If the Issuer develops this new lamp, once the extended dossier is submitted to the FDA as part of this approval process, it may take more than six months, plus, if needed, time required to answer questions or provide additional data. Prior to submission, Biofrontera Group will need to perform final tests on the lamp prototype, including technical tests by a certified laboratory and a usability study in the United States. During the process, there is a risk that the FDA might ask for additional tests or even clinical trials, and there is no assurance that Biofrontera Group will be able to satisfy the FDA's requests for additional tests or trials in a timely manner, or at all, and there is no assurance that Biofrontera will be able to develop this new lamp, or obtain approval to use it in the U.S. for PDT treatment of actinic keratosis.

Any adverse event involving Biofrontera Group's products could result in future voluntary corrective actions. Additionally, any delay in, or failure to receive or maintain, clearance or approval for the products under development could prevent it from generating revenue from these products or achieving profitability. Additionally, the FDA and comparable foreign regulatory authorities have broad enforcement powers., such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of Biofrontera Group's time and capital, distract management from operating the business and have adverse effects on the Issuer.

# 3.1.2.6 <u>If Biofrontera is unable to fulfill all regulatory requirements, the approval of its products may be withdrawn.</u>

Biofrontera Group's drug products Ameluz® and Xepi® and any other drug products it develops, licenses or acquires will be subject to ongoing regulatory requirements for labeling, packaging, storage, advertising, promotion, sampling, record-keeping, submission of safety and other post-market approval information, importation and exportation. In addition, approved products, manufacturers and manufacturers' facilities are required to comply with extensive FDA and EMA requirements and the requirements of other similar regulatory authorities, including ensuring that quality control and manufacturing procedures conform to cGMP requirements.

Accordingly, Biofrontera Group will be required to expend time, money and effort in all areas of regulatory compliance, including manufacturing, production and quality control. It will also be required to report certain adverse reactions and production problems, if any, to the FDA and EMA and other similar regulatory authorities and to comply with certain requirements concerning advertising and promotion for its products and potential products.

If a regulatory authority discovers previously unknown problems with a product, such as adverse events of unanticipated or unacceptable severity or frequency, or problems with the facility where the product is manufactured, or disagrees with the promotion, marketing or labeling of a product, it may impose restrictions on that product or Biofrontera Group, including requiring withdrawal of the product from the market. If Biofrontera Group's products or potential products fail to comply with applicable regulatory requirements, a regulatory authority may, among other actions:

- issue warning letters or Form 483 (or similar) notices requiring Biofrontera Group to modify certain activities or correct certain deficiencies;
- require product recalls or impose civil monetary fines;
- mandate modifications to promotional materials or require Biofrontera Group to provide corrective information to healthcare practitioners;
- require Biofrontera Group or its potential future collaborators to enter into a consent decree or permanent injunction;
- impose other administrative or judicial civil or criminal actions, including monetary or other penalties, or pursue criminal prosecution;

- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or by our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Any of the above measures would cause adverse effects to the Issuer.

#### 3.1.3 Business Risks

3.1.3.1 <u>Biofrontera Group depends on a single unaffiliated contract manufac-</u> <u>turer to manufacture Ameluz®</u>. If Biofrontera Group fails to maintain the relationship with this manufacturer or if that manufacturer is unable to continue to produce Ameluz® for Biofrontera Group, Biofrontera Group's business could be materially harmed.

Biofrontera Group depends on a single unaffiliated contract manufacturer located in Switzerland to manufacture Ameluz<sup>®</sup>. If Biofrontera Group fails to maintain the relationship with this manufacturer, Biofrontera Group may be unable to obtain an alternative manufacturer of Ameluz<sup>®</sup> that could deliver the quantity of the product at the quality and cost levels that Biofrontera Group requires. Even if an acceptable alternative manufacturer could be found, Biofrontera Group would expect long delays in transitioning the manufacturing from the existing manufacturer to a new manufacturer. Problems of this kind could cause Biofrontera Group to experience order cancellations and loss of market share. The failure of the manufacturer to supply Ameluz<sup>®</sup> that satisfies quality, quantity and cost requirements in a timely manner could impair Biofrontera Group's ability to deliver Ameluz<sup>®</sup> and could increase costs, particularly if Biofrontera Group is unable to obtain Ameluz<sup>®</sup> from alternative sources on a timely basis or on commercially reasonable terms. In addition, the manufacturer is regulated by the country of Switzerland and by the FDA and must comply with applicable laws and regulations. Finding a suitable replacement of this particular partner would therefore be extremely difficult. If Biofrontera Group lost this manufacturer, this would cause highly adverse effects.

# 3.1.3.2 <u>If Biofrontera fails to manufacture Ameluz®, BF-RhodoLED®, Xepi<sup>TM</sup></u> or other marketed products and product candidates in sufficient quantities and

## at acceptable quality and cost levels, Biofrontera Group may face adverse consequences.

The manufacture of Biofrontera's products requires significant expertise and capital investment. Currently, all commercial supply for Ameluz<sup>®</sup> is manufactured by a single unaffiliated contract manufacturer. Biofrontera would need to spend substantial time and expense to replace that manufacturer if it failed to deliver products in the quality and quantities Biofrontera demands or failed to meet any regulatory or cGMP requirements. Biofrontera takes precautions to help safeguard the manufacturing facilities, including acquiring insurance and performing on site audits. However, vandalism, terrorism or a natural or other disaster, such as a fire or flood, could damage or destroy manufacturing equipment or Biofrontera's inventory of raw material or finished goods, cause substantial delays in its operations, result in the loss of key information, and cause Biofrontera to incur additional expenses. Biofrontera's insurance may not cover its losses in any particular case. In addition, regardless of the level of insurance coverage, damage to Biofrontera's facilities may have a material adverse effect on Biofrontera's business, financial condition and operating results.

Biofrontera must comply with federal, state and foreign regulations, including FDA regulations governing cGMP enforced by the FDA through its facilities inspection program and by similar regulatory authorities in other jurisdictions where it does business. These requirements include, among other things, quality control, quality assurance and the maintenance of records and documentation. For Biofrontera's medical device products, it is required to comply with the FDA's Quality System Regulation, or QSR, which covers the methods and documentation of the design, testing, production, control, quality assurance, labeling, packaging, sterilization, storage and shipping of its medical device products.

Biofrontera's contract facilities have been inspected by the FDA for cGMP compliance. If Biofrontera does not successfully maintain cGMP compliance for these facilities, commercialization of its products could be prohibited or significantly delayed. Even after cGMP compliance has been achieved, the FDA or similar foreign regulatory authorities at any time may implement new standards or change their interpretation and enforcement of existing standards for manufacture, packaging, testing of or other activities related to Biofrontera's products. For Biofrontera's commercialized medical device product, the FDA audits compliance with the QSR through periodic announced and unannounced inspections of manufacturing and other facilities. The FDA may conduct inspections or audits at any time. Similar audit rights exist in Europe and other foreign jurisdictions. Any failure to comply with applicable cGMP, QSR and other regulations may result in fines and civil penalties, suspension of production, product seizure or recall, imposition of a consent decree, or withdrawal of product approval, and would limit the availability of Biofrontera's product. Any manufacturing defect or error discovered after products have been produced and distributed also could result in significant consequences, including adverse health consequences, injury or death to patients, costly recall procedures, re-stocking costs, warning letters,
Form 483 reports, civil monetary penalties, product liability, damage to Biofrontera's reputation and potential for product liability claims. If Biofrontera is required to find a new manufacturer or supplier, the process would likely require prior FDA and/or equivalent foreign regulatory authority approval and would be very time consuming. An inability to continue manufacturing adequate supplies of Biofrontera's products at any contract facilities could result in a disruption in the supply of its products. Delay or disruption in Biofrontera's ability to meet demand may result in the loss of potential revenue. Biofrontera has licensed the commercial rights in specified foreign territories to market and sell its products. Under those licenses, Biofrontera has obligations to manufacture commercial product for its commercial partners in a timely manner, it may potentially lose revenue and be in breach of its licensing obligations under agreements with them.

In addition, Biofrontera is subject to regulations in various jurisdictions, including the Federal Drug Supply Chain Security Act in the U.S., the Falsified Medicines Directive in the EU and many other such regulations in other countries that require it to develop electronic systems to serialize, track, trace and authenticate units of its products through the supply chain and distribution system. Compliance with these regulations may result in increased expenses for Biofrontera or impose greater administrative burdens on its organization, and failure to meet these requirements could result in fines or other penalties.

Failure to comply with all applicable regulatory requirements may subject Biofrontera to operating restrictions and criminal prosecution, monetary penalties and other disciplinary actions, including, sanctions, warning letters, product seizures, recalls, fines, injunctions, suspension, shutdown of production, revocation of approvals or the inability to obtain future approvals, or exclusion from future participation in government healthcare programs. Any of these events could disrupt Biofrontera's business and have a highly adverse effect on the business.

## 3.1.3.3 <u>Biofrontera Group relies on a unaffiliated third party for the supply of</u> raw materials and manufacture of its principal product.

In addition to its reliance on a single contract manufacturer for Ameluz<sup>®</sup>, Biofrontera generally relies on third parties for the timely supply of raw materials and for the manufacture of its products. Although Biofrontera actively manage these third-party relationships to provide continuity and quality, some events which are beyond Biofrontera's control could result in the complete or partial failure of these goods and services. A loss of a contract manufacturer may also cause delays in the production process of Biofrontera Group while procuring a replacement, in particular since the active agent in Ameluz<sup>®</sup> is currently sourced from a single deliverer. Any such failure could have a material adverse effect on Biofrontera's financial condition and operations.

 3.1.3.4 <u>Certain of Biofrontera Group's important patents expired in 2019</u>, which may result in the entry into the market of generic versions of Ameluz<sup>®</sup>. If this happens, Biofrontera Group may need to reduce the price of Ameluz<sup>®</sup> significantly and may lose significant market share.

The patent family that protects aminolevulinic acid hydrochloride, an active ingredient in Ameluz<sup>®</sup>, against copying by competitors expired on November 12, 2019. This patent family serves as a material, significant, and possibly the only barrier to entry into the market by generic versions of Ameluz<sup>®</sup>. Since this patent has expired, Biofrontera Group is not be able to prevent generic versions of Ameluz<sup>®</sup> from entering the market and competing with Ameluz<sup>®</sup>. This may cause a significant price drop and, therefore, a significant drop in profits. Biofrontera Group may also lose significant market share for Ameluz<sup>®</sup>.

Biofrontera Group hold another patent family protecting its technology relating to nanoemulsions for which it has been issued patents in various jurisdictions and which expires in December 2027. A corresponding U.S. patent application has been filed but is still pending. Biofrontera Group cannot guarantee that this U.S. patent will be issued or, if issued, will adequately protect it against copying by competitors. The entry of competitors would have an adverse effect.

## 3.1.3.5 <u>Competing products and technologies based on traditional treatment</u> methods may make Biofrontera Group's products or potential products noncompetitive or obsolete.

Well-known pharmaceutical, biotechnology and medical device companies are marketing well-established therapies for the treatment of actinic keratosis and basal cell carcinoma. Doctors may prefer to use familiar therapies, rather than trying Biofrontera Group's products.

Additionally, reimbursement issues affect the economic competitiveness of Biofrontera Group's products as compared to other therapies.

Biofrontera Group's industry is subject to rapid, unpredictable and significant technological change and intense competition. Biofrontera Group's competitors may succeed in developing, acquiring, or licensing on an exclusive basis products that are safer, more effective or more desirable than Biofrontera Group's. Many competitors have substantially greater financial, technical and marketing resources than Biofrontera Group. In addition, several of these companies have significantly greater experience than Biofrontera Group in developing products, conducting preclinical and clinical testing, obtaining regulatory approvals to market products for health care, and marketing healthcare products.

Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in even more resources being concentrated in competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

Biofrontera Group cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on its business. Increased competition could result in price reductions, lower levels of government or other third party reimbursements, failure to achieve market acceptance and loss of market share. Further, Biofrontera Group cannot give any assurance that developments by competitors or future competitors will not render technologies obsolete or less advantageous. This could have adverse effects on the Issuer.

> 3.1.3.6 <u>Biofrontera Group faces significant competition from other pharmaceu-</u> <u>tical and medical device companies and operating results will suffer if Bio-</u> <u>frontera Group fails to compete effectively. Biofrontera Group also must com-</u> <u>pete with existing treatments, such as simple curettage and cryotherapy, which</u> <u>do not involve the use of a drug but have gained significant market acceptance.</u>

The pharmaceutical and medical device industry is characterized by intense competition and rapid innovation. Competitors may be able to develop other products that are able to achieve similar or better results for the treatment of actinic keratosis. Potential competitors include mostly established pharmaceutical companies, such as Sun Pharma and Galderma. Most competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Competitors may succeed in developing, acquiring or licensing products that are more effective or less costly than Biofrontera Group's products and product candidates. In addition, Biofrontera Group's products must compete with other therapies, such as simple curettage and, particularly in the U.S., cryotherapy, which do not involve the use of a drug but have gained significant market acceptance. An increase in alternative treatments would cause adverse effects to the Issuer.

> 3.1.3.7 <u>Biofrontera Group is highly dependent on key personnel, and if Bio-</u> frontera Group is not successful in attracting and retaining highly qualified personnel, Biofrontera Group may be unable to successfully implement its <u>business strategy.</u>

Biofrontera Group's ability to compete in the highly competitive pharmaceutical industry depends upon its ability to attract and retain highly qualified managerial, scientific and medical personnel with specialized scientific and technical skills. Biofrontera Group is highly dependent on its management, scientific, medical and operations personnel, including Prof. Hermann Lübbert, Ph.D., chairman of the management board and chief executive officer and Thomas Schaffer, member of the management board and chief financial officer. Biofrontera Group does not maintain "key man" insurance for any officers. The loss of the services of any executive officers or other key employees and an inability to find suitable replacements would cause adverse effects on the Issuer.

> 3.1.3.8 <u>Global economic, political and social conditions and local epidemics or</u> global pandemics have adversely impacted Biofrontera's sales and operations and may continue to do so.

The uncertain direction and relative strength of the global economy, difficulties in the financial services sector and credit markets, continuing geopolitical uncertainties and other macroeconomic factors all affect spending behavior of potential end-users of Biofrontera's products. The prospects for economic growth in Europe, the U.S. and other countries remain uncertain and may cause end-users to further delay or reduce purchases of drugs or therapies that are not fully reimbursed by governmental or other third-party payors. In particular, a substantial portion of Biofrontera's sales are made to customers in countries in Europe, which has recently experienced significant economic disruptions. If global economic conditions remain volatile for a prolonged period or if European economies experience further disruptions, Biofrontera's results of operations could be adversely affected.

Since the beginning of 2020, for instance, COVID-19 has become a global pandemic. As a result of the measures implemented by governments around the world, Biofrontera's business operations have been directly affected. In particular, there is a risk of a temporary and significant decline in demand for Biofrontera's products worldwide as a result of different priorities for medical treatments emerging, thereby causing a delay of actinic keratosis treatment for most patients. An event such as COVID-19, may lead to disruptions that could have an adverse effect on the business, operations, sales and marketing, as well as preclinical studies and clinical trials.

## 3.1.3.9 If product liability lawsuits are brought against Biofrontera, it may incur substantial liabilities and may be required to limit commercialization of its products.

Biofrontera faces an inherent risk of product liability as a result of the clinical testing of its products and face an even greater risk if it commercializes its products on a larger scale. For example, Biofrontera may be sued if the products allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing; defects in design; a failure to warn of dangers inherent in the product, negligence, strict liability; and a breach of warranties. Claims could also be asserted under state consumer protection acts. In Europe, medical products and medical devices may, under certain circumstances, be subject to no-fault liability. Biofrontera currently maintains product liability insurance. If such insurance

is not sufficient, or if Biofrontera is not able to obtain such insurance at an acceptable cost in the future, potential product liability claims could prevent or inhibit the commercialization of the products and the products it develops. A successful claim could have adverse effects on the business, financial condition or results of operations.

#### 3.1.4 Intellectual Property (IP) Risks

## 3.1.4.1 If Biofrontera Group's efforts to protect the proprietary nature of the intellectual property related to Biofrontera Group's technologies are not adequate, Biofrontera Group may not be able to compete effectively in its market.

Biofrontera Group relies upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to technologies and products. Any disclosure to or misappropriation by third parties of confidential proprietary information could enable competitors to quickly duplicate or surpass Biofrontera Group's technological achievements, thus eroding the competitive position in the market.

In addition, the patent applications that Biofrontera Group owns or that it may license may fail to result in issued patents in the U.S., the EU or in other countries or jurisdictions. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, patents and patent applications may not adequately protect intellectual property or prevent others from designing around Biofrontera Group's claims. Further, if Biofrontera Group encounters delays in clinical trials, the period of time during which Biofrontera Group could market products under patent protection would be reduced.

In addition to the protection afforded by patents, Biofrontera Group seeks to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although Biofrontera Group requires all of its employees to assign their inventions to Biofrontera Group to the extent permitted by law, and requires all employees, consultants, advisors and any third parties who have access to Biofrontera Group's proprietary know-how, information or technology to enter into confidentiality agreements, Biofrontera Group cannot be certain that trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. or the EU. As a result, Biofrontera Group may encounter problems in protecting and defending intellectual property both in the U.S., in the EU and in other countries. An inability to protect trade secrets may result in material adverse effects to the Issuer.

## 3.1.4.2 <u>Third-party claims of intellectual property infringement may affect Bio-</u> frontera's ability to sell its products and may also prevent or delay the product discovery and development efforts.

Biofrontera's commercial success depends in part on its avoiding infringement of the patents and proprietary rights of third parties.

There is a substantial amount of litigation involving patents and other intellectual property rights in the biotechnology and pharmaceutical industries, as well as administrative proceedings for challenging patents, including interference and reexamination proceedings before the USPTO, or oppositions and other comparable proceedings in foreign jurisdictions. Recently, following U.S. patent reform, new procedures including inter partes review and post grant review have been implemented. This reform includes changes in law and procedures that are untried and untested and will bring uncertainty to the possibility of challenge to Biofrontera's patents in the future. Numerous U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which Biofrontera is developing its product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Biofrontera's products may give rise to claims of infringement of the patent rights of others.

Third parties may assert that Biofrontera is employing their proprietary technology without authorization. There may be third party patents of which Biofrontera is currently unaware with claims to materials, formulations, devices, methods of manufacture or methods for treatment related to the use or manufacture of Biofrontera's products. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that Biofrontera's product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of Biofrontera's technologies infringes upon such patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of Biofrontera's products or product candidates, any molecules formed during the manufacturing process or any final product itself, the holders of any such patents may be able to block Biofrontera's ability to commercialize the product unless Biofrontera obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of Biofrontera's formulations, processes for manufacture or methods of use, including combination therapy or patient selection methods, the holders of any such patent may be able to block Biofrontera's ability to develop and commercialize the product unless Biofrontera obtained a license or until such patent expires or is finally determined to be held invalid or unenforceable. In either case, such a license may not be available on commercially reasonable terms or at all. If Biofrontera is unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, its ability to commercialize its products or product candidates may be impaired or delayed, which could in turn significantly harm its business.

Parties making claims against Biofrontera may seek and obtain injunctive or other equitable relief, which could effectively block Biofrontera's ability to sell its products and to further develop and commercialize its products and product candidates. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from Biofrontera's business. In the event of a successful claim of infringement against Biofrontera, it may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing products, which may be impossible or require substantial time and monetary expenditure. Biofrontera cannot predict whether any such license would be available at all or whether it would be available on commercially reasonable terms. Furthermore, even in the absence of litigation, Biofrontera may need to obtain licenses from third parties to advance its research or allow commercialization of its products or product candidates. The Issuer may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, Biofrontera would be unable to further develop and commercialize the products or product candidates, which could harm the business significantly.

In March 2018, DUSA brought a lawsuit against Biofrontera 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<sup>®</sup> in the United States. 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. Biofrontera cannot guarantee that the outcome will be successful. This may have material adverse effect on the business.

## 3.1.4.3 <u>The Issuer may become involved in lawsuits to defend or enforce its</u> patents in the future, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe upon of Biofrontera's patents. To counter infringement or unauthorized use, the Issuer may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of Biofrontera's patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that Biofrontera's patents do not cover the technology in question. An adverse result in any litigation or defense proceedings, including Biofrontera's litigation against DUSA as described above, could put one or more of Biofrontera's patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put Biofrontera's patent applications at risk of not issuing. Defense of

these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from Biofrontera's business. In the event of a successful claim or counterclaim of infringement against Biofrontera, it may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign its infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to Biofrontera's patents or patent applications. An unfavorable outcome in Biofrontera's litigation against DUSA or other patent related litigation could require the company to cease using the related technology or to attempt to license rights to it from the prevailing party. Biofrontera's business could be harmed if the prevailing party does not offer Biofrontera a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract Biofrontera's management and other employees and thus, have an adverse effect on the business.

## 3.2 <u>Risks relating to the securities</u>

## 3.2.1 An investment in shares always bears the risk of a total loss of the invested capital.

Any investment in shares as corporate equity capital bears the risk that, in case of an insolvency of the target company, the shareholder loses the entirety of the capital invested in the shares; i.e. the investor may, in the case of an insolvency of the Issuer, lose the entire capital invested in the New Shares. In the case of an insolvency, the claims of debt capital creditors are settled, and claims of equity capital creditors will be paid only after a full settlement. In the case of an insolvency of the Issuer, shareholders may receive none or a minor quota of the monies invested for the acquisition of the New Shares. An investment in the Issuer should only be considered by experienced investors, who consciously accept high risks up to the total loss of their capital. An insolvency of the Issuer would have material adverse effects on the investor.

## 3.2.2 If the capital increase set out in this prospectus is not executed, buyers of subscription rights may lose the investment made into the subscription rights.

In particular, the commercial register might refuse entering the capital increase into the commercial register due to the litigation against the appointment of supervisory board members.

The offer under the capital increase described in this prospectus is subject to the condition that the execution of the capital increase is entered into the commercial register by no later than February 26, 2021. The agreements entered by accepting the subscription offer and other subscription agreements will not be executed and become void if the capital increase is not entered into the commercial register. Holders of subscription rights who acquired subscription rights against consideration will suffer a loss in the amount of the investment made for the acquisition of the subscription rights. As set out above, a share-holder has contested the appointment of three supervisory board members. If this lawsuit is successful, the approval of the supervisory board regarding this capital increase would be invalid. While entering the capital increase into the commercial register prevents retroactive invalidity of the capital increase, there is a risk that the lower court of Cologne might refuse entering the capital increase into the commercial register, in order to avoid an irreversible situation. This situation would cause adverse effects on the investor.

## 3.2.3 <u>An investment in the New Shares is not an appropriate investment for every inves-</u> tor.

Each investor must review whether an investment in the New Shares is an appropriate investment considering their personal circumstances, since each investment in shares is linked with substantial risks, up to and including total loss of the invested capital. In particular, any investor should have the required knowledge and experience to understand chances and risks of the investment in the New Shares and make an informed decision consider the investor's personal affairs, especially considering the economic situation of the Issuer. Furthermore, each investor should have sufficient financial reserves to compensate for the risks associated with an investment in the New Shares. Considering the situation of the Issuer, an investment in the New Shares is only appropriate for investors who consciously accept high risks up to a total loss of the invested capital. An investment in inappropriate financial products can cause adverse effects to the investor.

# 3.2.4 <u>The stock price and the trade volume of the New Shares may be subject to high</u> <u>volatility.</u>

The market for shares of the Issuer, including the New Shares, is limited, so that small volume trades may substantially affect the stock price. Furthermore, there is no guarantee that a disposal of the shares is possible at any time; in the worst case, a shareholder willing to sell New Shares may not be able to find a trading purchaser, so that a disposal of New Shares is not possible at all, only partially, at certain times or with loss realization. The stock price might develop detrimentally, independently of the business of the Issuer and Biofrontera Group, as driven by a disadvantageous environment. High volatility can cause adverse effects to the investor.

## 3.2.5 <u>Shareholders with large shareholding may exercise or achieve a controlling influ</u> ence on the general shareholder meeting of the Issuer.

Several shareholders with large individual shareholding are invested in the Issuer. The free float is comparatively low. There is a risk that shareholders with large individual shareholding may execute their influence on the Issuer. This may include using a majority of the votes present in the general meeting of the issuer to cause decisions that are in their particular interest, or using a majority of the votes present in the general meeting to appoint supervisory board members which may align the strategy of the Issuer and Biofrontera Group in the general interest of such influential shareholder. These decisions or strategical position may have adverse effects on the other shareholders, including the investor.

## 3.2.6 <u>A large-scale disposal of shares would have detrimental effects on the stock price</u> of the New Shares.

Should a shareholder of the Issuer offer a large number of the Issuer's shares for sale, or should a large number of the Issuer's shareholders attempt to dispose of their shareholding simultaneously, this would cause an oversupply of the Issuer's shares on the market. In consequence, there may not be purchasers for the Issuer's shares, including the New Shares, at all or not at a price expected by holders of the New Shares. This may prevent shareholders from disposing of their New Shares at all, and/or negatively affect the stock price of the New Shares, thereby causing adverse effects on the investor.

## 4. General Information

## 4.1 <u>Persons responsible</u>

The Issuer, Biofrontera Aktiengesellschaft with its seat in Leverkusen, Hemmelrather Weg 201, 51377 Leverkusen, registered with the commercial of the local court of Cologne under register number HRB 49717, and the bank filing for admission of the shares to the regulated market, Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin ("*QuirinBank*" or "*Underwriter*") have assumed responsibility for the contents of this Prospectus pursuant to Section 8 of the German Securities Prospectus Act (*Wertpapierprospektgesetz*) and Article 11 paragraph 1 sentence 2 Regulation (EU) 2017/1129 of the European Parliament and of the Council of 14 June 2017 on the prospectus to be published when securities are offered to the public or admitted to trading on a regulated market, and repealing Directive 2003/71/EC ("*Prospectus Regulation*") and hereby confirm that to the best of their knowledge, the information contained in this Prospectus is in accordance with the facts and that the Prospectus makes no omission likely to affect its import.

## 4.2 <u>Competent authority's prospectus approval; end of validity</u>

 This Prospectus has been approved by the German Federal Financial Supervision Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht*; "*BaFin*"), Marie-Curie-Straße 24-28, 60439
Frankfurt am Main, Germany (telephone +49 228 4108 0; website: www.bafin.de), as competent German authority under the Prospectus Regulation.

- BaFin only approved this Prospectus relating to its meeting the standards of completeness, comprehensibility and consistency imposed by the Prospectus Regulation.
- Such approval should not be understood as an endorsement of the issuer who is the subject of this Prospectus.
- This Prospectus has been drawn up as part of a simplified prospectus in accordance with Article 14 of the Prospectus Regulation.
- Investors should make their own assessment as to the suitability of investing in the New Shares.

## 4.3 <u>Auditing</u>

## 4.3.1 Identity of auditors

For the period covering the historical financial information (i.e. the fiscal year 2019), Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, Johannstr. 39, 40476 Düsseldorf, Germany ("*WKGT*") was appointed as auditor of the Issuer. WKGT is a member of the German Chamber of Public Auditors (*Wirtschaftsprüferkammer*) in Berlin.

## 4.3.2 <u>Results of auditing</u>

The annual reports for the fiscal year ending 31 December 2019 included in this prospectus have been audited. No audit reports on the historical financial information has been refused by the statutory auditors, nor do they contain qualifications or disclaimers.

However, the auditors' opinion regarding the report for the fiscal year 2019 contained the following note: "We draw attention to the comments in section 33 "Subsequent events" of the notes to the consolidated financial statements and to the "Liquidity, profitability, capital markets access and risks to the going concern status" subsection in the "Risk and opportunity report" section of the combined management report. There the executive directors of Biofrontera AG describe that a planned capital measure for March 2020 with a maximum total of up to EUR 16 million had to be cancelled due to the turmoil on the capital markets as a result of the Corona crisis and that in order to finance its business operations for a further 12 months and beyond, Biofrontera is dependent on a capital measure of at least EUR 5 million by no later than the end of the 2020 financial year. The executive directors expect, based on the assumption that the general economic conditions will normalize and based on the consistently successful track record with capital measures to date, that the required liquidity for the business can be ensured in the future, however, attention is drawn to the fact that should this no longer be possible due to a continuing crisis caused by the COVID-19 pandemic, this would pose a threat to the going concern status of the Biofrontera Group. Should the worldwide COVID-19 pandemic last longer than expected, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite the cost reduction measures that have been introduced, and also render further access to financing on the capital market impossible.

As stated in the quoted sections of the notes to the consolidated financial statements and the combined management report, these events or conditions indicate that material uncertainty exists that may cast significant doubt on the group's ability to continue as a going concern and that represents a going concern risk within the meaning of Section 322 para. 2 sentence 3 HGB.

As part of our audit we have assessed whether the executive directors' use of the going concern basis of accounting in the preparation of the consolidated financial statements and the disclosure of material uncertainty related to going concern in the consolidated financial statements and in the combined management report are appropriate in the circumstances. For this purpose, we assessed in particular the liquidity planning prepared by the executive directors of Biofrontera AG on the basis of the adopted budget of the Biofrontera Group for the financial year 2020 in consideration of the effects of the COVID-19 crisis which the executive directors expect on the business activities and the liquidity of the Biofrontera Group. In this context we determined whether the assumptions underlying the liquidity planning are sufficiently supported and assessed the reliability of the underlying data."

## 4.4 <u>Sources for information in this prospectus</u>

The financial information referred to in this prospectus was obtained from the 2019 audited consolidated financial report of the Issuer, as well as from the June 30, 2020 half-year unaudited financial reports of the Issuer, and the unaudited internal controlling of the Issuer.

The following third-party information in this prospectus has been accurately reproduced and, as far as the Issuer is aware and is able to ascertain from information published by that third party, no facts have been omitted which would render the reproduced information inaccurate or misleading.

- Technavio report on Global Non-melanoma Skin Cancer Market 2014-2018, by Infiniti Research Limited, 8 Wimpole Street, W1G 9SP London, United Kingdom (not publicly available).
- Research information from Insight Health GmbH & Co. KG, Auf der Lind 10, 65529 Waldem, Germany (not publicly available).

## 4.5 <u>Available documentation</u>

During the period of validity of this prospectus, the following documents (or copies thereof), may be inspected on the Issuer's website www.biofrontera.com:

- the articles of association of the Issuer;
- the audited consolidated financial statements as per December 31, 2019.

## 4.6 <u>Publication of this Prospectus</u>

This prospectus will be made available to the public on the website of the Issuer, <u>www.biofrontera.com</u> under "Investors / Key Stock Information" (direct link: https://www.biofrontera.com/en/investors/cur-rent-capital-measure).

## 5. Information regarding the offer and the securities

## 5.1 Subject of the offer and admission to trading

## 5.1.1 Offer of New Shares

Subject of the offer ("*Offer*") are a total of 8,969,870 no-par value ordinary shares of the Issuer which are registered in the name of the holder, each representing a notional interest in the registered capital of the Issuer of EUR 1.00, i.e. a total of EUR 8,969,870, to be issued against capital contributions in cash, with dividend rights from 1 January 2020 and ISIN DE0006046113 ("*New Shares*"). The delivery of the New Shares under the ISIN DE0006046113 requires an admission of the New Shares for trading to the regulated markets on which the existing shares are currently admitted.

The currency of the New Shares is the Euro. All New Shares are offered for subscription. If New Shares are not subscribed for within the subscription period by exercising the subscription right, they may, in accordance with the resolution of the shareholders' meeting dated May 28, 2020, be offered to shareholders in compliance with the principle of equal treatment in excess of their subscription right (additional subscription) and to third parties in a private placement at the fixed subscription price.

## 5.1.2 Legal basis of the New Shares

The New Shares are created under German law, by resolution passed on the Issuer's general shareholder meeting of May 28, 2020.

## 5.1.3 Takeover bids on shares

## 5.1.3.1 <u>Statutory rules regarding mandatory takeover bids</u>

Any person acquiring the control over a target must make a compulsory takeover offer. Control means 30 % of the voting rights of a target. In this case, the bidder must publish the fact that it has acquired control within seven calendar days. This publication replaces the publication regarding the decision to make an offer. Within four weeks after the publication, the bidder must file an offer document with the German Federal Financial Supervisory Authority (Bundesanstalt für Finanzdienstleistungsaufsicht, "*BaFin*"). The general provisions of the German Securities Acquisition and Takeover Act (WpÜG),

including the obligation to offer an adequate consideration, apply to the further procedure. In special cases, the BaFin may relieve an entity which has acquired control from the obligation to make an offer.

## 5.1.3.2 <u>Takeover bids on the shares of the Issuer</u>

No mandatory takeover bids exist, nor have public takeover bids by third parties in respect of the Issuer's equity occurred during the last financial year and the current financial year.

However, it should be noted that Heidelberger Beteiligungsholding AG announced on January 28, 2020 that it had decided to offer all shareholders of the Issuer to acquire their registered shares of the Issuer by way of a voluntary public takeover offer in the form of an exchange offer against shares of Heidelberger Beteiligungsholding AG. Heidelberger Beteiligungsholding AG had also announced that it had entered into a voting agreement with the following shareholders of the Issuer on January 28, 2020, with respect to the joint exercise of voting rights from shares in the Issuer: Deutsche Balaton AG, DELPHI Unternehmensberatung AG, Deutsche Balaton Biotech AG, SPARTA AG, Prisma Equity AG and ABC Beteiligungen AG. Heidelberger Beteiligungsholding AG announced on March 6, 2020 that BaFin had prohibited the takeover offer announced on January 28, 2020 pursuant to Sections 34, 15 (1) No. 1 and No. 2 of the German Securities Acquisition and Takeover Act (WpÜG).

## 5.1.4 Transferability

The New Shares will be freely transferable.

## 5.2 <u>Reasons for the Offer, use of proceeds</u>

Under the assumption of full placement at an assumed subscription price of EUR 3.50 per New Share, the Issuer expects gross proceeds of EUR 31,394,545, and assuming costs of EUR 2,500,000, net proceeds of EUR 28,894,545. Of this net amount, up to EUR 20 million will be used for clinical studies aimed at improving the market positioning of Biofrontera's products, in particular for the extension of the indication in the USA to basal cell carcinoma, acne and actinic keratoses on body areas other than the face and scalp. Up to EUR 4 million will be used to complete the development of a larger BF-RhodoLED<sup>®</sup> lamp, invest in the procurement of the necessary materials and the launch of the new lamp. The remaining amount of EUR 4.894.545 will be used to finance the business operations of the Issuer.

In the case of less than a full placement, the Issuer will prioritize the use of proceeds as follows: firstly, the Issuer will use the proceeds to finance its general business operations; secondly, the Issuer will pursue the clinical studies described above; and thirdly, the Issuer will fund the development of the larger BF-RhodoLED<sup>®</sup> lamp. In case of a full placement, the same prioritization will apply.

## 5.3 <u>Conditions and prerequisites of the Offer</u>

## 5.3.1 Conditions of the Offer

The following is the translation of the German language subscription offer in the form expected to be published on February 05, 2021 in the German federal gazette (*Bundesanzeiger*). Insofar as the actual timing schedule deviates from the expected timing schedule set out in this prospectus, such deviations will be disclosed in the offer as well as in a supplement to this prospectus.

"Not for distribution in the United States of America, Canada, Australia and Japan

Biofrontera AG

Leverkusen

## ISIN: DE0006046113 / WKN: 604611

Subscription offer

The shareholders' meeting of Biofrontera AG (hereinafter referred to as the "Company" or also the "**Issuer**") of May 28, 2020, resolved to increase the share capital of the Company by up to EUR 8,969,870 by issuing up to 8,969,870 new no-par value registered shares with a notional interest in the share capital of EUR 1.00 each ("New Shares") against cash contributions. The New Shares carry full dividend rights from January 1, 2020. They will be issued at an issue price of EUR 1.00 (par) per New Share, thus at a total issue price of up to EUR 8,969,870.

The New Shares are to be offered to the shareholders for subscription. The subscription right is granted in such a way that the New Shares are subscribed and taken over by a bank to be selected and instructed by the management board, or by a company operating in accordance with Section 53 para. 1 sentence 1 or Section 53b para. 1 sentence 1 or para. 7 of the German Banking Act (Kreditwesengesetz, KWG) with the obligation to offer them to the shareholders for subscription at a ratio of 5 : 1 at a subscription price still to be determined, and to transfer the additional proceeds - after deduction of fees, costs and expenses to be paid or reimbursed by the Company - to the Company (so-called indirect subscription right). One new share can therefore be subscribed for every five old shares. The subscription ratio is made possible by the waiver of subscription rights by a shareholder.

If New Shares are not subscribed for within the subscription period by exercising the subscription right, they may, in accordance with the resolution of the shareholders' meeting, be offered to shareholders in compliance with the principle of equal treatment (§ 53a Stock Corporation Act) in excess of their subscription right (additional subscription) and to third parties in a private placement at the fixed subscription price.

The management board was authorized, with the approval of the supervisory board, to determine the further details of the capital increase and its implementation, in particular the subscription price and the further conditions for the issue of the New Shares.

Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin (hereinafter also referred to as the "Underwriter") has undertaken in a share underwriting agreement dated February 04, 2021 (the "Underwriting Agreement"), subject to certain conditions, in particular the conditions set out below in the section "Important Notes", to offer the New Shares for subscription to the shareholders of the Company by way of indirect subscription rights and to offer any non-subscribed New Shares to existing shareholders of the Company and other investors by way of additional subscription and/or private placement, respectively, and to subscribe for New Shares at the fixed issue price of EUR 1.00 per New Share and to take them over with the obligation to deliver them to the shareholders of the Company who have exercised their subscription rights and to other investors who have been allocated non-subscribed shares in the course of the additional subscription and private placement, respectively, and to transfer the additional private placement, respectively, and to transfer the additional subscription and private placement, respectively, and to transfer the additional subscription rights and to other investors who have been allocated non-subscribed shares in the course of the additional subscription and private placement, respectively, and to transfer the additional proceeds, i.e. the difference between the issue price of EUR 1.00 and the subscription price, to the Company after deduction of fees, costs and expenses to be paid or reimbursed by the Company. In accordance with the resolution of the shareholders' meeting, the New Shares will be offered to the shareholders at a ratio of 5 : 1 ("Subscription Ratio") at a subscription price to be determined.

The Company hereby announces the subscription offer of the Underwriter.

The subscription rights (ISIN DE000A3H3LH0 / WKN A3H 3LH) (the "Subscription Rights") are expected to be booked to the shareholders' depositary banks by Clearstream Banking AG on the morning of February 10, 2021.

The shareholders or holders of Subscription Rights are requested to exercise their Subscription Rights to the New Shares, in order to avoid exclusion, in the period

from February 08, 2021(inclusive) to February 22, 2021 noon CET (the "Subscription Period").

via their respective depositary bank at the subscription agent. Subscription Rights not exercised in due time will expire and be derecognized without value after the end of the Subscription Period. There will be no compensation for Subscription Rights that were not exercised.

The subscription agent is Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin.

The Subscription Rights shall be deemed to be proof of subscription rights for the New Shares. For every five (5) no-par value shares or Subscription Rights of the Company, one (1) New Share may be subscribed for at the subscription price. No New Shares may be subscribed for fractions of New Shares resulting arithmetically from the individual shareholding on the basis of the Subscription Ratio; instead, only one New Share or a multiple thereof may be subscribed for.

#### Subscription price

The subscription price shall be announced by the management board, with the approval of the supervisory board, no later than three days prior to the end of the Subscription Period in the Company's official gazette (Bundesanzeiger) and via an electronic information medium. The subscription price shall be determined in the range between (in each case inclusive of) (i) the volume-weighted average price of the Company's shares in the XETRA electronic trading system of the Frankfurt Stock Exchange from the beginning of the Subscription Period to the day before the subscription price is determined, and (ii) the current share price of the Company at the time the subscription price is determined. When determining the final subscription price, the Company reserves the right to apply a discount of up to 20% from the price initially determined as described above. The subscription price will not exceed EUR 3.50 per share.

When deciding on the amount of the subscription price and any discount on the relevant stock market price, the management board will take into consideration, inter alia, the volatility of the share price up to the time the subscription price is determined, and capital market conditions.

Shareholders exercising Subscription Rights must pay the subscription price no later than the end of the Subscription Period (incoming). The receipt of the subscription application and the subscription price by the above-mentioned agent shall be decisive for compliance with the Subscription Period.

## Subscription rights trading

The Company will endeavor to arrange for Subscription Rights to be traded on the open market of a stock exchange in the Federal Republic of Germany. A guarantee that such a listing will take place is expressly not given. There are no plans to settle Subscription Rights not exercised via the Underwriter. It is expected that the old shares will be listed "ex-subscription rights" from February 08, 2021.

## Utilization of unsubscribed New Shares; additional subscription

In the event that not all New Shares are subscribed for under the statutory subscription right, the unsubscribed New Shares will be offered by the Underwriter (if necessary through other financial service providers) at the subscription price to new investors who are not yet shareholders of the Company (the "Private Placement"). In addition, they may be offered to shareholders of the Company or holders of Subscription Rights for further subscription (the "Additional Subscription").

Shareholders or holders of Subscription Rights who wish to subscribe for additional New Shares at the subscription price in excess of their Subscription Rights quota under the Additional Subscription must

submit their binding subscription order to the Underwriter via their custodian bank within the Subscription Period.

## Settlement

The depository banks are requested to submit the subscription applications (including Additional Subscription requests) collectively in one application to the Underwriter by February 22, 2021 noon CET at the latest and to pay the subscription price per New Share to the Underwriter also by the end of the Subscription Period at the latest.

For this purpose, we request that the depositary banks be instructed accordingly. The depository banks are requested to indicate separately in their subscription notification the New Shares to be subscribed for by way of Additional Subscription and to state the total number of securities accounts in whose favor the subscription and Additional Subscription will be exercised. If an Additional Subscription request cannot be fulfilled or cannot be fulfilled in full, the shareholder will be refunded the amount paid for the purchase, less any bank commission incurred.

Shareholders or holders of Subscription Rights will be charged the usual bank fees by the depositary banks for the subscription and Additional Subscription.

## Allocation

If, due to oversubscription, it is not possible to deliver all of the New Shares requested in the Additional Subscription and requested by new investors in the Private Placement, the New Shares will be allocated until the entire volume of the subscription offer has been exhausted. There will be no preferential treatment of shareholders vis-à-vis new investors. The shareholders are not entitled to an allocation within the scope of the Additional Subscription. If an allocation is made within the Additional Subscription, it will be made in compliance with the principle of equal treatment within the meaning of Section 53a of the German Stock Corporation Code (Aktiengesetz, AktG).

#### Important Notes

In connection with the subscription offer, the Company has prepared a securities prospectus which was approved by the German Federal Financial Supervisory Authority (BaFin) on February 04, 2021 (the "Prospectus") and is available on the Company's website (www.biofrontera.com).

Shareholders and investors are advised to read the Prospectus carefully before deciding on the exercise, acquisition or disposal of Subscription Rights or the acquisition of shares and, in particular, to consider the risks described in the section "Risk Factors" when making their decision.

Furthermore, pursuant to the provisions of the Underwriting Agreement, the Underwriter is entitled, under certain circumstances, to rescind the Underwriting Agreement and thus its obligation to the Company with respect to the subscription and securities settlement of the New Shares and to terminate the implementation of the subscription offer. Such circumstances include material adverse changes in the condition regarding assets and liabilities, financial position or operations of the Company and its subsidiaries, significant restrictions on stock exchange trading or banking activities in Frankfurt, London or New York, the outbreak or escalation of armed conflicts or other disasters or crises affecting the Federal Republic of Germany, the United Kingdom or the United States of America which result in or are expected to result in material adverse effects on the financial markets in these countries. Furthermore, the obligation of the Underwriter to subscribe for the New Shares shall end if the implementation of the capital increase has not been entered in the Commercial Register of the Local Court of Cologne by February 26, 2021, 24:00 hours (CET) at the latest.

In the event of rescission or termination of the Underwriting Agreement prior to registration of the implementation of the capital increase in the commercial register, the shareholders' Subscription Rights shall expire without compensation. In such case, there will be no reversal of Subscription Rights trading by the agents brokering the Subscription Rights transactions. Investors who have acquired Subscription Rights via a stock exchange would accordingly suffer a loss in this case. If short sales have already taken place prior to the entry of the New Shares in the securities accounts of the respective purchasers, the seller alone shall bear the risk of not being able to fulfill the obligations entered into through a short sale by timely delivery of New Shares.

However, if the Underwriter withdraws from the Underwriting Agreement after registration of the implementation of the capital increase in the Commercial Register, the shareholders who have exercised their Subscription Rights may acquire the New Shares at the subscription price, unless the Company for its part terminates the subscription offer, as it is entitled to do. In the latter case, the statements in the last paragraph shall apply.

If the Underwriting Agreement is terminated after settlement of the subscription offer by the Underwriter, which is also possible after delivery and settlement of the New Shares subscribed for in the subscription offer and listing, this would only apply to the New Shares not subscribed for. Share purchase agreements for unsubscribed New Shares are therefore subject to cancellation. If short sales have already taken place at the time of cancellation of share subscriptions, the seller of these shares alone bears the risk of not being able to fulfill his delivery obligation by delivering New Shares.

## Securitization and delivery of the New Shares

The New Shares will be securitized in a global certificate which will be deposited with Clearstream Banking AG, Frankfurt am Main. There is no entitlement to individual certificates. The acquired New

Shares are expected to be booked into the securities accounts of the acquirors on or about March 1, 2021.

## Stock exchange admission and trading in the New Shares

Application for admission of the New Shares to trading on the regulated market of the Düsseldorf Stock Exchange and the Frankfurt Stock Exchange with simultaneous admission to the sub-segment of the regulated market of the Frankfurt Stock Exchange with additional post-admission obligations (Prime Standard) is expected to be made on February 1, 2021. The admission decision is expected on or around February 25, 2021. Commencement of trading and inclusion of the New Shares in the existing listing on the aforementioned stock exchanges is expected on or about March 1, 2021.

#### Stabilization measures

No stabilization measures will be implemented.

## Selling restrictions

The subscription offer will be conducted exclusively in accordance with German law. It will be announced in the Federal Gazette in accordance with the relevant provisions of stock corporation law and with the articles of association of the Company. No further announcements, registrations, admissions or approvals by or with bodies outside the Federal Republic of Germany are envisaged either for the New Shares or for the Subscription Rights or for the subscription offer. The announcement of the subscription offer serves exclusively to comply with the mandatory provisions of the Federal Republic of Germany and is not intended to be used for the submission or publication of the subscription offer in accordance with the provisions of legal systems other than those of the Federal Republic of Germany, nor for any public advertising of the subscription offer which may be subject to the provisions of legal systems other than those of the Federal Republic of Germany.

Any publication, dispatch, distribution or reproduction of the subscription offer or of a summary or other description of the terms and conditions contained in the subscription offer may be subject to restrictions abroad. With the exception of publication in the Federal Gazette and forwarding of the subscription offer with the approval of the Company, the subscription offer may not be published, sent, distributed or forwarded by third parties, either directly or indirectly, in or to foreign countries, to the extent that this is prohibited under the applicable foreign provisions or is dependent on compliance with official procedures or the granting of approval. This also applies to a summary or other description of the terms and conditions contained in this subscription offer. The Company does not warrant that the publication, dispatch, distribution or dissemination of the subscription offer outside the Federal Republic of Germany is in compliance with the respective applicable legal provisions.

The acceptance of this subscription offer outside the Federal Republic of Germany may be subject to restrictions. Persons wishing to accept the subscription offer outside the Federal Republic of Germany are requested to inform themselves about any restrictions existing outside the Federal Republic of Germany.

An offer in the United States of America, Japan, Canada and Australia will not take place. The New Shares have not been and will not be registered under the United States Securities Act of 1933 (the "Securities Act") or with the securities regulatory authorities of any state of the United States of America. The New Shares may not be offered, sold or delivered, directly or indirectly, in or into the United States of America except pursuant to an exemption from the registration requirements of the Securities Act and the securities laws of each state of the United States of America. The same applies to an offer, sale or delivery to U.S. persons within the meaning of the Securities Act.

Leverkusen, February 2021

Biofrontera AG

The Management Board"

## 5.3.2 <u>Price</u>

The New Shares are first offered to the Issuer's shareholders, by way of admitting Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin, for subscribing and taking over the 8,969,870 New Shares at an issue price of EUR 1.00 per New Share, with the obligation to offer the New Shares to the shareholders in a quota of 1 New Share per 5 existing shares for subscription against payment of a subscription price ("*Subscription Price*").

The Subscription Price is expected to be determined on February 18, 2021. The Subscription Price shall be determined in the range between (in each case inclusive of) (i) the volume-weighted average price of the Company's shares in the XETRA electronic trading system of the Frankfurt Stock Exchange from the beginning of the Subscription Period to the day before the subscription price is determined, and (ii) the current share price of the Company at the time the subscription price is determined. When determining the final subscription price, the Company reserves the right to apply a discount of up to 20% from

the price initially determined as described above. The Subscription Price will be published presumably February 18, 2021 as an ad hoc release and on the same day in the German Federal Gazette. The Subscription Price will not exceed EUR 3.50 ("*Maximum Subscription Price*").

An offer to acquire or to subscribe to the New Shares may be revoked by the subscriber within two business days after the final issue price of the New Shares has been published.

No costs or taxes will be charged to subscribers; however, usual banking fees will be applied by the subscribers' depositary banks.

## 5.3.3 Subscription period and procedure / Private placement

The subscription offer is exclusively addressed to the shareholders of the Issuer, and, respectively, holders of subscription rights, to which the subscription offer is communicated via QuirinBank.

The shareholders are requested to execute their subscription right to the New Shares, in order to avoid exclusion, within the period from February 08, 2021 to February 22, 2021 noon CET ("*Subscription Period*") at QuirinBank.

In order to exercise their subscription rights, the Issuer requests shareholders or the holders of subscription rights, respectively, to instruct the depositary bank managing their securities account accordingly. For 5 existing shares of the Issuer, 1 New Share may be subscribed for at the Subscription Price. For any fractions resulting from the subscription quota of 5:1 for the respective number of existing shares held in each case, no New Shares may be subscribed to, only a subscription of 1 entire New Share or a multiple thereof is possible. The number of shares held at the end of February 09, 2021 shall be relevant for calculating the number of subscription rights allocated to each shareholder. At this time, the subscription rights (ISIN DE000A3H3LH0) are separated from the shares to the extent of the existing subscription rights and booked to the shareholders' securities accounts by their respective banks.

The Company will exercise reasonable efforts to allow a trading of subscription rights in the non-regulated market of a stock exchange in the Federal Republic of Germany. The Company explicitly makes no warranty that such trading will be possible. Subscription rights not executed are forfeit and will be booked out as invalid at the end of the subscription period.

From February 08, 2021 on, the old shares will be traded "ex subscription rights".

Shareholders executing subscription rights shall pay the Subscription Price upon execution of the subscription right, but no later than the end of the Subscription Period on February 22, 2021 noon CET. The subscription rights shall be proof that the shareholder is entitled to subscribe to New Shares.

The receipt of the subscription request and the Subscription Price at the depositary banks referred to above is relevant for keeping the deadline. Shareholders / holders of subscription rights are charged the usual bank fee for the subscription.

In the event that not all New Shares are subscribed for under the statutory subscription right, the unsubscribed New Shares will be offered by the Underwriter (if necessary through other financial service providers) at a purchase price equal to the subscription price to new investors who are not yet shareholders of the Company (the "*Private Placement*").

In addition, they may be offered to shareholders of the Company or holders of Subscription Rights for further subscription (the "*Additional Subscription*").

In addition, the unsubscribed New Shares shall furthermore be used as an underlying for the further creation of American Depositary Shares, each of which comprising two ordinary shares of the Issuer ("*ADS*") which, in turn, will be offered by a US financial institution with which the Issuer has entered into a corresponding underwriting and placement agreement to investors in the US ("*US Offer*"). QuirinBank will not participate in the US Offering. For the avoidance of doubt, no New Shares will be directly publicly offered in the US. The New Shares required to create the new ADSs subject of the US Offer will be delivered by QuirinBank to the US custodian who is safekeeping all the shares underlying the Issuer's ADSs, and who will create the new ADSs.

If, due to oversubscription, it is not possible to deliver all of the New Shares requested in the Additional Subscription and requested by investors in the Private Placement and (in the form of ADSs) in the US Offer, the New Shares will be allocated until the entire volume of the subscription offer has been exhausted. There will be no preferential treatment of shareholders vis-à-vis new investors. The shareholders are not entitled to an allocation within the scope of the Additional Subscription. If an allocation is made within the Additional Subscription, it will be made in compliance with the principle of equal treatment within the meaning of Section 53a of the German Stock Corporation Code (Aktiengesetz, AktG).

Anyone who exercises subscription rights may submit further binding subscription orders over and above the subscription ratio attributable to his or her holdings in accordance with the statutory subscription ratio. Shareholders or holders of subscription rights who wish to subscribe for additional New Shares at the subscription price in excess of their subscription right quota must submit their binding subscription orders within the subscription period via their depositary bank to QuirinBank.

## 5.3.4 <u>Revocation / suspension of the Offer</u>

## 5.3.4.1 <u>Revocation / suspension by the Issuer</u>

The subscription offer and the additional subscription are subject to the condition that the execution of the capital increase is entered into the commercial register no later than February 26, 2021. The subscriptions created by accepting the subscription offer, entering into additional subscriptions and in the private placement will not become effective in case of this dissolving condition. Furthermore, the Offer may be revoked or suspended by the Issuer until the date on which the execution of the capital increase is entered into the commercial register, thereby creating the New Shares, i.e. until February 24, 2021 (expected). After entering the execution of capital increase into the commercial register, the Offer cannot be revoked or suspended.

## 5.3.4.2 <u>Revocation by the subscriber</u>

A subscriber may revoke an executed subscription right or a declaration of additional subscription until the end of the subscription period. If payments were made to QuirinBank before revoking the subscription declaration or the declaration of additional subscription, these payments will be reimbursed in full. However, the depositary bank of the investor revoking a declaration might charge fees to the investor.

## 5.3.5 Minimum / maximum amount of application

A minimum number of 1 New Share must be subscribed to or purchased. No further minimum or maximum limits to the amounts of New Shares or aggregate amount for subscription or purchase exists.

## 5.4 <u>Allotment, delivery, exclusion of pre-purchase rights</u>

## 5.4.1 Allotment

The subscribers or purchasers will not be explicitly notified of the number of New Shares allotted to them; the notice will be limited to booking the respective number of allotted New Shares into their securities account.

In case of an oversubscription, the New Shares will be allotted in the discretion of the Issuer, pursuant to the statutory provisions, considering the general obligation to treat shareholders equally.

## 5.4.2 Delivery

The New Shares can only be delivered after entering the implementation of the capital increase into the commercial register.

The registration is expected to be effected by February 24, 2021. There is no guarantee that the execution of the capital increase will be effected by this date. The New Shares will be certificated in a global share certificate and will be deposited with Clearstream Banking AG. There is no right to individual securitization of the New Shares. The New Shares will be booked into the securities accounts of shareholders and subscribers, respectively, who have executed subscription rights or acquired the New Shares in Additional Subscription or during the Private Placement.

The delivery of the New Shares is expected to be effected on March 1, 2021.

## 5.4.3 <u>Pre-purchase rights, subscription rights trade, non-executed subscription rights</u>

With the exception of the general subscription right of all shareholders, no pre-purchase rights regarding the New Shares exist. The Issuer intends to facilitate the trading of subscription rights, however. Subscription rights not executed will become void without compensation.

## 5.5 <u>Disclosure of results</u>

The results of the Offer, i.e. the number of shares subscribed for, are expected to be disclosed by ad-hoc release on February 22, 2021.

## 5.6 Intentions of major shareholders and members of corporate bodies

Insofar as the Issuer is aware, its major shareholder Maruho Deutschland GmbH does not intend to exercise its subscription rights. The Issuer is not aware of the extent to which other major shareholders intent to participate in the capital increase, or whether any person intends to subscribe for more than 5 % of the Offer.

The members of the Issuer's management board currently have no fixed decision to participate in the capital increase.

## 5.7 <u>Time Schedule</u>

#### 5.7.1 Provisionary time schedule

Approval of the prospectus by BaFin	February 04, 2021
Publication of the prospectus on the Issuer's website	February 04, 2021
Publication of the subscription offer	February 05, 2021
Begin of the Subscription Period	February 08, 2021
Filing of application for admission for trading of the New Shares in the reg-	February 08, 2021

sion to the sub-segment of the regulated market with additional post-admission obligations ("Prime Standard") of Frankfurt Stock Exchange

ulated markets of Düsseldorf Stock Exchange and with simultaneous admis-

Booking shareholders' subscription rights pursuant to the shares held as of February 10, 2021 February 09, 2021, close of business

Determination of Subscription Price	February 18, 2021
End of the Subscription Period (noon CET) and the Placement	February 22, 2021
Ad-hoc release of the number of New Shares subscribed	February 22, 2021
Entering of the capital increase in the commercial register	February 24, 2021
Delivery of the global certificate to Clearstream Banking AG	February 24, 2021

Resolution regarding admission for trading of the New Shares in the regu-	February 25, 2021
lated markets of Düsseldorf Stock Exchange and with simultaneous admis-	
sion to the sub-segment of the regulated market with additional post-admis-	
sion obligations ("Prime Standard") of Frankfurt Stock Exchange	
Entering of the New Shares into existing trading	March 1, 2021

Delivery of New Shares

## 5.7.2 Expected issue date

The expected issue date of the New Shares, i.e. the date on which the New Shares are expected to be booked into the accounts of the subscribers, is March 1, 2021.

March 1, 2021

## 5.8 <u>Placing and underwriting</u>

## 5.8.1 European Bookrunner and Underwriter

The Offer is coordinated by QuirinBank. The function of QuirinBank is limited to underwriting the New Shares pursuant to the provision of sec. 186 German Stock Corporation Code, with the obligation to offer the New Shares to the shareholders for subscription and to use best efforts to place unsubscribed New Shares in the context of the Private Placement and the Additional Subscription. . No "hard" or "firm" underwriting will take place, meaning that QuirinBank will not subscribe for New Shares for distribution at their own risk. In particular, QuirinBank is under no obligation to subscribe for New Shares not subscribed for by shareholders or investors.

The Offer is solely conducted in the interest of the Issuer. The underwriting and placement agreement with QuirinBank is expected to be entered into on February 04, 2021.

## 5.8.2 <u>Underwriting Agreement</u>

## 5.8.2.1 <u>Underwriting commitment</u>

The Issuer and QuirinBank are expected to enter into an underwriting and placement agreement on February 04, 2021, with respect to the offer and sale of the New Shares to which this Prospectus relates (the "*Underwriting Agreement*").

Pursuant to the Underwriting Agreement, QuirinBank has agreed to offer the New Shares to the Issuer's shareholders or the holders of subscription rights, respectively, with respect to their subscription rights and to offer any non-subscribed New Shares to existing shareholders of the Issuer by way of additional subscription and to other investors in a private placement on a best efforts basis, and to subscribe for New Shares at the fixed issue price of EUR 1.00 per New Share and to take them up with the obligation to deliver them to the shareholders of the Company who have exercised their subscription rights and to other investors who have been allocated non-subscribed shares in the course of the Additional Subscription and private placement, respectively, and to transfer the difference between the issue price of EUR 1.00 and the subscription price to the Company after deduction of fees, costs and expenses to be paid or reimbursed by the Company.

The Underwriting Agreement does not contain a firm underwriting commitment of QuirinBank.

## 5.8.2.2 <u>Commission</u>

In the Underwriting Agreement the Issuer has agreed to pay to Quirin Bank a base fee, which depends on the number of shares issued under the offer, a fixed admission fee for the admission of the New Shares, a placement commission, which is dependent on the number of shares placed by Quirin Bank in the course of the private placement, and a success fee which will become payable if all New Shares under the Offer have been issued. Under the assumption of full placement of the New Shares at an expected subscription price of EUR 3.50 per New Share, the fees and commissions payable to QuirinBank by the Issuer are expected to range between approximately EUR 750,000 and approximately EUR 2,000,000, depending on the number of New Shares placed by QuirinBank on the one hand and within the US Offer on the other hand (for which the Issuer will enter into a separate placing agreement with a US financial institutions).

## 5.8.2.3 <u>Conditions, termination, indemnity</u>

Pursuant to the Underwriting Agreement QuirinBank has the right to terminate the Underwriting Agreement and its obligations thereunder upon the occurrence of certain events, such as circumstances having a material adverse effect on the Issuer, the state of the financial markets, or if conditions contained in the Underwriting Agreement, such as the delivery of certain documents by the Issuer, including legal opinions and disclosure letters, are not satisfied or waived.

In the event of a termination of the Underwriting Agreement prior to registration of the implementation of the capital increase in the commercial register, the shareholders' subscription rights will lapse and the Offer will not be consumed. Allocations of the New Shares to shareholders and investors will be cancelled and shareholders and investors will not have any claim to delivery of the New Shares. In such an event, the shareholders and investors will be informed thereof by a publication on the website of the Issuer.

If QuirinBank terminates the Underwriting Agreement after registration of the implementation of the capital increase in the commercial register, the shareholders who have exercised their subscription rights may acquire the New Shares at the subscription price, unless the Company for its part terminates the subscription offer, which it is entitled to do. In such case the Offer will not be consumed. Allocations of the New Shares to shareholders and investors will be cancelled and shareholders and investors will not have any claim to delivery of the New Shares.

If the Underwriting Agreement is terminated after settlement of the subscription offer by QuirinBank, which is still possible, such termination will only apply to the New Shares not subscribed for. Accordingly, QuirinBank remains obliged to deliver the New Shares subscribed for by shareholders of the Issuer in the subscription offer to those shareholders.

Furthermore, the Issuer has agreed in the Underwriting Agreement to indemnify QuirinBank against certain liabilities that may arise in connection with the Offer.

## 5.8.2.4 <u>Other relationships</u>

QuirinBank or its affiliates may, from time to time, engage in transactions or perform services to the Issuer or its subsidiaries in the ordinary course of business.

## 5.8.2.5 <u>Selling restrictions</u>

The distribution of the Prospectus and the placement of the New Shares are restricted by law in certain jurisdictions. Pursuant to the Underwriting Agreement, no action has been or will be taken by the Issuer or QuirinBank that will permit a public Offer of the New Shares anywhere other than Germany or the possession or distribution of this Prospectus in any other jurisdiction in which action for that purpose may be required by applicable law or regulation.

Accordingly, neither this Prospectus nor any advertisement or any other Offer material may be distributed or published in any jurisdiction except under circumstances that will result in compliance with any applicable laws and regulations. Persons into whose possession the Prospectus comes are required to inform themselves about or observe any such restrictions, including those set forth below. Any failure to comply with these restrictions may constitute a violation of the securities laws of any such jurisdiction.

## 5.8.2.5.1 European Economic Area

In relation to each EEA member state, no offer to the public of any shares may be made in that EEA member state (other than the offer in Germany contemplated herein once the Prospectus has been approved by the BaFin and published in accordance with the Regulation (EU) 2017/1129), except that an offer to the public in that EEA member state of any of the shares may be made at any time under the following exemptions under Regulation (EU) 2017/1129:

- to qualified investors (as defined in Article 2(e) of the Regulation (EU) 2017/1129);
- to fewer than 150 natural or legal persons per member state (other than qualified investors as defined in the Regulation (EU) 2017/1129), subject to obtaining the prior consent of European Bookrunner and Underwriter for any such offer;
- $\circ$  in any circumstances falling within Article 1(3) or 1(4) of the Regulation (EU) 2017/1129, or
- in any circumstances falling within Article 3(2) of the Regulation (EU) 2017/1129 if the respective member state decided to exempt such offers from the obligation to publish a prospectus.

For purposes of this section, the expression an "offer of securities to the public" in relation to any New Shares in any member state means a communication to persons in any form and by any means, presenting sufficient information on the terms of the offer and the shares to be offered so as to enable an investor to decide to purchase or subscribe for those shares.

## 5.8.2.5.2 United Kingdom

In the United Kingdom of Great Britain and Northern Ireland (the "**United Kingdom**") this Prospectus is directed only at persons who: (i) are qualified investors within the meaning of the Financial Services and Markets Act 2000 (as amended) and any relevant implementing measures and/or are outside the United Kingdom or (ii) have professional experience in matters relating to investments falling within the definition of "investment professionals" contained in Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (as amended) (the "Order") or are high net worth companies, unincorporated associations or partnerships or trustees of high value trusts as described in Article 49(2) of the Order (all such persons referred to in (i) and (ii) above together being referred to as "Relevant Persons"). Any person who is not a Relevant Person must not act or rely on this Prospectus

or any of its contents. Any investment or investment activity to which this Prospectus relates is available only to Relevant Persons and will be engaged in only with Relevant Persons.

## 5.8.2.5.3 United States

The Issuer does not intend to register either the Offer or any portion of the Offer in the United States, or to conduct a public Offer of New Shares in the United States. The New Shares and the subscription rights have not been and will not be registered pursuant to the provisions of the Securities Act or under the securities laws of any state of the United States. The New Shares may not be offered, sold or delivered, directly or indirectly, within or into the United States except pursuant to an exemption from, or in transactions not subject to, the registration and reporting requirements of the U.S. securities laws and in compliance with all other applicable provisions of U.S. law.

Until 40 days after the commencement of the Offer, an offer or sale of the New Shares and the subscription rights within the United States by any dealer (whether or not participating in the Offer) may violate the registration requirements of the Securities Act.

## 5.9 Payment / depositary agents

Bankhaus Gebrüder Martin Aktiengesellschaft, Kirchstr. 35, 73033 Göppingen, Germany, will function as payment agent. Clearstream Banking AG, Frankfurt, Mergenthalerallee 61, 65760 Eschborn, Germany will function as depositary agent.

## 5.10 Designated sponsor

ICF Bank AG, Frankfurt am Main, Germany, acts as designated sponsor for the Issuer. The function of the designated sponsor is set out in a designated sponsor agreement. The function of the designated sponsor is to provide trading liquidity, insofar as possible, in order to increase the trading options of the market participants. To this end, the designated sponsor files limited sale and purchase orders for shares of the Issuer in the electronic trading system XETRA of the Frankfurt stock exchange. The designated sponsor has to consider the provisions of the stock exchange; they must keep a minimum quotation period, a minimum volume and a minimum price range. They are expected to participate in the daily auctions and in particular in case of volatility interruptions to react and provide an appropriate quotation price.

## 5.11 Admission to trading

Shares of the same class as the New Shares are already admitted to trading in the regulated markets of Düsseldorf Stock Exchange and with simultaneous admission to the sub-segment of the regulated market with additional post-admission obligations ("Prime Standard") of Frankfurt Stock Exchange.

The Issuer intends to have the New Shares admitted to the regulated market of the Düsseldorf Stock Exchange and with simultaneous admission to the sub-segment of the regulated market with additional post-admission obligations ("Prime Standard") of Frankfurt Stock Exchange. The application is intended to be filed on February 8, 2021; the Issuer expects the admission of the New Shares on February 25, 2021 and an inclusion of the New Shares in the existing quotation of the Issuer's shares on March 1, 2021. An admission of the New Shares for trading to other regulated markets is not intended. An admission of the New Shares to the regulated markets referred to above is subject to the decision of the respective stock exchanges and not guaranteed.

It should be noted, that the Issuer intends to apply for admission of certificates representing New Shares, to the NASDAQ, a US stock exchange. The certificates to be listed at the NASDAQ are so-called ADSs (American Depositary Shares) or ADRs (American Depositary Receipts).

## 5.12 Selling Shareholders, lock-up agreements

The New Shares will not be sold by existing shareholders; New Shares will solely be issued by the Issuer.

In order to facilitate the orderly closing of the private placement of non subscribed New Shares, converted into ADSs, in the USA, the New Shares underlying the ADSs offered and allocated in the US be will granted to QuirinBank by way of a securities loan by a major shareholder of the Issuer (see 6.7.1 below).

No lock-up agreements regarding the New Shares exist.

## 5.13 Net Proceeds, expenses of the Offer

The Issuer will determine the subscription price only on February 18, 2021. While the Issuer has set a Maximum Subscription Price of EUR 3.50, for the purposes of this prospectus, the Issuer will calculate with an expected subscription price of EUR 3.50.

Under the assumption of full placement at an expected subscription price of EUR 3.50 per New Share, the Issuer expects gross proceeds of EUR 31,394,545, and assuming costs of EUR 2,500,000, net proceeds of EUR 28,894,545.

## 5.14 Dilution

## 5.14.1 Immediate dilution resulting from the Offer

Before the consummation of the capital increase, the net carrying value of the Biofrontera Group amounted to approximately EUR 9,955 thousand or to approximately EUR 0.22 per share (calculated on the basis of the number of 44,849,365 issued shares of the Issuer as of the date of this prospectus).

The net carrying value of the Biofrontera Group is calculated on the basis of the audited consolidated financial statements for the period ended December 31, 2019 by deducting the amount of the long-term liabilities (EUR 36,830 thousand) and the current liabilities (EUR 11,578 thousand) as of December 31, 2019 from the amount of total assets as of December 31, 2019 (EUR 58,363 thousand).

Under the assumption of full placement at an expected subscription price of EUR 3.50 per New Share, the Issuer expects gross results of EUR 31,394,545, and assuming costs of EUR 2,500,000, net results of EUR 28,894,545.

Assuming the capital increase against cash contributions is consummated in full at the expected subscription price of EUR 3.50, the net proceeds amount to approximately EUR 28,894,545, the net carrying value of the Biofrontera Group as December 31, 2019, would have amounted to approximately EUR 38849,545 or to approximately EUR 0.72 per share (calculated on the basis of the number of 53,819,235 issued shares of the Issuer after the consummation of the share capital increase against cash contributions).

Based on the assumed subscription price of EUR 3,50, this would result in an increase of the net carrying value of Biofrontera Group as of December 31, 2019, by approximately EUR 0.50 per share to EUR 0.72per share for existing shareholders. There would be an immediate dilution of EUR 2.78 per share or approximately 79.4 % for the purchasers of the New Shares since the subscription price of EUR 3.50 per share would be above the calculated net carrying value per share of approximately EUR 0.72. For existing shareholders, the net carrying value per existing share would correspondingly increase by EUR 0.50 per share, from EUR 0.22 to EUR 0.72. This would amount to an increase by approximately 225.2 %.

## 5.14.2 Dilution for shareholders not participating in the Offer

Insofar as shareholders do not exercise their subscription rights, and the New Shares from the capital increase which is described in this Prospectus (8,969,870 shares) are subscribed in full, the participation of such shareholders will be reduced by 20 %. The dilution will be lower if not all New Shares are subscribed to.

## 5.15 Interests of persons involved in the Offer, conflicts of interest

QuirinBank will receive, in addition to a fixed base fee for assuming the role of subscription and admission agent, a performance-based placement fee for its services in connection with the Offer. As a consequence, QuirinBank has an interest in the successful implementation of the Offer. In the opinion of the Issuer, this does not constitute a conflict of interest, since the individual interests of Quirin Bank regarding the Offer are aligned with the Issuer's interests. Members of the management and supervisory boards hold shares of the Issuer as well as option rights to the acquisition of shares of the Issuer. In the opinion of the Issuer, this does not constitute a conflict of interest, since the private interest of the members of the management and supervisory boards are not contrary to the company's interests.

The Issuer is not aware of any further interests, conflicts of interest or potential conflicts of interest of natural or legal persons which might be relevant for the Offer.

## 6. Information about the Issuer

## 6.1 General information

The legal and commercial name of the Issuer is "Biofrontera Aktiengesellschaft".

The Issuer is a German public stock corporation (*Aktiengesellschaft*) with the LEI 391200D6GFSVFGFQTL13. The Issuer's registered seat is Leverkusen, Germany. It operates under German law and is incorporated in Germany. The registered office of the Issuer is Hemmelrather Weg 201, 51377 Leverkusen, Germany, with telephone number +49 214 87632 66.

The Issuer's website is "www.biofrontera.com". Information on the website is not part of this Prospectus, insofar as such information has not been included by reference into the Prospectus.

## 6.2 Group structure

The Biofrontera Group consists of the Issuer, Biofrontera Aktiengesellschaft, as the parent company, and five wholly owned subsidiaries, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH each with a statutory seat in Leverkusen, Germany, and Biofrontera Inc., with a statutory seat in Wilmington, Delaware, USA.

The subsidiaries are in each case likely to have a significant effect on the assessment of the Issuer's own assets and liabilities, financial position or profits and losses.

## 6.2.1 Biofrontera Aktiengesellschaft

Biofrontera Aktiengesellschaft functions as operative and financial holding company of Biofrontera Group.

## 6.2.2 Biofrontera Bioscience GmbH

Biofrontera Bioscience GmbH is responsible for research and product development in Biofrontera Group.

## 6.2.3 Biofrontera Pharma GmbH

Biofrontera Pharma GmbH is responsible for sales and distribution in Biofrontera Group, and represents Biofrontera Group vis-à-vis dermatologists and physicians.

## 6.2.4 Biofrontera Development GmbH

Biofrontera Development GmbH holds since late 2012 the rights to the product candidate BF-Derm1. The intention of outsourcing the product candidate was to facilitate and external financing or to monetize the rights to the product candidate by disposing of the company or shares of the company.

## 6.2.5 Biofrontera Neuroscience GmbH

Biofrontera Neuroscience GmbH holds since late 2012 the rights to the product candidate BF-1. The intention of outsourcing the product candidate was to facilitate and external financing or to monetize the rights to the product candidate by disposing of the company or shares of the company.

## 6.2.6 Biofrontera Inc.

Biofrontera Inc. with its registered seat in Wilmington, Delaware, USA, and its headquarters in Woburn, Massachusetts, USA, was incorporated in 2015 with the goal of managing the US operations of Biofrontera. In December 2019, several entities involved with Cutanea Life Sciences, Inc., were merged into Biofrontera Inc.

## 6.3 <u>Rights attaching to shares</u>

## 6.3.1 Voting rights

Each share carries one vote. Resolutions are adopted by a simple majority of the votes cast unless a larger majority or other requirements are determined by law or the articles. A majority of 75 % of the capital represented in a general shareholder meeting is required, in particular, in order to pass the resolutions concerning the following:

- capital decreases;
- creation of authorised or conditional capital;
- exclusion of subscription rights;
- de-mergers and spin-offs;
- transfer of the entire assets of the Issuer;
- conclusions, amendments and terminations of management agreements (e.g. agreements regarding control and transfer of profits and losses);
- change of the legal form of the Issuer; and

• dissolution of the Issuer.

The right to vote may be exercised by proxy. Exercising the right to vote by proxy requires the issuing of a power of attorney. The power of attorney may be granted in writing or by facsimile. The articles do not restrict any other forms regulated by law for the granting of a proxy, its revocation and proof of authorization to the Issuer.

## 6.3.2 Dividend rights, profit entitlements and liquidation proceeds

The dividend available for distribution in any financial year is approved at the Issuer's general shareholder meeting. The dividend rights attached to the New Shares begin on 1 January 2020. The amount attributable to each share is based on the division of the total amount approved for distribution at the Issuer's annual general shareholder meeting by the number of dividend-bearing shares at the time the dividend is approved. Dividends are not cumulative. No special procedure exists for non-domestic shareholders to claim their dividends. Any claim to the payment of a dividend lapses three years after the year in which the relevant dividend is approved. Should a claim arising from payment of dividends lapse, the Issuer is entitled but not obliged to pay out the dividends to the shareholder whose claim has lapsed.

The Issuer may, except in the case of insolvency, be dissolved by a resolution of shareholders, which to be passed requires a majority of the votes cast and in addition a majority of at least three-quarters of the share capital represented. In this case, the remaining assets after the fulfillment of the Issuer's liability obligations would be distributed, according to the provisions of the German Stock Corporation Act, among the shareholders in proportion to their stake in the share capital, i.e. according to the number of shares held. Preference shares for the Issuer do not exist. If a surplus exists after any insolvency proceedings are completed, the surplus is distributed amongst the persons who could claim such surplus if the Issuer was subject to an orderly winding-up, i.e. the former shareholders of the Issuer.

Prospective investors should note that the Issuer has, in the past, not paid out dividends. Considering the substantial loss carry-forward of the Issuer, it is unlikely that the Issuer will pay out dividends in the near future.

## 6.3.3 Subscription rights

In case of an increase of capital and issue of further new shares of the Issuer, holders of New Shares generally have a subscription right to such further New Shares, unless the subscription right is excluded.

## 6.3.4 <u>Change of the rights attached to the shares</u>

The articles do not provide for special rules governing changing the rights attaching to shares. Therefore, the general rules set out in statutory law apply. Accordingly, the rights attaching to shares set out in the articles may be changed with a simple majority of votes and capital represented, with the exception of

the decisions requiring a majority of 75 % of the capital represented as set out above. Furthermore, if rights are only held by specific classes of share, the shareholders of such class have to take a separate decision. Individual rights attaching to shares can only be removed with the consent of each respective shareholder.

## 6.4 Administrative, Management, and supervisory bodies and senior management

## 6.4.1 <u>Members of the management board</u>

The management board of the Issuer is currently comprised of Prof. Hermann Lübbert, Ph.D., as CEO, and Thomas Schaffer as CFO. The business address of the members of the management board is Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen, Germany.

**Prof. Hermann Lübbert, Ph.D.**, is chairman of the management board of the Issuer and a managing director of all German subsidiaries of the Issuer, as well as a member of the board of directors of Biofrontera Inc. He studied biology in his home town of Cologne and received his doctorate there in 1984. Following eight years in academic research at the University of Cologne and the California Institute of Technology, he gained experience in managing a global research organization during ten years at Sandoz and Novartis Pharma AG. Prof. Lübbert founded the Issuer in 1997 and has been managing the Issuer ever since. He qualified as a university lecturer at the Swiss Federal Institute of Technology (ETH), Zurich, and in addition to his position in the Issuer and its subsidiaries, holds a professorship for animal physiology at the Ruhr-University Bochum.

**Thomas Schaffer** is a member of the management board of the issuer and a managing director of all German subsidiaries of the Issuer. He began his professional career with various positions in the finance and controlling division at Siemens Semiconductor. He held the position of vice president and CFO in the Security & Chipcard IC division of Siemens and the subsequently formed Infineon Technologies AG. Following this, he spent four years as managing director and CFO of Infineon Ventures GmbH and continued his career as vice president and CFO of the Specialty DRAM Division of Qimonda AG, where he also took over management of Qimonda Solar GmbH, Dresden. With positions as CFO at Heptagon Oy, Finland/Switzerland, and Ubidyne Inc., Delaware, USA, he expanded his extensive international experience. Since June 2013, Mr. Schaffer has held the position of CFO of the Issuer and is a managing director of all German subsidiaries of the Issuer. Mr. Thomas Schaffer has declared his resignation from the management of the Issuer effective February 28, 2021 (for details regarding the severance agreement, see 6.7.3).

**Ludwig Lutter** will be a member of the management board of the Issuer and a managing director of all German subsidiaries of the Issuer effective March 1, 2021 (for details regarding the service agreement, see 6.7.3). Before joining Biofrontera, Mr. Lutter served as CFO for brillen.de, Hotel Reservation Service, Intershop Communications AG, SOPHOS und Poet Holdings, Inc., among other start-ups and IT-
companies. Prior to that, he served in public accounting and tax consulting for KPMG and other public accounting firms. Mr. Lutter holds a degree in business administration from the University of Texas, USA, and is qualified as a certified tax advisor (Steuerberater) in Germany.

### 6.4.2 Members of the supervisory Board

The Issuer's supervisory board is currently composed of five members. The business address of the members of the management board is Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen, Germany.

**Ulrich Granzer, Ph.D.** (chairman of the supervisory board): Dr. Granzer is managing director of Granzer Regulatory Consulting & Services and was formerly director of regulatory affairs at GlaxoSmithKline plc., BASF Pharma AG and Bayer AG. Dr. Granzer is a pharmacist and has been a member of the supervisory board of the Issuer since 2003.

**Jürgen Baumann** (deputy chairman of the supervisory board): As an economics graduate, Mr. Baumann was formerly a member of the management board of Schwarz Pharma AG responsible for European operations with eight national subsidiaries and four production sites. Mr. Baumann has been a member of the supervisory board of Biofrontera since 2007. Up until October 2012, Mr. Jürgen Baumann was a member of the supervisory board of Riemser AG, Greifswald.

**John Borer III, J.D.,** is the senior managing director and head of investment banking at the Benchmark Company, LLC. He was formerly the CEO and head of investment banking at Rodman & Renshaw, and has held senior positions at Pacific Business Credit and Barclays American Business Credit. He holds a Doctor of Law degree (J.D.) from Loyola Law School in Los Angeles.

**Dr. Reinhard Eyring** is a partner and Head of Germany at Ashurst LLP. Previously he was a partner at Schürmann & Partner for 11 years. Mr. Eyring studied law at the University of Freiburg and subsequently worked as a trainee at the Regional Court of Frankfurt am Main.

**Prof. Dr. Franca Ruhwedel** is currently Professor of Finance and Accounting at the RheinWaal University of Applied Sciences in Kamp-Lintfort. Previously, she was Professor of Accounting and Controlling at the FOM University in Essen. During her professional career she held positions as project manager in M&A and corporate development at thyssenkrupp AG and thyssenkrupp Steel AG. Following her training as a banker at Commerzbank AG and her studies of business administration, Ms. Ruhwedel received her doctorate at the Ruhr University of Bochum.

**Kevin Weber** is the CEO of Paraffin International Inc. He has extensive experience in marketing and global operations and strategy, and has held senior roles at Depomed, Hyperion Therapeutics, and

Medicis Pharmaceuticals. Kevin Weber is also a board member of the American Academy of Pain Management Foundation and the American Chronic Pain Association. He holds a B.A. in Management and Marketing from Western Michigan University.

# 6.4.3 Other leading positions of board members

The following members of the management or supervisory board also hold or have held within the last five years further board memberships:

- Dr. Reinhard Eyring is also a member and chairman of the supervisory board of DESTAG Deutsche Steinindustrie AG, Lautertal (Odenwald);
- Prof. Dr. Franca Ruhwedel is also a member of the supervisory boards of National-Bank AG, Essen, and VTE AG, Hamburg.
- Mr. Ludwig Lutter was CFO (member of the management board) of SuperVista AG (brillen.de),
   Schönefeld, and managing director of IDL Beratung f
  ür integrierte DV-Lösungen GmbH,
   Schmitten. Mr. Lutter no longer holds these positions.

# 6.4.4 Disclosures

No family relationships exist between any of those persons referred to under 6.4.1 and 6.4.2 above.

No member of the management board or the supervisory board was convicted in relation to fraudulent offences in the previous five years.

No member of the management board or of the supervisory board were associated with bankruptcies, receiverships or liquidations when acting as member of the management board, the supervisory board, or as senior manager in the last five years.

No official public incrimination and/or sanctions were made against members of the management board or members of the supervisory board by statutory or regulatory authorities (including designated professional bodies); no member of the management board or of the supervisory board has ever been disqualified by a court from acting as a member of the administrative, management or supervisory bodies of an issuer or from acting in the management or conduct of the affairs of any issuer.

Regarding the members of the management board and the supervisory board, no potential conflict between their duties to the Issuer and their private interests and other duties exist.

No agreements or understandings with major shareholders, customers, suppliers or other persons exist, based on which a member of the management board or the supervisory board has been appointed to said boards.

No members of the management board or the supervisory board have entered into lockup-agreements with respects to the shares held of the Issuer.

For the avoidance of doubt, references to members of the management board apply to Mr. Lutter as future member of the management board.

## 6.5 Major shareholders

Insofar as known to the issuer, the following persons hold, directly or indirectly, an interest in the issuer's capital or voting rights, which is notifiable under German law:

## Direct interest:

- Maruho Deutschland GmbH, Düsseldorf, Germany: 28.1 %
- DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Germany: 3% or more voting rights
- Deutsche Balaton AG, Heidelberg, Germany: 3% or more voting rights
- SPARTA AG, Heidelberg, Germany: 3% or more voting rights
- Deutsche Balaton Biotech AG, Heidelberg, Germany: 3% or more voting rights

Note that due to limitation of mandatory information in voting rights disclosures, more detailed information regarding direct interest of shareholders is not available. Based on the disclosure requirements set out in the German Securities Trading Notification Regulation (Wertpapierhandelsanzeigeverordnung - WpAV), it is not possible to identify the number of voting rights directly held by one person if these voting rights are attributed to another person and the latter submits a so-called group voting rights notification. The above information regarding DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG is taken from a voting rights disclosure by Mr. Wilhelm K. T. Zours, to whom the voting rights held directly by DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton AG, SPARTA AG and Deutsche Balaton Biotech AG are accordingly attributed.

### Indirect interest:

- Maruho Co., Ltd., Osaka, Japan: 28.1 %
- Wilhelm K. T. Zours: 29.8 %
- DELPHI Unternehmensberatung Aktiengesellschaft, Heidelberg, Germany: 29.8 %
- Deutsche Balaton Aktiengesellschaft, Heidelberg, Germany: 29.8 %
- SPARTA AG, Heidelberg, Germany: 29.8 %
- Deutsche Balaton Biotech AG, Heidelberg, Germany: 29.8 %
- ABC Beteiligungen AG, Heidelberg, Germany: 29.8 %

• Heidelberger Beteiligungsholding AG, Heidelberg, Germany: 29.8 %

Note that DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton Aktiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG and Heidelberger Beteiligungsholding have entered into a voting pool agreement on January 28, 2020. Prisma Equity AG withdrew from this voting pool agreement as of December 21, 2020. The conclusion of the voting rights agreement has the effect that all voting rights held or attributable by the parties to the voting rights agreement are mutually attributed to the parties. The result is therefore only one indirect shareholding of 29.8%, which is mutually attributable to the parties to the voting rights agreement. All voting rights of the parties to the voting rights agreement are in turn attributed to Mr. Wilhelm K. T. Zours.

The Issuer's major shareholders do not have different voting rights. To the extent known to the Issuer, the Issuer is not directly or indirectly owned or controlled. No specific measures are in place to prevent abuse of a potential control of the Issuer.

No arrangement is known to the Issuer that may at a subsequent date result in a change in control of the Issuer.

### 6.6 Share capital

As of the date of the latest financial statements (December 31, 2019), the share capital of the Issuer is structured as follows:

#### 6.6.1 <u>Registered capital</u>

The registered share capital amounted to EUR 44,849,365 on December 31, 2019. It was divided into 44,849,365 registered shares with a nominal value of EUR 1.00 each. The shares are fully paid in. No shares are issued that are not fully paid in.

## 6.6.2 Authorized capital

The Issuer has no authorized capital at the date of this prospectus.

The general meeting of the Issuer had resolved, on May 24, 2017, to authorize the management board of the Issuer to increase the share capital by up to EUR 4,000,000 by issuing new ordinary registered shares, with the approval of the supervisory board, until May 23, 2022 against contribution in cash or in kind once or several times by issuing new ordinary shares, and entitle the management board to exclude the shareholders' subscription rights for effectively its entire amount (authorized capital II). This authorized capital II has been contested by a shareholder. The authorized capital II has not been entered

into the commercial register – which is required to render it effective – pending the results of the legal proceedings.

### 6.6.3 Shares held by the Issuer

No shares are held by or on behalf of the Issuer or subsidiaries of the Issuer.

### 6.6.4 Convertible bonds

### 6.6.4.1 <u>Convertible bond 2022</u>

On December 23, 2016, the Issuer's management board approved the issue of a convertible bond, which was placed in full in an amount of EUR 4.999.000 in January 2017. The individual bonds 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 term of the 2017/2022 convertible bond begins on the day of its initial issue and ends on December 31, 2021. As of December 31, 2019, bonds in a nominal amount of EUR 2,968,200 were converted into the company's shares, so that 2,030,800 bonds remain outstanding. The bonds may be converted at a conversion price (subject to adjustment in case of certain capital measures) of EUR 4.737 per share by notice of the holder to the Issuer. A conversion of all outstanding bonds would result in 428,710 new shares of the Issuer.

## 6.6.4.2 <u>Convertible bond 2021</u>

On July 27, 2020, the Issuer's management board approved the issue of a qualified subordinated mandatory convertible bond, which was placed in full in an amount of EUR 7,914,450 in August 2020.

The qualified subordinated mandatory convertible bond will mature on December 20, 2021, bears interest at 1% p.a. and consists of up to 2,638,150 bonds with a principal amount of EUR 3.00 each and a total principal amount of up to EUR 7,914,450. In accordance with the terms and conditions of the convertible bonds, each of these convertible bonds can be converted into no-par ordinary registered shares of the company with a notional interest in the share capital of EUR 1.00 per share and a right to dividends from the year of the share issue. The initial conversion price per share is EUR 3.00. The initial conversion ratio is 1 : 1. All convertible bonds 2020-2021 have been converted into shares following the mandatory conversion in November 2020.

### 6.6.5 <u>Conditional capital</u>

The Issuer has created several conditional capitals.

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 3,998,014 available as at December 31, 2019 and EUR 1,359,864 as

of the date of this prospectus. 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 Contingent Capital I increase serves (i) to secure granting of option rights and agreeing on option obligations pursuant to the terms of a respective bond, or (ii) to secure fulfillment of conversion rights and fulfillment of conversion obligations pursuant to the terms of a respective bond, each issued, agreed upon or guaranteed based on the authorization of the Issuers general meeting of shareholders of August 28, 2015, by the Issuer or his affiliates. The contingent capital increase will be implemented only if and insofar as (i) financial instruments based on the authorization of the general meeting of shareholders of August 28, 2015, are issued, and (ii) the holders or creditors of financial instruments, exercise their option or conversion rights, or fulfill an option or conversion obligation, as the case may be. The authorization to issue such financial instruments ended on August 27, 2020. The new shares issued on the basis of the previous sentence entitle their holders to dividends of the Issuer's profits from the beginning of the fiscal year in which they are issued.

The conditional increase in the share capital (Conditional Capital III) of EUR 542,400 was approved on July 2, 2010, of which is EUR 249,050 available as of December 31, 2019 and as of the date of this prospectus. The contingent capital increase serves exclusively to fulfill options granted until July 1, 2015 pursuant to the authorization by resolution of Issuers general meeting of shareholders held on July 2, 2010. The contingent capital increase will be implemented only if the holders of the options issued exercise their right to purchase shares of the Issuer, and if the Issuer does not grant own shares or pays a cash settlement in order to fulfill the options. The new shares entitle their holders to dividends from the Issuer's profits from the beginning of the fiscal year in which they are issued.

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 of the date of this prospect. The contingent capital increase serves to ensure that option rights are fulfilled which were granted on the basis of the authorization of the Issuer's shareholders' meeting held on August 28, 2015, in the period up to August 27, 2020. The capital increase must be implemented only insofar as the holders of the share options exercise their options and the Issuer does not fulfill the option rights by delivering own shares or paying a cash compensation. The new shares entitle their holders to dividends of the Issuer's profits from the beginning of the fiscal year in which they are issued.

# 6.7 <u>Related party transactions</u>

### 6.7.1 Agreements with major shareholders

With agreement dated March 11, 2020, the Issuer had entered into an agreement with its major shareholder Maruho Deutschland GmbH regarding the support of the Issuer's capital market activities. The goal of the agreement was to facilitate the issue of convertible bonds, by Maruho providing shares in the Issuer to the underwriting financial institution by way of a share loan. For this service, Maruho received a compensation for costs incurred in an amount of EUR 45,000.

The Issuer has entered into an agreement with its major shareholder Maruho Co. Ltd. in April 2020. For details, please see 9.9.1.3 below.

Issuer intends to enter into an agreement with its major shareholder Maruho Deutschland GmbH regarding the support of the US offer. Therefore, Maruho Deutschland GmbH will provide a share loan of up to 8,969,870 existing shares of the Issuer to QuirinBank. These loan shares would be converted to ADS in an amount as US Investors subscribe ADS in the US Offer, each ADS representing two shares of the Issuer. The reason for choosing this structure is to comply with the expectations of US Investors regarding the settlement process for the ADS. QuirinBank will subscribe for New Shares in an amount equal to the number of shares required to create the ADS subscribed by US Investors and deliver these New Shares back to Maruho Deutschland GmbH. For this service, Maruho Deutschland GmbH will receive a compensation for own costs. In case the issue of the New Shares will not be implemented and QuirinBank will therefore not fully return the loan shares, but will have to pay the Subscription Price per loan share converted to ADS; in addition the Issuer will pay a compensation to Maruho Deutschland GmbH. The compensation amounts to the difference between the closing price of the Issuers shares in XETRA-trading on the Frankfurt Stock Exchange on the day of the transfer of the loan shares to QuirinBank ("Reference Price") and the Subscription Price per New Share, multiplied with the number of Loan-Shares placed with Investors. Should the Subscription Price be higher than the Reference Price, no compensation is owed.

# 6.7.2 Agreements with subsidiary

By resolution and subscription agreement between the Issuer and its 100% subsidiary Biofrontera Inc. dated December 31, 2020, the Issuer has converted an intra-group loan of USD 46,986,126 granted by the Issuer to Biofrontera Inc. to into 7,999,000 shares of Biofrontera Inc., which were subscribed by and transferred to the Issuer.

#### 6.7.3 Agreements with management

In January 2020, the Issuer had entered into a severance agreement with its former management board member Christoph Dünwald in relation to the service agreement that had a term until November 30, 2020. No financial incentives were made to Mr. Dünwald beyond the rights existing under the service agreement, however the parties agreed to measure the annual bonus for the business year 2020 as an average of the annual bonuses 2017, 2018 and 2019. Mr. Dünwald was relieved from the obligation to provide services to the Issuer from the date of the agreement on.

On July 23, 2020, the service agreement between the Issuer and Prof. Dr. Hermann Lübbert was extended until December 31, 2022, and the service agreement between the Issuer and Thomas Schaffer was extended until December 31, 2022. They may terminate their agreements with six months' notice, which right expires with the end of the second month after the month in which the annual general meeting 2021 has taken place. Prof. Dr. Hermann Lübbert receives a fixed annual remuneration of EUR 390,000, which will be increased to EUR 440,000 following annual profitability, Mr. Thomas Schaffer receives a fixed annual remuneration of EUR 275,000. Prof. Dr. Hermann Lübbert and Mr. Thomas Schaffer also receive a short-term incentive which is dependent on the achievement of annual targets. In case of target overachievement, the STI may be increased to up to 200 % of the target amount; in case of achievement of less than 70 %, the STI will not be paid at all. The target STI of Prof. Dr. Hermann Lübbert amounts to EUR 195,000, the target STI of Mr. Thomas Schaffer amounts to EUR 137,500. Furthermore, Prof. Dr. Hermann Lübbert and Mr. Thomas Schaffer are granted stock appreciation rights ("SARs") as a long term incentive ("LTI") in a target amount of 150% of the STI target amount. SARs cannot be exercised insofar as the gross amount from all exercised SARs would exceed the fixed remuneration by more than 300%. Prof. Dr. Hermann Lübbert and Mr. Thomas Schaffer must invest 25% of the payments received under the SAR plan in shares of the Issuer, which they may divest no earlier than 4 years after grant of the SARs. Furthermore, Prof. Dr. Hermann Lübbert and Mr. Thomas Schaffer must invest part of the STI to hold at least 100,000 shares of the Issuer until the expiry of the respective service agreement, whereas shares acquired under the SAR plan and shares already held are offset.

In January 2021, the issuer and Mr. Schaffer agreed that Mr. Schaffer will resign from the Issuer's management board with effect from February 28, 2021. In addition, the termination of the existing service agreement between Mr. Schaffer and the Issuer was agreed as of February 28, 2021. Mr. Schaffer was granted a severance payment of EUR 210,000. Mr. Schaffer has waived bonus entitlements for 2021. Mr. Schaffer has agreed to serve as a consultant to the Issuer and its affiliates without additional compensation during the period from March 1, 2021 to June 30, 2021 to ensure a proper handover to his designated successor.

In January 2021, the Issuer entered into a service agreement with Mr. Ludwig Lutter. Simultaneously, Mr. Lutter was appointed as a member of the Issuer's management board for the period from March 1, 2021 to February 29, 2024. The service agreement has a term from March 1, 2021 to February 29, 2024. Mr. Lutter receives a fixed annual remuneration of EUR 270,000. He also receives a short-term incentive which is dependent on the achievement of annual targets. In case of target overachievement, the short-term incentive may be increased to up to 200 % of the target amount; in case of achievement of less than 70 %, the short-term incentive will not be paid at all. The target short-term incentive of Mr. Lutter amounts to EUR 135,000. Furthermore, stock appreciation rights ("SARs") as a long term incentive in a target amount of 150% of the short-term incentive target amount are granted to Mr. Lutter. SARs

cannot be exercised insofar as the gross amount from all exercised SARs would exceed the fixed remuneration by more than 300%. Mr. Lutter must invest 25% of the payments received under the SAR plan in shares of the Issuer, which they may divest no earlier than 4 years after grant of the SARs. Furthermore, Mr. Lutter must invest part of the short-term incentive to hold at least 100,000 shares of the Issuer until the expiry of the respective service agreement whereas shares acquired under the SAR plan and shares already held are offset.

After the end of the last financial period for which audited financial information have been published, i.e. 31 December 2019, the Issuer has not entered into further transactions with related parties.

# 6.8 **Dividend policy**

The Issuer has to date not made dividend payments. Considering the substantial loss carry-forward, no dividend payments are expected in the near future.

# 7. Financial Information

# 7.1 <u>Capitalization and indebtedness</u>

The following table shows the Issuer's capital as of November 30, 2020. The figures are taken from the internal controlling of the Issuer, and are unaudited.

Capitalization according to IFRS	As of November 30, 2020 in thousand EUR
Total current debt (including current portion of non-	8,325
current debt)	0,525
Guaranteed	-
Secured	-
Unguaranteed / unsecured	8,325
Total non-current debt (excluding current portion of non-current debt)	48,733
Guaranteed	-
Secured	-
Unguaranteed / unsecured	48,733
Shareholder Equity	(1,144)
a. Share capital	45,109
b. Legal reserve	119,567
c. Other Reserves (1)	(165,820)
Total	55,914

(1) loss carry-forward and accumulated losses

The following table shows the Issuer's indebtedness as of November 30, 2020. The figures are taken from the internal controlling of the Issuer.

Indebtedness according to IFRS	As of November 30, 2020 in thousand EUR
indebicaness according to it KS	As of November 50, 2020 in thousand EOK

A. Cash	16,112
B. Cash equivalent	-
C. Other current financial assets	3,325
D. Liquidity (A.+B.+C)	19,437
E. Current financial debt (including debt instruments, but excluding current portion of noncurrent financial debt)	2,006
F. Current portion of non-current financial debt	1,179
G. Current financial indebtedness (E + F )	3,185
H. Net current financial indebtedness (G - D	(16,252)
I Non-current financial debt (excluding current por- tion and debt instruments)	38,818
J. Debt instruments	9,916
K. Non-current trade and other payables	-
L. Non-current financial indebtedness (I + J + K)	48,733
M. Total financial indebtedness (H + L)	32,481

There is no indirect or contingent indebtedness.

## 7.2 Working capital statement

The Issuer is of the opinion that the working capital of Biofrontera Group is currently sufficient to meet the obligations due in the next twelve months. The proceeds expected from the Offer have not been included in the calculation of the working capital.

For the calculation of the working capital, the Issuer has counted in its working capital all amounts which it reasonably expects to be received or fall due to be paid for a minimum of the next 12 months from the date of approval of this prospectus.

# 8. Profit forecast

Due to the uncertainties associated with the COVID-19 pandemic, the Issuer has not published a profit forecast that is still outstanding and valid.

# 9. Business overview

# 9.1 <u>Principal activities</u>

Biofrontera Group is an international biopharmaceutical enterprise specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Biofrontera Group's approved products focus on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer (also "AK") in Europe and the United States, as well as the

treatment of basal cell carcinoma (also "*BCC*") in the EU. Actinic keratoses typically appear on sunexposed 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. Because of their location and appearance, actinic keratoses are often cosmetically unappealing.

Biofrontera Group's principal product is Ameluz<sup>®</sup>, which is a prescription drug approved for use in combination with photodynamic therapy (also "*PDT*" and as PDT with Ameluz<sup>®</sup> "*Ameluz<sup>®</sup> PDT*").

Ameluz<sup>®</sup> received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz<sup>®</sup>, the European Commission granted label extensions for the use of Ameluz<sup>®</sup> PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses, (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome, (iii) for treatment of actinic keratosis with Ameluz<sup>®</sup> in combination with daylight-PDT (i.e., using natural daylight to activate the drug), and (iv) for treatment of mild and moderate actinic keratosis on the extremities and trunk/neck with PDT. A major advantage of treating actinic keratosis and basal cell carcinoma with photodynamic therapy (as opposed to other common treatments such as surgery and cryotherapy) is that it is a non-invasive alternative that can have better cosmetic results, i.e., removal of tumors without leaving clearly visible scarring.

In addition, Biofrontera Group has developed its own PDT lamp, BF-RhodoLED<sup>®</sup>, for use in combination with Ameluz<sup>®</sup>. The BF-RhodoLED<sup>®</sup> lamp was approved as a medical device in the EU in November 2012 and is approved for sale in all EU countries, although the use of the BF-RhodoLED<sup>®</sup> lamp is not required to be used in combination with Ameluz<sup>®</sup> in the EU or Switzerland.

In May 2016, Biofrontera Group received approval from the U.S. Food and Drug Administration ("*FDA*"), for US marketing of Ameluz<sup>®</sup> in combination with photodynamic therapy using the BF-RhodoLED<sup>®</sup> lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Group launched the commercialization of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> for actinic keratosis in the US in October 2016.

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. Through the acquisition of Cutanea Life Sciences, Inc. in March 2019, Biofrontera was able to expand the product portfolio in the USA with the FDA-approved drug Xepi<sup>\*</sup>. Xepi<sup>\*</sup> is the first topical antibiotic in the USA that has been approved by the FDA in about 10 years. Xepi<sup>\*</sup> is approved for the treatment of impetigo. The approval also includes the treatment of infections with antibiotic-resistant bacterial strains such as MRSA. The companies of Cutanea Life Sciences, Inc. as well as Biofrontera Newderm

LLC were merged with Biofrontera Inc. at the end of the year. While Biofrontera Inc. assumes all commercial activities, Biofrontera Bioscience GmbH takes over all regulatory tasks.

# 9.2 <u>Business model / group structure</u>

Biofrontera AG assumes the holding function within Biofrontera Group. 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<sup>®</sup>. According to a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also the holder of the CE certificate of BF-RhodoLED<sup>®</sup>, 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<sup>®</sup>. The marketing and sales of Aktipak<sup>®</sup> was suspended in August 2019 until further notice due to unsolvable quality deficiencies of the batches that had been produced by a contract manufacturer on behalf of Cutanea.

Production of Ameluz<sup>®</sup> 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<sup>®</sup> 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 Group's core business and therefore currently cannot be sufficiently financed within the normal business activities. The product BF-derm1 for the treatment of severe chronic urticaria is owned by Biofrontera Development GmbH, the product BF-1 for the prophylactic treatment of migraine (without patent protection since 2009) 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<sup>®</sup> and Xepi<sup>®</sup>. 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.

### 9.3 Group strategy

The strategic goal of Biofrontera Group is to optimize the global positioning and market potential of Biofrontera's products Ameluz<sup>®</sup> and Xepi<sup>®</sup>, 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 its products and the development of further market potential through label extensions of Ameluz<sup>®</sup> as well as broader distribution of Xepi<sup>®</sup>.

Biofrontera Group has received a centralized approval for its own self-developed drug, which is marketed under the brand name Ameluz<sup>®</sup>. Since the market launch in February 2012, Biofrontera has been selling Ameluz<sup>®</sup> with its own sales force to dermatologists in Germany and since March 2015 also in Spain. Ameluz<sup>®</sup> 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 as well as in Israel and Switzerland is carried out through licensing partnerships.

A US subsidiary, Biofrontera Inc., was set up in order to market Ameluz<sup>®</sup> in the USA. The US subsidiary has established all functions and obtained all licenses required for a sales company in the pharmaceuticals and medical devices 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.

### 9.4 Products

# 9.4.1 <u>Ameluz<sup>®</sup></u>

In December 2011, Ameluz<sup>®</sup> 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 on the face and scalp. Its significant superior effect in combination with an LED lamp compared to the direct competitor product Metvix<sup>®</sup> 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<sup>®</sup> with light treatment is an innovative form of treatment that is classified as photodynamic therapy ("*PDT*").

Based on the Phase III field trial for field therapy, the European Commission also approved Ameluz<sup>®</sup> for the treatment of field cancerization following a positive vote by the EMA. In addition to its high efficacy in the removal of actinic keratoses, the results relating to the improvement of skin appearance were included in the official product information in the EU.

In May 2016, Biofrontera received approval for Ameluz<sup>®</sup> in the USA. The approved indication concerns the "lesion and field directed PDT of mild and moderate actinic keratoses on the face and scalp". As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT

lamp, the BF-RhodoLED<sup>®</sup>, and has obtained CE certification in the EU, which also required the entire company to be certified according to ISO 13485. The ISO certification was renewed regularly in 2019.

The overall advantages of Ameluz<sup>®</sup> 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 Group submitted an application for approval for daylight PDT with Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC) in March 2020.

In fall 2019, the Issuer submitted the application for label extension to the European Medicines Agency (EMA) to include the treatment of mild and moderate AK on the extremities and trunk/neck with conventional PDT using Ameluz<sup>®</sup> and the BF-RhodoLED<sup>®</sup>. Following the positive vote of the EMA in February 2020, the European Commission formally approved the label extension for Ameluz<sup>®</sup> in March 2020. Based on these results, Biofrontera has also started discussions with the US Food and Drug Administration (FDA) about a corresponding extension of the approval for Ameluz<sup>®</sup> in the USA.

# 9.4.2 <u>BF-RhodoLED<sup>®</sup></u>

BF-RhodoLED<sup>®</sup> is a lamp designed for PDT, and utilizes LEDs emitting red light at a wavelength of approximately 635 nm. Light at this wavelength, which is suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED<sup>®</sup> lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. In the European version, light energy and fan power settings can be adjusted during a PDT treatment session to reduce any pain caused by the treatment. BF-RhodoLED<sup>®</sup> has been CE-certified since November 2012 and is distributed throughout the EU. In order to distribute the lamp in the USA, the final assembly of the PDT lamp was moved to Biofrontera Group's headquarters in Leverkusen where it has been produced by Biofrontera Group since 2016. This makes Biofrontera Group the responsible manufacturer from the perspective of the authorities.

# 9.4.3 <u>Xepi<sup>®</sup></u>

The acquisition of Cutanea Life Sciences, Inc. in March 2019 has enabled Biofrontera Group to market a FDA-approved drug that has been introduced in the US market. Xepi<sup>\*</sup> (ozenoxacin cream, 1%) is a non-fluorinated quinolone that not only inhibits bacterial growth but also kills the bacteria directly. It is the first new topical antibiotic to enter the American market in 10 years. To date, no antibiotic resistance to Xepi<sup>\*</sup> is known and it has been specifically approved by the FDA for the treatment of antibioticresistant bacteria. The approved indication is impetigo, a common skin infection in children with staphylococci and streptococci. Xepi<sup>\*</sup> has an excellent safety profile that even allows for use on infants from the age of two months.

Increasing resistance to known antibiotics is a concern that is taken very seriously by American doctors. The Issuer is of the opinion that with Xepi<sup>®</sup> its portfolio now includes an innovative, promising product with a positive market potential.

The drug Xepi<sup>\*</sup> in-licensed by Biofrontera is protected by two patent families in the USA and other countries. With regard to the USA, patent protection applies for the composition of Xepi<sup>\*</sup> until January 29, 2032 and for the approved treatment of impetigo until December 15, 2029.

## 9.5 Sales and markets

The company underwent organizational restructuring at the beginning of 2020, and after the reorganization of the operational leadership of its subsidiary Biofrontera Inc., Biofrontera also announced an organizational restructuring of the sales organization in Europe.

Under the new structure, Biofrontera Group's worldwide sales organization now stands on two pillars: sales and marketing in the USA, Biofrontera Group's largest market, and a unified management of all sales activities in Europe.

# 9.5.1 <u>USA</u>

Biofrontera launched Ameluz<sup>®</sup> in the USA in October 2016. The distribution of Ameluz<sup>®</sup> in the U.S. is handled by its subsidiary Biofrontera Inc. founded in March 2015. Since then, Biofrontera's U.S. sales team has grown to over forty employees. Biofrontera's sales force is supported by four scientific consultants, Biofrontera's Market Access and Managed Markets Team as well as a Customer Service Team. In March 2019, Biofrontera acquired all shares of Cutanea Life Sciences, Inc. thereby expanding its portfolio in the USA with the FDA-approved drug Xepi<sup>™</sup>.

## 9.5.2 Germany and Europe

With its central European approval, Ameluz<sup>®</sup> 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. In these countries the drug is available at pharmacy retail prices ranging from 150 EUR to approximately 220 EUR per 2g tube.

In Europe, Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> have been marketed in Germany (since 2012), Spain (since 2015) and the United Kingdom (since May 2018) by a dedicated sales force. In other European countries, the products are distributed through distribution partners: Denmark, Sweden, Norway, Austria, Switzerland and Liechtenstein. Independent approval procedures were required in Switzerland, which were carried out by Biofrontera's local marketing partners in cooperation with Biofrontera. The licensing agreements with distributors were structured in such a way that Biofrontera has received no or only a moderate down payment and the regional partners buy Ameluz<sup>®</sup> from Biofrontera at a price that is linked to their own sales price. Depending on the market conditions of a country, Biofrontera Group's share of the sales price varies significantly and ranges between 35% and 55% of net sales. Overall, however, marketing through Biofrontera Group's own sales forces has proven to be much more successful in recent years, so that sales through distribution partners now account for only a small proportion of total sales.

### 9.5.3 Other regions

In April 2020, Biofrontera signed an exclusive licensing agreement with Maruho Co, Ltd, Osaka, Japan (Maruho) for the development and commercialization of Ameluz<sup>®</sup> for all indications in East Asia and Oceania. The agreement is described in more detail under 9.9.1.3.

#### 9.6 Research and development

All research and development activities of the Biofrontera Group regarding the nanoemulsion and Ameluz<sup>®</sup> are carried out by Biofrontera Bioscience GmbH, which is responsible for clinical studies as well as for the granting, maintenance and expansion of Biofrontera Group's 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<sup>®</sup> XL is the responsibility of Biofrontera Pharma GmbH.

Costs for the clinical studies are expected to be approx. EUR 20 million. The capital increase that is described in this Prospectus is intended to cover these costs.

# 9.6.1 <u>Phase III study for the treatment of actinic keratoses on the extremities or</u> <u>trunk/neck</u>

The study report was submitted to the European Medicines Agency (EMA), and following a positive assessment of the Committee for Medicinal Products for Human Use (CHMP) of the EMA in February 2020, the European Commission granted the formal extension of approval in March 2020.

Based on these results, Biofrontera has also started discussions with the US Food and Drug Administration (FDA) about an expanded approval of Ameluz<sup>®</sup> in the USA, to include the treatment of AK on the extremities and trunk/neck. The FDA provided positive feedback and proposed an additional clinical trial to include additional body regions into the label of the Ameluz<sup>®</sup>. The study protocol is currently being developed according to FDA guidance, with patient recruitment expected to start in the second half of 2020.

# 9.6.2 <u>Phase I pharmacokinetics study (PK study) to test the safety of PDT simultane-</u> ously using three tubes of Ameluz<sup>®</sup>

Following consultation with the FDA, Biofrontera has initiated a pharmacokinetics study (PK study) to test the safety of PDT using three tubes of Ameluz<sup>®</sup> at the same time. The aim of this phase I study is to obtain pharmacokinetic profiles following an Ameluz<sup>®</sup> PDT in patients with AK in an extended treatment area in the face/head or peripheral area. In addition, safety and tolerability for the patient during and after treatment will be investigated. The clinical phase of the study was completed in early October 2020 with the so-called "last subject last visit". The Issuer is currently completing the study report for submission to the FDA.

# 9.6.3 <u>Phase III study for the treatment of superficial basal cell carcinoma (BCC) with</u> <u>Ameluz® in combination with Biofrontera's red-light lamp BF-RhodoLED® in</u> <u>the USA</u>

To further increase Biofrontera's growth potential in the US market in the medium term, Biofrontera is currently conducting a clinical trial in the USA for the treatment of superficial basal cell carcinoma (BCC) with Ameluz<sup>®</sup> in combination with Biofrontera's BF-RhodoLED<sup>®</sup> lamp. Biofrontera has 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. Following successful FDA approval, Ameluz<sup>®</sup> would be the only drug in the United States for the treatment of superficial BCC with PDT.

# 9.6.4 <u>Development for label extension of Ameluz for the treatment of acne</u>

With respect to the potential label extension of Ameluz<sup>®</sup> for acne, 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. This will allow the study program to start in 2021 provided the Issuer has the necessary funds to do so.

# 9.6.5 <u>Development of the BF-RhodoLED<sup>®</sup> XL</u>

In 2019, Biofrontera Group developed a new lamp called BF-RhodoLED<sup>®</sup> XL. The future use of the BF-RhodoLED<sup>®</sup> XL will allow the application of Ameluz<sup>®</sup> on larger areas as well as the simultaneous exposure of several interspersed lesions. Furthermore, the BF-RhodoLED<sup>®</sup> XL will offer a significantly improved user experience with highly customizable settings. Biofrontera Group hopes thereby to increase customer acceptance, especially in the USA, and thus an increase in Ameluz<sup>®</sup> sales. Submission of the dossier for marketing approval to the FDA is expected in the first quarter of 2021. Costs for the development, procurement of parts and market introduction are expected to be approx. EUR 4 million. The capital increase that is described in this Prospectus is intended to cover these costs.

# 9.7 <u>Competition</u>

The following description of the competitive environment of Biofrontera Group is based on the estimate of the management board of Biofrontera Group.

# 9.7.1 <u>Competition in the EU</u>

### 9.7.1.1 <u>Competing PDT products</u>

There are a few other companies that are selling photodynamic therapy agents other than Ameluz<sup>®</sup> for the treatment of actinic keratoses and certain other skin conditions. Available PDT drugs for treatment of actinic keratosis in Europe include Ameluz<sup>®</sup> gel, Metvix<sup>®</sup> cream, Alacare<sup>®</sup> adhesive plaster and Luxerm<sup>®</sup> cream. Metvix<sup>®</sup> has been on the market in the EU since 2002 and is the most frequently used PDT drug for treatment of actinic keratosis throughout the EU with the exception of Germany, where Ameluz<sup>®</sup> is the leader in the PDT therapy market with over 60% market share in 2020.

### 9.7.1.2 <u>Competing treatment concepts</u>

Since March 2018, the label of Ameluz<sup>\*</sup> 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<sup>®</sup> 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 in Germany. The results of the follow-up phase of the clinical comparison study on daylight PDT with Ameluz<sup>®</sup> and Metvix<sup>®</sup>, which show significant superior efficacy compared to Metvix<sup>®</sup> one year after treatment, were included in the product information (SmPC) in March 2020.

In addition, Biofrontera Group also competes with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions. In Europe, the most commonly prescribed drugs for actinic keratosis at present are Solaraze<sup>®</sup>, Aldara<sup>®</sup> and Actikerall<sup>®</sup>.

The Issuer believes that only a small proportion of patients in the EU who could be treated with medication in combination with photodynamic therapy are currently being so treated because dermatologists in the EU favor topical prescriptions, which require the least work from medical practitioners (since no office procedure is required). In the EU, cryotherapy is not a common practice due of its limited efficacy, high recurrence rates and the lack of reimbursement. Photodynamic therapy for actinic keratosis is not reimbursed in all markets in the EU. Particularly in those countries where dermatology is mostly a hospital-based discipline, dermatologists typically treat basal cell carcinoma (and not actinic keratosis). The Issuer expects sales of Ameluz<sup>®</sup> to increase in the EU because of the higher efficacy rate demonstrated in clinical trials, better cosmetic results compared to other treatment options, the label extension of daylight PDT and the extension of indications to field cancerization and basal cell carcinoma in addition to actinic keratosis.

# 9.7.2 Competition in the US

# 9.7.2.1 Competing PDT products and other treatment options

The market for the treatment of actinic keratosis in the U.S. differs significantly from the European market. The Issuer believes this is because the U.S. reimbursement system generally has favored procedures, for which physicians get paid or reimbursed. In the U.S., the most common treatment for actinic keratosis is still cryotherapy. Simple curettage is generally not used to treat actinic keratosis in the U.S.

In the U.S., Levulan<sup>®</sup> has been approved for the treatment of minimally to moderately thick actinic keratosis of the face or scalp in combination with PDT with a blue light source since 1999. In addition, Biofrontera Group also competes with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions such as self-applied topical products similar to the ones in the EU as listed above, as well as cryotherapy with liquid nitrogen.

Because the approval for Ameluz<sup>®</sup> in the U.S. covers not only lesion-directed treatment, but also fielddirected therapy, the approval provides Biofrontera Group with the ability to provide broader treatment possibilities compared to certain competitor products.

Both Ameluz<sup>®</sup> and Levulan<sup>®</sup> are FDA-approved for the photodynamic treatment of mild-to-moderate actinic keratoses on the face and scalp, Levulan<sup>®</sup> is also approved for mild-to-moderate actinic keratosis on the upper extremities. The Ameluz<sup>®</sup> approval covers both lesion-directed and field-directed treatment, while the Levulan<sup>®</sup> approval is restricted to lesion-directed treatment. Ameluz<sup>®</sup> consist of 10% 5-aminolevulinic acid in a nanoemulsion gel formulation that can be easily applied. Levulan<sup>®</sup> is a 20% alcoholic solution that comes in a 2-compartment stick (Kerastick<sup>®</sup>), in which the two glass containers have to be broken and mixed by the doctor, followed by application with a ball point at the end of the stick. Both drugs are combination products, but with completely different lamp systems, and their labels require different posologies. While Ameluz<sup>®</sup> is applied for 3 hours under occlusion prior to a 10-minute illumination with the red-light lamp BF-RhodoLED<sup>®</sup>, Levulan<sup>®</sup> requires a 14-18-hour incubation without occlusion for the face and scalp, and a 3-hour incubation with occlusion for the upper extremities prior to a 16 minute and 40 second illumination with the blue lamp Blu-U<sup>®</sup>. Before Ameluz<sup>®</sup> application, crusts are removed and the treatment field is gently roughened, which is not done in a treatment with Levulan<sup>®</sup>.

To further increase Biofrontera Group's opportunities in the U.S. market in the future, Biofrontera Group is working on expanding the U.S. label for Ameluz<sup>®</sup> to include the treatment of AK on the extremities and trunk/neck. Biofrontera has also initiated a pharmacokinetics study (PK study) to test the safety of PDT using three tubes of Ameluz<sup>®</sup> at the same time. The aim of this phase I study is to obtain pharmacokinetic profiles following an Ameluz<sup>®</sup> PDT in patients with AK in an extended treatment area in the face/head or peripheral area. In addition, safety and tolerability for the patient during and after treatment will be investigated. To further increase the growth potential in the US market in the medium term, Biofrontera is currently conducting a clinical trial in the US for the treatment of superficial basal cell carcinoma (BCC) with Ameluz<sup>®</sup> in combination with its BF-RhodoLED<sup>®</sup> lamp. The Issuer has 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. Following successful FDA approval, Ameluz<sup>®</sup> would be the only drug in the United States for the treatment of superficial BCC with PDT.

Biofrontera Group hopes that the improved lamp BF-RhodoLED<sup>®</sup> XL, the costs of which are to be raised by the capital increase described in this Prospectus, will improve the competitive position in the USA.

# 9.7.2.2 <u>Competing products with Xepi<sup>®</sup></u>

In total, around 11 million prescriptions for drugs in indications where Xepi<sup>®</sup> may be effective are issued annually in the USA, a significant proportion of which are by dermatologists. The majority of the prescriptions are written for generic Mupirocin, a topical antibiotic with fairly high resistance throughout the US patient population. Due to Xepi<sup>®</sup>'s dual-mechanism of action and thus its superior efficacy, the Issuer sees considerable growth potential for Xepi<sup>®</sup>.

### 9.8 <u>Regulatory environment</u>

### 9.8.1 <u>European regulatory environment regarding drugs</u>

In the European Economic Area ("*EEA*") medicinal products can only be commercialized after obtaining a marketing authorization ("*MA*"). There are two types of marketing authorizations:

The Community MA, which is issued by the European Commission in the so-called Centralized Procedure, based on the opinion of the EMA Committee for Medicinal Products for Human Use (CHMP), is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union.

Biofrontera Group has received Community MA for Ameluz® in November 2011.

National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Biofrontera Group currently does not have products which are subject to National MAs.

Also after approval, stringent regulatory requirements apply at the EU/member state level.

# 9.8.2 <u>European regulatory environment regarding medical devices</u>

The advertising and promotion of Biofrontera Group's products in the EEA is subject to the provisions of the Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as national legislation in the EEA countries governing the advertising and promotion of medical devices.

Regulation (EU) 2017/745 (Medical Devices Regulation) which amended Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009and repealed Council Directives 90/385/EEC and 93/42/EEC entered into force on May 27, 2017 and will apply to all medical devices in the EEA from 27 May 2021 onwards. Originally approved medical devices will have a transitional period of four years (until 26 May 2021) to meet the new requirements. Thereafter a re-certification in line with the requirements set by the Medical Devices Regulation will be required. , The Medical Devices Regulation imposes changes in the regulatory requirements for medical devices in Europe. Such changes include, *inter alia*, stricter ex-ante control for high-risk devices via a new pre-market scrutiny mechanism with the involvement of a pool of experts at EU level; the inclusion of certain aesthetic devices which present the same characteristics and risk profile as analogous medical devices under the scope of these regulations; improved transparency through the establishment of a comprehensive EU database on medical devices and of a device traceability system based on Unique Device Identification; the reinforcement of the rules on clinical evidence, including an EU-wide coordinated procedure for authorization of multi-center clinical investigations; and increased post-market surveillance requirements for manufacturers.

In Germany, medical devices are subject to the Medical Devices Act (*Medizinproduktegesetz*), which will be replaced by the Medical Devices Law Implementation Act (*Medizinprodukte-Durchführungsgesetz*) once the Medical Devices Regulation enters into full force. In addition, the advertising and promotion of medical products can also be subject to restrictions provided by the German Act Against Unfair Competition (Gesetz gegen den unlauteren Wettbewerb) and the law on the advertising of medicines (Heilmittelwerbegesetz), criminal law, and some codices of conduct with regard to medical products and medical devices among others. These laws may limit or restrict the advertising and promotion of medical products to the general public and may impose limitations on Biofrontera Group's promotional activities with healthcare professionals.

In the EEA, Biofrontera Group is required to obtain so-called Certificates of Conformity before drawing up an EC Declaration of Conformity and affixing the CE Mark of conformity to medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval (see below) although others, such as Brazil, Canada and Japan require separate regulatory filings.

# 9.8.3 <u>US regulatory environment regarding drugs</u>

Any drug products for which Biofrontera Group receives FDA approvals – at this time, Ameluz<sup>®</sup> in combination with its red-light lamp BF-RhodoLED<sup>\*</sup> - are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include,

among other requirements, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "offlabel use"), limitations on industry sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval. Biofrontera Group is relying exclusively on manufacturing partner's facilities for the production of clinical and commercial quantities of Biofrontera Group's products in accordance with cGMP regulations, which has not yet been cGMP approved. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented and development of and submission of data to support the change. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, as well as, possibly, the development and submission of data to support the change.

The FDA also may require post-approval trials and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of Biofrontera's product label extensions or products under development.

## 9.8.4 <u>US regulatory environment regarding medical devices</u>

After a medical device is placed on the market in the US, regardless of its classification or premarket pathway, numerous regulatory requirements apply. These include:

- establishing establishment registration and device listings with the FDA;
- Quality System Regulation, or QSR, which requires manufacturers, including third party manufacturers and certain other parties, to follow stringent design, testing, process control, documentation, CAPA, complaint handling and other quality assurance procedures, as applicable;
- labeling statutes and regulations, which prohibit the promotion of products for uncleared or unapproved, or off-label, uses and impose other restrictions on labeling;
- clearance or approval of product modifications that could affect safety or effectiveness or that would constitute a change in intended use;
- medical device reporting regulations, which require that manufacturers report to the FDA if an event reasonably suggests that their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the same or a similar device of the manufacturer were to recur;;
- corrections and removals reporting regulations, which require that manufacturers report to the
  FDA field corrections and product removals if undertaken to reduce a risk to health posed by the
  device or to remedy a violation of the FDCA, that may present a risk to health. In addition, the
  FDA may order a mandatory recall if there is a reasonable probability that the device would cause
  serious adverse health consequences or death; and
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish additional safety or efficacy data.

The FDA has broad post-market and regulatory enforcement powers. The agency may conduct announced and unannounced inspections to determine compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of subcontractors. Failure by Biofrontera Group or its suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions and related consequences

### 9.9 <u>Recent developments</u>

### 9.9.1 Ad-hoc disclosures during the last 12 months

### 9.9.1.1 Sales development in 2020

In the first half of 2020, Biofrontera Group generated total revenue of EUR 16.0 to 16.2 million, which corresponds to an increase of about 16% compared to EUR 13.9 million in the same period of 2019. Total revenue includes a EUR 6.0 million up-front payment received from Maruho Co., Ltd. Biofrontera Group generated revenue from product sales between EUR 9.5 to 9.7 million, a decrease of about 30% compared to the first half of 2019. Sales revenue in the U.S. were between EUR 6.3 and 6.4 million, compared to EUR 10.2 million, a decrease of about 38%, in the same period in 2019 (numbers are unaudited and excerpted from the half-year financial report 2020).

In the third quarter of 2020, Biofrontera Group generated total preliminary unaudited revenue of approximately EUR 20.8 to 21.0 million in the period from January 1st to September 30th, 2020. This corresponds to revenue growth of about 9% compared to the same period last year (EUR 19.1 million). Despite the economic and social impact of the corona pandemic, product sales in the German market increased significantly compared to 2019. Revenues in the United States were negatively affected, where the crisis continues to have a much stronger impact on the market (numbers are unaudited and taken from the Issuer's internal accounting).

For the period January 1 to December 31, 2020, revenues of Biofrontera Group were in the range of approx. EUR 30.3 million to EUR 30.6 million (compared to EUR 31.3 million in 2019). Revenues from product sales in the US were around EUR 16.6 million, compared to EUR 23.3 million in 2019 (-29%). In Germany, revenues from product sales amounted to approximately EUR 5.2 million, compared to EUR 4.6 million in fiscal year 2019 (+13%). In the rest of Europe, Biofrontera Group generated product sales of around EUR 2.1 million, compared to EUR 2.6 million in 2019 (-18%) (numbers are unaudited and taken from the Issuer's internal accounting).

The 2020 financial year was dominated by the economic and social impacts of the Corona pandemic. The decline in US sales in particular was due to the development of the crisis situation there.

### 9.9.1.2 <u>Financing measures</u>

The Issuer had announced that it would propose an ordinary capital increase to the general meeting (which is subject to this Prospectus). In addition, the Issuer had announced to issue two mandatory convertible bonds in a total amount of EUR 8,000,000 in March 2020. However, due to the negative effects of the COVID-19 pandemic on the capital markets, the Issuer withdrew the offer of the bonds.

The Issuer then offered a mandatory convertible subordinated bond in August 2020, which was placed in full in an amount of EUR 7,914,450. In November 2020, the Issuer resolved to convert the bonds.

# 9.9.1.3 International distribution

With respect to the commercialization of Ameluz<sup>®</sup> in East Asia and Oceania, Biofrontera Group entered into a licensing agreement with Maruho in April 2020. The Agreement has a term of 15 years from the start of distribution in each country covered under the Agreement. Under the terms of the agreement, Maruho will obtain exclusive development and commercialization rights including the right to sublicense Ameluz<sup>®</sup> in East Asia and Oceania and Maruho is, with the consent of Biofrontera, entitled to carry out its own research and development within the scope of the license. Maruho will grant to Biofrontera a free and unlimited license for the results of such research and development activities for commercialization outside the territory. Under the terms of the agreement, Biofrontera will supply Ameluz<sup>®</sup> to Maruho at external costs plus 25%, while Maruho has an obligation to use commercially reasonable efforts to develop, approve and market Ameluz<sup>®</sup> in East Asia and Oceania. Upon signing of the licensing agreement in April 2020, Maruho made an upfront payment to Biofrontera AG in the amount of EUR 6 million plus additional future payments subject to achievement of certain regulatory and sales milestones. Maruho will also make royalty payments at an initial rate of 6% of net sales in the countries of the territory, which will increase depending on sales volume and will be reduced should generic products become available in the respective countries.

Furthermore, in March 2020, the Issuer signed a non-binding term sheet for an exclusive license agreement with medac GmbH Sp. z o.o., the Polish branch of medac Gesellschaft für klinische Spezialpräparate mbH, for the marketing of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in Poland. The term sheet contains terms and conditions regarding the amount of the one-time upfront payment of around EUR 200,0000, the term of approximately 5 years, the transfer price for Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> as well as local regulatory responsibilities in Poland.

### 9.9.1.4 Litigation / Mediation process with Deutsche Balaton Group

The shareholder's meeting of the Issuer of May 28, 2020 resolved to increase the share capital of the issuer by issuing the New Shares. A shareholder had filed an action to declare this resolution null and void (see 9.13.7). However, the Issuer has successfully pursued a release procedure pursuant to Section 246a German Stock Corporation Act before the Higher Regional Court of Cologne which on January 7, 2021 ruled in favor of the Issuer and declared that the pending contestation action against the resolution does not prevent the registration of the resolution and the corresponding capital increase in the commercial register.

In September 2020, Biofrontera Group announced that it has entered into a mutual agreement with Mr. Wilhelm K.T. Zours and Deutsche Balaton AG on the key elements of a mediation agreement. Within the framework of the mediation process, a mediator will be called in to find solutions for the settlement of disputes as well as disagreements on personnel and strategic corporate matters.

### 9.9.2 <u>Recent trends since the end of the last fiscal year</u>

(All financial information in the following paragraph is unaudited and excerpted from the Issuer's unaudited half-year report for the first six months of 2020).

For the period from the end of the last fiscal year (December 31, 2019) until the date of this prospectus, the following trends have influenced the Issuer and Biofrontera Group, and are expected to influence the prospects of the Issuer and Biofrontera Group for the ongoing financial year.

During the first six months of 2020, the business performance of Biofrontera Group was mixed. At the beginning of the year, Biofrontera Group was initially able to record a solid sales performance. In addition, Biofrontera Group successfully reorganized the global sales structure, from which Biofrontera Group expected a further acceleration of sales growth in the short term. Since mid-March Biofrontera Group have had to accept declining sales figures, particularly in the USA, due to the dynamic development of the COVID-19 pandemic. Biofrontera Group were therefore forced to implement company-wide cost reduction measures.

The Biofrontera Group generated total revenues of EUR 16.1 million in the period between January 1 and June 30, 2020, an increase of 16% compared to EUR 13.9 million revenues in the same period of the previous year. Total revenues include a onetime payment of EUR 6.0 million, which the company received from Maruho Co., Ltd. under the licensing agreement signed on April 20, 2020. Revenues from product sales amounted to EUR 9.7 million, a decline of 30% compared to the first half of 2019, with revenues in the second quarter being strongly influenced by the effects of the global coronavirus crisis.

As already described, the coronavirus crisis has led to a decreasing number of treatments and thus to a sharp drop in sales in Biofrontera Group's most important market, the USA. On March 20, 2020, the Issuer announced that it would take comprehensive cost reduction and control measures during the COVID-19 pandemic.

Consequently, Biofrontera Group had introduced short-time work for all employees in Germany until the end of July 2020. Similar measures were implemented for the subsidiaries in Spain and the UK. Biofrontera Inc, the wholly owned subsidiary in the USA, also introduced significant cost reduction measures. There, as already described above, the number of employees was significantly reduced and a furlough program was implemented, under which all employees were obliged to take temporary unpaid leave. In addition, the members of the Management Board of the Issuer and the management of Biofrontera Inc. voluntarily agreed to waive a substantial portion of their salaries. While these cost reduction measures were in effect, the Company was able to ensure full compliance with all regulatory requirements in both financial and medical terms, and to meet all disclosure obligations at all times. The continued uncertain business outlook due to the COVID-19 crisis has impacted the valuation of certain of the Company's assets and liabilities. Reduced sales of Xepi<sup>TM</sup> have led to a different assessment of the medium-term business and profit outlook for Xepi<sup>TM</sup> and thus, in the first quarter of 2020, to a re-evaluation of both the balance sheet value of the Xepi<sup>TM</sup> license and the purchase price liability to Maruho.

This has caused a substantial change of the financial and earnings situation of the Issuer and Biofrontera Group, since the date of the last reporting period which was covered by audited financial information (i.e. December 31, 2019).

### 9.9.3 Corporate developments after the last audited financial reports

### 9.9.3.1 Label extension for AK on extremities and trunk/neck

In fall 2019, the company submitted the application for label extension to the European Medicines Agency (EMA) to include the treatment of mild and moderate AK on the extremities and trunk/neck with conventional PDT using Ameluz<sup>®</sup> and the BF-RhodoLED<sup>®</sup>. Following the positive vote of the EMA in February 2020, the European Commission formally approved the label extension for Ameluz<sup>®</sup> in March 2020.

## 9.9.3.2 <u>Comparative daylight PDT results</u>

In addition to the EU-label extension for Ameluz<sup>®</sup> described above, the results of the follow-up phase of the clinical comparison study on daylight PDT with Ameluz<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC) in March 2020. The significantly lower recurrence rates of Ameluz<sup>®</sup> in comparison to the competitor products Metvix<sup>®</sup> and Luxerm<sup>®</sup> again document the superior efficacy of Biofrontera's product.

### 9.9.3.3 <u>Reorganization of sales structures</u>

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

### 9.9.3.4 <u>Clinical updates</u>

Since January 2020, the first patients enrolled in the pharmacokinetics study in the US were treated to evaluate the safety of PDT using three tubes of Ameluz<sup>®</sup>. This study is a prerequisite for the treatment of larger body areas with several tubes of Ameluz<sup>®</sup> and aligning reimbursement modalities with those of the competitor product. Following a temporary interruption of the study, patient screening has already been resumed following the first relaxation of the contact ban in the USA. The company has also been working diligently to complete the development and the application for approval of the new BF-RhodoLED<sup>®</sup> XL lamp, which enables the application of Ameluz<sup>®</sup> on larger areas. And Biofrontera is continuing to pursue patient recruitment in the phase III study for the treatment of basal cell carcinoma with Ameluz<sup>®</sup> in the United States.

# 9.9.3.5 <u>Material changes in financial position</u>

On July 27, 2020, Biofrontera AG announced the issuance of up to 2,638,150 1.00% qualified subordinated mandatory convertible bonds 2020/2021 ("Bonds") with pre-emptive subscription rights for shareholders. The subscription price was set at 100% of the nominal value, corresponding to EUR 3.00 per Bond. On August 18, 2020, the company announced that all of the Bonds would be placed. The gross proceeds from the capital measure amounted to EUR 7.9 million.

Since the date of the last interim financial information published by the Issuer (i.e. June 30, 2020), no further material changes have occurred in the financial position of the Issuer or Biofrontera Group.

### 9.9.3.6 <u>Considerations regarding alternative financing options</u>

Biofrontera Group is currently looking for alternative financing measures in addition to the capital increase described in this prospectus. The management is in particular reviewing the feasibility of distribution joint ventures or independent investments on entity or project or local levels, including the United States. At the time of this prospectus, however, no discussions with third parties have been held, nor have any specific decisions been taken.

### 9.10 Intellectual Property

The most relevant intellectual properties relate to the Biofrontera brand, the Ameluz<sup>®</sup> technology and brand, and the Belixos<sup>®</sup> technology and brand:

### 9.10.1 Biofrontera brand

The Biofrontera brand is protected by the following word- and figurative marks:

The Biofrontera brand is protected by the following word- and figurative marks:

Trademark	Biofrontera® (word mark)
Registration number	DE 30656877
Registration date (DE)	20.10.2006
Protection period (DE)	30.09.2026
Classes (DE)	1, 5, 35, 42, 44, 45
Registration number of the international registration (WO)	IR 935601 (classes: 01, 05, 42, 44)
Registration date of the international registration (WO)	09.03.2007
Protection period of the international registration (WO)	09.03.2027
National registrations (CL)	Chile (classes: 01, 05)
Protection period of the national registration (CL)	24.06.2028, 28.11.2027
Granted	Armenia, Australia, Chile, China, European Union, Germany, Islamic Republic of Iran, Japan, Norway, Russian Federation, Singapore, Re- public of Korea, Switzerland, Syrian Arab Republic, USA

Trademark	Biofrontera (figurative mark)
Registration number	DE 302010066561
Registration date (DE)	04.03.2011
Protection period (DE)	31.10.2030
Classes (DE)	01, 05, 35, 42, 44, 45
Registration number of the international registration (WO)	IR 1075749 (classes: 05)
Registration date of the international registration (WO)	06.04.2011
Protection period of the international registration (WO)	06.04.2021
Granted	Armenia, Australia, China, European Union, Germany, Islamic Repub- lic of Iran, Japan, Norway, Russian Federation, Singapore, Republic of Korea, Switzerland, Syrian Arab Republic, USA

Trademark	Biofrontera (figurative mark)
Registration number (EM)	EM 000927921
Registration date (EM)	08.12.1999
Protection period (EM)	11.09.2028
Classes (EM)	05, 35, 42

Trademark	Biofrontera (figurative mark)
Registration number (CH)	(Swiss Trademark) P-467208
Registration date (CH)	30.11.1999
Protection period (CH)	06.10.2028
Classes (CH)	05, 35, 42

# 9.10.2<u>Ameluz<sup>®</sup> IP</u>

Ameluz<sup>®</sup> and the underlying technology is protected by the following marks and patents:

Trademark	AMELUZ <sup>®</sup> (word mark)
Registration number	DE 302008040753
Registration date (DE)	14.11.2008
Protection period (DE)	30.06.2028
Classes (DE)	05
Registration number of the international registration (WO)	IR 1031222 (classes: 05)
Registration date of the international registration (WO)	23.12.2009
Protection period of the international registration (WO)	23.12.2029
Granted	Armenia, Australia, Canada, China, European Union, Germany, Islamic Republic of Iran, Israel, Liechtenstein, Norway, Russian Federation, Singapore, Republic of Korea, Switzerland, Syrian Arab Republic, USA

Trademark	BF-RhodoLED <sup>®</sup> (word mark)
Registration number	DE 302011056690
Registration date (DE)	24.01.2012
Protection period (DE)	31.10.2021
Classes (DE)	10
Registration number of the international registration (WO)	IR 1113422 (classes: 10)
Registration date of the international registration (WO)	16.02.2012
Protection period of the international registration (WO)	16.02.2022
National registrations	Israel, Canada
Granted	Armenia, Australia, Canada, China, European Union, Germany, Islamic Republic of Iran, Israel, Japan, Liechtenstein, Norway, Russian Federa- tion, Singapore, Republic of Korea, Switzerland, Syrian Arab Republic, USA

Trademark	RHODOLED <sup>®</sup> (word mark)
Registration number	DE 302011056689
Registration date (DE)	24.01.2012
Protection period (DE)	31.10.2021
Classes (DE)	10
Registration number of the international registra- tion (WO)	IR 1111189 (classes: 10)
Registration date of the international registration (WO)	16.02.2012
Protection period of the international registration (WO)	16.02.2022
National registrations	Israel, Canada
Granted	Armenia, Australia, Canada, China, European Union, Germany, Is- lamic Republic of Iran, Israel, Japan, Norway, Russian Federation, Singapore, Republic of Korea, Syrian Arab Republic, USA

Trademark	Nanoxosan <sup>®</sup> (word mark)
Registration number	DE 302009017727
Registration date (DE)	09.10.2009
Protection period (DE)	31.03.2029
Classes (DE)	01, 03, 05
Registration number of the international registra- tion (WO)	IR 1027173 (classes: 01, 03, 05)
Registration date of the international registration (WO)	12.11.2009
Protection period of the international registration (WO)	12.11.2029
Granted	Austria, Germany, Switzerland

Trademark	BF-200 ALA® (word mark)
Registration number	DE 302008017906
Registration date (DE)	31.07.2008
Protection period (DE)	17.03.2028
Classes (DE)	01, 03, 05
Registration number of the international registra- tion (WO)	IR 998636 (classes: 01, 03, 05)
Registration date of the international registration (WO)	09.09.2008
Protection period of the international registration (WO)	09.09.2028
Granted	Austria, Germany, Switzerland

Trademark	Dynala <sup>®</sup> (word mark)
Registration number	DE 302008040755
Registration date (DE)	14.11.2008
Protection period (DE)	30.06.2028
Classes (DE)	05
Granted	Germany

Trademark	Lumixeen <sup>®</sup> (word mark)
Registration number	DE 302008040756
Registration date (DE)	14.11.2008
Protection period (DE)	30.06.2028
Classes (DE)	05
Granted	Germany

Patent (application)	Nanoemulsion (used in "Ameluz®")
International PCT application through WIPO	
(based on an European Patent Office application)	
PCT application number	PCT/EP2007/011404
PCT application filing date	21.12.2007
Priority	22.12.2006
Priority number	EP 06026698
Patents granted (end of protection 21.12.2027)	European Patent (Switzerland/Liechtenstein, Germany, Spain, France, United Kingdom, Italy) Australia, Belarus, Canada, Chile, China, Hong Kong, Israel, Japan, Mexico, New Zealand, Russian Federation, Singapore, Ukraine,
Patent applications pending	South Africa USA

Patent application	Photodynamic therapy comprising two light exposures at different wavelengths
International PCT application through EPO	
PCT application number	PCT/EP2018/072823
PCT application filing date	23.08.2018
Priority	23.08.2018
Status	International application filed, all PCT member states designated.
	International publication published with international search report on 27.02.2020 (publication number WO 2020/038583 A1)

Patent application	Illumination for photodynamic therapy
International PCT application through EPO	
PCT application number	PCT/EP2019/064642
PCT application filing date	05.06.2019
Priority	05.06.2019
Status	International application filed, all PCT member states designated.
	International publication published with international search report on 10.12.2020 (publication number WO 2020/244751 A1).
	National phase in USA entered.

Patent application	Illumination device for photodynamic therapy, method for treat- ing a skin disease and method for operating an illumination de- vice
Patent application through USPO	
US application number	17/071,496
US application filing date	15.10.2020
Priority	15.10.2020
Status	US patent application filed.

# 9.10.3<u>Belixos<sup>®</sup> IP</u>

The Belixos brand is protected by the following word- and figurative marks:
Trademark	Belixos <sup>®</sup> (word mark)
Registration number	DE 302009060491
Registration date (DE)	31.03.2010
Protection period (DE)	31.10.2029
Classes (DE)	03, 05
Registration number of the international registra- tion (WO)	IR 1033935 (classes: 03)
Registration date of the international registration (WO)	10.02.2010
Protection period of the international registration (WO)	10.02.2030
National registrations	Brazil, Lebanon
Granted	Brazil, Lebanon, European Union, Germany, Switzerland
Pending	

Trademark	Belixos <sup>®</sup> (word mark)
Registration number	DE 302008040757
Registration date (DE)	14.11.2008
Protection period (DE)	30.06.2028
Classes (DE)	05
Registration number of the international registra- tion (WO)	IR 1007314 (classes: 05)
Registration date of the international registration (WO)	27.05.2009
Protection period of the international registration (WO)	27.05.2029
National registrations	Canada
Granted	Armenia, Australia, Canada, China, European Union, Germany, Is- lamic Republic of Iran, Japan, Norway, Russian Federation, Singa- pore, Republic of Korea, Switzerland, Syrian Arab Republic

Trademark	Natural heritage with herbal biocolloids (colored) (figurative mark)
Registration number	EM 012224192
Registration date (EM)	11.03.2014
Protection period (EM)	15.10.2023
Classes (EM)	03, 05, 10
Registration number of the international registra- tion (WO)	IR 1206693 (classes: 03)
Registration date of the international registration (WO)	09.04.2014
Protection period of the international registration (WO)	09.04.2024
Granted	Australia, European Union, Japan, Russian Federation, Singapore, Switzerland

Trademark	Natural heritage with herbal biocolloids (gray) (figurative mark)
Registration number	EM 012224218
Registration date (EM)	11.03.2014
Protection period (EM)	15.10.2023
Classes (EM)	03, 05, 10
Registration number of the international registra- tion (WO)	IR 1210184 (classes: 03)
Registration date of the international registration (WO)	09.04.2014
Protection period of the international registration (WO)	09.04.2024
Granted	Australia, European Union, Japan, Russia, Singapore, Switzerland

Trademark	Gefühlt mir <sup>®</sup> (word mark)
Registration number	EM 012224267
Registration date (EM)	11.03.2014
Protection period (EM)	15.10.2023
Classes (EM)	03, 05, 10
National registrations	Switzerland (class 03)
Granted	European Union, Switzerland

# 9.10.4<u>Migraine IP</u>

The migraine related product candidate BF-1 is protected by the following IP:

Patent	Derivatives of 4-(thio- or selenoxanthene-9-ylidene)-piperidine or ac- ridine and its use as a selective 5- $HT_{2B}$ receptor antagonist
US application number	10/281,415
US application date	25.10.2002
Priority	25.10.2001
Priority number	US Provisional Application No. 60/343,817
Patent granted (end of protection 25.10.2022)	USA

Patent	Salt polymorph of thioxanthene-9-ylidene-1-methyl piperidine acid addition salts as antimigraine compounds
International PCT application through WIPO	
PCT application number	PCT/EP2013/052060, PCT/EP2014/051863
PCT application filing date	01.02.2013, 31.01.2014
Priority	01.02.2013
Priority number	PCT/EP2013/052060
Patents granted (end of protection 31.01.2034)	European patent (Germany, Spain, France, United Kingdom, Italy), USA

# 9.10.5<u>Aktipak<sup>®</sup>brand</u>

Aktipak<sup>®</sup> is protected by the following US word and figurative marks held by Biofrontera:

Trademark	Aktipak <sup>®</sup> (word mark)
Registration number (US)	5324789
Registration date (US)	31.10.2017
Classes (US)	05
Granted	US

Trademark	Aktipak (figurative mark)
Registration number (US)	5448116
Registration date (US)	17.04.2018
Classes (US)	05
Granted	US

### 9.10.1 <u>Xepi<sup>®</sup> brand</u>

Xepi<sup>®</sup> is protected by the following word and figurative marks held by the licenser Ferrer Internacional S.A.:

Trademark	Xepi <sup>®</sup> (word mark)
Registration number (US)	6118384
Registration date (US)	04.08.2020
Classes (US)	05
Granted	US

Trademark	Xepi (figurative mark)
Registration number (US)	5699059
Registration date (US)	12.03.2019
Classes (US)	05
Granted	US

### 9.11 Material Agreements

### 9.11.1 Manufacturing agreements

Biofrontera Pharma GmbH and Glaropharm AG ("**Glaropharm**") have entered into a manufacturing agreement dated October 4, 2017, for the contract manufacturing and delivery of Ameluz<sup>®</sup> and Belixos<sup>®</sup>, pursuant to which Glaropharm agreed to produce the products according to a quality assurance agreement concluded between the two parties and guarantees that the products are manufactured in accordance with the rules and regulations of Switzerland, the United States and the European Union and that Glaropharm has all the necessary permits and licenses required for manufacturing. Biofrontera

Pharma GmbH is largely dependent on Glaropharm to produce the products, but Biofrontera is under no fixed obligation to commission specific quantities. The contract provides for a limitation of Glaropharm's liability in the amount of CHF 10 million per claim. The agreement may be terminated with 12 months' notice, initially with effect of December 31, 2022, or for good cause without notice period. The agreement is subject to Swiss law.

Biofrontera Pharma GmbH has an agreement with Midas Pharma GmbH ("**Midas**") to obtain 5-aminolevulinic acid hydrochloride (5-ALA), the active pharmaceutical ingredient contained in Ameluz<sup>®</sup>. Midas, located in Germany, relies on a sub-contractor, located in Italy, to manufacture the 5-ALA that it supplies to Biofrontera Group. 5-ALA provided by Midas is approved for use in the U.S. and the European Union. Pursuant to Biofrontera Pharma GmbH's contract with Midas, Midas supplies, upon request by Biofrontera Pharma GmbH, the volumes of 5-ALA that Biofrontera Pharma GmbH requires according to pre-agreed specifications. Under the agreement, Biofrontera Pharma GmbH obliged to commission a fixed high percentage of its annual purchasing requirements of the 5-ALA during the initial contractual period ending 31 December 2021. After this period, Biofrontera is obliged to purchase no less than certain minimum quantities per calendar year. The agreement with Midas has an initial term until December 31, 2021, and automatically renews for further two-year periods, unless terminated with six months' notice. The agreement may be terminated for good cause without notice period. The agreement is subject to German law.

### 9.11.2 EIB Credit Facility

On 19 May 2017, the Issuer entered into a finance contract with the European Investment Bank (EIB) ("*EIB Credit Facility*"), whereby EIB has committed to lend an amount of up to EUR 20 million to the Issuer. The loan terms of the EIB Credit Facility specify that the amounts drawn shall be used to finance up to approximately 50% of specified research and development expenses forecast to be made by Biofrontera Group between 2017 and 2020. The key terms of the EIB Credit Facility, as last amended on 28 July 2020, are as follows:

The EIB Credit Facility could be drawn in tranches of at least EUR 5 million, each of which matures 5 years from the scheduled date of disbursement for the relevant tranche. The final availability date for the EIB Credit Facility was 19 May 2020. At the date of this Prospectus, the Issuer has drawn tranches in a total amount of EUR 15 million. The remaining tranche of EUR 5 million has expired and can no longer be drawn.

The EIB Credit Facility provides for three interest components to be paid by the Issuer: (i) quarterly floating interest payments based on a rate per annum equal to EURIBOR plus 4.00%; (ii) deferred interest payable in full on the maturity date of the relevant tranche (or on any earlier date in the event of a prepayment or an acceleration of all or part of that tranche), which accrues at a rate of 6.0% per annum;

(iii) performance participation interest payable in full on the maturity date of the relevant tranche (or on any earlier date in the event of a prepayment or an acceleration of all or part of that tranche), in an amount equal to the product of (x) the percentage that EIB would hold in the shares of the Issuer if EIB had acquired shares at the disbursement date of the respective tranche instead of granting the loan (no-tional equity proportion) multiplied by (y) the Issuer's market capitalization on the maturity date of the respective tranche. For the first tranche drawn down by the Issuer in an amount of EUR 10.0 million, the notional equity proportion is 0.64%; for the second tranche drawn down by the Issuer in an amount of EUR 5.0 million, the notional equity proportion is 0.20 %. This last component effectively reflects the increase in value that an equity investment in an equal amount of the debt investment by EIB would have had).

On 6 July 2022, the Issuer will be required to repay the EUR 10.0 million principal amount, plus EUR 3 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in market capitalization between disbursement and maturity of the loan. On 3 February 2024, the Issuer will be required to repay another principal amount of EUR 5.0 million, plus EUR 1.5 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in the Issuer's market capitalization between disbursement and maturity of the loan.

The EIB Credit Facility provides for certain covenants. In particular, the Issuer may generally not incur additional third-party debt of more than EUR 1 million without EIB's consent. Furthermore, the Issuer has – inter alia – agreed to refrain from granting securities, loans and guarantees as well as from disposing of assets or subsidiaries or changing its business. The Issuer is further under an obligation to report on the research to be financed by the EIB Credit Facility.

In certain events of default, EIB may request an immediate repayment of the EIB Credit Facility. The Issuer's financial obligations under the EIB Credit Facility are guaranteed by the material subsidiaries of the Issuer at the time, namely Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH and Biofrontera Inc. by way of a separate guarantee agreement. The EIB Credit Facility is governed by the laws of England and Wales.

### 9.11.3 Acquisition of Cutanea Life Sciences, Inc., USA

On March 25, 2019, Biofrontera Inc. entered into an Agreements to acquire all shares in Cutanea Life Sciences, Inc., USA through its subsidiary Biofrontera Newderm LLC as the acquirer, with Maruho Co., Ltd., Japan, as the seller. Under the share purchase agreement and its ancillary agreements, the aim of the acquisition of Cutanea by Biofrontera is to effectively exploit the sales potential of AKTIPAK<sup>®</sup> and XepiTM in the USA. Any rights in Cutanea's existing research and development activities originated from Maruho will remain with Maruho. Any other rights in Cutanea's other research and development

activities will be transferred to Maruho during a transition time. Maruho will provide up to 7.3 million US dollars to start financing the commercialization of the two new drugs in Biofrontera's portfolio. Maruho will also indemnify Biofrontera and Cutanea, respectively, from all existing liabilities and will bear any costs of the operational business of Cutanea in the first three months after the acquisition. Biofrontera will use its experience and expertise as well as its sales structure already successfully operating in the USA for the future successful marketing of AKTIPAK<sup>®</sup> and XepiTM. Biofrontera acquires Cutanea for an initial purchase price of 1.00 US dollar. The profits from the sale of AKTIPAK<sup>®</sup> and XepiTM, shown after deduction of all costs, will in the future be split between Maruho and Biofrontera, whereby Biofrontera guarantees Maruho as a further purchase price payment until 31 December 2023 a sum in the amount of the start-up costs. Thereafter, profits will be distributed equally. Due to problems in manufacturing Biofrontera has discontinued all activities with AKTIPAK<sup>®</sup>, all costs resulting from this discontinuation were born by Maruho. As of the date of this prospectus, Maruho has provided the full amount of 7.3 million US dollars of start-up costs to Biofrontera Group, of which Biofrontera Group must repay an amount of 3.6 million US dollars until December 31, 2022, and an amount of 3.7 million US dollars until December 31, 2023.

### 9.12 Investments

No significant investments in property, plant and equipment were made after the date of the most recently published accounts (i.e. 31 December 2019). The Issuer has not resolved on specific material investments at the date of this prospectus.

#### 9.13 Legal and arbitration proceedings

During the 12 months prior to the date of this Prospectus, the following legal proceedings which had significant effects on the Issuer and/or Biofrontera Group's financial position or profitability took place. No other governmental, legal or arbitration proceedings (including any such proceedings which are pending or threatened of which the Issuer is aware) have nor have had in the past 12 months any significant effects on the Issuer and/or Biofrontera Group's financial position or profitability.

### 9.13.1 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 none-theless denying institution of the review petitions because the PTAB disagreed on the remainder of claims.

DUSA has asserted considerable claims for damages in these proceedings. However, the Company considers these to be unfounded and unsubstantiated.

Biofrontera Group has incurred, and expects to continue to incur, significant expenses in defending these claims, and expects to have to divert significant employee resources, including management resources, to defend the claims.

### 9.13.2 Biofrontera v. DUSA

In July 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. 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. Though the court has dismissed Biofrontera Group's claims related to DUSA's sampling and pricing practices, 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.

### 9.13.3 Biofrontera v. Deutsche Balaton AG 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.

### Deutsche Balaton AG v. Biofrontera AG - Special Audit Request

In 2017, Deutsche Balaton AG had filed an application for a special audit (*Sonderprüfung*) with the Cologne Regional Court (*Landgericht*), Germany, to investigate the contractual situation with Maruho Co. Ltd., Japan and related matters. The special audit request was rejected by the Cologne Regional Court in November 2017. Deutsche Balaton AG filed an appeal against the rejection, which was dismissed by the Cologne Higher Regional Court (*Oberlandesgericht*) by order on July 31, 2019. DELPHI Unternehmensberatung AG, which indirectly holds the majority of the shares of Deutsche Balaton AG, filed an identical application for a special audit with the Cologne Regional Court in January 2018. These

proceedings were suspended until the Cologne Higher Regional Court had ruled on the appeal by Deutsche Balaton AG. Meanwhile DELPHI Unternehmensberatung AG has withdrawn its application. Both legal proceedings were thus terminated in favour of Biofrontera AG.]

### 9.13.4 Deutsche Balaton AG v. Biofrontera AG – General Meeting 2017

In June 2017, the Issuer was served with a claim for rescission and nullification (*Anfechtungs- und Nichtigkeitsklage*) by its shareholder Deutsche Balaton AG, which sued for nullification of certain resolutions of Issuer's annual general meeting held on May 24, 2017. The lawsuit was dismissed by Cologne Regional Court (*Landgericht*) in December 2017. On appeal by Deutsche Balaton AG, the Cologne Higher Regional Court granted the action in November 2018. The Cologne Higher Regional Court did not allow a review of its ruling by the Federal Supreme Court. Since the Issuer considers the ruling of the Cologne Higher Regional Court to be incorrect, it filed an appeal against the decision with the Federal Supreme Court (*Bundesgerichtshof*), which was granted in May 2020. With regard to agenda item 6 (creation of authorized capital), an application for release (*Freigabeantrag*) was filed with the Cologne Higher Regional Court (*Oberlandesgericht*) in 2020. The Cologne Higher Regional Court dismissed the application for release on July 9, 2020.

In its reasons for the decision, the Cologne Higher Regional Court assumed that the Management Board had violated the requirement of equal treatment of shareholders in connection with a capital increase carried out in October/November 2016 in a severe and unequivocal manner. The German Federal Supreme Court has, by decision dated 22 September 2020, determined that the violation of law assumed by the Cologne Higher Regional Court has not occurred. The Federal Supreme Court annulled the judgment of the Cologne Higher Regional Court and referred the matter back to the Cologne Higher Regional Court for a new hearing and decision.

### 9.13.5 Deutsche Balaton AG v. Biofrontera AG – General Meeting 2018

Deutsche Balaton AG has further brought a claim for rescission and nullity (*Anfechtungs- und Nichtigkeitsklage*) against the following rejecting of the Issuer's annual general meeting held on July 11, 2018: 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 declarative resolution action (*positive Beschlussfeststellungsklage*) 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 declarative resolution action (*positive Beschlussfeststellungsklage*) 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 (*Anfechtungs- und Nichtigkeitsklage*) 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.

### 9.13.6DELPHI Unternehmensberatung AG v. Biofrontera AG – General Meeting 2019

DELPHI Unternehmensberatung AG, Heidelberg, filed an action for rescission and annulment (*Anfechtungs- und Nichtigkeitsklage*) against resolutions of the annual general meeting of Biofrontera AG held on 10 July 2019.

The complaint has been 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, DELPHI Unternehmensberatung AG has filed a positive declarative resolution action (*positive Beschlussfeststellungsklage*) according to which the court is to declare that Mr. Wilhelm K.T. Zours was elected to the supervisory board.

The action is also directed against the following rejecting resolutions of the annual general meeting: Agenda item 7 (Resolution to conduct a special audit regarding the circumstances of the acquisition of Cutanea Life Sciences, Inc. from Maruho); agenda item 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<sup>®</sup>): agenda item 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 (*Besonderer Vertreter*) to assert these claims in accordance with section 147 (2) AktG); agenda item 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);

agenda item 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); agenda item 12 (Amendment of Article 13 of the Articles of Association (resignation from the supervisory board / dismissal from office)); agenda item 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 (*Besonderer Vertreter*) for the assertion of these claims in accordance with section 147 (2) of the AktG); and agenda item 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, a positive declarative resolution action (*positive Beschlussfeststel-lungsklage*) was filed requesting the court to state that the annual general meeting adopted the resolutions in accordance with the resolution proposals of Deutsche Balaton AG, or, respectively, in the form of countermotions to these proposals (*Gegenanträge*) submitted in the annual general meeting. The law-suit is currently pending at the Cologne Regional Court.

If the claim concerning the election and dismissal of members of the supervisory board would be successful, the election of Prof. Dr. Franca Ruhwedel to the supervisory board would be cancelled with retroactive effect as of July 10, 2019. Dr. Ulrich Granzer and John Borer would be removed from the supervisory board with retroactive effect as of July 10, 2019. Legally, a supervisory board member whose election is void or declared void shall be deemed as a non-member for the purposes of voting and passing resolutions of the supervisory board with retroactive effect (*ex tunc*). In the event that the dismissal of Dr. Granzer and/or John Borer is ruled by the court, the same would apply. The supervisory board of the Issuer consists of six members. Pursuant to Section 16 (5) of the Issuer's articles of association, the supervisory board constitutes a quorum if at least three members of the supervisory board, a majority of the members participating in the resolution, Baumann, Eyring and Weber, does not vote in favor of the resolution, resolutions adopted would subsequently prove to be invalid if the claim would be successful.

### 9.13.7 ABC Beteiligungen v. Biofrontera AG – General Meeting 2020

An action for rescission and nullification (*Anfechtungs- und Nichtigkeitsklage*) was brought by ABC Beteiligungen AG, Heidelberg, against resolutions of the Annual General Meeting of Biofrontera AG held on May 28, 2020. The action for rescission and nullification (*Anfechtungs- und Nichtigkeitsklage*)

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 the supervisory board member John Borer 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 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 a positive declarative resolution action (*positive Beschlussfeststellung-sklage*) was also filed, requesting the court to declare that the Annual General Meeting adopted the resolutions in accordance with the resolution proposals published in this regard in the supplementary request (*Ergänzungsverlangen*) of Deutsche Balaton AG. The lawsuit is pending before the Cologne Regional Court.

With regard to agenda item 6 (resolution on the increase of share capital against cash contributions with the granting of an indirect subscription right), an application for release (*Freigabeantrag*) was filed with the Cologne Higher Regional Court on 20 October 2020. The Cologne Higher Regional Court granted the motion for release on January 7, 2021.

### **10.** Tax

### 10.1 TAX WARNING

The tax legislation of an investor's Member State and of Germany as the Issuer's country of incorporation may have an impact on the income received from the New Shares. It is therefore recommended that investors consult their own tax advisors regarding the tax implications of acquiring, holding or transferring New Shares. Only qualified tax advisors are in a position to adequately consider the particular tax situation of individual investors.

### 10.2 No specific tax regime

The investment proposed in this Prospectus does not attract a tax regime specific to that type of investment.

# 11. Glossary

0	Accovion	0	Accovion GmbH
0	Additional Subscription	0	Further binding subscription requests made by the Issuer's shareholders regarding New Shares beyond the respective shareholder's subscription rights
0	ADRs	0	Securitizations of ADSs
0	ADS	0	American Depositary Shares
0	ADS Agreement	0	Agreement regarding the creation of ADS between the Is- suer, the Custodian and the Depositary
0	AK	0	Actinic keratoses
0	Ameluz <sup>®</sup> PDT	0	Photodynamic therapy using Ameluz®
0	BaFin	0	Bundesanstalt für Finanzdienstleistungsaufsicht, the German Federal Financial Supervisory Authority
0	Bankhaus Gebr. Martin Aktienge- sellschaft	0	Bankhaus Gebr. Martin Aktiengesellschaft, Kirchstraße 35, 73033 Göppingen
0	BCC	0	Basal cell carcinoma
0	Biofrontera Group	0	Biofrontera AG with registered seat in Leverkusen, and busi- ness address Hemmelrather Weg 201, 51377 Leverkusen to- gether with its subsidiaries
0	cGCP	0	current Good Clinical Practices
0	cGMP	0	current good manufacturing practice
0	Clearstream Banking AG	0	Clearstream Banking Aktiengesellschaft, with registered seat in Frankfurt / Main, Germany, and business address Mer- genthalerallee 61, 65760 Eschborn, Germany
0	Conditional Capital I	0	The conditionally increased registered capital of the Issuer, by up to EUR 4,137,601 by issuing up to 4,137,601 new reg-

			istered no-par shares with a participation in the Issuer's reg- istered capital of EUR 1.00 each, under § 7(2) of the Issuer's articles
0	Conditional Capital III	0	The conditionally increased registered capital of the Issuer, by up to EUR 542,000 by issuing up to 542,000 new regis- tered no-par shares with a participation in the Issuer's regis- tered capital of EUR 1.00 each, under § 7(6) of the Issuer's articles
0	Convertible Bond 2022	0	The Issuer's subordinated convertible bond with a term until 31 December 2021, to be repaid on 1 January 2022
0	CRO	0	Clinical research organization
0	Cutanea	0	Cutanea Life Sciences, Ltd.
0	Custodian	0	Bank of New York Mellon SA/NV, Asset Servicing, Nieder- lassung Frankfurt am Main; Friedrich-Ebert-Anlage 49, 60308 Frankfurt am Main, acting as custodian
0	Depositary	0	Bank of New York Mellon Corp., 225 Liberty Street, New York, NY 10286, United States
0	EEA	0	European Economic Area
0	EIB	0	European Investment Bank
0	EIB Credit Facility	0	The finance contract with EIB entered into in May 2017
0	EMA	0	European Medicines Agency
0	FDA	0	U.S. Food and Drug Administration
0	Global Share Certificates	0	The global share certificate or certificates representing the New Shares, to be deposited with Clearstream Banking AG
0	Issuer	0	Biofrontera AG with registered seat in Leverkusen, and busi- ness address Hemmelrather Weg 201, 51377 Leverkusen
0	J-code	0	A code in the US health system that facilitates reimburse- ments for doctors subscribing a drug
0	QuirinBank	0	Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin

0	МА	0	Marketing Authorization
0	Maruho	0	Maruho Co., Ltd
0	Maximum Subscription Price	0	EUR 3.50
0	New Shares	0	8,969,870 new, no-par registered shares, representing a total notional participation in the registered share capital of the Is- suer of EUR 8,969,870, with the German Securities Identifi- cation Number WKN 604611 and the International Securities Identification Number ISIN DE0006046113
0	Offer	0	The public offering of 8,969,870 New Shares from the capi- tal increase
0	PDT	0	Photodynamic therapy
0	Prime Standard	0	Regulated market with simultaneous admission to the sub- segment of the regulated market with additional post-admis- sion obligations of the Frankfurt Stock Exchange
0	Placement	0	The offer of any New Shares which are not subscribed for in the context of the execution of subscription rights
0	QSR	0	The FDA's Quality System Regulation
0	Securities Act	0	U.S. Securities Act 1933 as amended from time to time
0	Share Loan Service Agreement	0	Agreement between the Issuer, QuirinBank and Maruho Deutschland GmbH regarding the loan of shares
0	Stock Option Program 2015	0	The stock option program implemented under the authoriza- tion of the general meeting of the Issuer of 28 August 2015
0	Subscription Offer	0	Admission of QuirinBank to subscribe and take over up to 8,969,870 New Shares at an issue price of EUR 1.00 per New Share, together with the obligation to offer the New Shares to the shareholders for subscription
0	Subscription Period	0	Period from February 08, 2021 to February 22, 2021

0	Susbcription Price	0	Price per New Share, expected to be determined on February 18, 2021. The Subscription Price will be published presuma- bly on February 18, 2021 as an ad hoc release and in the Ger- man Federal Gazette.
0	Underwriter	0	Quirin Privatbank AG, Kurfürstendamm 119, 10711 Berlin
0	US Offer	0	The sponsored Level-III-program under which ADSs will be offered in the US
0	WKGT	0	Warth & Klein Grant Thornton AG Wirtschaftsprüfungsge- sellschaft, Johannstr. 39, 40476 Düsseldorf, Germany

F.1. Annual Report for the fiscal year ending December 31, 2019

# F.1.1 Consolidated management and group management report for the fiscal year 2019

# Basis of the Group

# Group structure

As of December 31, 2019, the Biofrontera Group (hereinafter also called "Biofrontera" or "Biofrontera Group") consists of a parent company, Biofrontera AG and 5 (previous year: 5) wholly owned subsidiaries. The parent company's head office is 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 the year. While Biofrontera Inc. assumes all commercial activities, Biofrontera Bioscience GmbH takes 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<sup>®</sup>. According to a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also the holder of the CE certificate of BF-RhodoLED<sup>®</sup>, 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<sup>™</sup>. The marketing and sales of Aktipak<sup>®</sup> was suspended in August 2019 until further notice due to unsolvable quality deficiencies of the batches that had been produced by a contract manufacturer on behalf of Cutanea.

Production of Ameluz<sup>®</sup> 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<sup>™</sup> 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 for the treatment of severe chronic urticaria is owned by Biofrontera Development GmbH, the product BF-1 for the prophylactic treatment of migraine (without patent protection since 2009) 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<sup>®</sup> and Xepi<sup>™</sup>. 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<sup>®</sup> and Xepi<sup>™</sup>, 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<sup>®</sup> as well as broader distribution of Xepi<sup>™</sup>.

Biofrontera has received a centralized approval for its own self-developed drug, which is marketed under the brand name Ameluz<sup>®</sup>. Since the market launch in February 2012, Biofrontera has been selling Ameluz<sup>®</sup> with its own sales force to dermatologists in Germany and since March 2015 also in Spain. Ameluz<sup>®</sup> 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 as well as in Israel and Switzerland is carried out through licensing partnerships.

A US subsidiary, Biofrontera Inc., was setup in order to market Ameluz<sup>®</sup> in the USA. The US subsidiary has established all functions and obtained all licenses required for a sales company in the pharmaceuticals and medical devices sector. Departments supporting sales, such as Finance, Customer Service, Market Access, Medical Affairs, Compliance, Quality Assurance, Logistics, etc. were established locally. Other group functions necessary for a pharmaceutical company, such as management of regulatory approvals, interaction with regulatory authorities, patents, manufacturing, IT, regulatory relevant clinical trials, etc. continue to be provided exclusively by the German companies of the Biofrontera Group with worldwide responsibility.

# Products

### Ameluz®

In December 2011, Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> with light treatment is an innovative form of treatment that is classified as photodynamic therapy (PDT).

Based on the Phase III field trial for field therapy, the European Commission also approved Ameluz<sup>®</sup> for the treatment of field cancerization following a positive vote by the EMA. In addition to its high efficacy in the removal of actinic keratoses, the results relating to the improvement of skin appearance were included in the official product information in the EU.

In May 2016, Biofrontera received approval for Ameluz<sup>\*</sup> in the USA. The approved indication concerns the "lesion and field directed PDT of mild and moderate actinic keratoses on the face and scalp". As approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, the BF-RhodoLED<sup>\*</sup>, and has obtained CE certification in the EU, which also required the entire company to be certified according to ISO 13485. The ISO certification was renewed regularly in 2019.

The overall advantages of Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC) in March 2020. It is expected that the significantly superior efficacy compared to Metvix<sup>®</sup> one year after treatment will further enhance the market positioning of Ameluz<sup>®</sup>.

In fall 2019, the company submitted the application for label extension to the European Medicines Agency (EMA) to include the treatment of mild and moderate AK on the extremities and trunk/neck with conventional PDT using Ameluz<sup>®</sup> and the BF-RhodoLED<sup>®</sup>. Following the positive vote of the EMA in February 2020, the European Commission formally approved the label extension for Ameluz<sup>®</sup> in March 2020.

Based on these results, Biofrontera has also started discussions with the US Food and Drug Administration (FDA) about a corresponding extension of the approval for Ameluz<sup>\*</sup> in the USA. The FDA provided positive feedback and proposed an additional clinical trial to approve the label extension for Ameluz<sup>\*</sup> to additional body regions. Patient recruitment is scheduled to start in the second half of 2020. Within this context, Biofrontera, following consultation with the FDA, has also initiated a pharmacokinetics study (PK study), in which the safety of PDT is tested using three tubes of Ameluz<sup>\*</sup>. According to the program schedule, patient recruitment will take 3-5 months and the Phase I study is expected to be completed in the third quarter of 2020.

### BF-RhodoLED®

BF-RhodoLED<sup>\*</sup> is a lamp designed for PDT, and utilizes LEDs emitting red light at a wavelength of approximately 635 nm. Light at this wavelength, which is ideally suited for PDT illumination with drugs containing ALA or methyl ALA, is red but is still below the warming infrared range. The BF-RhodoLED<sup>\*</sup> lamp combines a controlled and consistent emission of light at the required wavelength with simplicity, user-friendliness and energy efficiency. In the European version, light energy and fan power settings can be adjusted during a PDT treatment session to reduce any pain caused by the treatment. No other lamp on the market offers comparable power and flexibility. BF-RhodoLED<sup>\*</sup> has been CE-certified since November 2012 and is distributed throughout the EU. In order to distribute the lamp in the USA, the final assembly of the PDT lamp was moved to Biofrontera's headquarters in Leverkusen where it has been produced by Biofrontera since 2016. This makes Biofrontera the responsible manufacturer from the perspective of the authorities.

### Belixos®

Belixos<sup>\*</sup> 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<sup>\*</sup> series includes the following products: belixos<sup>\*</sup> Cream, belixos<sup>\*</sup> Liquid, belixos<sup>\*</sup> Gel and belixos<sup>\*</sup> 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<sup>®</sup> is obtainable in selected pharmacies, dermatological institutes and from the online retailer Amazon.

### 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<sup>™</sup> (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. To date, no antibiotic resistance to Xepi<sup>™</sup> is known and it has been specifically approved by the FDA for the treatment of antibiotic-resistant bacteria. The approved indication is impetigo, a common skin infection in children with staphylococci and streptococci. Xepi<sup>™</sup> has an excellent safety profile that even allows for use on infants from the age of two months.

Xepi<sup>™</sup> 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<sup>™</sup> our portfolio now includes an innovative, promising product with a great million market potential.

The drug Xepi<sup>™</sup> in-licensed by Biofrontera is protected by two patent families in the USA and other countries. With regard to the USA, patent protection applies for the composition of Xepi<sup>™</sup> until January 29, 2032 and for the approved treatment of impetigo until December 15, 2029.

### **Aktipak**®

The second product approved in the USA, which Biofrontera added to its product portfolio through the acquisition of Cutanea Life Sciences, Inc., is called Aktipak<sup>®</sup> (BPO/Erythromycin Gel, 3%/5%) and is a convenient combination product of two known active ingredients for the treatment of acne. Due to unresolved quality problems in the production of Aktipak<sup>®</sup> at the contract manufacturer commissioned by Cutanea in the past and the comparatively lower market opportunities, Biofrontera decided in August 2019 not to pursue its activities with this product for the time being.

# Sales and markets

The company underwent organizational restructuring at the beginning of 2020, and after the reorganization of the operational leadership of its subsidiary Biofrontera Inc. (published on January 5, 2020), Biofrontera also announced an organizational restructuring of the sales organization in Europe (published on January 31, 2020).

Under the new structure, Biofrontera's worldwide sales organization now stands on two pillars: sales and marketing in the USA, Biofrontera's largest market, and a unified management of all sales activities in Europe.

### USA

Biofrontera launched Ameluz<sup>®</sup> in the USA in October 2016. The distribution of Ameluz<sup>®</sup> in the U.S. is handled by its subsidiary Biofrontera Inc. founded in March 2015. Since then, our U.S. sales team has grown to over forty employees. Our sales force is supported by four scientific consultants, our Market Access and Managed Markets Team as well as a Customer Service Team. In March 2019, Biofrontera acquired all shares of Cutanea Life Sciences, Inc. thereby expanding its portfolio in the USA with the FDA-approved drug Xepi<sup>™</sup>.

### Germany and Europe

With its central European approval, Ameluz<sup>®</sup> 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. In these countries the drug is available at pharmacy retail prices ranging from 150 EUR to approximately 220 EUR per 2g tube.

In Europe, Ameluz<sup>\*</sup> and BF-RhodoLED<sup>\*</sup> have been marketed in Germany (since 2012), Spain (since 2015) and the United Kingdom (since May 2018) by a dedicated sales force. In other European countries, the products are distributed through distribution partners: Denmark, Sweden, Norway, Austria, Switzerland and Liechtenstein as well as Israel. Independent approval procedures were required in Switzerland and Israel, which were carried out by our local marketing partners in cooperation with Biofrontera. The licensing agreements with distributors were structured in such a way that Biofrontera has received no or only a moderate down payment and the regional partners buy Ameluz<sup>\*</sup> 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 significantly and ranges between 35% and 55% of net sales. Overall, however, marketing through Biofrontera's own sales forces has proven to be much more successful in recent years, so that sales through distribution partners now account for only a small proportion of total sales.

# Personnel matters

### Management Board

As at December 31, 2019, the Management Board was comprised of Prof. Hermann Lübbert (Chief Executive Officer), Mr. Thomas Schaffer (Chief Financial Officer) and Mr. Christoph Dünwald (Chief Commercial Officer).

Name	Nationality	Age	Position	Date of first appointment	Term
Prof. Dr. Hermann Lübbert	German	64	Chair	2000	Oct. 31, 2020
Christoph Dünwald*	German	52	Sales & Marketing	2016	Nov. 30, 2020
Thomas Schaffer	German	57	Finance	2013	Nov. 30, 2020

\* On January 31, 2020, Mr. Christoph Dünwald resigned from his position as Chief Commercial Officer (CCO).

### Employees

As of December 31, 2019, 174 (previous year: 157) employees were working in the Biofrontera Group, distributed as follows:

Company	Employees as of December 31, 2019	Employees as of December 31, 2018	
Biofrontera AG	30	28	
Biofrontera Bioscience GmbH	19	18	
Biofrontera Pharma GmbH*	52	49	
Biofrontera Inc.	73	62	

\* includes the subsidiaries in Spain and the UK

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH do not employ any staff.

In order to maintain a competitive edge in recruiting and retaining staff, the company must be able to offer compensation that is both attractive and in line with the market. One component of this is share-based compensation as part of an employee stock option plan.

### Supervisory Board

In 2019, 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	Chair	May 12, 2006	2021
Jürgen Baumann	German	66	Deputy Chair	May 24, 2007	2021
John Borer	USA	63	Member	May 31, 2016	2021
Reinhard Eyring	German	62	Member	February 2, 2018	2021
Hansjörg Plaggemars *)	USA	50	Member	May 31, 2016	until Mar 22,
Prof. Dr. Franca Ruhrwedel	German	47	Member	July 10, 2019	2021
Kevin Weber	USA	61	Member	May 31, 2016	2021

\* Hansjörg Plaggemars was removed from his position as a member of the Supervisory Board of Biofrontera AG by the Cologne District Court on March 22, 2019. Pursuant to a decision of the Local Court of Cologne on March 22, 2019, Mr. Hansjörg Plaggemars was dismissed as a member of the Supervisory Board of Biofrontera AG in accordance with Section 103 (3) of the German Stock Corporation Act for good cause. The resolution was issued on March 22, 2019 and came to the attention of the Company on March 26, 2019. The dismissal resolution is effective immediately. However, it was possible to lodge an appeal within one month, which was granted. The appeal was rejected by Cologne Local Court on April 30, 2019 and the proceedings were referred to the Higher Regional Court for further decision. The Cologne Higher Regional Court finally dismissed the appeal on 29 August 2019. The Annual General Meeting on 10 July 2019 elected Prof. Dr. Franca Ruhwedel, Professor of Finance and Accounting at Rhine-Waal University of Applied Sciences, Kamp-Lintfort, resident in Duisburg, to the Supervisory Board as successor to Mr. Plaggemars.

# Research and development projects

All research and development activities of the Biofrontera Group regarding the nanoemulsion and Ameluz<sup>®</sup> 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 number of employees at Biofrontera Bioscience GmbH increased from 18 in 2018 to 19 in the reporting year. The development of the new red-light lamp BF-RhodoLED<sup>®</sup> XL is the responsibility of Biofrontera Pharma GmbH, which employed 52 people in 2019 (previous year: 49).

### 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.

In addition, on March 3, 2020 the company and Maruho signed a binding term sheet for a future licensing agreement for Ameluz<sup>®</sup> in East Asia and Oceania. With respect to the potential label extension of Ameluz<sup>®</sup> for acne, 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. This will allow the study program to start in 2020.

Phase III study 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<sup>®</sup> now also includes the treatment of mild and moderate actinic keratoses (AK) on the extremities and trunk/neck with photodynamic therapy (PDT).

As a prerequisite for the label extension of Ameluz<sup>®</sup> to include the treatment of mild and moderate AKs on the extremities as well as trunk/neck with conventional PDT using Ameluz<sup>®</sup> and the BF-RhodoLED<sup>®</sup> lamp, Biofrontera carried out a phase III study with 50 patients. The multi-center, randomized, double-blind, intraindividual study was conducted in six study centers in Germany, with each patient showing four to ten clinically confirmed AK lesions in comparable areas on the right and left side of the extremities and/or trunk/neck. The final investigation of the primary endpoint was conducted three months after the last PDT. The results for the primary regulatory endpoint published in a press release by Biofrontera on March 20, 2019 showed that Ameluz<sup>®</sup> was significantly superior (p<0.0001) to placebo based on an average total lesion clearance rate of 86% compared to 33%. Significant superiority of Ameluz<sup>®</sup> was also demonstrated for all secondary parameters. In this study, the average lesion recurrence rate after 12 months of Ameluz<sup>®</sup> treatment was 14.1% compared to 27.4% after placebo.

Based on these results, Biofrontera has also started discussions with the US Food and Drug Administration (FDA) about an expanded approval of Ameluz<sup>®</sup> in the USA, to include the treatment of AK on the extremities and trunk/neck. The FDA provided positive feedback and proposed an additional clinical trial to include additional body regions into the label of the Ameluz<sup>®</sup>. The study protocol is currently being developed according to FDA guidance, with patient recruitment expected to start in the second half of 2020.

Following consultation with the FDA, Biofrontera has also initiated a pharmacokinetics study (PK study) to test the safety of PDT using three tubes of Ameluz<sup>®</sup> at the same time. The aim of this phase I study is to obtain pharmacokinetic profiles following an Ameluz<sup>®</sup> PDT in patients with AK in an extended treatment area in the face/head or peripheral area. In addition, safety and tolerability for the patient during and after treatment will be investigated. Patient recruitment is expected to take 3-5 months and the Phase I study should be completed in the third quarter of 2020.

### Development of the BF-RhodoLED<sup>®</sup> XL

The reporting period marked the main development phase of the new lamp BF-RhodoLED<sup>®</sup> XL. The future use of the BF-RhodoLED<sup>®</sup> XL will allow the application of Ameluz<sup>®</sup> on larger areas as well as the simultaneous exposure of several interspersed lesions. Furthermore, the BF-RhodoLED<sup>®</sup> 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<sup>®</sup> sales. The company expects to submit the application for approval to the FDA during the second half of 2020.

# Phase III study for the treatment of superficial basal cell carcinoma (BCC) with Ameluz<sup>®</sup> in combination with our red-light lamp BF-RhodoLED<sup>®</sup> 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<sup>®</sup> in combination with our BF-RhodoLED<sup>®</sup> 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. Following successful FDA approval, Ameluz<sup>®</sup> would be the only drug in the United States for the treatment of superficial BCC with PDT.

# Patent and trademark development

The company maintains three different company-owned patent families and one German utility model worldwide. In addition, Biofrontera pursues patent families created in collaboration with Maruho under a partnership agreement that expired in March 2018. The Group's patents are held by Biofrontera Bioscience GmbH.

The patent families refer to our technologies related to our nanoemulsion, a patent for migraine prophylaxis and a patent related to PDT:

### Nanoemulsion

We have been issued composition of matter patents for our nanoemulsion technology in the EU (for France, Germany, Italy, Spain, Switzerland, and the UK), Australia, Belarus, Canada, Chile, China, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Russia, South Africa, Singapore, and the Ukraine. Patent protection in these jurisdictions will expire on December 21, 2027. We have filed patent applications pending in the United Arab Emirates and the USA. The patent in India and the patent application in Brazil were discontinued in 2019.

On November 12, 2019, protection for the patent family, describing the combination of nanoemulsions with aminolaevulinic acid hydrochloride, the active ingredient in Ameluz<sup>\*</sup>, expired. However, Ameluz<sup>\*</sup> 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<sup>\*</sup> 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<sup>\*</sup>, additional patent applications have been submitted (see below).

### Migraine prophylaxis BF-1

An international patent application regarding anti-migraine compounds and their use was submitted to the World Intellectual Property Organization. While the U.S. patent has been granted, expiring in January 2034, the EU patent assessment is ongoing.

### Photodynamic therapy

A new Patent Cooperation Treaty (PCT) application "Improved Photodynamic Therapy" was filed with the European Patent Office (EPO) on August 23, 2018. The application was registered under the official file number PCT/EP2018/072823. All countries that were members of the PCT on the filing date (including the USA) were listed in the application.

Another international patent application titled "Illumination for photodynamic therapy" was filed with the EPO on June 5, 2019. This application was registered under the official file number PCT/EP2019/064642. Again, all states which were contracting states of the PCT at the date of filing of the PCT application were listed in the application.

### Xepi™

The drug Xepi<sup>™</sup>, 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<sup>™</sup> 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

With regard to the company's operating performance, the key performance indicators are revenue, liquidity and, increasingly, the result from operating activities.

As part of internal reporting, revenue is the key performance indicator, which is reported by region and product. On a consolidated basis, revenues include sales to wholesalers, doctors and hospitals, sales to our licensing partners and revenues from research contracts.

Profit from operating activities measures the operating profitability of the Company independently of the financial structure and local taxation, which allows the performance indicator to be used for international comparison with other companies.

In addition, liquidity trends are utilized as an important key indicator and management metric and is monitored on a daily basis. Liquidity is defined as the sum of cash and cash held in bank account and is described as cash and cash equivalents.

### 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 2019

# **Business performance**

In the 2019 financial year, Biofrontera continued to significantly increase product sales. However, with consolidated revenues of 31.3 million euros and an increase in sales of around 48%, growth was below our initial expectations. As a result, we had to adjust our annual forecast during the year from originally EUR 35 to 40 million to EUR 28 to 31 million. In Germany, our revenues increased by around 40% to EUR 4.6 million, while in the USA revenues from product sales amounted to EUR 23.3 million, up around 57% from the previous year. In Spain, due to the growth in sales volume, a slight increase in sales was recorded despite a 27% price reduction imposed by the government. In the UK, improvements were achieved in particular in access to the major hospitals.

The most important growth driver continues to be our US business, where we already generate around 75% of total sales. Here, growth resulted primarily from further expansion of our sales and distribution infrastructure and improved reimbursement for the work performed by dermatologists using PDT. In 2019, the reimbursement, which is based on so-called CPT codes, was increased again, improving the positioning of PDT as a treatment option. Due to the typical seasonal nature of the business, the growth momentum in our most important market had slowed somewhat over the summer. Still, we were able to generate record sales in the fourth quarter of 2019 making it the best quarter in the company's history.

An estimated 40 million Americans develop actinic keratoses every year. We anticipate that the market share of Ameluz<sup>®</sup> within the PDT segment in the US will continue to grow steadily.

We expect a further sustained growth acceleration in the USA once two existing competitive disadvantages of Ameluz<sup>®</sup> relative to the competitor product are eliminated: Initially, our current approval only allows the reimbursement of one tube per application. Biofrontera is working diligently on improving the reimbursement modalities, as well as on extending the label to include the treatment of actinic keratoses on the extremities, trunk and neck. For the latter, Biofrontera will soon initiate another clinical trial in the USA with the aim of obtaining a corresponding extension of the approval. In order to ensure the reimbursement of several tubes for the treatment of larger body regions in the periphery, Biofrontera is currently planning a pharmacokinetics study to prove the safety of the treatment with three tubes of Ameluz<sup>®</sup>. The study is expected to be completed in the second half of 2020.

To overcome the second competitive disadvantage - our in comparison to the competitor's product small PDT lamp BF-RhodoLED<sup>®</sup> - Biofrontera is currently developing the new lamp "BF-RhodoLED<sup>®</sup> XL", which will allow the use of Ameluz<sup>®</sup> on larger areas. We expect the market launch of this new medical product to further boost sales of Ameluz<sup>®</sup>. The application for approval by the FDA is expected to be submitted in the second half of 2020.

To further increase our growth opportunities in the U.S. market in the future, we are working on expanding the U.S. label for Ameluz<sup>®</sup> to include superficial basal cell carcinoma (BCC). Since September 2018, we have been working intensively on patient recruitment for the Phase III study already underway; we expect the study results in 2021. Following successful FDA approval, Ameluz<sup>®</sup> would be the only PDT-drug available in the United States for the treatment of superficial BCC.

We also believe that the agreement with the U.S. Department of Veterans Affairs (VA) will provide further longterm business opportunities for us. With many young doctors being trained in VA hospitals and being able to experience Ameluz<sup>®</sup>- PDT, we will be able to use this platform to educate a new group of opinion leaders and innovation drivers in dermatology about the advantages of PDT in combination with Ameluz<sup>®</sup>. Despite the currently still very low business volume, the VA market remains a strategically important market.

Through the acquisition of Cutanea Life Sciences, Inc. (Cutanea) in March 2019, Biofrontera was able to expand the product portfolio in the USA with the FDA-approved drug Xepi<sup>™</sup>. Xepi<sup>™</sup> is the first topical antibiotic in the USA that has been approved by the FDA in about 10 years. The approval also includes the treatment of infections with antibiotic-resistant bacterial strains such as MRSA and is expressly approved by the FDA for infections with such bacteria. In total, around 10 million prescriptions for drugs in indications where Xepi<sup>™</sup> may be effective are issued annually in the USA, a significant proportion of which are by dermatologists. We therefore see very considerable growth potential for Xepi<sup>™</sup>. The integration of Cutanea was completed by the end of the 2019 financial year. While the great market potential of Xepi<sup>™</sup> will continue to be exploited and the marketing strategy further optimized, Ameluz<sup>®</sup> will remain our most important product in the near future.

In Germany, the largest European market for Ameluz<sup>\*</sup>, the market share of Ameluz<sup>\*</sup> within the PDT drug segment was approximately 57% in 2019, compared to approximately 52% in the previous year. As a result of the further establishment of daylight PDT, Ameluz<sup>\*</sup> continued to prove itself as a strong leader in the PDT market compared to its competitors' products. We estimate that daylight PDT will continue to capture additional market share that was previously reserved for self-applied topical creams. It is particularly interesting to note that Ameluz<sup>\*</sup> is reimbursed by the public health insurance companies when prescribed for daylight PDT. Consequently, the number of patients who have access to treatment with Ameluz<sup>\*</sup> has multiplied. This is also reflected in an approximately 27% increase in prescriptions of Ameluz<sup>\*</sup> in Germany last year.

Sales growth also increased steadily in Spain. Back in July 2018, we had to accept a significant price reduction of 27% in order to maintain reimbursement for Ameluz<sup>®</sup> in the Spanish national health system. However, a rapidly growing number of Ameluz<sup>®</sup> prescriptions, i.e. the number of tubes sold, more than compensated for the price reduction and enabled us to achieve sales growth of about 10%.

In the United Kingdom, distribution is currently focused on hospitals, especially on the administrative steps required to add Ameluz<sup>®</sup> to the lists of approved drugs in the respective hospital pharmacies, the so-called formularies. In some major hospitals, Ameluz<sup>®</sup> is now rated as the first choice of PDT drug for the treatment of AK and BCC ahead of the competitor product. These successes are already beginning to translate into sales figures. Overall, however, the UK still plays a minor role as a source of revenue.

In other European countries, sales have decreased slightly overall due to declining shipments to license partners.

Based on the positive results of the phase III – trial on the safety and efficacy of Ameluz<sup>\*</sup> in combination with Biofrontera's red light lamp BF-RhodoLED<sup>\*</sup> for the treatment of actinic keratoses on the extremities as well as the trunk and neck, the application for label expansion for Ameluz<sup>\*</sup> was submitted to the EMA in fall 2019. Following the positive opinion of the Committee for Medicinal Products for Human Use (CHMP) of the EMA on February 3, 2020, the European Commission formally granted the extension of the approval on March 10, 2020. In addition, the results of the follow-up phase of the clinical study comparing daylight PDT with Ameluz<sup>\*</sup> and Metvix<sup>\*</sup> were included in the product information (SmPC). Substantially lower recurrence rates of Ameluz<sup>\*</sup> compared to the competing products Metvix<sup>\*</sup> and Luxerm<sup>\*</sup> once again confirm the superiority of our drug. The company expects further sales growth in Europe as a result of the label expansion.

We were also able to make further progress in the research cooperation with Maruho Co. Ltd. for the further development of branded generics based on our nanoemulsion technology. All necessary studies and manufacturing steps for entry into the clinical phase have been initiated. Branded generics represent a sensible

addition to our product portfolio in the future. With Maruho we have found a long-term and reliable partner for the development of such products.

The Biofrontera Group's earnings before taxes in the 2019 fiscal year amounted to -4.8 million euros, compared to -19.3 million euros in the previous year.

In the HGB individual financial statements, Biofrontera AG shows a net loss for the year of 2.0 million EUR (previous year: loss of 9.1 million EUR).

# Biofrontera Group financial position and performance

As of December 31, 2019, the scope of consolidation of the Biofrontera Group include Biofrontera AG, as well as the subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc. Cutanea Life Sciences, Inc. and its subsidiaries Dermarc LLC and Dermapex LLC were fully consolidated at the time of acquisition on March 25, 2019. By the end of the financial year, the companies of Cutanea Life Sciences, Inc. as well as Biofrontera Newderm Inc. were merged into Biofrontera Inc.

### Results of operations of the Biofrontera Group

in EUR thousands	2019	2018
Sales revenue	31,265	21,107
Gross profit on sales	26,390	16,656
Research and development costs	(4,636)	(4,427)
General administrative costs	(16,275)	(12,963)
Sales and marketing costs	(28,856)	(17,744)
Loss from operations	(23,377)	(18,478)
Interest expenses and income	(2,584)	(1,760)
Other expenses	(799)	(332)
Other income due to PPA (badwill)	14,812	-
Other income	7,171	1.301
Loss before income tax	(4,777)	(19,269)
Income tax	(2,581)	10,391
Loss after income tax	(7,358)	(8,878)

### Impact of the Cutanea consolidation on the results of operations

Since the acquisition of Cutanea, revenues from Xepi<sup>™</sup> and Aktipak<sup>®</sup> amount to EUR 822 thousand in the financial year 2019.

The operating loss derived from Cutanea amounts to EUR 8,669 thousand. This is offset by income from the reimbursement of costs from Maruho for the restructuring carried out in the amount of EUR 6,215 thousand, which is reported under other income.

### Sales revenue

In the 2019 reporting year, the Biofrontera Group achieved total sales of EUR 31,265 thousand, an increase of 48% compared to the previous year (previous year: EUR 21,107 thousand). Revenues from product sales increased by almost 46% to EUR 30,579 thousand compared to the previous year (previous year: EUR 20,938

thousand). Sales in the USA continued to develop positively in the 2019 financial year, but still fell short of our expectations. Sales there increased by 57% to a total of EUR 23,343 thousand (previous year: EUR 14,894 thousand). This includes sales of EUR 822 thousand from Xepi<sup>™</sup> and Aktipak<sup>®</sup>. The growth was due to the continued expansion of our sales structures and improvements in the reimbursement of PDT for dermatologists in the USA. Sales in Germany improved by 40% to EUR 4,633 thousand (previous year: EUR 3,307 thousand). The increase in sales in Germany is mainly due to the introduction of daylight PDT approved in March 2018. In other European countries, total sales declined slightly by 5% to EUR 2,603 thousand (previous year: EUR 2,737 thousand), which is primarily due to declining deliveries to license partners. Revenues from other regions mainly relate to revenues from research cooperations and amounted to EUR 686 thousand (previous year: EUR 169 thousand).



### Gross profit on sales

In the 2019 reporting year, gross profit on sales increased by EUR 9,734 thousand, to reach EUR 26,390 thousand, compared with EUR 16,656 thousand in the prior-year period. The gross margin improved from 79% in 2018 to 84% in 2019.



### Research and development costs

Research and development costs of EUR 4,636 thousand in the reporting period were slightly above the previous year's level (EUR 4,427 thousand) and include the costs of clinical studies, but also the costs of regulatory affairs, i.e. the granting, maintenance and expansion of our approvals.

### General administrative costs

General and administrative expenses amounted to EUR 16,275 thousand in the 2019 financial year (previous year: EUR 12,963 thousand) and thus increased by a total of EUR 3,312 thousand compared with the previous year, in particular due to the initial consolidation of Cutanea. Legal and consulting costs increased to EUR 6,929 thousand (previous year: EUR 6,230 thousand).

### Sales and marketing costs

Sales and marketing costs totaled EUR 28,856 thousand in the 2019 financial year, a significant increase over the previous year (EUR 17,744 thousand). This was due to the costs for the further expansion of our US sales organization as well as sales costs incurred at Cutanea (EUR 5,906 thousand). Sales costs include the costs for our own sales force in Germany, Spain, Great Britain and the USA as well as marketing expenses.

### Loss on operations

The loss from operating activities of EUR 23,377 thousand fell by EUR 4,899 thousand compared with the previous year (EUR 18,478 thousand), primarily due to the first-time consolidation of Cutanea. Of this amount, EUR 8,669 thousand is attributable to Cutanea, which is offset by cost reimbursements from Maruho of EUR 6,215 thousand included in other income. The loss on operations includes the costs of the restructuring of Cutanea and the costs of setting up sales of Xepi<sup>™</sup>.

### Interest expenses

Interest expenses totaled EUR 2,711 thousand (previous year: EUR 1,784 thousand) and mainly comprise higher interest expenses for the EIB loan, which was increased by a further tranche in February 2019, and the fair value adjustment to the purchase price liability for Cutanea in the amount of EUR 650 thousand. Interest income in the 2019 reporting period amounted to EUR 127 thousand (previous year: EUR 24 thousand).

### Other income and expenses

Other expenses and income totaled EUR 21,184 thousand in the reporting period (previous year: EUR 969 thousand). This includes the negative difference arising from the purchase price allocation of the asset and liability items carried at fair market value in the amount of EUR 14,812 thousand. This item also includes cost reimbursements from Maruho of EUR 6,215 thousand based on the Share Purchase Agreement.

### Income taxes

The income tax expense results primarily from the use of the tax loss carryforwards of Biofrontera Pharma GmbH (EUR 256,000) and due to the reduction in the municipal business tax rate of the city of Leverkusen with

effect from January 1, 2020 (EUR 2,350,000). In the previous year, income from the first-time capitalization of deferred taxes on loss carryforwards was reported.

### Net assets of the Biofrontera Group

The acquisition of Cutanea is reflected in particular in the higher non-current assets (Xepi<sup>™</sup> license) and the purchase price liabilities reported under non-current liabilities. The net assets position as of December 31, 2019 is as follows:

in EUR thousands	31/12/2019	31/12/2018
Non-current assets	35,872	11,546
Current financial assets	17,227	23,642
Other current assets	5,264	3,945
Total assets	58,363	39,133
Equity	9,955	16,356
Non-current liabilities	36,830	15,007
Current financial liabilities	5,507	2,000
Other current liabilities	6,071	5,770
Total equity and liabilities	58,363	39,133

### Non-current assets

The non-current assets as of December 31, 2019 in the total amount of EUR 35,872 thousand (December 31, 2018: EUR 11,546 thousand) include deferred taxes on tax loss carryforwards of Biofrontera Pharma GmbH totaling EUR 7,794 thousand, tangible assets of EUR 5,230 thousand and the acquired Xepi<sup>™</sup> license valued at EUR 22,078 thousand.

### Current financial assets

Current financial assets amounted to EUR 17,227 thousand as of December 31, 2019 (December 31, 2018: EUR 23,642 thousand). This includes cash and cash equivalents of EUR 11,119 thousand (December 31, 2018: EUR 19,451 thousand), trade receivables of EUR 5,031 thousand (December 31, 2018: EUR 3,397 thousand) and other current financial assets in the amount of EUR 1,077 thousand (December 31, 2018: EUR 794 thousand).

### Other current assets

Other current assets mainly include inventories, which amounted to EUR 4,065 thousand (December 31, 2018: EUR 3,177 thousand).

### Equity

The Biofrontera Group has equity amounting to EUR 9,955 thousand based on IFRS accounting principles (previous year: EUR 16,356 thousand). The equity ratio fell from 42% to 17%, in particular due to the increased balance sheet total as a result of the Cutanea acquisition.

### Non-current liabilities

Non-current liabilities increased primarily due to the recognized purchase price liability from the Cutanea acquisition (EUR 14,720 thousand), a further tranche of the EIB loan (EUR 5,301 thousand) as well as liabilities from finance leases (EUR 2,987 thousand).

### Current financial liabilities

Current financial liabilities include mainly trade payables in the amount of EUR 4,196 thousand (31.12.2018: EUR 1,806 thousand) and increased due to legal and consulting fees, among other things.

### Other current liabilities

Other current liabilities amounted to EUR 6,071 thousand (December 31, 2018: EUR 5,770 thousand) and relate in particular to other provisions and other current liabilities, which are almost unchanged with the previous year.

### 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	2019	2018
Statement of cash flows		
Cash flow from operating activities	(32,894)	(13,434)
Cash flow from investing activities	21,053	(511)
Cash flow from financing activities	3,455	22,274
Liquidity/Cash and cash equivalents	11,119	19,451
Non-current financial liabilities	22,110	13,462
Current financial debt	1,212	165
Net liquidity	(12,203)	5,824

The net cash flow from operating activities, which decreased by EUR 19,460 thousand to EUR -32,894 thousand, resulted almost exclusively from the restructuring of Cutanea. Adjusted for the effects of EUR 22,814 thousand financed by Maruho, the net cash flow from operating activities would have been EUR -10,080 thousand.

The net cash flow from investing activities of EUR 21,053 thousand includes EUR 22,814 thousand in cash and cash equivalents taken over as part of the acquisition and start-up costs from Maruho, which were used to finance the restructuring and to set up sales activities of Xepi<sup>TM</sup>.

The net cash flow from financing activities amounted to EUR 3,455 thousand (previous year: EUR 22,274 thousand) and includes the drawdown of the further tranche of the EIB loan (EUR 5,000 thousand) and, in particular, lease payments (EUR 1,183 thousand). The previous year's net cash flow from financing activities

resulted primarily from payments received from the issue of new shares with gross issue proceeds totaling EUR 24,000 thousand.

The financial liabilities from the convertible bond 2017/2022 and the EIB loan have different maturities up to a maximum of 2024. The convertible bond 2017/2022 (EUR 1,977 thousand) and the first EIB tranche (EUR 11,845 thousand) will mature in 2022. The second EIB tranche (EUR 5,301 thousand) is due in 2024, and annual purchase price payments for the acquisition of Cutanea are expected from 2022 to 2030 depending on future profits from the sale of Xepi<sup>™</sup>.

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 totaled EUR 11,119 thousand as of December 31, 2019 (December 31, 2018: EUR 19,451 thousand).

# Biofrontera AG financial position and performance

in EUR thousands	2019	2018
Sales revenue	7,919	3,019
Other operating income	498	897
Personnel costs	(3,395)	(3,028)
Depreciation and amortization	(29)	(31)
Other operating expenses*	(8,474)	(10,929)
Other interest and similar income	3,435	2,676
Interest and similar expenses	(1,987)	(1,676)
Other taxes	(1)	(1)
Net loss for the year	(2,034)	(9,073)

### Results of operations of Biofrontera AG

\* There will be no reclassification of other operating expenses to cost of materials in 2019. To improve comparability, the previous year's figure has been adjusted in the presentation of the results of operations.

The increase in sales revenues reported in the single-entity financial statements prepared in accordance with German commercial law (HGB) is the result of higher revenues from services and costs passed on within the Group.

As part of the further development of business activities, additional employees were hired and resulted in higher payroll expenses in the year under review.

Operating expenses decreased, in particular due to lower financing costs at Biofrontera AG. The increase in interest and similar income is due to the continued granting of loans to Group companies. Interest expenses increased in particular due to the EIB loan.
The net loss for the year decreased to EUR 2,034 thousand due to the increased sales and simultaneously lower operating expenses.

# Net assets of Biofrontera AG

in EUR thousands	31 December 2019	31 December 2018
Non-current assets	32,262	32,270
Receivables due from affiliated companies	97,165	80,605
Cash and balances with banks	3,926	16,147
Other assets	285	367
Total assets	133,638	129,389
Equity	109,604	110,408
Provisions	4,026	4,732
Bonds	2,031	2,595
Liabilities to banks	16,900	10,990
Other liabilities	1,077	664
Total equity and liabilities	133,638	129,389

As in the previous year, non-current assets relate almost exclusively to interests held in affiliated companies.

Receivables from affiliated companies increased due to the further availability of funds to subsidiaries.

Cash on hand and bank balances decreased from EUR 16,147 thousand in the previous year to EUR 3,926 thousand in 2019. For further details on the financial position, please refer to the presentation of the consolidated financial position.

As of December 31, 2019, Biofrontera AG has equity in accordance with the German commercial law of EUR 109,604 thousand (previous year: EUR 110,408 thousand).

The provisions essentially include provisions for litigation costs of EUR 2,523 thousand (previous year: EUR 3,489 thousand) and provisions for the performance component of the EIB loan (EIB) of EUR 838 thousand (previous year: EUR 467 thousand).

The bonds include the 2017/22 convertible bond. The increase in liabilities to banks is due to the interest payable at the end of the term on the loan provided by the EIB as well as another drawdown on the EIB loan in the amount of EUR 5,000 thousand.

# Assessment of the financial position

In the single-entity financial statements of Biofrontera AG, liquidity amounts to EUR 3,926 thousand compared to EUR 16,147 thousand in the previous year. The reduction is mainly due to the continued transfer of funds to subsidiaries. In 2019, the liquidity of the Group decreased by EUR 8,332 thousand to EUR 11,119 thousand. The decrease is due to the operating losses.

With regard to the future development of the financial position and the associated risks threatening the going concern status, we refer to the disclosures in the Risk and Opportunity Report in the section on liquidity, profitability, capital market access and risks to the going concern status.

# Comparison of actual and forecast business performance

The financial performance of the Biofrontera Group in 2019 was below expectations. Detailed comparisons of projected targets and actual results are shown in the table below:

Key figures	Forecast 2019 (without Cutanea)	Revised Forecast 2019	Target achievement as of 31/12/2019 including Cutanea
Group sales revenue	EUR 35 to 40 million	EUR 28 to 31 million	EUR 31.3 million
Research and development costs	EUR 5 to 7 million		EUR 4.6 million
General administrative costs	EUR 10 to 12 million		EUR 16.3 million
Sales and marketing costs	EUR 20 to 22 million		EUR 28.9 million
Loss from operating activities	EUR 7 to 9 million		EUR 23.4 million
Loss before income tax	EUR 9 to 11 million	EUR 4 to 6 million	EUR 4.8 million

# Assessment of the business performance by the Management Board

As in past financial years, Biofrontera has again succeeded in increasing product sales in 2019. However, with an increase in sales of around 48%, growth was below our initial expectations, so that we had to adjust our annual forecast during the year from EUR 35 to 40 million to EUR 28 to 31 million. However, due to a strong 4th quarter, we were able to slightly exceed the most recent forecast.

All in all, we have achieved revenues of over EUR 31 million. This is primarily due to the continued dynamic growth in our top-selling market, the USA. The EU label extension to include daylight PDT had a positive effect on sales growth in Europe.

At EUR 4.6 million, research and development costs remained slightly below the original forecast. This is mainly due to lower costs for clinical studies, such as the phase III study for the label extension to BCC in the USA as a result of slower patient recruitment.

At EUR 16.3 million, general administrative expenses were significantly higher than forecast. Expenses include the budgeted increase in administrative costs, particularly in the USA due to the expanded business activities, as well as administrative costs of Cutanea Life Sciences, Inc.

At just under EUR 29 million, sales and marketing costs in fiscal year 2019 were well above guidance. As planned, Biofrontera continued to invest in marketing and sales activities in the USA in 2019. The increased expenses are due to the restructuring of Cutanea and the development of sales for Xepi<sup>TM</sup>.

The operating loss of EUR 23 million is lower than forecast, mainly due to the first-time consolidation of Cutanea and lower than expected sales. However, this result is offset by cost reimbursements from Maruho reported as other income.

At just under EUR -4.8 million, earnings before taxes are in line with the most recent forecast. This includes positive effects from the difference between the values of the asset and liability positions of Cutanea (badwill) determined as part of the purchase price allocation for the first-time consolidation of Cutanea Life Sciences Inc in the amount of EUR 14,812 thousand.

# Outlook

# Business environment and forecast

The coronavirus pandemic, which is continuing to worsen around the world, is causing massive disruptions in global supply chains, consumer markets and the economy as a whole. Developments in the wake of the pandemic are both very dynamic and severely limit predictability.

The IFO Institute explains: "A precise prediction of the economic costs of the corona crisis is almost impossible at this point in time, given the high level of uncertainty about the continuing spread of the virus and, in particular, the measures taken by governments to contain the pandemic. Moreover, there is no historical experience of comparable events from which probable crisis patterns could be derived. Finally, very few economic indicators are currently available that would allow an assessment of the macroeconomic impact of the corona crisis. The corona pandemic has rendered all previously made forecasts obsolete." It is currently impossible to predict how the economy will develop worldwide, in Europe and in Germany. Central banks and governments have announced extensive plans of action. However, it is certain that the outbreak of the corona virus has had a significant impact on the prospects of the global economy.

The special opinion report of the German Council of Economic Experts published on March 30, 2020, describes three scenarios for economic development in the years 2020 and 2021. They differ in how long and to what extent the restrictive health policy measures will continue and how quickly a recovery will take place afterwards. In all three scenarios, the spread of the coronavirus puts an abrupt end to the emerging economic recovery, so that a recession in Germany in the first half of 2020 will be unavoidable. In the base scenario, the German Council of Economic Experts expects average annual decrease in gross domestic product (GDP) of 2.8 % in 2020. In 2021, GDP could increase by 3.7 %. In the base scenario, which according to current information is the most likely scenario, the economic situation will return to normal over the summer. The risk scenario with a course in the form of a more pronounced V would occur, for example, in the event of large-scale production shutdowns or longer-lasting health policy measures. Due to the more severe slump in the first half of the year, this scenario would result in GDP decrease of 5.4 % in 2020. In 2021, catch-up effects could ensure that GDP grows by 4.9%, to which the high statistical overhang would contribute in particular. The risk scenario in the form of a long U could occur if health policy measures continue beyond the summer and the economic recovery does not materialize until 2021. The policy measures taken may then not be sufficient to prevent profound damage to the economic structure. Worsening financing conditions and entrenched uncertainty could also slow down investment and lead to a reluctance to spend on the part of households. In such a scenario, GDP decrease in 2020 would be 4.5 %. In 2021, economic output would grow more slowly at 1.0 %.

In a publication on March 27, 2020, Deloitte describes the possible impact of the COVID-19 crisis on the development of the US economy. In two scenarios, Deloitte assumes that the spread of the disease will recede at the beginning of May and that the US population can return to normal activities in late spring and summer 2020. In the third, the most unlikely scenario, the COVID-19 crisis will continue to affect economic activity for over a year. In the most likely scenario, once the disease is under control, economic recovery is expected to begin by the end of 2020. An aggressive monetary and fiscal policy helps to get the recovery underway, similar to the economic recovery in other countries. GDP growth falls to a negative 8.3 % in 2020, but starts to recover in 2021 and rises rapidly in 2022 and 2023 before settling at a long-term level of 1.6 %. The second scenario assumes a financial crisis and deep recession, as the COVID-19 outbreak affects both the supply and the demand side of the economy. The economy shrinks to GDP growth of -15.6% in 2020, rapid and substantial fiscal and monetary policy interventions create enough demand to lift the economy out of recession by mid-2021 and a strong recovery occurs in 2022, when GDP could grow by 12.5%. In the third possible scenario of the impact on the US economy, Deloitte predicts GDP growth of -11.0% in 2020 and high unemployment in the range of -0.4% in 2021. Growth then rises to at least 3% or more by 2023 and remains high for another year

due to pent-up demand for high-priced consumer goods combined with very conservative monetary and fiscal policies.

Chronic diseases such as actinic keratosis are currently not the main focus of medical attention. As it is currently impossible to foresee how long and how strongly the pandemic will affect the economy, no reliable estimate or more precise quantification of the specific implications for sales and earnings can be made for the 2020 financial year. For this reason, Biofrontera's ability to forecast is significantly impaired at this time. In its initial budget for the 2020 financial year, the Group had assumed a 25% increase in revenue compared to the previous year, and operating costs at approximately the same level as in the previous year. However, the effects of the coronavirus pandemic may lead to a significant deviation from previous projections and to a noticeable decline in sales compared to previous plans and possibly even compared to the previous fiscal year. The anticipated reduced revenue will also have a negative impact on the profitability of the Group and the liquidity of Biofrontera AG as well as the Group in the 2020 financial year, as the lack of revenue may not be fully offset by cost reduction measures. At the same time, the cost reduction measures already initiated and published on March 20, 2020 will continue. These measures include in particular the introduction of short-time work in Germany and comparable measures in Spain and the UK, the reduction of the workforce in the USA by almost 20% and mandatory unpaid leave for all employees in the USA. Steps to secure liquidity and strengthen cash flow are given high priority.

Under the license agreement concluded with Maruho in April 2020, a one-time payment in the amount of EUR 6.0 million from Maruho is to be received in the short term.

Long-term, structural growth drivers - including the reimbursement framework in the USA, the label expansions for Ameluz<sup>®</sup> and, in Europe, the increasing acceptance of daylight PDT - remain intact. In fact, it is likely that they will accelerate once the coronavirus crisis is overcome.

# Planned regulatory progress

Patient recruitment for the phase III trial to extend the US approval to include BCC has already started in September 2018. Due to the demanding study protocol imposed by the FDA, patient recruitment is proceeding slowly, prompting us to take various measures in the past financial year to accelerate recruitment. Nevertheless, we do not expect the study results until 2021.

Following the recent label extension for Ameluz<sup>\*</sup> in the EU, Biofrontera has also agreed with the US regulatory authority FDA on a corresponding extension of the approval for Ameluz<sup>\*</sup> in the USA, with the aim of obtaining approval for the treatment of AK on the extremities and trunk/neck. The FDA provided positive feedback and requested additional clinical trials to approve the label extension of Ameluz<sup>\*</sup> for additional body regions.

Following consultation with the FDA, Biofrontera has initiated a pharmacokinetics study (PK study) in the USA in order to ensure the reimbursement of several tubes of Ameluz<sup>®</sup> for the treatment of larger body regions in the periphery. The aim of this phase I study is to obtain pharmacokinetic profiles following an Ameluz<sup>®</sup> PDT in patients with actinic keratosis in an extended treatment area in the face/head or peripheral area. In addition, safety and tolerability for the patient during and after treatment will be evaluated. Patient recruitment was planned to take 3-5 months and the phase-I trial is expected to be completed in the third quarter of 2020. It is still unclear whether this timeline can be met due to the corona crisis.

To support this progress with an optimized light source, Biofrontera is developing a new lamp, the BF-RhodoLED<sup>®</sup> XL, which can be used to illuminate larger areas of skin. The company plans to submit the approval applications in the second half of 2020.

In addition, on March 3, 2020, the company signed a binding term sheet for a research and development collaboration to expand the indications of Ameluz<sup>®</sup> to include the treatment of moderate to severe acne, as well as negotiations for a marketing license for Ameluz<sup>®</sup> in parts of Asia and Oceania by Maruho. With respect to the possible label extension of Ameluz<sup>®</sup> for acne, Biofrontera has prepared a corresponding development plan and has received feedback from the FDA on the design of the necessary clinical trials to allow the study program to start in 2020.

However, due to the corona crisis, there are considerable uncertainties whether all planned measures and activities can be implemented as planned.

# 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 company'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. In the 2019 financial year, Biofrontera's existing risk management structures were 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 decisionmaking 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 centrally organized 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 control system

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, and the combined company and Group 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.

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 currency and credit risks that may have an impact on its net assets, financial position and results of operations.

# Market risk

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. Lower sales of Xepi<sup>™</sup> may lead to a different evaluation of the medium-term sales and earnings prospects for Xepi<sup>™</sup> and consequently to a revaluation of the value of the Xepi<sup>™</sup> license on the balance sheet. The purchase price liability to Maruho for future profits from the sale of Xepi<sup>™</sup> is subject to market risk (earn-out) and depends on the amount of profits generated.

Furthermore, in the event of a prolonged decline in business activity, the shelf life of already produced Ameluz<sup>\*</sup> tubes may expire and inventories may have to be destroyed.

# Currency risks

As a result of the company's internationalization, the company is exposed to currency risks in its sales and procurement markets. The development of exchange rates can have both a positive and a negative impact on the company's financial results.

The valuation of financial instruments may also involve risks related to currency exchange rate, which are described in more detail in the chapter on reporting on the financial instruments deployed by Biofrontera.

The development of financial markets is continuously monitored in order to identify potential opportunities and risks and to be able to respond accordingly.

# Interest rate risks

Biofrontera is subject to interest rate risks, which are deemed to be low, as the existing interest rate modalities for the respective financings of the Biofrontera Group can usually be adjusted to market conditions in the short to medium term. The performance component of the EIB loan is calculated based on the change in the market capitalization of the company, capped at 4%.

# 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.

# 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<sup>\*</sup>, 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<sup>™</sup> 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<sup>™</sup> our portfolio now includes an innovative, promising product with a large market potential.

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, the novel coronavirus (COVID-19) has become a global pandemic. As a result of the measures implemented by governments around the world, Biofrontera's business operations is directly affected. In particular, there is a risk of a temporary and significant decline in demand for Biofrontera's products worldwide. The upkeep of business processes may also be impeded by lower revenue, and if employees of the company or key suppliers contract an infection with COVID-19.

The direct and indirect effects of the pandemic can have a negative impact on the company's liquidity position as the pandemic develops. In addition, the success of required capital measures by the company could be jeopardized.

To this end, the company has taken 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.

With regard to the risks that may threaten the going concern status, we refer to the disclosures in the Risk and Opportunity Report, section Liquidity, profitability, capital market access and risks to the going concern status.

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, capital markets access and risks to the going concern status

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

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

In this connection, the company's going concern status could depend on the injection of further funds by current shareholders or other investors. Access to the capital market and the acceptance of investors are consequently of great importance for the company, which could also in future be dependent on the further injection of necessary equity capital by the capital market.

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. The company is currently sufficiently financed due to the drawdown of several tranches totaling EUR 15 million from the European Investment Bank Ioan as well as the one-time down payment in the amount of EUR 6 million from the licensing agreement with Maruho signed in April 2020. The planned capital measure for March 2020 with a maximum total of up to EUR 16 million had to be cancelled due to the turmoil on the capital markets as a result of the Corona crisis.

In order to finance its business operations for a further 12 months and beyond, Biofrontera is dependent on a capital measure of at least EUR 5 million by no later than the end of the 2020 financial year. The Management Board expects, based on the assumption that the general economic conditions will normalize and based on the consistently successful track record with capital measures to date, that the required liquidity for the business can be ensured in the future. However, should this no longer be possible due to a continuing crisis caused by the COVID 19 pandemic, this would pose a threat to the going concern status of the Biofrontera Group.

Should the worldwide COVID-19 pandemic last longer than expected, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite the cost reduction measures that have been introduced, and also render further access to financing on the capital market impossible. However, the Management Board currently assumes that following the end of the current crisis, it will once again be possible to successfully implement appropriate capital measures.

# **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 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 counterbalance 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<sup>®</sup>, which it markets in Europe and the USA and Xepi<sup>™</sup>, which is limited to the US market and is still in its launch phase. A risk exists that neither Ameluz<sup>®</sup> nor Xepi<sup>™</sup> 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<sup>™</sup> 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<sup>™</sup> in the product portfolio has already made a significant contribution to mitigating this risk.

# Patent protection

The company may be subject to patent protection risks. If our products are marketed successfully, the resultant 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<sup>®</sup>, expired. However, Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, additional patent applications have been submitted

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 results and liquidity targets as well as impairments of intangible assets.

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<sup>®</sup>, 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.

# Purchasing and production

As a pharmaceutical manufacturer, the company is exposed to various risks in connection with the procurement and production of its products. Biofrontera is dependent on suppliers for its production, 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<sup>®</sup> 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 is 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 counteract this risk, such as a comprehensive authorization concept. 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 personal 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 cover

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 cover.

# 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.

# 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.

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

# 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 sees opportunities in the expansion of its products' regulatory approvals, especially in the label extension for Ameluz<sup>®</sup> in our all markets, especially in the USA, to expand and exploit market potential. In addition, there is a medium and long-term opportunity to expand the portfolio by developing new products based on our nanoemulsion technology.

On March 19, 2019, Biofrontera signed an agreement to continue the expired research collaboration with Maruho regarding branded generics. As part of the newly agreed project phase Biofrontera will prepare the formulation of one of the four active ingredients in Biofrontera's nanoemulsion jointly tested during a previous project phase (Phase 1) for clinical trials. The agreement does not cover clinical testing possibly carried out during a subsequent project phase, which will be the subject of an additional agreement to be concluded between the parties in due course, depending on the results of the new project phase. Previously existing intellectual property (IP), in particular Biofrontera's nanoemulsion technology, shall remain the property of the respective owner. New IP and results of the new project phase, including project documentation, shall be shared equally by the parties. According to the current budget, the new project phase will require up to EUR 1.1 million in research costs, which are to be borne exclusively by Maruho. Should the costs exceed the currently budgeted amount to be borne by Maruho, the parties have agreed to consult on the next steps and the issue of how to bear the costs.

In addition, at the time of publication of the annual report, Maruho and Biofrontera are in negotiations about a cooperation in the research and development regarding the use of Ameluz<sup>®</sup> for the treatment of acne. Maruho and Biofrontera initially signed a non-binding term sheet on March 19, 2019. A corresponding development plan for the indication expansion was prepared and, in consultation with the FDA, the design of the necessary clinical studies was determined. On March 3, 2020 a binding term sheet was signed regarding a license agreement for the marketing of Ameluz<sup>®</sup> in East Asia and Oceania. In April 2020, the licensing agreement was signed by both parties and Maruho made the one-time down payment in the amount of EUR 6.0 million to Biofrontera.

# Overall opportunity and risk situation at Biofrontera

The Biofrontera Management Board believes that the current COVID 19 crisis 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 2020 and that the planned capital measure can be executed.

However, 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.
  The full impact on the future performance of the business remains unknown at the time of publication
  of the 2019 Annual Report.
- To date, the Group has been able to meet its payment obligations at all times. The company's current level of liquidity is sufficient due to the drawdown of the second tranche of the EIB loan in February 2019 as well as the receipt of the EUR 6.0 million down payment form Maruho as part of the licensing agreement signed in April 2020. A further capital increase, scheduled for March 2020, was cancelled until further notice due to the corona crisis. There is no guarantee that Biofrontera will be able to carry out any such capital measure at a later date. Should this no longer be possible due to an ongoing crisis caused by the COVID 19 pandemic, this would pose a threat to the going-concern status of the Biofrontera Group,
- With the approval of daylight PDT with Ameluz<sup>®</sup> in the EU in 2018, Biofrontera's market position was further strengthened. We hope to further increase the market potential of Ameluz<sup>®</sup> from the recently

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<sup>®</sup> in combination with our redlight lamp BF-RhodoLED<sup>®</sup>, for which we started patient recruitment in September 2018.
- In the United States, the company is also working diligently to improve reimbursement modalities and to expand the approval to include the treatment of actinic keratoses on the extremities, trunk and neck. For the latter, Biofrontera will soon conduct a further clinical trial in the USA in order to obtain a respective label extension. To ensure the reimbursement of several tubes for the treatment of larger body regions in the periphery, Biofrontera is currently planning a pharmacokinetics study in which the safety of the treatment with three tubes of Ameluz<sup>®</sup> will be tested.
- To further strengthen its competitive position, Biofrontera is working on the development of the new lamp "BF-RhodoLED<sup>®</sup> XL", which will allow the application of Ameluz<sup>®</sup> on larger areas. With the market launch of this new medical product, the company expects a further increase in sales of Ameluz<sup>®</sup>, 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 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 FDAapproved drug Xepi<sup>TM</sup>, 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 company growth and strengthening of the US-market presence.
- Biofrontera considers itself well positioned with regard to the legal disputes described in the following chapter. Provisions were made in the year under review 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

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<sup>\*</sup> 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<sup>\*</sup> and Ameluz<sup>\*</sup> in the United States.

Submission of expert reports and related discovery regarding these claims finished in early December 2019. The parties have filed motions for summary judgment and motions to exclude certain expert testimony, with briefing closing on February 18, 2020. Through these expert reports and motions, our responses to the patent

claims include that we do not infringe the DUSA patents and that the patents are invalid. With regard to the non-patent claims, our responses include that the information does not constitute trade secrets and that Biofrontera's actions do not constitute any violation of trade practices. With regard to DUSA's claims for damages, our responses include that DUSA has not proven it is entitled to lost profits or unjust enrichment.

We believe the court likely will next set a hearing date and issue a decision on the motions, and will then set a schedule for the case to proceed to trial if necessary. Although as of the date of this annual report, no dates have been assigned, we expect the case to proceed through 2020 or 2021. We believe that these claims lack merit and intend to defend against them vigorously; however, we cannot guarantee that we will be successful. The court largely denied a motion by DUSA for a preliminary injunction, but did order Biofrontera not to use any documents, or documents derived from documents, that originated at DUSA.

In addition, Biofrontera 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.

We have incurred, and expect to continue to incur, significant expenses in defending these claims, and we expect to have to divert significant employee resources, including management resources, to defend the claims.

In July 2018, Biofrontera Inc. brought a lawsuit against DUSA in California Superior Court. Biofrontera's complaint alleges that DUSA engaged in unfair competition by providing excessive product samples to physicians and by using its distributor to inflate product prices. Biofrontera's complaint also alleges that DUSA engaged in tortious interference by making statements to third parties regarding the off-label use of its products. Though the court has dismissed Biofrontera's claims related to DUSA's sampling and pricing practices, the court has allowed Biofrontera's tortious interference claims to proceed to discovery.

On June 11, 2018, Biofrontera 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's shares that were designed to defame Biofrontera 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 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'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's common law claims.. Deutsche Balaton AG, Wilhelm Konrad Thomas Zours and Delphi Unternehmensberatung AG are among our major shareholders.

Deutsche Balaton AG had filed in 2017 an application for a special audit with the Regional Court of Cologne to investigate the contractual situation with Maruho Co. Ltd., Japan and related matters. The special audit request was rejected by the Cologne Regional Court in November 2017. Deutsche Balaton AG filed an appeal against the rejection, which was dismissed by the Cologne Higher Regional Court by order on July 31, 2019. DELPHI

Unternehmensberatung AG, which indirectly holds the majority of the shares of Deutsche Balaton AG, filed an identical application for a special audit with the Cologne Regional Court in January 2018. These proceedings were suspended until the Cologne Higher Regional Court had ruled on the appeal by Deutsche Balaton AG. Meanwhile DELPHI Unternehmensberatung AG has withdrawn its application. Both legal proceedings were thus terminated in favour of Biofrontera AG. annual general meeting

Deutsche Balaton AG has further brought a claim for rescission and nullity 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 10 July 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 action 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<sup>\*</sup>), 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 supervisory board member) 12 (Amendment of Article 13 of the Articles of Association (resignation from the supervisory 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 Shareholders' 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 Shareholders' Meeting. The lawsuit is currently pending at Cologne Regional Court under file number 82 O 75/19.

Biofrontera AG has applied for and received various 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 publishes a blog with false and defamatory allegations about Biofrontera AG and its management. Corresponding lawsuits against Automattic Inc. are being prepared.

A shareholder has claimed against Biofrontera AG that on the occasion of the capital increase conducted in April 2016, fewer shares were allocated to him than in his opinion should have been allocated. The shareholder is claiming alleged damages of EUR 48,500. The claim has so far only been asserted out of court. A claim to the competent court has not yet been filed. Biofrontera AG considers the demand to be without merit.

# **Remuneration report**

The remuneration of the Management Board members consists of a fixed salary that is paid in twelve equal monthly instalments. In addition, an annual performance-related bonus payment is planned for the members of the Management Board, which must be linked to the long-term success of the company in accordance with the law on the appropriateness of Management Board remuneration. A long-term compensation component also exists through participation in the company's stock option plan.

The total remuneration paid to members of the Management Board in the 2019 financial year and the total accumulated number of stock options issued to the Management Board as of December 31, 2019 were as follows:

in Euro thousands unless otherwise indicated	Prof. Dr. Hermann Lübbert	Thomas Schaffer	Christoph Dünwald
Non-performance-based salary component 2019	350	257	275
Compensation in kind 2019	16	12	16
Retirement benefit expenses 2019	-	-	-
Non-performance-based salary component 2018	350	230	250
Compensation in kind 2018	16	11	14
Retirement benefit expenses 2018	-	-	-
Performance-based salary component 2019	167	154	140
Performance-based salary component 2018	80	70	50
Fair value of stock options granted 2019	37	25	25
Fair value of stock options granted 2018	188	117	117
Income from the exercise of stock options 2019	149	-	-
Income from the exercise of stock options 2018	94	83	-
Number of stock options (Dec 31, 2019)	244,495	150,000	150,000
Fair value when granted (2019)	414	255	255
Number of stock options (Dec 31, 2018)	276,850	140,000	140,000
Fair value when granted (2018)	423	230	230
thereof granted 2019 (number of stock options)	14,495	10,000	10,000
thereof granted 2018 (number of stock options)	80,000	50,000	50,000

Company cars are also available to the members of the Management Board for business and private use. The existing employment contracts stipulate that – depending on the achievement of targets to be mutually agreed – an annual bonus is payable. If the targets are exceeded, the maximum annual bonus payable is capped. If the targets are missed by less than 70%, the bonus payment is reduced straight-line. No bonus is to be paid, if the targets are missed by a greater margin than this. At the end of each fiscal year, the performance measurements for the following fiscal year are mutually agreed upon in a performance target agreement.

Severance pay in the event of premature termination of a member of the Management Board's duties without good cause is capped at twice the specified annual salary and amounts to no more than the total remuneration due for the remaining period of the contract (severance cap). In the event of a takeover offer within the meaning of the German Securities Acquisition and Takeover Act (WpÜG), all members of the Management Board are entitled to severance payments amounting to three years' salary.

To further enhance the long-term incentive effect of variable compensation and consequently align it with the company's sustainable development and growth, the members of the Management Board have obligated themselves to hold as private assets ordinary shares in the company for share options granted from the 2010 share option program for a three-year period beginning one month after the options' issue date ("restricted shares"), and thereby be invested in the company. The level of personal commitment is specified differently in detail for each member of the Management Board. An early sale of such restricted ordinary share must be

reported immediately to the Supervisory Board Chair, and the company can request a return transfer of an equivalent number of stock options free of charge within a month of receiving such notification, with the most recently granted options being those that must be returned first (last in, first out). A return transfer is not required if the Management Board member can demonstrate that the sale of the restricted shares was necessary to meet pressing financial obligations.

# 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.

# Shareholders

The detailed presentation of the positions held by the shareholders as of December 31, 2018 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 6 Subscribed capital, capital reserve, conditional capital.

# Share capital and existing capital

The detailed presentation of share capital as of December 31, 2019, 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 6 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 on 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 <u>www.biofrontera.com</u> in the section "Investors", subsection "Corporate Governance".

Leverkusen, April 20, 2020 Biofrontera AG

U. Leles

Villah

Prof. Dr. Hermann Lübbert Thomas Schaffer Chief Executive Officer Chief Financial Officer

# F.1.2) Consolidated financial statements as of December 31, 2019

39,133

58,363

Assets			
in EUR thousands		December 31, 2019	December 31, 2018
Non-current assets			
Tangible assets	(1)	5,230	794
Intangible assets	(1)	22,848	352
Deferred taxes	(8)	7,794	10,400
Total non-current assets		35,872	11,546
Current assets			
Current financial assets			
Trade receivables	(3)	5,031	3,397
Other financial assets	(4)	1,077	794
Cash and cash equivalents	(7)	11,119	19,451
Total current financial assets		17,227	23,642
Other current assets			
Inventories	(2)	4,065	3,177
Income tax reimbursement claims	(6)	4	53
Other assets	(5)	1,195	715
Total other current assets		5,264	3,945
Total current assets		22,491	27,587

Consolidated balance sheet as of December 31, 2019

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

Total assets

# Equity and liabilities

in EUR thousands		December 31, 2019	December 31, 2018
Equity	(9)		
Subscribed capital		44,849	44,632
Capital reserve		118,103	117,109
Capital reserve from foreign currency		(288)	(2)
Loss carried forward		(145,351)	(136,505)
Loss for the period		(7,358)	(8,878)
Total equity		9,955	16,356
Non-current liabilities			
Financial debt	(10)	22,110	13,462
Other provisions	(13)	-	1,545
Other financial liabilities	(11)	14,720	-
Total non-current liabilities		36,830	15,007
Current liabilities			
Current financial liabilities			
Trade payables	(12)	4,196	1,806
Current financial debt	(10)	1,212	165
Other financial liabilities	(11)	99	29
Total current financial liabilities		5,507	2,000
Other current liabilities			
Income tax	(6)	11	-
Other provisions	(13)	3,495	2,891
Other current liabilities	(14)	2.565	2,879
Total other current liabilities		6,071	5,770
Total current liabilities		11,578	7,770
Total equity and liabilities		58,363	39,133

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

# F.1.3) Consolidated statement of comprehensive income for the fiscal year 2019

in EUR thousands		2019	2018
Sales revenue	(16)	31,265	21,107
Cost of sales	(17)	(4,875)	(4,451)
Gross profit from sales		26,390	16,656
Operating expenses			
Research and development costs	(18)	(4,636)	(4,427)
General administrative costs	(19)	(16,275)	(12,963)
Sales costs	(20)	(28,856)	(17,744)
Loss from operations		(23,377)	(18,478)
Interest expenses	(21)	(2,466)	(1,614)
Effective interest expenses	(21)	(245)	(170)
Interest income	(21)	127	24
Other expenses	(22)	(799)	(332)
Other income	(22)	7,171	1,301
Other income from the PPA (Badwill)	(22)	14,812	-
Loss before income tax		(4,777)	(19,269)
Income tax	(23)	(2.581)	10,391
Loss for the period		(7,358)	(8,878)
Expenses and income not included in profit/loss			
Items which may in future be regrouped			
into the profit and loss statement under			
certain conditions.		(286)	(702)
Translation differences resulting from the conversion of		(200)	(702)
Other income total		(286)	(702)
Total loss for the period		(7,644)	(9,580)
Basic/diluted earnings per share	(24)	(0,16)	(0,20)

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.

(in EUR thousands except for share information	)	Ordinary shares	Subscribed capital	Capital reserve	Capital from foreign currency conversion adjustments (OCI)	Accumulated loss	Total
Balance as of January 1, 2018		38,416,828	38,417	100,769	700	(136,505)	3,381
Loss for the period		-	-	-	-	(8,878)	(8,878)
Foreign currency conversion		-	-	-	(702)	-	(702)
Consolidated result		-	-	-	(702)	(8,878)	(9,580)
Capital Increase		6,000,000	6,000	18,000	-	-	24,000
Conversion from convertible bond 2016/20	021	6,874	7	26	-	-	33
Conversion from convertible bond 2017/20	022	13,472	13	51	-	-	64
Conversion of stock options from the stock	< option	195,500	195	433	-	-	628
Costs of equity procurement		-	-	(2,432)	-	-	(2,432)
Increase in capital reserve from the stock of	option	-	-	262	-	-	262
Balance as of December 31, 2018	(9)	44,632,674	44,632	117,109	(2)	(145,383)	16,356
Balance as of December 31, 2018	(9)	44,632,674	44,632	117,109	(2)	(145,383)	16,356
First-time application of IFRS 16		-	-	-	0	32	32
Balance as of January 1, 2019		44,632,674	44,632	117,109	(2)	(145,351)	16,388
Loss for the period		-	-	-	-	(7,358)	(7,358)
Foreign currency conversion		-	-	-	(286)	-	(286)
Consolidated result		-	-	-	(286)	(7,358)	(7,644)
Conversion from convertible bond 2017/20	022	118,841	119	429	-	-	548
Conversion of stock options from the stock	< option	97,850	98	207	-	-	305
Costs of equity procurement		-	-	(2)	-	-	(2)
Increase in capital reserve from the stock of	option	-	-	360	-	-	360
Balance as of December 31, 2019		44,849,365	44,849	118,103	(288)	(152,709)	9,955

# F.1.4.) Consolidated statement of changes in equity for the fiscal year 2019

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

# Consolidated cash flow statement for the fiscal year 2019

in EUR thousands	01.0131.12.2019	01.0131.12.2018
Cashflows from operations		
Loss before income tax	(4,777)	(19,269)
Adjustments to reconcile loss before income tax to cash flow into operations		
Income tax	36	(9)
Financial result	2,658	1,784
Depreciation	3,156	754
Other non-current provisions	(1,545)	1,545
Losses from disposal of assets	386	5
Non-cash (income) and expenses	(15,334)	(328)
Changes in operating assets and liabilities		
Trade receivables	(673)	(1,836)
Other assets and income tax assets	3,044	(149)
Inventories	(148)	368
Trade payables	596	185
Provisions	710	2,366
Other liabilities	(21,003)	1,150
Net cash flow used in operational activities	(32,894)	(13,434)
Cash flow from investment activities		
Purchase of intangible and tangible assets	(1,854)	(513)
Business combination Cutanea	22,814	-
Proceeds from sale of intangible and tangible assets	93	2
Net cash flow from (used in) investment activities	21,053	(511)
Cashflows from financing activities		
Proceeds from the issue of shares	-	24,000
Costs of equity procurement	(3)	(1,768)
Proceeds from draw down of EIB loan	5,000	-
Proceeds from exercise of employee stock options	305	628
Leasing payments	(1,183)	-
Interest paid	(664)	(536)
Repayment of convertible bond 2016/2021	-	(50)
Net cash flows provided by financing activities	3,455	22,274
Net increase/(decrease) in cash and cash equivalents	(8,386)	8,329
Changes from exchange rate differences	54	39
Cash and cash equivalents at the beginning of the period	19,451	11,083
Cash and cash equivalents at the end of the period (27)	11,119	19,451

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

# F.1.6) Notes to the consolidated financial statements as of December 31, 2019

# 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. At year-end, the companies of Cutanea Life Sciences, Inc. acquired in 2019 as well as Biofrontera Newderm Inc. were merged with Biofrontera Inc.

# 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, 2019 to December 31, 2019 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. With regard to material uncertainties in connection with the going concern status, we refer to Note 33 Subsequent events.

Biofrontera AG is the parent company, which prepares consolidated financial statements for the group companies.

The consolidated financial statements as at December 31, 2019 are presented in euros (EUR) or thousands of euros. Rounding differences can arise in the tables due to commercial rounding.

On April 20, 2020, the Management Board approved the consolidated financial statements for the financial year ending 31 December 2019 for publication and forwarding to the Supervisory Board.

# Changes in accounting standards

The accounting policies applied are consistent with those applied on December 31, 2018, with the exception of the new and revised standards and interpretations described below that were applied for the first time starting with the 2019 financial year.

Standard	Description	Mandatory application	Expected effects
IFRS 16	"Leases"	January 1, 2019	See below
Amendment to IFRS 9	"Financial instruments" Early repayment regulations with negative compensation	January 1, 2019	No effects

Standard	Description	Mandatory application	Expected effects
IFRIC 23	Uncertainty over income tax treatments	January 1, 2019	No effects
Amendment to IAS 19	"Employee benefits" Plan Amendments, curtailments or settlements	January 1, 2019	No effects
Amendment to IAS 28	"Holdings in associated companies and joint ventures" Long term holdings in associated companies and joint ventures	January 1, 2019	No effects
Annual Improvements to IFRSs	Annual improvements to IFRSs Cycle 2015-2017	January 1, 2019	No effects

# First-time application of IFRS 16

Biofrontera has applied the new standard IFRS 16 "Leases" for the first time for the 2019 financial year.

For financial years beginning on or after January 1, 2019, IFRS 16 requires the application of a new lease standard. Contrary to the previous regulation, it provides for lessees to recognize on the balance sheet the rights of use and lease liabilities resulting from leases. The previous distinction between operating leases, which are generally off-balance sheet, and finance leases, which are on-balance sheet, is therefore no longer applicable. The leasing liability to be carried as a liability is calculated as the net present value of the highly probable payments to be made to the lessee. They are carried forward using the so-called effective interest method. The right of use of the underlying asset to be recognized in return is to be recognized 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 straight-line basis and tested for impairment if there is any indication of impairment.

The new regulations for lessors essentially correspond to the previous regulations.

The leasing contracts concluded by Biofrontera as lessee mainly relate to buildings and motor vehicles used for operational and administrative purposes. The company has applied the new accounting standard under the modified retrospective method to leases with a remaining term of more than one year as of January 1, 2019. Leases of lesser value are excluded.

The carrying amounts of the rights of use and lease liabilities to be recognized are carried forward as if the new standard had already been applied in the past. Future lease payments are to be discounted at the imputed interest rate of the lessor or, if not available, at the marginal borrowing rate on the date of first application. Differences between the carrying amounts of the lease rights to be recognized for the first time and the lease liabilities change the Group's reserves, taking deferred taxes into account. The previous year's figures have not been adjusted.

Biofrontera has decided to make use of the simplification of IFRS 16.6 for expenses from leasing relationships with a remaining term of no more than one year and from leasing relationships with a low value, and to immediately expense monthly leasing instalments, in other words, applying the same accounting treatment as with IAS 17.

Biofrontera will not show the rights of use and leasing liabilities separately on its balance sheet, but rather include them in items that contain comparable assets and liabilities.

The first-time application of IFRS 16 had no material effect on the calculation of the basic earnings per share.

The marginal interest rate on the date of first-time application was 1.53% for buildings, 1.85% for motor vehicles (Germany) and 5.20% (USA). There were no onerous leases as of January 1, 2019. The first-time application of IFRS 16 had the following effects:

Leasing	31.12.2018	Amendment	01.01.2019
in EUR thousands	carrying amount	IFRS 16	carrying amount
Tangible assets	794	2,335	3.129
Loss carried forward	(145,383)	32	(145,350)
Non-current financial liabilities	13,462	1,698	15,160
Current financial liabilities	165	606	771

# 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": Definition of a business	January 1, 2020	No effects
Amendment to IFRS 9	"Financial instruments", IFRS 7 "Financial instruments: Disclosures" and IAS 39 "Financial instruments: Recognition and valuation": Interest Rate Benchmark Reform	January 1, 2020	No effects
Amendment to IAS 1	"Presentation of financial statements" and IAS 8 "Accounting policies, changes in accounting estimates and errors": definition of "material"	January 1, 2020	No effects
Amendment to IAS 1, IAS 8*	"Presentation of financial statements": classification of liabilities as current or non- current	January 1, 2022	No effects
Amendments to References to the Conceptual Framework*	References to the Conceptual Framework	January 1, 2020	No effects
IFRS 17*	Insurance Contracts	January 1, 2021	No effects

\* Adoption by the EU still pending

# Basis of consolidation

The consolidated financial statements for the financial year ending 31 December 2018 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 following companies are included in the consolidated financial statements as of December 31, 2019. These were merged with Biofrontera Inc. in 2019:

- 6. Biofrontera Newderm LLC, Woburn, Massachusetts, USA, with a direct shareholding of 100% (founded March 21, 2019; merged on December 31, 2019)
- 7. Cutanea Life Sciences, Inc., Wayne, Pennsylvania, USA, with a direct shareholding of 100% (acquisition date March 25, 2019; merged on December 30, 2019)
- 8. Dermarc LLC, Wayne, Pennsylvania, USA, with a direct shareholding of 100% (acquisition date March 25, 2019; merged on December 27, 2019)
- 9. Dermapex LLC, Wayne, Pennsylvania, USA, with a direct shareholding of 100% (acquisition date March 25, 2019; merged on December 27, 2019)

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, 2019 pursuant to uniform principles. The consolidated financial statements as of December 31, 2019 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. Interim results were eliminated

# Business combinations

# Cutanea Life Sciences, Inc.

On March 25, 2019, Biofrontera Inc. entered into an agreement with Maruho to acquire 100% of the shares of Cutanea Life Sciences, Inc., USA including its subsidiaries Dermark LLC and Dermapex LLC (together "Cutanea") through its wholly owned subsidiary Biofrontera Newderm LLC, USA, ("Biofrontera"), newly founded on March 21, 2019. Cutanea has been marketing Aktipak<sup>®</sup>, a prescription gel for the treatment of acne, as well as Xepi<sup>™</sup>, a prescription cream for the treatment of impetigo, since November 2018. Due to technical difficulties in the manufacturing process of Aktipak<sup>®</sup>, sales of the drug were discontinued in summer 2019.

The acquisition of Cutanea Life Sciences, Inc. in March 2019 has enabled Biofrontera to market a FDA-approved drug that has already been introduced in the US market. We are convinced that with Xepi<sup>™</sup> our portfolio now includes an innovative, promising product with a large market potential.

Biofrontera acquired Cutanea for an initial purchase price of USD 1.00. Maruho will provide up to USD 7.3 million in start-up financing for Cutanea's redesigned business activities (start-up costs). An additional part of the purchase price equal to the start-up costs actually paid is to be paid back to Maruho by 2023.

As part of the earn-out agreement with Maruho, the profits from the sale of Cutanea products will be shared equally between Maruho and Biofrontera until 2030. Maruho has also agreed to assume all running costs that may be incurred during the first three months after completion of the transaction. Maruho also indemnifies Biofrontera and Cutanea against all liabilities relating to or resulting from the pre-contractual period. In addition, Maruho assumed all Cutanea restructuring costs that incurred in the period up to three months after the acquisition.

According to the purchase agreement, the acquisition date is March 25, 2019. As a consequence, the acquisition was made with economic effect from that date. As of the same date, Biofrontera gained control over the acquired companies, which means that Cutanea will be fully consolidated in the consolidated financial statements of Biofrontera in accordance with IFRS 3 with effect from March 25, 2019.

# Estimates related to the acquisition of Cutanea Life Sciences, Inc. on March 25, 2019

The fair values of the assets and liabilities (in accordance with IFRS 3) on the acquisition date March 25, 2019 are as follows:

in EUR thousands	March 25, 2019
Non-current assets	
Property, plant and equipment	1,340
Intangible assets	23,604
Total non-current assets	24,944
Current assets	
Trade receivables	1,004
Cash and cash equivalents	20,231
Inventories	763
Other assets	3,758
Total other current assets	25,756
Total assets	50,700
Non-current liabilities	
Financial liabilities	495
Current liabilities	
Trade payables	1,795
Other current liabilities	22,110
Total current liabilities	23,905
Total equity and liabilities	24,400
Net assets	26,300
Purchase price (earn out)	11,488
Badwill	14,812

The badwill, i.e. the difference between the assets and liabilities of Cutanea at the time of acquisition and the carrying amounts of the assets and liabilities of Cutanea at the time of acquisition, is offset by future expenses for reorganizing the business activities of Cutanea and establishing the distribution of Xepi<sup>™</sup>. The seller

(Maruho) hopes that the successful marketing of Cutanea products by Biofrontera and the associated share of profit will bring economic advantages over continuing this business on its own.

Based on the assumption that Maruho would fully finance the start-up costs, the purchase price increases to EUR 17,325 thousand as of April 1, 2019. No contingent liabilities were identified.

The following assets and liabilities were measured at fair value as part of the purchase price allocation. The assumptions for the valuation of the intangible assets are as follows:

Assets and liabilities identified at acquisition date	Fair value in EUR thousands	Valuation method	Operating life	Cost of capital
Intangible assets				
Xepi <sup>™</sup> marketing license	23,604	Acquisition method	139 months	9.1 %

The results of operations of Cutanea Life Sciences, Inc. including all subsidiaries is as follows:

in EUR thousands	March 25 – December 31, 2019
Sales revenue	822
Cost of sales	(1,148)
Gross profit on sales	(326)
Research and development costs	(103)
General administrative costs	(2,334)
Sales costs	(5,906)
Loss on operations	(8,669)
Interest expenses	(16)
Interest income	85
Other expenses	(1,996)
Other income due to reimbursement by Maruho	6,215
Other income	108
Loss before income tax	(4,273)
Income tax	65
Loss after income tax	(4,208)

If the acquisition had taken place on January 1, 2019, the contribution to sales would have been EUR 1,635 thousand. The loss of Cutanea could not be determined.

The transaction costs included in current expenses amount to EUR 297 thousand.

Due to the integration of Cutanea's activities into Biofrontera Inc., the existing deferred tax assets at Cutanea were not capitalized, as these probably cannot be offset against future profits.

# Translation of amounts in foreign currencies

The consolidated financial statements as of December 31, 2019 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 (2019: 1.1227 USD/EUR, previous year 1.1445 USD/EUR). Income and expense items are translated applying the average exchange rates applicable to the relevant period (2019: 1.1194 USD/EUR, previous year: 1.1818 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 (2019: EUR -286 thousand, previous year: EUR -702 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 in the amount of EUR 324 thousand (previous year: EUR 650 thousand).

# Application of estimates

The preparation of the consolidated financial statements for December 31, 2019 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.

The main areas of application for assumptions, estimates and the exercise of scope for discretion lie in the fair value measurements in accordance with IFRS 13, in particular the determination of the fair values of assets and liabilities as part of the purchase price allocation (PPA). In addition, estimates are made in the context of the measurement of provisions, leases in accordance with IFRS 16, stock options, EIB loans and income taxes as well as in determining the useful lives of non-current assets. Estimates are based on historical experience and other assumptions that are considered appropriate under the given circumstances. These are reviewed on an ongoing basis, but may differ from the actual values.

The carrying amounts of items affected by estimates are presented in the respective 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
- Fixtures and equipment 4 years, straight-line
- Office and laboratory facilities 10 years, straight-line
- Laboratory devices 13 years, straight-line

Since January 1, 2018, 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<sup>®</sup>. 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. 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. Receivables denominated in foreign currencies have been translated into euros applying the exchange rates on the balance sheet date, with any translation differences being recognized in profit or loss.

# 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.

# **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".

# 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. Foreign currency liabilities are translated applying the period-end exchange rate. Exchange rate losses and gains are reported in the income statement.

# 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

In May 2017, the company arranged a loan agreement for up to EUR 20 million with the European Investment Bank (EIB). The loan is unsecured and guaranteed by our major subsidiaries. Originally, it was available in tranches within a two-year period. At the beginning of 2019, it has been extended for another year. In July 2017, the company drew down a first tranche of EUR 10.0 million, with a further tranche of EUR 5 million being drawn down after the reporting date in February 2019. Each tranche must be paid back within five years after it has been made available. 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 first tranche is calculated based on a notional 0.64% 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 12.33% for the 2017 EIB loan and 10.63% for the 2019 EIB loan.

# 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.

# Share options

Share 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.

#### 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 – claims from deferred taxes are only recognized to the extent that it is probable that taxable profits will be available to utilize the claims. 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<sup>\*</sup> 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<sup>\*</sup> is reimbursed as a so-called "buy-and-bill drug" and consequently marketed directly to physicians.

Xepi<sup>™</sup> 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.

In the case of direct sales of BF-RhodoLED<sup>\*</sup>, 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<sup>®</sup> 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<sup>®</sup> 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 certain conditions are fulfilled depending on the possible outcome of development activities.

Estimates of such possible outcomes involve management making significant assumptions. In the management's opinion, due to uncertainties related to the development of new products, the criteria prescribed under IAS 38.57 "Intangible Assets" for capitalizing development costs as assets are only fulfilled by the Biofrontera Group, if the prerequisites for the expansion of the European approval and the approval in the U.S. are met, and if it is likely a future economic benefit will accrue to the company.

Research and development costs relating to the drug Ameluz<sup>\*</sup>, 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<sup>®</sup>, as this will generate future economic benefits.

# Notes to the consolidated balance sheet

## 1. Intangible and tangible assets

In the 2019 financial year, impairment losses on tangible assets were recognized in the amount of EUR 527 thousand (previous year: EUR 0).

The cost of short-term and low-value leases amounts to EUR 386 thousand. The income from a sublease agreement amounts to EUR 34 thousand.

Tangible and intangible assets are composed as follows:

# Consolidated statement of changes in non-current assets in 2019

in EUR thousands		P	urchase and	production	cost		Ą	ccumulated de	preciation a	nd amortizati	on	Carrying	amounts
	Jan 1, 2019	Currency translation	Addition s	Change of consolid ation	Disposal s	Dec 31, 2019	Jan 1, 2019	Currency translation	Addition s	Disposal s	Dec 31, 2019	Dec 31, 2019	Jan 1, 2019
I. Tangible assets and leases													
1. 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
2. Right-of-use leasing properties	1,768	-	1,792	-	-	3,560	-	-	505	-	505	3,055	1,768
3. 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
II. Intangible assets													
1. Software and licenses	446	-	20	-	260	206	427	-	21	258	190	16	21
2. Right-of-use assets	1,101	(69)	92	23,604	254	24,474	1,035	(5)	1,556	230	2,356	22,118	66
3. Intangible assets 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

The opening balance of leasing use rights is due entirely to the first-time application of IFRS 16 and amounts to EUR 2,335 thousand.

# Consolidated statement of changes in non-current assets in 2018

EUR thousands		Р	urchase and	production	cost		A	ccumulated de	preciation ar	nd amortizati	on	Carrying	amounts
	Jan 1, 2018	Currency translation	Addition s	Transfer s	Disposal s	Dec 31, 2018	Jan 1, 2018	Currency translation	Addition s	Disposal s	Dec 31, 2018	Dec 31, 2018	Jan 1, 2018
Tangible assets													
Operating and business equipment	4,089	5	240	-	230	4,104	3,343	1	194	229	3,309	795	746
Intangible assets													
1. Software and licenses	458	-	5	-	17	446	428	-	16	17	427	21	30
2. Right-of-use assets	6,188	-	10	(9)	5,088	1,101	5,570	-	545	5,080	1,035	66	618
3. Intangible assets under development	-	-	258	9	-	267	-	-	-	-	-	267	-
	6,646	-	273	-	5,105	1,814	5,998	-	561	5,097	1,462	352	648
-	10,735	5	513	-	5,335	5,918	9,341	1	755	5,326	4,771	1,147	1,394

#### 2. Inventories

in EUR thousands	December 31, 2019	December 31, 2018
Raw materials	893	1,098
Unfinished goods	201	320
Finished goods and products	2,971	1,759
	4,065	3,177

In 2019, inventories were written down by EUR 24 thousand (previous year: EUR 187 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 (EUR 89 thousand; previous year: EUR 75 thousand).

## 3. Trade receivables

Trade receivables are mainly attributable to the sale of Ameluz<sup>®</sup>, the PDT lamp BF-RhodoLED<sup>®</sup>, Xepi<sup>™</sup> and the medical cosmetics product Belixos<sup>®</sup>. 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 43 thousand (previous year: TEUR 0). 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 178 thousand (previous year: EUR 187 thousand) are attributable to finance leases for PDT-lamps.

# 4. Other financial assets

Other financial assets comprise mainly prepayments rendered for studies (EUR 359 thousand; previous year: EUR 614 thousand) and the depositing of collateral, mainly for leasing property, credit cards and leasing vehicles (EUR 300 thousand; previous year: EUR 164 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 1,113 thousand; previous year: EUR 664 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 (EUR 4 thousand; previous year: EUR 53 thousand). Income tax liabilities relate to current income tax liabilities for fiscal year 2019 (EUR 11 thousand; previous year: 0).

# 7. Cash and cash equivalents

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

EUR 19,451 thousand). The carrying amounts of the cash and cash equivalents correspond to their fair value, due to the short-term nature of these investments.

#### 8. Deferred income tax

Deferred tax assets amount to EUR 7,794 thousand (previous year: EUR 10,400 thousand). In the 2018 financial year, deferred taxes in the amount of EUR 10,486 thousand were capitalized for the first time on loss carryforwards to the extent that these can probably be offset against future taxable earnings. This is based on a planning period of five years. These relate to the deferred tax assets on losses carried forward for Biofrontera Pharma GmbH to be recognized for the first time as of December 31, 2018.

The reduction in deferred tax assets results from the use of the tax loss carryforwards of Biofrontera Pharma GmbH (EUR 256 thousand) and the reduction in the trade tax rate of the city of Leverkusen with effect of January 1, 2020 (EUR 2,350 thousand).

The subsidiary Biofrontera Pharma GmbH has generated profits in 2019 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 153 thousand and at Biofrontera Inc. in the amount of 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:

	December 31, 2	2019	December 31,	2018
in EUR thousands	Loss carried forward	Deferred tax assets	Loss carried forward	Deferred tax assets
Corporation tax including Solidarity Surcharge	135,415	21,436	131,928	20,884
Business tax	120,692	10,561	118,548	19,703
U.S. corporation tax	23,616	6,140	14,452	3,613
Total		38,137		44,200

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 (EUR 8,595 thousand), and indefinitely when occurred from January 1, 2018 (EUR 15,021 thousand).

	December 3	1, 2019	December 31, 2018		
in EUR thousands	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities	
Loss carried forward	8,568	-	10,674	-	
Non-current assets - Intangible assets - Tangible assets - Financial assets	- - -	(620) (1,002) -	- -	(87) - -	
Current assets - Receivables and other assets	43	-	59	-	
Non-current liabilities - Provisions	-	(54)	_	(82)	

Current liabilities - Provisions	859	-	-	(152)
- Liabilities and other	-	-	-	(12)
Total Netting of deferred tax assets and liabilities	9,470 (1,676)	(1,676) 1,676	10,733 (333)	(333) 333
As recognized on balance sheet	7,794	-	10,400	-

Deferred taxes on losses carried forward are capitalized to the extent that they can probably be offset against future profits or to the same extent are offset by deferred tax liabilities. Due to the lack of predictability regarding future taxable profits, the remaining deferred tax assets deriving from loss carryforwards in the amount of EUR 29,569 thousand (previous year: EUR 33,526 thousand) and deferred tax assets in the amount of EUR 2,000 thousand (previous year EUR 782 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 rounded income tax rate of 32.5% currently applicable to the Biofrontera Group. The expected income tax rate of the parent company will amount to 24.6% with effect from January 1, 2020 due to the reduction of the trade tax multiplier:

in EUR thousands	December 31, 2019	December 31, 2018
Consolidated loss before tax	(4,777)	(19,269)
Expected income tax reimbursement at the tax rate of the parent company	1,550	6,252
Differences arising from different tax rates	(839)	(685)
Adjustment of deferred taxes due to tax rates - from temporary differences - from loss carryforwards	16 (2,350)	-
Tax increases due to non-deductible expenses	(538)	(100)
Changes in unrecognized deferred tax assets - from active temporary differences - from loss carryforwards	(1,217) (4,251)	(895) 5,343
Taxfree income (badwill)	4,807	-
Other effects	241	475
Income taxes as per statement of comprehensive income	(2,581)	10,390

# 9. Equity

#### Share capital

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 44,849,365 on December 31, 2019. It was divided into 44,849,365 registered shares with a nominal value of EUR 1.00 each. On December 31, 2018, the share capital amounted to EUR 44,632,674.

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, 2019, based on the most recent mandatory disclosures, are as follows:

	December 31, 2019	December 31, 2018
Maruho Deutschland Co., Ltd., Osaka Japan		
The total share of voting rights is assigned to Maruho Co., Ltd, Osaka,	13,047,754	8,891,843
through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.		
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	13,300,694	8,935,384
Prisma Equity AG		
Sparta AG		
ABC Beteiligungen AG		
AEE Ahaus-Enscheder AG		
MARNA Beteiligungen AG		
Youbisheng Green Paper AG		
Strawtec Group AG		
Free float	18,500,917	26,805,447
Total	44,849,365	44,632,674

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 are 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 3,998,014 available as at December 31, 2019. 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, 2019, and serves exclusively to fulfill option rights granted on July 1, 2015 on the basis of the 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 serves exclusively to fulfill option rights granted until August 27, 2020 on the basis of the annual general Meeting ("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.

As of December 31, 2019, bonds in a nominal amount of EUR 2,030,800 were converted into the company's shares. In 2019 bonds with a nominal amount of EUR 564,500 (previous year: EUR 66,500) were converted into 118,841 shares (previous year: 13,472).

#### 2010 share option program

At the AGM on July 2, 2010, the Management and Supervisory boards proposed a share option program for employees to the AGM, which approved the initiative. Accordingly, the Management Board, or the Supervisory Board if the beneficiaries are Management Board members, are entitled to issue up to 839,500 share options, the exercising of which is linked to specific targets.

The program has a total nominal volume of EUR 839,500 and a term of six years from the issue date, in other words, until November 24, 2016. For this, conditional capital amounting to EUR 839,500 was approved by means of the issuing of up to 839,500 registered no par value unit shares with a proportional amount of the share capital of EUR 1.00 per share, in accordance with Section 192 (1) No. 3 of the German Stock Corporation Act (AktG). The conditional capital was registered on July 30, 2010 in the commercial register of the Cologne District Court, under commercial register sheet number 49717. Eligibility for the 2010 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.

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 14 banking days after the date of the Annual General Meeting (exclusive),
- b) on the 6th and subsequent 14 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 share 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	106,400	96,400	65,000	51,500	179,500	159,350
Date of issue	24.11.2010	30.09.2011	23.03.2012	11.05.2012	02.09.2013	02.04.2014
		07.10.2011				
Exercise price	EUR 1.91	EUR 2.48	EUR 3.30	EUR 4.09	EUR 3.373	EUR 3.43
Adjusted exercise price March 2018	-	-	EUR 3.02	EUR 3.81	EUR 3.093	EUR 3.15
End of vesting period	24.11.2014	30.09.2015	23.03.2016	11.05.2016	02.09.2017	02.04.2018
		07.10.2015	11.05.2016			
End of exercise window	24.11.2016	30.09.2017	23.03.2018	11.05.2018	02.09.2019	02.04.2020
		07.10.2017				
Fair value per option	EUR 0.57	EUR 1.24	EUR 1.60	EUR 2.06	EUR 1.07	EUR 0.83
Share price volatility	45.78%	51.30%	53.50%	65.00%	39.20%	32.30%
Dividend yield	0%	0%	0%	0%	0%	0%
Risk-free interest rate	1.75%	1.21%	0.9%	0.82%	0.71%	0.68%
Fluctuation rate	20%	20%	20%	20%	20%	20%

The fair value of one of the stock options in this option program is determined on a binominal model. The pro rata amounts are recognized over the vesting period up to the end of the vesting period on a pro rata basis as personnel expenses and an increase in capital reserves.

2010 share option program	December 31, 2019	December 31, 2018
Number of options issued	658,150	658,150
Outstanding at the beginning of the period	137,850	364,350
Granted during the period	-	-
Forfeited during the period	17,000	19,000
Exercised during the period	97,850	195,500
Expired during the period	-	12,000
Outstanding at the end of the period	23,000	137,850
Exercisable at the end of the period	23,000	137,850
Range of exercise prices for outstanding options	3.15 EUR	EUR 3.093 - 3.15
Weighted average of remaining contractual life	3 months	12 months
Cost	-	EUR 6,000

The Conditional Capital III for servicing options from this program amounts to EUR 249,050.

During the 2019 financial year, the share capital was increased by EUR 97,850 divided into 97,850 registered shares, from the conversion of options from the 2010 employee stock option plan.

#### 2015 share 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 Annual General Meeting, 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. For this, conditional capital amounting to EUR 1,814,984 was approved by means of the issuing of up to 1,814,984 registered no par value unit shares with a proportional amount of the share

capital of EUR 1.00 per share, in accordance with Section 192 (1) No. 3 of the German Stock Corporation Act (AktG). The conditional capital was registered on September 18, 2015 in the commercial register of the Cologne District Court, under commercial register sheet number 49717. 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.

The conditions of the 2015 share option program are to a large extent identical to those of the 2010 share option program, therefore, with respect to the 2015 share option program, we refer to the explanations of the conditions of the share option program 2010 provided above, however 20 banking days are being used instead of 14 banking days.

	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 share option program	December 31, 2019	December 31, 2018
Outstanding at the beginning of the period	1,252,000	1,143,500
Granted during the period	333,485	180,000
Forfeited during the period	88,500	71,500
Exercised during the period	-	-
Expired during the period	-	-
Outstanding at the end of the period	1,496,985	1,252,000
Exercisable at the end of the period	-	-
Range of exercise prices for outstanding options	EUR 2.25 – 6.708	EUR 2.25 - 5.73
Weighted average of remaining contractual life	44 months	50 months
Cost	EUR 360,000	EUR 257,000

#### Capital reserves

The capital reserves shown on the balance sheet comprise the capital reserve as well as the reserves from currency translation and the loss carried forward. 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 2 thousand (previous year: EUR 2,432 thousand) for the year ended December 31, 2019.

#### 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, 2019	December 31, 2018
Non-current financial liabilities		
Convertible bond 2017/2022	1,977	2,495
EIB loan 2017	11,845	10,967
EIB loan 2019	5,301	0
Leasing liabilities	2,987	0
Total non-current financial liabilities	22,110	13,462
Current financial liabilities		
Leasing liabilities	1,038	0
Other current liabilities	174	165
Total current liabilities	1,212	165

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, 2019						
	2020	2021	2022	2023	2024	2025	Total
Convertible bond							
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

in EUR thousands	December 31, 2018						
	2019	2020	2021	2022	Total		
Convertible bond 2017/2022:					2,595		

in EUR thousands	December 31, 2018							
Principal repayment				2,595				
Interest payment	156	156	156	78	546			
<u>EIB loan</u>								
Principal repayment				10,000	10,000			
Interest payment	405	433	461	5,039	6,338			

#### 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, 2019, the carrying amount of the liability component on this basis was EUR 15,684 thousand (previous year: EUR 9,887 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, 2018, the discounted interest payment or fair value of the performance component amounted to EUR 1,462 thousand (previous year: EUR 1,080 thousand).

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

#### Leasing liabilities

As a result of the first-time application of IFRS 16, in the 2019 financial year, the contracts entered into by Biofrontera as a lessee will be applied according to the modified retrospective method to leases that have a remaining term of more than one year on January 1, 2019.

The carrying amount of the current and non-current leasing liabilities amounts to EUR 4,025 thousand (January 1, 2019: EUR 2,302 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, 2019	December 31, 2018
Purchase price liability (earn-out and start-up costs)	14,720	0
Current financial liabilities	99	29

The purchase price liability was discounted at a market interest rate of 9% based on the expected annual purchase price payments. The expected annual purchase price payments are due from 2022 to 2030 depending on future profits from sales of Xepi<sup>™</sup>. In total, without repayment of the start-up costs, the nominal repayment amount in this period is USD 28.9 million / EUR 25.8 million. The start-up costs of USD 2.9 million (EUR 2.5 million) received to date are repayable by 2022.

For further details, please refer to the section on business combinations.

# 12. Trade payables

As of December 31, 2019, trade payables amounted to EUR 4,196 thousand (previous year: EUR 1,806 thousand).

# 13. Other provisions

Current and non-current other provisions of the Biofrontera Group show the following changes: Other current provisions

in EUR thousands	01.01.2019	Utilization	Released	Added	Translation difference	31.12.2019
Outstanding invoices	944	746	105	292	8	393
Auditing costs	224	224	0	323	0	323
Provisions for litigation costs	1,696	426	0	1,035	0	2,305
Other provisions	27	0	0	447	0	474
Total current provisions	2,891	1,396	105	2,097	8	3,495

#### Other non-current provisions

EUR thousands	01.01.2019	Utilized	Released	Added	Translation difference	31.12.2019
Provisions for litigation costs	1,545	1,545	-	-	-	-
Other non-current provisions	1,545	1,545	-		-	-

The additions in the amount of EUR 447 thousand to other provisions include additions of EUR 291 thousand due to extensions to the scope of consolidation (Cutanea).

Other provisions concern various individually identifiable risks and contingent liabilities. Provisions classified as current are expected to lead to an outflow of economic benefits prospectively within the subsequent financial year.

The companies included in the consolidated financial statements of Biofrontera AG are exposed to several threatened or pending legal proceedings, the outcome of which either cannot be determined or cannot be predicted due to the uncertainty associated with such legal proceedings. The claims asserted against Biofrontera were not carried as liabilities, as the Management Board asserts that claims cannot be estimated or probable to be incurred.

Provisions were made in the year under review 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.

In 2019, a total of EUR 2,305 thousand (previous year: EUR 3,241 thousand) was accrued for costs to defend against litigation in connection with pending proceedings in the U.S. and Germany. Due to the increased legal consulting costs, further amounts of EUR 1,035 thousand were added.

#### 14. Other current liabilities

Other current liabilities (in EUR thousands)	December 31, 2019	December 31, 2018
Accrual for employee bonuses	1.731	2,099
Accrual for outstanding vacation	403	315
Payroll tax	135	267
Wages and salaries	212	141

Other current liabilities (in EUR thousands)	December 31, 2019	December 31, 2018
Social security	21	13
Other	63	44
Total other current liabilities	2,565	2,879

#### 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)

To date, no rights have been issued under the Stock Appreciation Rights Program 2019.

# 15. Reporting on financial instruments

The financial assets and liabilities can be subdivided into measurement categories with the following carrying amounts, and net gains and losses:

Financial assets in EUR thousands	Fair value as of 31.12.2019	Carrying amount as of 31.12.2019	Fair value as of 31.12.2018	Carrying amount as of 31.12.2018	Net gains (+) or losses (-) 31.12.2019	Net gains (+) or losses (-) 31.12.2018
Category: Held						
Cash and cash equivalents	11,119	11,119	19,451	19,451	(15)	(10)
Trade receivables	5,031	5,031	3,397	3,397	(33)	1
Other financial assets	1,077	1,077	794	794	-	-
Total	17,227	17,227	23,642	23,642	(48)	(9)

Financial liabilities in EUR thousands	Fair value as of 31.12.2019	Carrying amount as of 31.12.2019	Fair value as of 31.12.2018	Carrying amount as of 31.12.2018	Net gains (+) or losses (-) 31.12.2019	Net gains (+) or losses (-) 31.12.2018
Financial liabilities at amortized						
Financial liabilities, current	1,212	1,212	165	165	-	-
Trade payables	4,196	4,196	1,805	1,805	(2)	(13)
Other current financial	99	99	29	29	-	-
Financial liabilities, non-	20,648	20,648	12,382	12,382	-	-
Total	26,155	26,155	14,382	14,382	(2)	(13)
Financial liabilities at fair value through profit or loss						
Financial liabilities, non-	1,462	1,462	1,080	1,080	(82)	(528)
Other financial liabilities, non-current	14,720	14,720	-	-	(650)	-
Total	16,182	16,182	1,080	1,080	(732)	(528)

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).

These relate to the performance component of the EIB loan (EUR 1.5 million; December 31, 2018: EUR 1.1 million) included under non-current financial liabilities and the purchase price liability arising in 2019 from the acquisition of Cutanea (EUR 14.7 million). No reclassifications were made between the individual levels of the fair value category during the 2019 fiscal year.

#### Principles of risk management

As part of its operating activities, the Group is exposed to market price and credit risk, as well as liquidity risk, which could have an effect on its financial position and performance.

Market price risk: Biofrontera's exposure to market risks consists of foreign exchange and interest rate risks. The risk of interest rate changes is regarded as low as the existing interest rate modalities for the relevant financing of the Biofrontera Group can usually be adapted to market conditions in the short to medium term. Exceptions are the performance component, although this is mitigated by a limit to 4% of the market price risk as well as the purchase price liability from the acquisition of Cutanea (earn-out). An interest rate-related change in the value of the purchase price liability by 1 % would result in a change in interest expense of EUR 1 million (previous year: 0)

Cash flow risk: There is no cash flow risk for the fixed-interest option bonds. The fixed interest rate means that no disadvantageous changes in interest payments can occur. As the liabilities are not carried at fair value but at amortized cost, there is also no fair value risk. A change of +5 % (-5 %) in the expected profits from the sale of the Cutanea products would result in a change of EUR +0.9 million (EUR -0.6 million) for the purchase price liability.

Foreign currency risk: The Biofrontera Group was exposed to foreign currency risks on the balance sheet date, especially as a result of the intragroup loan to the subsidiary Biofrontera Inc. Trade receivables arise to a greater extent than in the past due to the expansion of business in the U.S. and are regularly reviewed for a potential default risk. Trade payables denominated in foreign currency are of minor importance. The company does not conclude any special hedging transactions. Currency exchange rate fluctuations are recognized in profit or loss.

The balance of financial assets and liabilities in foreign currencies amounts to EUR 29,1 million (previous year: EUR 27.0 million). A 5% change in the value of financial assets and financial liabilities in foreign currency would result in a change of EUR 1.5 million (previous year: EUR 1.4 million) in the income statement item "Other expenses and income".

Credit risk: A credit risk arises for the Group if transaction partners cannot meet their obligations by the normal payment deadlines. On the balance sheet, the maximum non-payment risk is represented by the carrying amount of the relevant financial asset. The situation regarding receivables is monitored so that any possible non-payment risks can be identified at an early stage and appropriate steps taken.

In the 2019 financial year, individual value adjustments in the amount of EUR 43 thousand (previous year: 0) were applied to trade receivables. Cash and cash equivalents are invested with banks and insurance companies with sufficient deposit protection.

Liquidity risk: Liquidity risk refers to the inability to meet existing or future payment obligations on time. To ensure solvency at all times and to avoid financial bottlenecks, Biofrontera has established a central liquidity management system that monitors liquidity requirements in the short, medium and long term. The refinancing of all Group companies is generally performed centrally by Biofrontera AG.

The monitoring and management of liquidity is based on short-term and long-term corporate planning. Liquidity risks are identified at an early stage, using simulations of various scenarios. Current liquidity is reported and monitored on a daily basis.

At present, the company is sufficiently financed. However, the cost-cutting measures introduced may not be sufficient to continue operations for 12 months and beyond. So far, the company has always succeeded in securing financing for the company through additional capital measures.

With regard to material uncertainties in connection with the going concern status, we refer to Note 33 Subsequent events.

With regard to the (undiscounted) payments from financial liabilities due in the next few years, reference is made to the corresponding notes on this item on the balance sheet.

All other financial liabilities are current and are expected to be settled within one year.

# Notes to the consolidated statement of comprehensive income for the fiscal year 2019

01.0131.12.2019			(	)1.0131.12.2018		
Sales revenue (in EUR thousands)	Product revenue	Development revenues	Other	Product revenue	Development revenues	Other
Germany	4,633	-	-	3,307	-	-
Europe	2,603	-	-	2,737	-	-
U.S.	23,343	-	-	14,894	-	-
Other regions	-	686	-	-	129	40
Total	30,579	686	-	20,938	129	40

#### 16. Sales revenue

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

In the 2019 financial year, we generated EUR 72 thousand of income from operating leases (previous year: EUR 94 thousand). We generated income of EUR 126 thousand from finance leases (previous year: EUR 240 thousand).

#### 17. Cost of sales, gross profit

The cost of materials included in the cost of sales amounted to EUR 3,827 thousand for the 2019 financial year (previous year: EUR 3,636 thousand).

The gross profit on sales increased by EUR 9,734 thousand in the 2019 reporting year, to reach EUR 26,390 thousand, compared with EUR 16,656 thousand in the prior-year period.

# 18. Research and development costs

Research and development costs amounted to EUR 4,636 thousand (previous year: EUR 4,427 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. Sales and marketing costs

Sales and marketing costs amounted to EUR 28,856 thousand in the 2019 financial year (previous year: EUR 17,744 thousand). Sales and marketing costs include costs for our own sales force in Germany, Spain, the UK and the U.S., as well as marketing expenses. The increase in sales costs is due to the further expansion of the sales organization in the USA as well as sales-related costs incurred at Cutanea.

## 20. General administrative costs

General administrative costs amounted to EUR 16,275 thousand in the 2019 financial year (previous year: EUR 12,963 thousand) and thus increased by a total of EUR 3,312 thousand compared to the previous year, in particular due to the Cutanea acquisition. Legal and consulting costs amounted to EUR 6,929 thousand (previous year: EUR 6,230 thousand).

# 21. Interest expenses and income

Interest income mainly results from investments of cash and cash equivalents of EUR 124 thousand (previous year: EUR 24 thousand).

in EUR thousands	2019 Interest expense from compounding	2019 Interest expense and the like	2018 Interest expense from compounding	2018 Interest expense and the like
Convertible bond 2017/22	32	136	30	156
EIB loan 2017	202	1,046	140	1,458
EIB loan 2019	11	457	-	
Cutanea purchase price liability	-	650	-	-
Leasing	-	124	-	-
Other	-	53	-	-
	245	2,466	170	1,614

# 22. Other expenses and income

Other income mainly includes the negative difference (bad will) of EUR 14,812 thousand arising from the purchase price allocation and other income from the assumption of costs by Maruho EUR 6,215 thousand. In addition, the items include expenses and income from currency translations in the amount of EUR 324 thousand (previous year: EUR 650 thousand).

#### 23. Income tax

in EUR thousands	2019	2018
Deferred taxes	(2,606)	10,400

Actual income taxes	25	(9)
Income tax	(2,581)	10,391

The expense from deferred taxes results from the use of the tax loss carryforwards of Biofrontera Pharma GmbH (EUR 256 thousand) and from the reduction in the municipal trade tax rate of the city of Leverkusen with effect from January 1, 2020 (EUR 2,350 thousand).

# 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, 2019	December 31, 2018
Number of weighted ordinary shares in circulation (on average)	44,690,009	43,695,794
Net loss for the year in EUR thousands	(7,358)	(8,878)
Basic/diluted earnings per share in EUR	(0.16)	(0.20)

The instruments are generally diluted. Due to the loss situation, the basic EPS corresponds to the diluted EPS.

## 25. Additional information about 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	2019	2018
Research and development costs	72	595
General administrative costs	383	109
Cost of sales	17	15
Sales and marketing	2.684	34
Depreciation and amortization expense	3.156	754

#### Personnel costs

in EUR thousands	2019	2018
Wages and salaries	19,894	14,252
Social security charges	2,958	1,973
Costs for pension schemes	391	191
Total	23,243	16,416

#### 26. Staff

	2019	2018
Total employees (average)	180	141

2019	2018
2019	2010
154	122
30	29
16	13
5	4
16	12
73	70
9	7
ĘQ	35
56	33
89	75
80	56
8	7
3	3
	30 16 5 16 73 9 58 58 89 89 80 80

# 27. Other information

In the USA, BF-RhodoLED<sup>®</sup> 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 2019, the company generated income of EUR 71 thousand (previous year: EUR 94 thousand) from operating lease agreements. Income of EUR 126 thousand (previous year: EUR 240 thousand) was generated from finance lease agreements. The future expected leasing income as of December 31, 2019 is as follows:

in EUR thousands	2019	2018	2019	2018	2019	2018
	≤ 2	l year	1 year to	o 5 years	> 5 ye	ears
Finance lease BF-RhodoLED* interest income	24	19	9	11	0	0
Finance lease BF-RhodoLED <sup>®</sup>	160	121	57	72	0	0

# 28. Notes to the cash flow statement

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 664 thousand (previous year: EUR 536 thousand). Taxes paid amounted to EUR 36 thousand (previous year: EUR 9 thousand). Interest received amounted to EUR 127 thousand (previous year: EUR 24 thousand).

The changes are comprised as follows:

	Non-cash changes				
in EUR thousands	January 1, 2019	Cash flow	Addition/ retirement	Fair value change	December 31, 2019
Convertible bond 2017/2022	2,495	-	-518	-	1,977
EIB loan 2017	10,967	-	810	68	11,845
EIB loan 2019	-	5,000	287	14	5,301
Interest convertible Bond	78	(153)	136	-	61
Interest EIB loan 2017	87	(372)	369	-	84
Interest EIB loan 2019	-	(139)	168	-	29
Leasing liabilities	2,303	(1,183)	2,905	-	4,025
Total financial liabilities	15,930	3,153	4,157	82	23,322

# 29. Members of the Management Board

In 2019, the Management Board consisted of Prof. Dr. Hermann Lübbert (Chief Executive Officer), Mr. Thomas Schaffer (Chief Financial Officer) and Mr. Christoph Dünwald (Chief Commercial Officer).

#### Prof. Dr. rer. nat. Hermann Lübbert, CEO

Prof. Dr. rer. nat. Hermann Lübbert is the Management Board Chairman (Chief Executive Officer) of Biofrontera AG and Managing Director of Biofrontera Bioscience GmbH and of Biofrontera Pharma GmbH. He studied biology in his native city of Cologne, where he also received his doctorate in 1984.

After eight years in academic research at Cologne University and at the California Institute of Technology (U.S.), he obtained his postdoctoral qualification in 1994 from the Eidgenössische Technische Hochschule (ETH) Zürich. Since 1998, he has led the Chair for Animal Physiology at Ruhr University Bochum. During ten years at Sandoz and Novartis Pharma AG, Professor Lübbert acquired experience in managing a globally active research organization. He founded Biofrontera in 1997 and has since managed the company.

#### Thomas Schaffer, CFO

Thomas Schaffer started his career in various positions in the finance and controlling area at Siemens Semiconductor. He was Vice President and CFO in the Security & Chipcard ICs area at Siemens.

He was then Managing Director and CFO at Infineon Ventures GmbH for a four-year period and continued his career as Vice President and CFO of the Specialty DRAM Division of Qimonda AG, where he also assumed the Managing Director role at Qimonda Solar GmbH. He added to his significant international experience with appointments as CFO at Heptagon Oy, Finland/Switzerland, and Ubidyne Inc., Delaware, U.S.. Mr. Schaffer has been CFO of Biofrontera AG since June 2013.

#### Christoph Dünwald, CCO

Christoph Dünwald started his career at Bayer AG, where he held various positions in marketing (U.S. and Spain) and in strategic business management in Germany and Southeast Asia over a 15-year period.

In his last position at Bayer, he managed the Bayer Healthcare Diagnostics Division in Belgium and Luxembourg as General Manager. After two years as International Sales and Marketing Director in Spain and England for Corporación Dermoestética SA, he moved to become Senior Commercial Director at U.S. pharmaceuticals group Allergan in 2008. From 2009 until 2015, he managed its Medical Business Unit in Spain and Portugal.

Mr. Dünwald has been responsible for marketing and sales as well as for the further development of the US business at Biofrontera since 2016. He resigned as Chief Commercial Officer (CCO) on January 31, 2020.

#### Management Board compensation

in EUR thousands	2019	2018
Short-term benefits	1,387	1,071
Performance-based compensation	87	422
Total compensation	1,474	1,493

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	Data first appointment	Term until	
Dr. Ulrich Granzer	German	59	Chair	12.05.2006	2021	
	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.					
Curriculum vitae:	Previously, he was Head of Regulatory Affairs at GlaxoSmithKline, and Global Regulatory					
	Centers BASF Pharma and VP Global Regulatory Affairs at Bayer Pharma. He is a proven					
	expert in the drug	g approval area	э.			
Jürgen Baumann	German	65	Deputy Chair	24.05.2007	2021	
Curriculum vitae	Mr. Jürgen Baumann, Deputy Supervisory Board Chairman, is an independent management consultant and has been Supervisory Board Chairman since 2007. 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.	62	Member	31.05.2016	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					
Reinhard Eyring	German	61	Member	07.02.2018	2021	

Name	Nationality	Age	Position	Data first appointment	Term until
Curriculum vitae	partner at Schürn	nann & Partnei d law at the Ur	niversity of Freiburg an		-
Hansjörg Plaggemars*	U.S.	49	Member	31.05.2016	2021
Curriculum vitae	Mr. Hansjörg Plaggemars is an independent management consultant (Value Consult) as well as a Management Board member of various companies as part of projects, including at Delphi Unternehmensberatung AG and Strawtec Group AG. Until the end of May 2017, he was a member of the Management Board of Deutsche Balaton AG and previously managing director and CFO at CoCreate Software GmbH, KAMPA AG, Unister Holdings and Müller Holdings. Mr. Plaggemars is also a member of the supervisory boards of Ming Le Sports AG, Deutsche Balaton Immobilien I AG, Carus AG and Youbisheng Green Paper AG. He studied business management at Bamberg University.				
Prof. Dr. Franca Ruhwedel*	German	47	Member	10.07.2019	2021
Curriculum vitae	Prof. Dr. Ruhwedel is currently Professor of Finance and Accounting at the Rhine-Waal University of Applied Sciences in Kamp-Lintfort. Previously, she was held the position of Professor of Accounting and Controlling at the FOM University in Essen. During her professional career she has held positions as project manager in the areas of M&A and corporate development at thyssenkrupp AG and tyssenkrupp Steel AG. After her training as a banker at Commerzbank AG and her studies of business administration, Ms. Ruhwedel obtained her doctorate at the Ruhr University of Bochum.				
Kevin Weber	USA	61	Member	31.05.2016	2021
Curriculum vitae	Mr. Kevin Weber is Managing Director at Skysis, LLC. He was previously CEO at Paraffin International Inc., and has extensive experience in marketing as well as worldwide marketing strategies. He previously held senior roles at Depomed, Hyperion Therapeutics and Medicis Pharmaceuticals. Kevin Weber is also a member of the Boards of Directors of the American Academy of Pain Medicine Foundation and of the American Chronic Pain Association. He holds a degree in management and marketing from Western Michigan University.				

\* By order of the Cologne District Court dated March 22, 2019, Mr. Hansjörg Plaggemars was dismissed as a member of the Supervisory Board of Biofrontera AG pursuant to Section 103 (3) of the German Stock Corporation Act (AktG) for good cause. The ruling was issued on March 22, 2019 and came to the company's attention on March 26, 2019. The ruling regarding the removal from office was effective immediately. However, an appeal was filed and subsequently was rejected by the Cologne District Court on April 30, 2019 and the case was referred to the Higher Regional Court for a further ruling. The Higher Regional Court of Cologne dismissed the appeal on August 29, 2019 finally dismissed the appeal. The Annual General Meeting on July 10, 2019 elected Prof. Dr. Franca Ruhwedel, Professor of Finance and Accounting at the Rhein-Waal University of Applied Sciences, Kamp-Lintfort, Duisburg, to the Supervisory Board as successor to Mr. Plaggemars.

#### Supervisory board compensation

in EUR thousands	Compensation 2019	Compensation 2018
Dr. Ulrich Granzer	30	30
Jürgen Baumann	23	23
John Borer	15	15
Reinhard Eyring	15	14
Hansjörg Plaggemars	3	15
Prof. Dr. Franca Ruhwedel	7	-
Kevin Weber	15	15
Total	108	112

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	Supervisory	Chair
Prof. Dr. Franca Ruhwedel	NATIONAL-BANK AG, Essen	Management	Member
	VTG AG, Hamburg	Management	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, 2019	December 31, 2018
Revenue from research collaborations	686	129
Income from the reimbursement of costs by Maruho	6.215	-
Income from subleases	34	34
Accounts receivables	149	-
Receivables from start-up costs	3.646	-
Purchase price liability Cutanea (earn-out and start-up costs)	15.487	-
Other liabilties	72	-

With regard to the acquisition of Cutanea, we refer to the disclosures on business combinations.

On March 19, 2019, the Company signed an agreement to continue its research collaboration with Maruho Co., Ltd. of Osaka, Japan ("Maruho") in the field of branded generics. Under the new project phase, Biofrontera will prepare the formulation of one of four active ingredients in Biofrontera's nanoemulsion for clinical trials, which were jointly researched in an earlier project phase (phase 1). According to current planning, research costs of up to EUR 1.1 million will be incurred in the new project phase, which will be fully borne by Maruho.

During 2019, our company received additional advisory services from supervisory board member Dr. Ulrich Granzer. Dr. Granzer assisted our 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, 2019, advisory services in the amount of EUR 1 thousand were provided by Granzer Regulatory Consulting & Services (previous year: 0). 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 2019 financial year, there were no further reportable transactions or relationships with related parties beyond those described above or in sections 28 and 29.

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 2019 financial years consist of:

in EUR thousands	2019	2018
Auditing services	571	580
[of which for the previous year]	[102]	[221]
Other audit services	-	85
	571	665

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.

Other audit services in the previous year related to the audit of the profit forecast and the issue of a comfort letter.

# 33. Subsequent events

Strengthening of the commercial focus through reorganization of the US business

On January 6, 2020, the company announced a new organizational structure of its US-subsidiary Biofrontera Inc. to strengthen its commercial activities in the USA.

Since then, the operating business in the USA is managed by Christopher Pearson as Chief Commercial Officer USA and Erica Monaco as Chief Financial Officer USA. Chris Pearson is responsible for Sales, Marketing and Market Access. Erica Monaco is responsible for Finance & Operations, Human Resources, Legal and Compliance. Organizationally, Biofrontera Inc. is now managed by a 4-member Board of Directors, consisting of Prof. Hermann Lübbert (Chairman) and Thomas Schaffer as non-executive board members, Chris Pearson and Erica Monaco as executive board members.

# Organizational restructuring of Biofrontera and resignation of Chief Commercial Officer Christoph Dünwald

On January 31, 2020, the company announced that - following the operational reorganization of the company's US-subsidiary Biofrontera Inc. - it has reorganized its European sales structure. As part of the restructuring of Biofrontera, Christoph Dünwald, Chief Commercial Officer (CCO), has resigned from his position to pursue new challenges.

As a result of the restructuring, Biofrontera's worldwide sales organization now stands on two pillars: Sales and marketing in the USA, Biofrontera's largest market, and a uniform management of all sales organizations in Europe. Dr. Matthias Naumann, who has been successfully working for the company since 2016 as Sales

Manager Germany, has assumed the management of the sales organization in Europe. As Head of Sales and Marketing Europe, Mr. Naumann now manages the sales and marketing activities comprehensively across Europe.

# Approval for Ameluz<sup>®</sup> label extension for the treatment of actinic keratosis on extremities and trunk/neck by the European Commission

Based on the positive assessment of 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 extension of approval on March 10, 2020. The extended approval of Ameluz<sup>®</sup> now also includes 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 study comparing daylight PDT with Ameluz<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC). With a recurrence rate of 19.5%, Ameluz<sup>®</sup> showed significantly lower recurrence rates after 12 months than Metvix<sup>®</sup> with 31.2%.

#### Subscription offers for mandatory convertible bonds

On February 26, 2020, the Management Board resolved to issue up to 1,600,000 of the 0.5% qualified subordinated mandatory convertible bonds 2020/2024 ("Bonds 2020/2024") with a nominal value of EUR 5.00 each and a total nominal value of up to EUR 8,000,000 as well as up to 1,600,000 of the 1.00 % qualified subordinated mandatory convertible bonds 2020/2026 ("Bonds 2020/2026") with a nominal value of EUR 5.00 each and a total nominal value of up to EUR 8,000,000.

As capital market conditions had changed as a result of the coronavirus crisis, the Management Board had resolved on March 12, 2020 to extend the subscription period for the Bonds 2020/2024 and for the Bonds 2020/2026 until March 31, 2020.

On March 23, 2020, the Management Board resolved not to offer the Bonds 2020/2024 and the Bonds 2020/2026 based on the previously determined conditions due to further substantially changed conditions since March 12, 2020 as a result of the coronavirus crisis. Both the subscription offers for the Bonds 2020/2024 and the subscription offer for the Bonds 2020/2026 were therefore withdrawn and will not be completed.

#### Non-binding term sheet for licensing agreement for Ameluz<sup>®</sup> in Poland with medac GmbH Sp. z o.o.

On March 13, 2020, the company signed a non-binding term sheet for an exclusive license agreement with medac GmbH Sp. z o.o., the Polish branch of medac Gesellschaft für klinische Spezialpräparate mbH, for the marketing of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in Poland.

The term sheet contains terms and conditions regarding the amount of the one-time upfront payment of around EUR 200,0000, the term of approximately 5 years, the transfer price for Ameluz<sup>\*</sup> and BF-RhodoLED<sup>\*</sup> as well as local regulatory responsibilities in Poland.

#### Licensing agreement for Ameluz® with Maruho Co., Ltd.

On March 3, 2020, the company entered into a binding term sheet ("Binding Term Sheet") with Maruho Co, Ltd, Osaka, Japan, which sets out the main terms of a future license agreement for East Asia and Oceania. The Agreement has a term of 15 years from the start of distribution in each country covered under the Agreement. The agreement has a term of 15 years from the start of distribution in each country covered under the agreement.

Under the terms of the agreement, Maruho will obtain exclusive development and commercialization rights including the right to sublicense Ameluz<sup>®</sup> East Asia and Oceania

Maruho is, with the consent of Biofrontera, entitled to carry out its own research and development within the scope of the license. Maruho will grant to Biofrontera a free and unlimited license for the results of such research and development activities for commercialization outside the territory.

Under the terms of the agreement, Biofrontera will supply Ameluz<sup>®</sup> to Maruho at cost plus 25%, while Maruho has an obligation to use commercially reasonable efforts to develop, approve and market Ameluz<sup>®</sup> in East Asia and Oceania.

Upon signing of the licensing agreement in April 2020, Maruho will make an upfront payment to Biofrontera AG in the amount of EUR 6 million plus additional future payments subject to achievement of certain regulatory and sales milestones. Maruho will also make royalty payments at an initial rate of 6% of net sales in the countries of the territory, which will increase depending on sales volume and will be reduced should generic products become available in the respective countries.

#### Effects of the COVID-19 pandemic

The coronavirus pandemic, which is continuing to worsen around the world, is causing massive disruptions in global supply chains, consumer markets and the economy as a whole. As a result of the measures implemented by governments around the world, Biofrontera's business operations is directly affected. In particular, there is a risk of a temporary and significant decline in demand for Biofrontera's products worldwide.

On March 20, 2020, the company announced that is has adopted comprehensive measures to reduce costs during the global COVID-19 pandemic. As such, Biofrontera has implemented short-time work for all employees in Germany. Similar measures were implemented at its subsidiaries in Spain and the UK. Biofrontera Inc., the US-based wholly owned subsidiary, also initiated substantial cost cutting measures by significantly reducing its workforce and implementing a mandatory furlough program, under which all employees will be required to take temporary periods of unpaid time off. In addition, the members of the Management Board of Biofrontera AG as well as the management of Biofrontera Inc. are voluntarily waiving a substantial portion of their salaries until further notice.

While these cost-cutting measures are in place, the company ensures full medical and financial regulatory compliance and continuous disclosure of its business is maintained at all time.

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. The company is sufficiently financed due to the drawdown of several tranches totaling EUR 15 million from the European Investment Bank loan as well as the one-time down payment in the amount of EUR 6 million from the licensing agreement with Maruho signed in April 2020. The planned capital measure for March 2020 with a maximum total of up to EUR 16 million had to be cancelled due to the turmoil on the capital markets as a result of the Corona crisis.

In order to finance its business operations for a further 12 months and beyond, Biofrontera is dependent on a capital measure of at least EUR 5 million by no later than the end of the 2020 financial year. The Management Board expects, based on the assumption that the general economic conditions will normalize and based on the consistently successful track record with capital measures to date, that the required liquidity for the business can be ensured in the future. However, should this no longer be possible due to a continuing crisis caused by the COVID 19 pandemic, this would pose a threat to the going concern status of the Biofrontera Group.

Should the worldwide COVID-19 pandemic last longer than expected, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite the cost reduction measures that have been introduced, and also render further access to financing on the capital market impossible. However, the Management Board currently assumes that following the end of the current crisis, it will once again be possible to successfully implement appropriate capital measures.

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. Lower sales of Xepi<sup>™</sup> may lead to a different evaluation of the medium-term sales and earnings prospects for Xepi<sup>™</sup> and consequently to a revaluation of the value of the Xepi<sup>™</sup> license on the balance sheet. The purchase price liability to Maruho for future profits from the sale of Xepi<sup>™</sup> is subject to market risk (earn-out) and depends on the amount of profits generated. Furthermore, in the event of a prolonged decline in business activity, the shelf life of already produced Ameluz<sup>®</sup> tubes may expire and inventories may have to be destroyed.

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

Leverkusen, April 20, 2020

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Prof. Dr. Hermann Lübbert

**Chief Executive Officer** 

Miliola

**Thomas Schaffer** 

**Chief Financial Officer** 

# F.1.7) Independent Auditor's Report

To Biofrontera AG, Leverkusen

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

# Audit opinions

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 2019, 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 2019 to 31 December 2019, 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 2019 to 31 December 2019. 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 the 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 2019 and of its financial performance for the financial year from 1 January 2019 to 31 December 2019, 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.

#### Material uncertainty related to going concern

We draw attention to the comments in section 33 "Subsequent events" of the notes to the consolidated financial statements and to the "Liquidity, profitability, capital markets access and risks to the going concern status" subsection in the "Risk and opportunity report" section of the combined management report. There the executive directors of Biofrontera AG describe that a planned capital measure for March 2020 with a maximum total of up to EUR 16 million had to be cancelled due to the turmoil on the capital markets as a result of the Corona crisis and that in order to finance its business operations for a further 12 months and beyond, Biofrontera is dependent on a capital measure of at least EUR 5 million by no later than the end of the 2020 financial year. The executive directors expect, based on the assumption that the general economic conditions will normalize and based on the consistently successful track record with capital measures to date, that the required liquidity for the business can be ensured in the future, however, attention is drawn to the fact that should this no longer be possible due to a continuing crisis caused by the COVID 19 pandemic, this would pose a threat to the going concern status of the Biofrontera Group. Should the worldwide COVID-19 pandemic last longer than expected, it could lead to a drastic decline in liquidity of the Biofrontera Group due to significantly reduced sales, despite the cost reduction measures that have been introduced, and also render further access to financing on the capital market impossible.

As stated in the quoted sections of the notes to the consolidated financial statements and the combined management report, these events or conditions indicate that material uncertainty exists that may cast significant doubt on the group's ability to continue as a going concern and that represents a going concern risk within the meaning of Section 322 para. 2 sentence 3 HGB.

As part of our audit we have assessed whether the executive directors' use of the going concern basis of accounting in the preparation of the consolidated financial statements and the disclosure of material uncertainty related to going concern in the consolidated financial statements and in the combined management report are appropriate in the circumstances. For this purpose, we assessed in particular the liquidity planning prepared by the executive directors of Biofrontera AG on the basis of the adopted budget of the Biofrontera Group for the financial year 2020 in consideration of the effects of the COVID-19 crisis which the executive directors expect on the business activities and the liquidity of the Biofrontera Group. In this context we determined whether the assumptions underlying the liquidity planning are sufficiently supported and assessed the reliability of the underlying data.

Our audit opinions are not modified in respect of this matter.

#### 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 2019 to 31 December 2019. 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, and we do not provide a separate audit opinion on these matters.

In addition to the matter described in the "Material uncertainty related to going concern" section we determined the matters described below as key audit matters to be included in our Auditor's Report:

- 1) Evaluation of the Xepi license obtained in connection with the acquisition of Cutanea Life Sciences and the financial liabilities from the variable purchase price from the earn out agreement.
- 2) Capitalisation of tax loss carryforwards.

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 Xepi license obtained in connection with the acquisition of Cutanea Life Sciences and the financial liabilities from the variable purchase price resulting from the earn out agreement

1) Financial Statement Risk

On 25 March 2019, Biofrontera Inc. entered into an agreement with Maruho Co., Ltd, Japan ("Maruho") to acquire 100% of the shares of Cutanea Life Sciences, Inc., Wayne/USA, including its subsidiaries Dermark LLC, Wayne/USA, and Dermapex LLC, Wayne/USA, (together "Cutanea") through its newly founded subsidiary Biofrontera Newderm LLC, Woburn/USA. In connection with the acquisition of the shares in Cutanea, in particular a license was acquired as an asset, which has enabled Biofrontera to market Xepi, a prescription cream for the treatment of impetigo ("Xepi license").

Biofrontera acquired Cutanea at an initial purchase price of US dollar 1.00 Additionally, an earn-out agreement was entered into, according to which the profits from the sale of the Xepi license will be shared equally between Maruho and Biofrontera until 2030.

The amount of the Xepi license recognised in the consolidated balance sheet in connection with the purchase price allocation at the time of acquisition is kEUR 23,604. The recognised financial liability from the variable purchase price at the time of acquisition amounted to kEUR 11,488.

The evaluation of the obtained Xepi license as well as of the financial liabilities from the variable purchase price resulting form the earn out is based on discretionary assumptions of the executive directors and is therefore subject to high estimation uncertainty. Particular risks for the financial statements are also attributable to the assumption-based measurement methods used to determine the fair values. Against this background and considering the importance of the acquisition for the Biofrontera Group's financial performance, the adequate recognition in the balance sheet of the acquisition completed in the financial year was of particular importance in our audit.

#### 2) Audit Approach

As part of the evaluation of the Xepi license and the purchase price liability, we first evaluated the competence, capability and objectivity of the external expert engaged by Biofrontera AG to carry out the evaluation. We reconciled the amount of the Xepi license and of the foregoing financial liability recognised in the consolidated balance sheet with the valuation report of the external expert. With the involvement of our internal valuation experts we evaluated the appropriateness of the valuation methods employed by the expert engaged by Biofrontera AG in the consideration of the Xepi license and the aforementioned financial liability in the context of the general accounting policies and assessed the content of the applied measurement assumptions and parameters. For this purpose we analysed the methodological approach used for determining the fair value of the Xepi license and the appropriateness of the resulting cash flows on which the determination of the fair value of the Xepi license and of the Xepi license and of the purchase price liability was based. For this purpose, we checked the planning calculations for their arithmetical correctness and assessed the planned future revenue and resulting cash flows from the sale of the Xepi medicine and the expected conditional purchase price payments, among other things, on the basis of interviews with the executive directors and of the external experts engaged to prepare the purchase price allocation. In the calculation of the fair value of the external expert engaged to prepare the purchase price allocation.

Xepi license and of the present value of the purchase price liability, we recalculated the used capital costs and compared their underlying parameters with publicly available information.

#### 3) Reference to Related Disclosures

The disclosures relating to the valuation of the Xepi license and the financial liabilities from the variable purchase price resulting from the earn out agreement are shown in the notes to the consolidated financial statements in the "Basis of consolidation" section.

## Capitalisation of tax loss carryforwards

#### 1) Financial Statement Risk

In the consolidated balance sheet as of 31 December 2019 of Biofrontera AG, a balance from deferred tax assets in the amount of kEUR 9,470 and deferred taxes amounting to kEUR 1,676 are recognised under the line item "Deferred taxes".

Of the deferred tax assets, an amount of kEUR 7,883 relates to capitalised tax loss carryforwards of Biofrontera Pharma GmbH. It generated profits in 2019, and the executive directors of Biofrontera AG assume in their planning, based on knowledge as of the balance sheet date, that Biofrontera Pharma GmbH will continue to generate positive results in the future and thus use its tax loss carryforwards.

Further deferred tax claims in Germany and in the USA were recognised in the consolidated financial statements only in the amount of the existing deferred tax liabilities, with reference of the executive directors of Biofrontera Pharma GmbH to IAS 12.34 due to the lack of predictability regarding future taxable profits, and therefore total deferred tax assets in the amount of kEUR 29,569 were not recognised.

Whether the deferred tax assets from the loss carryforwards of Biofrontera Pharma GmbH are eligible for capitalisation largely depends on assessments and assumptions of the executive directors of Biofrontera AG and is therefore subject to high estimation uncertainty. In consideration of the foregoing and of the importance of the recognition of these deferred tax assets in the consolidated financial statements for the presentation of the assets, liabilities and financial position of the Biofrontera Group, this matter was of particular importance in our audit.

#### 2) Audit Approach

As part of our audit of the capitalisation and of the non-recognition of deferred tax assets on the foregoing loss carryforwards we critically assessed the executive directors' estimates of the predictability of future taxable profits of the relevant taxable entities. For this purpose we evaluated the assessment of the executive directors of Biofrontera AG that the positive earnings development of Biofrontera Pharma GmbH in 2019 and in the planning period is expected to be sustainable. In this context we reconciled the planning of Biofrontera AG and approved by the Supervisory Board, and we reconciled the medium-term planning until 2022 and the forward projection planning being based on knowledge existing or to be expected on the balance sheet date. On the basis of the information obtained in this process, we finally evaluated the assessment of the executive directors to continue to capitalise the loss carryforwards at Biofrontera Pharma GmbH and recalculated the tax loss carryforwards as well as deferred tax assets. We checked the arithmetical correctness of the recognised deferred tax assets. Furthermore, we evaluated the assessment of the executive directors with regard to the existing uncertainties in relation to the predictability of future taxable profits of the other Biofrontera Group entities.

#### 3) Reference to Related Disclosures

The disclosures of Biofrontera AG relating to accounting policies with regard to deferred taxes are shown in the "Summary of significant accounting policies" section of the notes to the consolidated financial statements and the disclosures relating to existing loss carryforwards in the "Notes to the consolidated balance sheet - 8. Deferred income tax" section of the notes to the consolidated financial statements.

# Other information

The executive directors or, respectively, the supervisory board are responsible for the other information. 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 297 para. 2 sentence 4 HGB and pursuant to Section 315 para. 1 sentence 5 HGB, and
- the remaining parts of the 2019 annual report with the exception of the audited consolidated financial statements, the audited parts of the combined management report and 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 and, in so doing, to consider whether the other information

- is materially inconsistent with the consolidated financial statements, the audited parts of 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 statement 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 Financial 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

#### Further Information pursuant to Article 10 of the EU Audit Regulation

We were elected as group auditor by the annual general meeting on 10 July 2019. We were engaged by the audit committee of the supervisory board on 20 November 2019. 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, 20 April 2020

Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft

Prof. Dr. Thomas Senger Wirtschaftsprüfer [German Public Auditor] Michael Gottschalk Wirtschaftsprüfer [German Public Auditor]

## **Responsibility Statement**

# Affirmation of the legal representatives pursuant to Sections 297 (2) Clause 4 and 315 (1) Clause 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 20, 2020 Biofrontera AG

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Prof. Dr. Hermann Lübbert

Villal

**Thomas Schaffer** 

F.2) Half-year financial report as of June 30, 2020

# F.2.1) Interim group management report for the first half of the 2020 financial year

## Group structure

As of June 30, 20202, the Biofrontera Group (hereinafter also called "Biofrontera" or "Biofrontera Group") 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<sup>®</sup>. According to a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, which is also the holder of the CE certificate of BF-RhodoLED<sup>®</sup>, 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<sup>™</sup>.

Production of Ameluz<sup>®</sup> 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<sup>™</sup> 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<sup>®</sup> and Xepi<sup>™</sup>. 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<sup>®</sup> and Xepi<sup>™</sup>, 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<sup>®</sup> as well as broader distribution of Xepi<sup>™</sup>.

Biofrontera has received a centralized approval for its own self-developed drug, which is marketed under the brand name Ameluz<sup>®</sup>. Since the market launch in February 2012, Biofrontera has been selling Ameluz<sup>®</sup> with its own sales force to dermatologists in Germany and since March 2015 also in Spain. Ameluz<sup>®</sup> 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<sup>®</sup> 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.

The company's growth strategy is supported and backed by the vast majority of its shareholders. Unfortunately, a group of minority shareholders has for several years now succeeded in effectively revoking the power of the Annual General Meeting and thus the majority of shareholders by challenging relevant resolutions of all ordinary Annual General Meetings since 2016 by means of lawsuits and by blocking the resolutions due to the long judicial decision-making processes. As a result, the company is seriously restricted in its development at the expense of the majority of shareholders.

## Products

## Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup>

In December 2011, Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>\*</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC) in March 2020. It is expected that the significantly superior efficacy compared to Metvix<sup>®</sup> one year after treatment will further enhance the market positioning of Ameluz<sup>®</sup>.

In March 2020, the European Commission granted a label extension for Ameluz<sup>®</sup> to cover the treatment of mild and moderate actinic keratoses by photodynamic therapy with Ameluz<sup>®</sup> 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<sup>®</sup> on one randomized side 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<sup>®</sup> 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<sup>®</sup> was also demonstrated for all secondary parameters studied. In this study, the average lesion recurrence rate 12 months after Ameluz<sup>®</sup> 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<sup>®</sup>. The Company expects that this label extension will also further strengthen the market position of Ameluz<sup>®</sup> in Europe.

In May 2016, Biofrontera received the marketing approval for Ameluz<sup>®</sup> in the USA. The approved indication is "lesion and field directed PDT 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<sup>®</sup>. 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 2018 at regular intervals.

The BF-RhodoLED<sup>\*</sup> 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<sup>\*</sup> 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<sup>\*</sup> is available throughout the EU.

#### **Belixos**®

Belixos<sup>®</sup> 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<sup>®</sup> series includes the following products: belixos<sup>®</sup> Cream, belixos<sup>®</sup> Liquid and belixos<sup>®</sup> 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<sup>®</sup> is obtainable in selected pharmacies, dermatological institutes and from the online retailer Amazon.

#### Хері™

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<sup>™</sup> (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. To date, no antibiotic resistance to Xepi<sup>™</sup> is known and it has been specifically approved by the FDA for the treatment of antibiotic-resistant bacteria. The approved indication is impetigo, a common skin infection in children with staphylococci and streptococci. Xepi<sup>™</sup> has an excellent safety profile that even allows for use on infants from the age of two months.

Xepi<sup>™</sup> 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<sup>™</sup> our portfolio now includes an innovative, promising product with a three-figure million market potential.

The drug Xepi<sup>™</sup> in-licensed by Biofrontera is protected by two patent families in the USA and other countries. With regard to the USA, patent protection applies for the composition of Xepi<sup>™</sup> until January 29, 2032 and for the approved treatment of impetigo until December 15, 2029.

## Sales and markets

#### USA

In the USA, Ameluz<sup>®</sup> was launched by Biofrontera in October 2016. The distribution of Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>TM</sup>.

#### Germany and Europa

With its central European approval, Ameluz<sup>®</sup> 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 150 EUR to approximately 220 EUR per 2g tube.

In Europe, Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> are marketed in Germany (since 2012), Spain (since 2015) and Great Britain (since May 2018) by our own sales force. 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 downpayment and the regional partners buy Ameluz<sup>®</sup> 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<sup>®</sup> and BF-RhodoLED<sup>®</sup> in Israel and Desitin Arzneimittel GmbH for the commercialization of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> in Scandinavia were terminated by mutual agreement during the reporting period. Biofrontera's efforts to maintain the approval or other drug regulatory requirements were not justified by the relatively low sales volume in these markets.

#### Other regions

In April 2020, Biofrontera signed an exclusive licensing agreement with Maruho Co, Ltd, Osaka, Japan (Maruho) for the development and commercialization of Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to Maruho at cost plus 25%, while Maruho has the obligation to make commercially reasonable efforts to develop, register and market Ameluz<sup>®</sup> in all countries within the Territory.

Under the licensing 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.

## Research and development projects

All research and development activities of the Biofrontera Group regarding the nanoemulsion and Ameluz<sup>®</sup> 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<sup>®</sup> XL is the responsibility of Biofrontera Pharma GmbH.

#### 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. The agreement for this phase of the research collaboration expired at the end of the reporting period.

## Phase II study for the treatment of mild to severe acne

With regard to the possible label extension of Ameluz<sup>®</sup> 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, so that the study program can start in 2020 or 2021 as soon as the necessary funds are available.

#### Phase III study 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> to include additional body regions. The study protocol is currently being developed according to FDA guidelines, so patient recruitment could start in the first half of 2021, if funds are available.

Following consultation with the FDA, Biofrontera has also initiated a pharmacokinetics study (PK study) to test the safety of PDT using three tubes of Ameluz<sup>®</sup> at the same time. The aim of this phase I study is to obtain pharmacokinetic profiles following an Ameluz<sup>®</sup> PDT in patients with AK in an extended treatment area in the face/head or peripheral area. In addition, safety and tolerability for the patient during and after treatment will be investigated. Patient recruitment is expected to take 3-5 months and the Phase I study should be completed in the third quarter of 2020.

## Development of the BF-RhodoLED® XL lamp

The future use of the BF-RhodoLED<sup>®</sup> XL will allow the application of Ameluz<sup>®</sup> on larger areas as well as the simultaneous exposure of several interspersed lesions. Furthermore, the BF-RhodoLED<sup>®</sup> 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<sup>®</sup> sales. The company expects to submit the application for approval to the FDA during the second half of 2020.

## Phase III study for the treatment of superficial basal cell carcinoma (BCC) with Ameluz<sup>®</sup> in combination with our red-light lamp BF-RhodoLED<sup>®</sup> 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<sup>®</sup> in combination with our BF-RhodoLED<sup>®</sup> 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. Following successful FDA approval, Ameluz<sup>®</sup> would be the only drug in the United States for the treatment of superficial BCC with PDT.

## Patent development

The company maintains four different company-owned patent families worldwide. In addition, Biofrontera pursues patent families created in collaboration with Maruho under a partnership agreement that expired in March 2018. The Group's patents are held by Biofrontera Bioscience GmbH.

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

#### Nanoemulsion

We have been issued composition of matter patents for our nanoemulsion technology in the EU (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. We have filed patent applications that are pending in the United Arab Emirates and the USA. The patent in India and the patent application in Brazil were discontinued in 2019 and 2020, respectively.

On November 12, 2019 protection for the patent family describing the combination of nanoemulsions with aminolevulinic acid hydrochloride, the active ingredient in Ameluz<sup>®</sup>, expired. However, Ameluz<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup>, additional patent applications have been submitted (see below).

#### Migraine prophylaxis BF-1

An international patent application regarding anti-migraine compounds and their use was submitted to the World Intellectual Property Organization (WIPO). A patent in the USA has been granted, expiring in January 2034. The European Patent Office announced on May 13, 2020, that the examining division intends to grant a European patent.

#### Photodynamic therapy

A new international patent application "Improved Photodynamic Therapy" 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.

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.

#### Xepi™

The drug product Xepi<sup>™</sup>, 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<sup>™</sup> 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").

## Employees

As of June 30, 2020, 154 employees (December 31, 2019: 174) were employed by the Biofrontera Group, distributed as follows:

Company	Employees as of June 30, 2020	Employees as of December 31, 2019
Biofrontera AG	29	30
Biofrontera Bioscience GmbH	24	19
Biofrontera Pharma GmbH*	45	52
Biofrontera Inc.	56	73

\* includes the subsidiaries in Spain and the UK

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH do not employ any staff.

# Management report for the first six months of the 2020 financial year for the Biofrontera Group

## **Business performance**

During the first six months of 2020, the business performance of Biofrontera AG was mixed. At the beginning of the year, we were initially able to record a solid sales performance. In addition, we successfully reorganized the global sales structure, from which we expected a further acceleration of sales growth in the short term. Since mid-March we have had to accept declining sales figures, particularly in the USA, due to the dynamic development of the COVID-19 pandemic. We were therefore forced to implement company-wide cost reduction measures.

The Biofrontera Group generated total revenues of EUR 16.1 million in the period between January 1 and June 30, 2020, an increase of 16% compared to EUR 13.9 million revenues in the same period of the previous year. Total revenues include a one-time payment of EUR 6.0 million, which the company received from Maruho Co., Ltd. under the licensing agreement signed on April 20, 2020. Revenues from product sales amounted to EUR 9.7 million, a decline of 30% compared to the first half of 2019, with revenues in the second quarter being strongly influenced by the effects of the global coronavirus crisis. However, a recovery in sales is expected in the second half of the year, together with a further decline in COVID-19 infection numbers.

#### Commercialization of Ameluz® in the USA

Sales in the USA amounted to EUR 6.3 million in the first half of the year, compared to EUR 10.2 million in the same period of 2019, representing a 38% decline in sales compared to the same period of the previous year. Revenues include EUR 0.2 million from product sales from Xepi<sup>™</sup> (previous year: EUR 0.3 million).

Since mid-March 2020, Biofrontera has been directly affected by the global coronavirus crisis. Starting in mid-March, rising infection rates and the official recommendation of the American Academy of Dermatology to treat patients by remote diagnosis and treatment, if possible, led to a significant decrease in patient numbers and extensive, albeit temporary, practice closures. As a result, our sales slumped sharply, particularly in the USA. Biofrontera Inc, the wholly-owned subsidiary in the USA, has responded by introducing significant costcutting measures, including a reduction of 17 employees. At the same time, a furlough program was introduced in which all employees were obliged to take temporary unpaid leave. After sales of our products had initially dropped to almost zero in April, we were already able to observe a slow recovery of our US business in May and June. In many parts of the US, medical practices have reopened at least in part and patients are increasingly willing to undergo treatment for actinic keratoses. However, due to the continuing dynamics of the coronavirus crisis in the U.S. and the delays of the pandemic in many states, the situation remains difficult to assess.

#### Commercialization of Ameluz® in Europe

Product-related revenues in Germany increased by around 10% to EUR 2.4 million in the first six months of 2020 compared to EUR 2.2 million in the first six months of 2019, while product sales of EUR 1.0 million were generated in the rest of Europe, compared to EUR 1.4 million in the same period of last year.

In Germany, the sales and marketing team was able to successfully leverage an approval extension granted in March to include the treatment of actinic keratoses on the body and extremities, as well as current study results, in order to bring the benefits of Ameluz<sup>®</sup> to the attention of dermatologists even during the crisis, albeit only in written or electronic form. It was precisely during this period that the advantages of daylight PDT, which allowed the patient to be treated without direct contact with a doctor, became particularly clear, given the consistently good weather. In Spain, we recorded a very positive sales trend before the outbreak of the pandemic, followed by an almost complete standstill due to the very strict lockdown regulations there. However, we are confident that we will soon be able to build on the sales successes achieved to date and record a rapid recovery in sales.

Sales with distribution partners in other European countries now only make a small contribution to total sales. Effects of the COVID-19 pandemic

As already described, the coronavirus crisis has led to a decreasing number of treatments and thus to a sharp drop in sales in our most important market, the USA. On March 20, 2020, the Company announced that it would take comprehensive cost reduction and control measures during the COVID-19 pandemic.

Consequently, Biofrontera had introduced short-time work for all employees in Germany until the end of July 2020. Similar measures were implemented for the subsidiaries in Spain and the UK. Biofrontera Inc, the wholly owned subsidiary in the USA, also introduced significant cost reduction measures. There, as already described above, the number of employees was significantly reduced and a furlough program was implemented, under which all employees were obliged to take temporary unpaid leave. In addition, the members of the Management Board of Biofrontera AG and the management of Biofrontera Inc. voluntarily agreed to waive a substantial portion of their salaries.

While these cost reduction measures were in effect, the Company was able to ensure full compliance with all regulatory requirements in both financial and medical terms, and to meet all disclosure obligations at all times.

The continued uncertain business outlook due to the COVID-19 crisis has impacted the valuation of certain of the Company's assets and liabilities. Reduced sales of Xepi<sup>™</sup> have led to a different assessment of the medium-term business and profit outlook for Xepi<sup>™</sup> and thus, in the first quarter of 2020, to a re-evaluation of both the balance sheet value of the Xepi<sup>™</sup> license and the purchase price liability to Maruho.

#### Reorganisation of the sales structure and the USA business

In January, following the reorganisation 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<sup>®</sup> 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<sup>®</sup> and Metvix<sup>®</sup> were included in the product information (SmPC). Ameluz<sup>®</sup> showed significantly lower recurrence rates after 12 months at 19.5% compared to Metvix<sup>®</sup> at 31.2%.

Furthermore, during the first quarter, the first treatments in the US pharmacokinetics study evaluating the safety of PDT with three tubes of Ameluz<sup>®</sup> were performed. This study is a prerequisite for the treatment of larger body areas with multiple tubes of Ameluz<sup>®</sup> as well as for the alignment of reimbursement modalities with the competitor product. After the study had to be interrupted, patient screening has already been resumed after the first relaxation of the COVID-19 restrictions in the USA.

At the same time, we are working diligently to complete the development and the application for approval of the new lamp BF-RhodoLED<sup>®</sup> XL, which enables the application of Ameluz<sup>®</sup> on larger areas. We intend to submit this application together with the results of the pharmacokinetics study to the FDA in the second half of the year despite the corona crisis. And we are also continuing patient recruitment for the Phase III study of Ameluz<sup>®</sup> for the treatment of basal cell carcinoma (BCC) in the United States. Despite the difficult conditions, Biofrontera is working intensively to continue the various clinical studies and to meet the communicated timelines as far as possible.

#### 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.

On March 23, due to the further significant changes in the general conditions since March 12, 2020 as a result of the coronavirus crisis, the Management Board resolved to withdraw from offering the 2020/2024 and 2020/2026 bonds at the conditions previously set out in the bond terms and conditions. Both subscription offers for the bonds 2020/2024 and the bonds 2020/2026 were therefore withdrawn and not executed.

#### 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., the Polish subsidiary of medac Gesellschaft für klinische Spezialpräparate mbH, for the commercialization of Ameluz<sup>®</sup> and BF-RhodoLED<sup>®</sup> 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<sup>®</sup> and BF-RhodoLED<sup>®</sup>, as well as the local regulatory responsibilities in Poland.

On April 20, 2020, Biofrontera concluded an exclusive licensing agreement with Maruho Co, Ltd, Osaka, Japan (Maruho) for the development and commercialization of Ameluz<sup>®</sup> 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.

## Biofrontera Group financial position and performance

## Results of operations

in EUR thousands	6M 2020	6M 2019
Sales revenue	16,116	13,904
Gross profit on sales	14,625	11,421
Research and development costs	(2,389)	(2,322)
General administrative costs	(4,412)	(7,768)
Sales and marketing costs	(12,151)	(14,195)
Loss from operations	(4,327)	(12,864)
Interest expenses and income	(715)	(1,345)
Other expenses	(301)	(188)
Other income	110	23,424
Loss before income tax	(5,233)	9,027
Income tax	(338)	(26)
Loss after income tax	(5,571)	9,001

#### Sales revenue

The Biofrontera Group generated revenues of EUR 16,116 thousand in the first six months of 2020, an increase of 16% compared to the same period last year (prior year period: EUR 13,904 thousand). Product sales generated revenues of EUR 9,676 thousand, a decrease of 30% compared to the first half of 2019.

The largest impact of the COVID-19 pandemic was felt in the USA, where revenues decreased by 38% to EUR 6,347 thousand (prior year period: EUR 10,231 thousand). This includes EUR 157 thousand (prior year period: EUR 282 thousand) in sales from the new product Xepi<sup>TM</sup>.

By contrast, sales in Germany increased by EUR 210 thousand or 10% to EUR 2,364 thousand (prior year period: EUR 2,154 thousand). Sales in other European countries decreased by 29% to EUR 965 thousand (prior year period: EUR 1,357 thousand). Sales from other regions amounted to EUR 6,441 thousand (prior year period: EUR 162 thousand) and include revenues from a downpayment in the amount of EUR 6,000 thousand.



#### Gross profit on sales

Gross profit increased by EUR 3,204 thousand in the first six months of 2020 to EUR 14,625 thousand compared to EUR 11,421 thousand in the previous year period. The gross margin increased to 91% compared to 82% in the same period of the prior year, which is mainly due to revenues from downpayments, which are not directly attributable to cost of sales.



#### Research and development costs

During the first six months of 2020, research and development costs amounted to EUR 2,389 thousand, slightly above the level of the previous year (EUR 2,322 thousand). This includes costs for clinical studies, but also expenses for regulatory affairs, i.e. for granting, maintaining and expanding our labels.

#### General administrative costs

General and administrative expenses amounted to EUR 4,412 thousand in the first half of 2020 (prior year: EUR 7,768 thousand), a significant decrease of EUR 3,356 thousand. This was mainly driven by the cost saving measures introduced due to the COVID-19 pandemic but also due to lower legal costs.

#### Sales and marketing costs

Sales and marketing expenses amounted to EUR 12,151 thousand in the first six months of 2020, a decrease of EUR 2,044 thousand compared to the previous year (EUR 14,195 thousand). The effects of the cost reduction measures are offset by the non-cash impairment of the Xepi<sup>™</sup> license in the amount of EUR 2,001 thousand. Sales and marketing expenses include the costs for our own sales force in Germany, Spain, Great Britain and the U.S. as well as marketing expenses.

#### Loss on operations

The result from operating activities improved by EUR 8,537 thousand to EUR -4,327 thousand (previous year: EUR -12,864 thousand), mainly due to the cost saving measures implemented in the reporting period and the effects from the first-time consolidation of Cutanea included in the previous year's figure.

#### Interest expenses

The amount of net interest was EUR -715 thousand (prior year: EUR -1,345 thousand), and mainly includes interest expenses for the EIB loan made available in July 2017 and which was increased by a further tranche in February 2019. Interest income of EUR 516 thousand (prior year: interest expense of EUR 252 thousand) is reported from the re-evaluation of the performance component of the EIB loan. In addition, interest expenses include higher amounts from the compounding of non-current liabilities.

#### Other expenses and income

Other expenses and income totaled EUR 191 thousand in the reporting period (previous year: EUR 23,235 thousand), whereby last year's figure includes one-time effects of EUR 22,845 thousand from the acquisition of Cutanea Life Sciences Inc. This item also includes expenses and income from currency translation.

This item includes current income taxes of EUR 19 thousand (previous year: EUR 26 thousand) and deferred tax expenses of EUR 319 thousand (previous year: EUR 0 thousand) from the use of tax loss carryforwards for Biofrontera Pharma GmbH.

#### Net assets of the Biofrontera Group

in EUR thousands	June 30, 2020	December 31, 2019
Non-current assets	33,099	35,872
Current financial assets	13,514	17,227
Other current assets	5,350	5,264
Total assets	51,963	58,363
Equity	4,737	9,955
Non-current liabilities	39,261	36,830
Current financial liabilities	3,605	5,507
Other current liabilities	4,360	6,071
Total equity and liabilities	51,963	58,363

#### Non-current assets

Non-current assets totaling EUR 33,099 thousand include the recognized deferred tax assets on tax loss carryforwards for Biofrontera Pharma GmbH of EUR 7,475 thousand and the purchased Xepi<sup>™</sup> license in the amount of EUR 19,123 thousand. The value of the carrying amount was verified by an impairment test, which also includes the current market situation caused by the COVID-19 pandemic and the resulting delays in the market penetration of Xepi<sup>™</sup>. As a result, this led to a non-cash impairment in the amount of EUR 2,001 thousand.

#### Current financial assets

Current financial assets amounted to EUR 13,514 thousand as of June 30, 2020. They include cash and cash equivalents of EUR 10,550 thousand (Dec 31, 2019: EUR 11,119 thousand) and trade receivables in the amount of EUR 2,191 thousand (Dec 31, 2019: EUR 5,031 thousand).

#### Other current assets

Other current assets mainly include inventories in the amount of EUR 4,384 thousand (Dec 31, 2019: EUR 4,065 thousand).

#### Equity

In accordance with IFRS, the Group reports equity in the amount of EUR 4,737 thousand (Dec 31, 2019: EUR 9,955 thousand).

The Company's fully paid-in share capital amounts to EUR 44,849,365 as at June 30, 2020.

As at June 30, 2020, based on the most recent mandatory shareholder disclosures, the shareholder structure is as follows:

	June 30, 2020	December 31, 2019
Maruho Deutschland Co., Ltd., Osaka Japan All voting rights are attributed to Maruho Co., Ltd. through Maruho Deutschland GmbH, Düsseldorf, which is controlled by Maruho Co., Ltd.	13,399,965	13,047,754
<ul> <li>Wilhelm Konrad Thomas Zours</li> <li>The voting rights are allocated to Mr. Zours through the chain of subsidiaries listed below according to voting rights disclosure: <ul> <li>DELPHI Unternehmensberatung AG*</li> <li>Deutsche Balaton AG*</li> <li>Sparta AG*</li> <li>Deutsche Balaton Biotech AG*</li> <li>Prisma Equity AG*</li> <li>Heidelberger Beteiligungsholding*</li> <li>ABC Beteiligungen AG</li> <li>AEE Ahaus-Enscheder AG</li> <li>MARNA Beteiligungen AG</li> <li>Altech Advanced Materials AG</li> <li>Ming Le Sports AG</li> </ul> </li> </ul>	13,400,957	13,300,694
Free float	18,048,443	18,500,917
Total	44,849,365	44,849,365

On January 28, 2020, DELPHI Unternehmensberatung Aktiengesellschaft, Deutsche Balaton Aktiengesellschaft, SPARTA AG, Deutsche Balaton Biotech AG, Prisma Equity AG, ABC Beteiligungen AG and Heidelberger Beteiligungsholding signed a voting pool agreement.

#### Non-current liabilities

Non-current liabilities include financial debt (EUR 22,305 thousand; Dec 31, 2019: EUR 22,110 thousand) as well as the other non-current financial liability resulting from the purchase price for Cutanea Life Sciences, Inc. (EUR 16,956 thousand; Dec 31, 2019: EUR 14,720 thousand). The increase in the purchase price liability recognized at fair value is mainly due to the availability of further start-up costs by Maruho in the amount of EUR 2,264 thousand.

Non-current financial liabilities include the EIB loan incl. performance component totaling EUR 17,224 thousand (Dec 31, 2019: EUR 17,146 thousand), the as yet unconverted portions of the convertible bond 2017-22 in the amount of EUR 1,989 thousand (Dec 31, 2019: EUR 1,977 thousand) and liabilities from leases in the amount of EUR 3,092 thousand (Dec 31, 2019: EUR 2,987 thousand) to be recognized in accordance with IFRS 16.

#### **Current financial liabilities**

Current financial liabilities mainly include trade payables of EUR 2,240 thousand (December 31, 2019: EUR 4,196 thousand) and liabilities from leases of EUR 1,116 thousand (December 31, 2019: EUR 1,038 thousand) to be recognized in accordance with IFRS 16.

#### Other current liabilities

Other current liabilities amounted to EUR 4,360 thousand (Dec 31, 2019: EUR 6,071 thousand) and primarily comprise provisions of EUR 2,888 thousand (Dec 31, 2019: EUR 3,506 thousand) and accrued liabilities of EUR 1,118 thousand (Dec 31, 2019: EUR 2,167 thousand).

## Financial position of the Biofrontera Group

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

in EUR thousands	6M 2020	6M 2019
Cash flow from operating activities	(1,246)	(21,87)3
Cash flow from investing activities	1,764	19,718
Cash flow from financing activities	(1,079)	4,278
Liquidity/Cash and cash equivalents	10,550	21,579
Non-current financial liabilities	22,305	22,528
Current financial debt	1,291	188
Net liquidity	(13,046)	(1,137)

Net cash flows from operating activities of EUR -1,246 thousand improved by EUR 20,627 thousand compared to the first six months of 2019, mainly due to the effects of the restructuring of Cutanea in the previous year.

Net cash flows from investing activities amounted to EUR 1,764 thousand (previous year: EUR 19,718 thousand) and mainly contain the further cash inflow from start-up costs in connection with the Cuteanea acquisition.

The decrease of net cash flows from financing activities from EUR 4,278 thousand in the prior year to EUR - 1,079 thousand is mainly due to the payment of another tranche of the EIB loan in the first half of 2019.

The financial liabilities from the convertible bond 2017/2022 and the EIB loan mature differently until 2024 at the latest. The convertible bond 2017/2022 (EUR 1,977 thousand) and the first EIB tranche (EUR 11,845 thousand) mature in 2022. The second EIB tranche (EUR 5,301 thousand) is due in 2024 and the annual purchase price payments for the Cutanea acquisition are expected from 2022 to 2030 depending on future profits from the sale of Xepi<sup>™</sup>.

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 whose amount depends on the market capitalization of Biofrontera AG, but is limited to an interest rate of 4% p.a.

#### Cash and cash equivalents

Cash and cash equivalents amounted to EUR 10,550 thousand at June 30, 2020 (Dec 31, 2019: EUR 11,119 thousand). The above amount does not include any income from the capital measure executed only after the balance sheet date.

On July 27, 2020, the Management Board, with the approval of the Supervisory Board, authorized the issuance of of up to 2,638,150 units of a 1.0% qualified subordinated mandatory convertible bond 2020/2021 with a nominal value of EUR 3.00 each and a total nominal value of up to EUR 7,914,450. On August 18, 2020, the Company announced that the mandatory convertible bond 2020/2021 was fully placed. The gross proceeds from the issuance amount to EUR 7,914 thousand.

## Outlook and forecast of key financial indicators

#### Business environment and forecast

Due to the ongoing dynamic development of the coronavirus pandemic, the Company's ability to forecast the future continues to be severely limited.

Following the special report on the corona pandemic published by the German Council of Economic Experts in March 2020, the Council issued an economic forecast for Germany in June for 2020 and 2021. According to this, the economic development is described as a pronounced V-scenario, in which the German Council of Economic Experts expects a decline in real gross domestic product (GDP) of 6.5% in 2020 and positive growth of 4.9% in 2021. Thus, the gross domestic product would not return to its pre-pandemic level until 2022.

Between April and June 2020, the US economy shrank at an annual rate of 32.9% (not annualized, GDP declined by 9.5% between April and June), as the Bureau of Economic Analysis announced on July 30, 2020. US economists are forecasting a strong upswing for the currently ongoing third quarter of the year. The Federal Reserve Bank of New York, for example, expects an annualized increase of 13.3% between July and September 2020 and extended its various credit programs until the end of the year to support economic and market activity. The basic scenario (with a second coronovirus wave) of the OECD assumes an annual growth of the US gross domestic product of -8.5% in 2020 and +1.9% in 2021.

The economic outlooks described above are also incorporated into the Management Board's assumptions concerning the Company's operations for the next 12 months. This outlook is based on the assumption that the gradual easing of measures to contain the coronavirus pandemic, especially in the U.S., will lead to a significant increase in revenues at the end of Q3 and then especially in Q4 2020 and Q1 2021. These assumptions concerning the US business are also supported by the traditional seasonality of sales, which, despite a short-term recovery, affects US sales in the summer. Overall, the Company expects revenues of EUR 34 to 38 million in 2020 (including the license payment of EUR 6 million received from Maruho Co., Ltd. in April 2020), assuming a corresponding recovery of the business development. The Company expects that cash costs will increase again in Q3 and Q4 2020, but not quite to the level of Q1 2020. In order to achieve the revenue targets, it is essential to reinvest in sales and marketing, particularly in the US. In a press release dated June 30, 2020, the Company confirmed the statement already made in the 2019 annual financial statements that, from today's perspective, further financing in the amount of EUR 5 million is required to maintain business operations until the end of April 2021. Due to the capital increase in August 2020 with gross proceeds of EUR 7.9 million, the Company has sufficient funds under the above mentioned planning assumptions to continue operations for at least 12 months after the reporting date of these interim financial statements.

The Biofrontera Group plans to cover the financing requirements for further growth in the long term through an additional capital measure already approved by the Annual General Meeting. This capital measure is intended to raise funds that will enable the Group to strategically develop its products and expand its market positioning. This capital measure is currently blocked by an action for rescission and nullity initiated by a shareholder. The Company will seek a fast track release in an accelerated release procedure before the Higher Regional Court of Cologne, in order to enable the implementation of the resolution passed by the majority of shareholders at the Annual General Meeting and thus allow the long-term financing for Biofrontera.

## Risk and opportunity report

A detailed description of the risks and opportunities existing in the Group is provided in the Risk and Opportunity Report of the Group Management Report as of December 31, 2019. As of June 30, 2020, there have been no further significant changes compared to the risks and opportunities described there, with the exception of the risks and legal proceedings described below.

#### Risks and opportunities relating to future business development and growth

#### External influences and global risks

The increasing integration of the global economy through globalization and digitalization can exert a negative impact on the achievement of Biofrontera's goals in the context of macroeconomic developments. In addition, political developments in our markets can influence the structures relevant for Biofrontera in the respective healthcare sector.

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

Since the beginning of 2020, for instance, the novel coronavirus (COVID-19) has become a global pandemic. As a result of the measures implemented by governments around the world, Biofrontera's business operations is directly affected. In particular, there is a risk that a temporary, significant reduction in global demand for Biofrontera's products will continue. The maintenance of business processes may continue to be hampered by reduced revenues, by the implementation of (regional) governmental measures that do not allow full business operations, or by employees of the Biofrontera Group or relevant suppliers suffering from an infection with COVID-19.

The direct and indirect effects of the pandemic can have a negative impact on the company's liquidity position as the pandemic develops. In addition, the success of required capital measures by the company could be jeopardized.

To this end, the company has taken 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.

With regard to the risks that may threaten the going concern status, we refer to the disclosures in the Risk and Opportunity Report, section Liquidity, profitability, capital market access and risks to the going concern status.

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

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

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

The Biofrontera Group may not be able to meet existing or future payment obligations due to insufficient availability of cash. So far, the Group has been able to meet its payment obligations at all times. By injecting equity or debt capital, Biofrontera has so far always succeeded in providing the necessary funds for business operations. Through the medium-term financing of a total of EUR 15 million from the loan from the European Investment Bank, the downpayment of EUR 6 million from Maruho as part of the licensing agreement

concluded in April 2020, as well as the capital measure carried out in August 2020 with gross proceeds of EUR 7.9 million, the Company currently has sufficient available funds under the above planning assumptions to continue operations for at least 12 months from the reporting date of these six-month financial statements.

An action for rescission and nullity was filed by one shareholder against an ordinary capital increase of up to 20% of the Company's share capital, which was resolved by the AGM in May 2020. This capital increase can therefore not be implemented in the short term. The Company will seek a fast track release in an accelerated release procedure before the Higher Regional Court of Cologne (see also section "Litigation").

The Company's growth strategy is supported and backed by the large majority of shareholders. Unfortunately, a group of minority shareholders has succeeded for several years now in effectively depriving the Annual General Meeting, and thus the majority of shareholders, of their power by challenging relevant resolutions of all ordinary Annual General Meetings since 2016 with lawsuits and blocking them due to the long judicial decision paths. As a result, the company is severely restricted in its development at the expense of the majority of shareholders.

If the improvement of the COVID-19 pandemic - particularly in the U.S. - and the associated sales recovery fail to materialize or are even less pronounced, the financing requirements would increase and would have to be implemented sooner, even taking into account the expected lower cost burden. However, if coverage of this further financing requirement is not possible in a timely manner, this would result in a threat to the going concern status of the Biofrontera Group.

Long-term, structural growth drivers - including the improvement of the reimbursement situation in the USA, the expansion of the indications for Ameluz<sup> $^{\circ}</sup>$  and in Europe the increasing acceptance of daylight PDT - remain intact.</sup>

#### Litigation

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<sup>®</sup> 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<sup>®</sup> and Ameluz<sup>®</sup> in the United States. A preliminary injunction requested by DUSA to stop Biofrontera's business operations was not granted by the court at an early stage of the trial.

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

We believe the court likely will next set a hearing date and issue a decision on the motions, and will then set a schedule for the case to proceed to trial if necessary. Although as of the date of this annual report, no dates have been assigned, we expect the case to proceed through 2020 or 2021. We believe that these claims lack merit and intend to defend against them vigorously; however, we cannot guarantee that we will be successful. As mentioned above, the court largely denied a motion by DUSA for a preliminary injunction, but did order Biofrontera not to use any documents, or documents derived from documents, that originated at DUSA.

The defense of Biofrontera's legal interests may incur considerable costs, since, in addition to internal resources, lawyers in the USA have been mandated to defend the case. The costs arising from this for Biofrontera would not be reimbursed by the plaintiff due to the customs of the US legal system, even in the event of a positive outcome of the proceedings in for Biofrontera.

In 2018, Biofrontera Inc. sued DUSA in California state court alleging that DUSA engaged in unfair competition by providing excessive product samples to physicians and by using its distributor to inflate product prices. After filing suit, DUSA stopped using Foundation Care as its distributor to dispense its drug products, which was in substantial part Biofrontera Inc.'s goal in filing this lawsuit. Doctors are no longer preferred in reimbursement by prescribing DUSA's product. The court also ruled early in the case that Biofrontera Inc. adequately alleged claims against DUSA based on DUSA engaging in tortious interference by making statements to third parties regarding the off-label use of its products, and allowed those 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.

On June 11, 2018, Biofrontera 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's shares that were designed to defame Biofrontera 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 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'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's common law claims. On June 10, 2020, at the parties' request, the court entered an order staying the litigation until November 10, 2020, to allow the parties to conduct a mediation of the dispute. Deutsche Balaton AG, Wilhelm Konrad Thomas Zours and Delphi Unternehmensberatung AG are among our shareholders.

In June 2017, the company was served with a claim for rescission and nullification by the shareholder Deutsche Balaton AG, in which it sued for nullification of certain resolutions of the Annual General Meeting held on May 24, 2017. The lawsuit was dismissed by Cologne Regional Court in December 2017. On appeal by Deutsche Balaton AG, the Cologne Higher Regional Court granted the action in November 2018. The Cologne Higher Regional Court did not allow a review of the judgment by the Federal Supreme Court in its ruling. Since the company considers the judgment of the Cologne Higher Regional Court to be incorrect, it filed an appeal against the decision with the Federal Supreme Court, which was granted in May 2020. The Federal Supreme Court has set September 22, 2020 as the date of publication. With regard to agenda item 6 (creation of authorized capital), an application for release was filed with the Cologne Higher Regional Court in 2020. The Higher Regional Court of Cologne dismissed the application for release on July 9, 2020.

Deutsche Balaton AG has further brought a claim for rescission and nullity 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 10, 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). 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 action 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<sup>®</sup>), 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 authorized capital in the amount of EUR 4,000,000 with the option to exclude shareholders' subscription rights), creation of new authorized 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 Shareholders' Meeting. The lawsuit is currently pending at Cologne Regional Court under file number 82 O 75/19.

An action for rescission and nullification 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.

Biofrontera AG has applied for and received various 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 publishes a blog with false and defamatory allegations about Biofrontera AG and its management. Automattic Inc. has appealed some of the injunctions obtained. The Hamburg Regional Court will now decide on these objections Automattic Inc. in oral hearings.

A shareholder has claimed against Biofrontera AG that on the occasion of the capital increase conducted in April 2016, fewer shares were allocated to him than in his opinion should have been allocated. The shareholder is claiming alleged damages of EUR 48,500. The claim has so far only been asserted out of court. A claim to the competent court has not yet been filed. Biofrontera AG considers the demand to be without merit.

# F.2.2) Condensed interim consolidated financial statements as of June 30, 2020

## Consolidated balance sheet as of June 30, 2020

Assets		
in EUR thousands	June 30, 2020	December 31, 2019
Non-current assets		
Tangible assets	5,559	5,230
Intangible assets	20,065	22,848
Deferred taxes	7,475	7,794
Total non-current assets	33,099	35,872
Current assets		
Current financial assets		
Trade receivables	2,191	5,031
Other financial assets	773	1,077
Cash and cash equivalents	10,550	11,119
Total current financial assets	13,514	17,227
Other current assets		
Inventories	4,384	4,065
Income tax reimbursement claims	5	4
Other assets	961	1,195
Total other current assets	5,350	5,264
Total current assets	18,864	22,491
Total assets	51,963	58,363

#### Equity and liabilities

in EUR thousands	June 30, 2020	December 31, 2019
Equity		
Subscribed capital	44,849	44,849
Capital reserve	118,291	118,103
Capital reserve from foreign currency conversion	(123)	(288)
Loss carried forward	(152,709)	(145,351)
Loss for the period	(5,571)	(7,358)
Total equity	4,737	9,955
Non-current liabilities		
Financial debt	22,305	22,110
Other provisions	16,956	14,720
Total non-current liabilities	39,261	36,830
Current liabilities		
Current financial liabilities		
Trade payables	2,240	4,196
Current financial debt	1,291	1,212
Other financial liabilities	74	99
Total current financial liabilities	3,605	5,507
Other current liabilities		
Income tax	26	11
Other provisions	2,862	3,495
Other current liabilities	1,472	2,565
Total other current liabilities	4,360	6,071
Total current liabilities	7,965	11,578
Total equity and liabilities	51,963	58,363

## F.2.3) Consolidated statement of comprehensive income for the first six months of the fiscal years 2020 and 2019

in EUR thousands	6M 2020	6M 2019
Sales revenue	16,116	13,904
Cost of sales	(1,491)	(2,483)
Gross profit from sales	14,625	11,421
Operating expenses		
Research and development costs	(2,389)	(2,322)
General administrative costs	(4,412)	(7,768)
Sales costs	(12,151)	(14,195)
Loss from operations	(4,327)	(12,864)
Interest expenses	(439)	(1,057)
Effective interest expenses	(807)	(497)
Interest income	531	209
Other expenses	(301)	(188)
Other income	110	6,101
Other income from the PPA (Badwill)	-	17,323
Loss before income tax	(5,233)	9,027
Income tax	(338)	(26)
Loss for the period	(5,571)	9,001
Expenses and income not included in profit/loss		
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	165	(444)
Other income total	165	(444)
Total loss for the period	(5,406)	8,557
Basic earnings per share in EUR	(0.12)	0.20
Diluted earnings per share in EUR	(0.12)	0.20

Both the result after income taxes and the total result are fully attributable to the shareholders of Biofrontera AG.

	Number of ordinary shares	Subscribed capital	Capital reserve	Capital from foreign currency conversion adjustments (OCI)	Accumulated loss	Total
		EUR thousands	EUR thousands	EUR thousands	EUR thousands	EUR thousands
Balance as of Januuary 1, 2019	44,632,674	44,632	117,109	(2)	(145,383)	16,356
Loss for the period	-	-	-	-	9,001	9,001
Foreign currency conversion	-	-	-	(444)	-	(444)
Consolidated result	-	-	-	(444)	9,001	8,557
First-time application of IFRS 16	-	-	-	-	33	33
Conversion of stock options from the stock option	5,500	6	11	-	-	17
Increase in capital reserve from the stock option	-	-	166	-	-	166
Balance as of June 30, 2019	44,638,174	44,638	117,286	(446)	(136,349)	25,129
Loss for the period	-	-	-	-	(16,360)	(16,360)
Foreign currency conversion	-	-	-	158	-	158
Consolidated result	-	-	-	158	(16,360)	(16,202)
Conversion from convertible bond 2017/2022	118,841	119	429	-	-	548
Conversion of stock options from the stock option	92,350	92	196	-	-	288
Costs of equity procurement	-	-	(2)	-	-	(2)
Increase in capital reserve from the stock option	-	-	194	-	-	194
Balance as of December 31, 2019	44,849,365	44,849	118,103	(288)	(152,709)	9,955
Balance as of January 1, 2020	44,849,365	44,849	118,103	(288)	(152,709)	9,955
Loss for the period	-	-	-	-	(5,571)	(5,571)
Foreign currency conversion	-	-	-	165	-	165
Consolidated result	-	-	-	165	(5,571)	(5,406)
Increase in capital reserve from the stock option	-	-	188	-	-	188
Balance as of June 30, 2020	44,849,365	44,849	118,291	(123)	(158,280)	4,737

## F.2.4) Consolidated statement of changes in equity for the first six months of the fiscal year 2020 and fiscal year 2019

## F.2.5) Consolidated cash flow statements for the first six months of the fiscal years 2020 and 2019

in EUR thousands	6M 2020	6M 2019
Cash flows from operations		
Loss before income tax	(5,233)	9,027
Adjustments to reconcile loss before income tax to cash flow into		
Income tax	(19)	(26)
Financial result	731	1,377
Depreciation	3,822	1,121
Non-current provisions and liabilities	-	(503)
Losses from disposal of assets	(13)	-
Non-cash (income) and expenses	(117)	(18,028)
Changes in operating assets and liabilities		
Trade receivables	2,840	979
Other assets and income tax assets	537	(3,036)
Inventories	(319)	(560)
Trade payables	(1,956)	195
Provisions	(416)	(159)
Other liabilities	(1,103)	(12,260)
Net cash flow used in operational activities	(1,246)	(21,873)
Cash flows from investment activities		
Purchase of intangible and tangible assets	(527)	(513)
Business combinations (including cash and cash equivalents)	2,264	20,231
Proceeds from sale of intangible and tangible assets	27	-
Net cash flow from investment activities	1,764	19,718
Cash flows from financing activities		
Proceeds from draw down of EIB loan	-	5,000
Proceeds from exercise of employee stock options	-	17
Leasing payments	(744)	(392)
Interest paid	(335)	(347)
Net cash flows from (used in) financing activities	(1,079)	4,278
Net increase/(decrease) in cash and cash equivalents	(561)	2,123
Changes from exchange rate differences	(8)	5
Cash and cash equivalents at the beginning of the period	11,119	19,451
Cash and cash equivalents at the end of the period	10,550	21,579

# F.2.6) Select explanatory notes to the interim consolidated financial statements as of June 30, 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 interim financial statements

In accordance with the provisions of section 115 of the Wertpapierhandelsgesetz (WpHG - German Securities Trading Act) in conjunction with section 117 of the WpHG, the half-year financial report as of June 30, 2020 comprises condensed interim consolidated financial statements, an interim Group management report and a responsibility statement by the legal representatives in accordance with the provisions of section 264 (2) sentence 3 and section 289 (1) sentence 5 of the German Commercial Code (HGB).

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

The condensed consolidated interim financial statements of Biofrontera AG as of June 30, 2020 were prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) and the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) for "Interim Financial Reporting" according to IAS 34, as they are to be applied in the European Union. Accordingly, they do not contain all the information and disclosures required for consolidated financial statements and should therefore be read in conjunction with the consolidated financial statements for the year ended December 31, 2019.

On August 26, 2020, the Management Board approved the half-year financial report of Biofrontera AG for publication.

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

The interim report as of June 30, 2020 does not contain separate segment reporting, as the activities of the Biofrontera Group are limited to one business segment as defined by IFRS 8. The entire operating activity is focused on the sale of dermatological products, in particular Ameluz<sup>®</sup> including the complementary products BF-RhodoLED<sup>®</sup> (PDT-lamp) and Belixos<sup>®</sup> as well as Xepi<sup>™</sup>, and is therefore uniformly monitored and controlled internally.

## Changes in accounting standards

For the preparation of the condensed consolidated interim financial statements, the same accounting policies have been applied as for the consolidated financial statements as of December 31, 2019. The new IFRS rules to be applied for the first time as of January 1, 2020 have no material effect on the interim consolidated financial statements.

The preparation of the interim consolidated financial statements requires the Management Board to make estimates and assumptions that affect the application of accounting policies in the Group and the presentation of assets and liabilities, income and expenses. The actual amounts may differ from these estimates.

Changes to previous estimates due to the impact of the COVID-19 pandemic have occurred with respect to the valuation of the Xepi<sup>™</sup> license, the purchase price payment from the Maruho earn-out agreement and the EIB loan.

The expected proceeds from the sale of Xepi<sup>™</sup> and the related 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 the resulting delays in the market penetration of Xepi<sup>™</sup>. This resulted in an impairment of the Xepi<sup>™</sup> license and a reduction of the nominal amount of the expected purchase price payment. As a result of the significant decline in market capitalization in the first half of 2019, there was a reduction in the performance component of the EIB loan in the first half of 2020 which was recognized in income.

#### Basis of consolidation

The financial statements as of June 30, 2020 include the financial statements of the parent company, Biofrontera AG, and the subsidiaries in which the parent company holds a direct majority of the voting rights. The companies listed below were included in the consolidated financial statements:

- 9. Biofrontera Bioscience GmbH, Leverkusen, Germany, with a direct interest of 100%
- 10. Biofrontera Pharma GmbH, Leverkusen, Germany, with a direct interest of 100%
- 11. Biofrontera Development GmbH, Leverkusen, Germany, with a direct interest of 100%
- 12. Biofrontera Neuroscience GmbH, Leverkusen, Germany, with a direct interest of 100%
- 13. Biofrontera Inc., Woburn, Massachusetts, U.S., with a direct interest of 100%.

The basis for the consolidation of the companies included in the consolidated financial statements were the interim financial statements of these companies as of June 30, 2020, prepared in accordance with uniform principles (or "Handelsbilanz II" according to IFRS). The financial statements as of June 30, 2020 were prepared on the basis of uniform accounting and valuation principles (IFRS).

The subsidiaries are fully consolidated from the date of acquisition. The date of acquisition is the date on which the parent company gained control of these subsidiaries. Subsidiaries are included in the consolidated financial statements until such time as the parent company no longer controls these companies.

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

#### Significant events in the first six months of 2020

The performance of Biofrontera AG in the first half of 2020 was mixed. At the beginning of the year, we were initially able to record a good sales development as well as positive regulatory and clinical developments. We

also successfully restructured the global sales and marketing structure. Since mid-March we have had to accept declining sales figures, particularly in the USA, due to the dynamic development of the COVID-19 pandemic. This forced us to implement company-wide cost reduction measures.

The Biofrontera Group achieved total sales of EUR 16.1 million for the period from January 1 to June 30, 2020, which represents an increase of 16% compared to sales of EUR 13.9 million in the same period of the previous year. Total revenues include a one-time payment of EUR 6.0 million, which the company received from Maruho Co., Ltd. under the license agreement signed on April 20, 2020. The Group generated revenues from product sales of EUR 9.7 million, a decrease of 30% compared to the first six months of 2019. Overall, revenues in the first half of 2020 and particularly in the second quarter were strongly affected by the effects of the global coronavirus crisis. However, a recovery in sales is expected for the second half of the year.

As already explained, the coronavirus crisis has led to a decreasing number of treatments and thus to a sharp drop in sales in our most important market, the USA. On March 20, 2020, the Company announced that it would take comprehensive measures to reduce and control costs during the COVID-19 pandemic.

Consequently, Biofrontera had introduced short-time work for all employees in Germany until the end of July 2020. Similar measures were implemented for the subsidiaries in Spain and the UK. Biofrontera Inc, the wholly owned subsidiary in the USA, has also initiated significant cost reduction measures. There, the number of employees was significantly reduced and a furlough program was implemented, under which all employees were obliged to take temporary unpaid leave. In addition, the members of the Management Board of Biofrontera AG and the management of Biofrontera Inc. voluntarily decided to forgo a substantial portion of their salaries.

While these cost reduction measures were in effect, the Company was able to ensure full compliance with all regulatory requirements in both medical and financial respects, and to meet all disclosure requirements at all times.

The continued uncertain business outlook due to the COVID-19 crisis has had an impact on the valuation of certain assets and liabilities of the Company. Reduced sales of Xepi<sup>™</sup> have resulted in a different assessment of the medium-term business and profit outlook for Xepi<sup>™</sup> and, consequently, in a re-evaluation of both the balance sheet value of the Xepi<sup>™</sup>-license and the purchase price liability to Maruho in the first quarter of 2020.

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

#### Sales revenue

	Janu	ary 1 – June, 30 2020		Janua	ary 1 – June, 30 2019	
Sales revenue (in EUR	Product revenue	Development revenues	Other	Product revenue	Development revenues	Other
Germany	2,364	-	-	2,154	-	-
Europe	965	-	-	1,357	-	-
U.S.	6,347	-	-	10,231	-	-
Other regions	-	441	6,000	-	162	-
Total	9,676	441	6,000	13,742	162	-

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

In the first six months of 2020, we generated EUR 31 thousand of income from operating leases (previous year period: EUR 41 thousand). We generated income of EUR 75 thousand from finance leases (previous year period: EUR 19 thousand).

#### Personnel costs

in EUR thousands	June 30, 2020	June 30, 2019
Wages and salaries	6,529	10,641
Social security charges	1,148	1,593
Costs for pension schemes	161	253
Total	7,838	12,487

In the reporting period, Biofrontera Group received subsidies for short-time work in the amount of EUR 599 thousand.

#### Intangible assets

The value of the balance sheet recognition for the Xepi<sup>™</sup> license was reviewed as of March 31, 2020 by means of an impairment test, which also takes the current market situation influenced by the COVID-19 pandemic and the resulting delays in the market penetration of Xepi<sup>™</sup> into account. As a result, this led to a non-cash impairment of EUR 2,001 thousand, which is reported in sales costs.

In determining the utility value as of March 31, 2020, the expected cash flows within the remaining term of the license agreement of 10 years and 7 months were discounted. The cash flows were discounted on the basis of a market interest rate of 9% (previous year 9%).

## Trade receivables

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

Value adjustments for doubtful accounts were made in the amount of EUR 53 thousand (previous year: EUR 43 thousand). As in the previous year, there were no overdue, non-adjusted receivables in significant amounts on the reporting date.

Of the receivables, EUR 160 thousand (previous year: EUR 153 thousand) relate to finance leases for PDT-lamps.

#### Inventories

in EUR thousands	June 30, 2020	December 31, 2019
Inventories		
Raw materials	1,021	893
Unfinished goods	362	201
Finished goods and products	3,001	2,971
Total	4,384	4,065

During the reporting period, impairment losses on inventories were recognized in the amount of EUR 5 thousand (previous year: EUR 24 thousand).

#### Deferred taxes

As of June 30, 2020, the company reported deferred taxes on losses carried forward in the amount of EUR 7,475 thousand (previous year: EUR 7,794 thousand). These are capitalized to the extent that they are likely to be offset against future tax profits. This is based on a planning period of five years. These relate to the deferred tax assets to be recognized on loss carry-forwards for Biofrontera Pharma GmbH, which were reduced in the first half of the year due to the utilization of the positive tax result. For the entire year 2020 and also in the future, it can still be assumed that Biofrontera Pharma GmbH will generate positive results and thus use its tax loss carryforwards.

#### **Financial liabilities**

in EUR thousands	June 30, 2020	December 31, 2019
Non-current financial liabilities		
Convertible bond 2017/2022	1,989	1,977
EIB loan 2017 tranche	11,869	11,845
EIB loan 2019 tranche	5,355	5,301
Leasing liabilities	3,092	2,987
Total non-current financial liabilities	22,305	22,110
Total current liabilities	1,291	1,212

## Other financial liabilities

in EUR thousands	June 30, 2020	December 31, 2019
Purchase price liability (earn-out and start-up costs)	16,956	14,720
Current financial liabilities	74	99

## Reporting on financial instruments

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

#### **Financial assets**

in EUR thousands	Fair Value as of June 30, 2020	Carrying amount as of June 30, 2020	Fair Value as of Dec. 31, 2019	Carrying amount as of Dec. 31, 2019
Financial assets at amortized cost				
Cash and cash equivalents	10,550	10,550	11,119	11,119
Trade receivables	2,191	2,191	5,031	5,031
Other financial assets	773	773	1,077	1,077
Total	13,514	13,514	17,227	17,227

#### **Financial liabilities**

in EUR thousands	Fair Value as of June 30, 2020	Carrying amount as of June 30, 2020	Fair Value as of Dec. 31, 2019	Carrying amount as of Dec. 31, 2019
Financial liabilities at amortized cost				
Current financial liabilities	1,291	1,291	1,212	1,212
Trade payables	2,240	2,240	4,196	4,196
Other current financial liabilities	74	74	99	99
Non-current financial liabilities	21,359	21,359	20,648	20,648
Total	24,964	24,964	26,155	26,155
Financial liabilities at fair value recognized in profit				
Non-current financial liabilities	946	946	1,462	1,462
Other non-current financial liabilities	16,956	16,956	14,720	14,720
Total	17,902	17,902	16,182	16,182

The financial assets are still allocated to "financial assets at amortized cost". The carrying amounts correspond to the fair values.

The performance component (financial instrument at level 3 of the fair value hierarchy) as a further variable interest component and embedded derivative requiring separation is subsequently measured at fair value on each balance sheet date and is allocated to the category "financial liabilities at fair value recognized in profit or loss". To simplify matters, the market capitalization at the end of the term is initially determined on the basis of the market capitalization on the respective valuation date, which is based on the 90 trade days preceding the measurement cut-off date. The performance-based interest payment for the first tranche is calculated based on a notional 0.64% (EIB 2017 tranche) or 0.20% (EIB 2019 tranche) participation rate in the market capitalization (Notional Equity Proportion). This is discounted to the measurement cut-off date applying a market interest rate.

As of June 30, 2020, the discounted interest payment (carrying amount) or fair value of the performance component of the 2017 tranche of the EIB loan was EUR 744 thousand (previous year: EUR 1,148 thousand)

and of the 2019 tranche of the EIB loan EUR 202 thousand (previous year: EUR 314 thousand). The net profits on the performance component amounted to EUR 516 thousand (previous year period: loss of EUR 252 thousand).

The purchase price liability of EUR 16,956 thousand (previous year: EUR 14,720 thousand) reported under noncurrent financial liabilities was discounted at a market interest rate of 9% based on the expected annual purchase price payments. The expected annual purchase price payments were re-estimated as of March 31, 2020 due to the current market situation influenced by the COVID-19 pandemic and the resulting delays in the market penetration of Xepi<sup>™</sup>. Accordingly, the purchase price payments will be due from 2022 to 2030 depending on future profits generated from the sale of Xepi<sup>™</sup>. The total purchase price in this period, excluding repayment of start-up costs, amounts to a nominal USD 26.8 million / EUR 23.3 million (previous year: USD 28.9 million / EUR 25.8 million). The start-up costs received to date in the amount of USD 5.4 million / EUR 4.8 million (previous year: USD 2.9 million / EUR 2.5 million) are repayable by 2022.

The net losses on the purchase price liability amounted to EUR 16 thousand (previous year: EUR 162 thousand) and are lower due to the re-evaluation, in particular the adjusted estimate of the purchase price liability.

The fair values of the performance component of the EIB loan would be EUR 95 thousand higher or lower in the event of a 10% increase or decrease respectively in market capitalization. The fair value of the purchase price liability would be EUR 655 thousand higher or lower in the event of an 5% increase or decrease in cash flows respectively and EUR 914 thousand lower or EUR 851 thousand higher in the event of 1% an increase or decrease respectively in the weighted average cost of capital.

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

#### Provisions

The companies included in the consolidated financial statements of Biofrontera AG face several threatened or pending legal proceedings, the outcome of which is either not determinable or cannot be predicted due to the uncertainty associated with such legal proceedings. No provisions were made for the claims asserted against Biofrontera, as the Management Board does not believe that such claims are enforceable.

For pending proceedings in the USA and Germany, provisions for legal costs totalling EUR 2,051 thousand (previous year: EUR 2,183 thousand) exist. EUR 471 thousand were utilized in the first half of 2020. Based on a current estimate of the outstanding litigation costs, no further amounts were accrued.

Biofrontera assumes that the lawsuits are unjustified and will defend itself vigorously against the claims, but cannot guarantee that this will be successful.

Biofrontera may incur further significant costs in the future from the defense of its case, as in addition to internal resources, lawyers in the USA have been mandated to defend the case. The costs arising from this for Biofrontera would not be reimbursed by the plaintiff even in the event of a positive outcome of the proceedings, due to the practices of the US legal system.

#### Related party disclosures

#### Maruho Co., Ltd.

As a result of the research cooperation, licensing agreement and the acquisition of Cutanea, the following relationships exist with the Maruho Group:

in EUR thousands	June 30, 2020	December 31, 2019
Revenue from research collaborations and licensing agreement	6,441	686
Income from the reimbursement of restructuring expenses	-	6,215
Rental income	20	34
Receivables from research cooperation	48	149
Receivables from the Share Purchase Agreement (earn out and start-up costs)	16,956	14,720
Other liabilities	-	72

Under the purchase agreement with Maruho, the company can still draw down funds from start-up costs of a nominal USD 1.9 million / EUR 1.7 million (previous year USD 4.4 million / EUR 3.9 million).

#### Subsequent events

#### Renewal of Management Board appointment

On July 23, 2020, the Supervisory Board of Biofrontera AG announced that the appointments as well as the service contracts of both Management Board members were each extended for another 2 years until December 31, 2022.

#### Mandatory convertible bond 2020/2021

On July 27, 2020, the Management Board resolved, with the approval of the Supervisory Board, to issue up to 2,638,150 bonds of a 1.0%-qualified subordinated mandatory convertible bond 2020/2021 with a nominal value of EUR 3.00 each and a total nominal value of up to EUR 7,914,450 to cover short-term liquidity requirements.

On August 18, 2020, the company announced that the mandatory convertible bond 2020/2021 had been placed in full. The gross proceeds from the issue amount to EUR 7,914 thousands.

Leverkusen, August 26, 2020

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Prof. Dr. Hermann Lübbert Chief Financial Officer

Thomas Schaffer Chief Financial Officer

## F.2.7) Review report

#### To Biofrontera AG, Leverkusen

We have reviewed the condensed interim consolidated financial statements – comprising the condensed statement of financial position, the condensed statement of profit or loss and other comprehensive income for the period, the condensed statement of changes in equity, the condensed statement of cash flows and selected explanatory notes – and the interim group management report of Biofrontera AG, Leverkusen, for the period from 1 January 2020 to 30 June 2020 which form part of the half-year financial reporting in accordance with section 115 German Securities Trading Act (Wertpapierhandelsgesetz – WpHG). The preparation of the condensed interim consolidated financial statements in accordance with those IFRS applicable to interim financial reporting as adopted by the EU, and of the interim group management report in accordance with the requirements of the German Securities Trading Act applicable to interim group management reports, is the responsibility of the Company's management. Our responsibility is to issue a report on the condensed interim consolidated financial statements and on the interim group management report based on our review.

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

Based on our review no matters have come to our attention that cause us to believe that the condensed interim consolidated financial statements of Biofrontera AG, Leverkusen, for the period from 1 January 2020 to 30 June 2020 have not been prepared, in material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU, or that the interim group management report has not been prepared, in material resplations of the German Securities Trading Act applicable to interim group management reports."

Without qualifying this opinion, we refer to the statements in the section "Risk and Opportunities Report" of the interim Group management report and in the section "Basis of Preparation of the Interim Consolidated Financial Statements" in the selected explanatory notes to the interim consolidated financial statements as of June 30, 2020. There it is stated that if the improvement of the COVID-19 pandemic - particularly in the USA - and the associated sales recovery fail to materialize or are even less pronounced, the financing requirement would increase and would have to be implemented sooner, even taking into account the expected lower cost burden. Should it not be possible to cover this further financing requirement in a timely manner, this would result in a threat to the going concern status of the Biofrontera Group.

Düsseldorf, August 26, 2020 Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft Eckhard Lewe German Public Auditor

Michael Gottschalk German Public Auditor

## **Responsibility statement**

## Affirmation of the legal representatives

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

Leverkusen, August 26, 2020 Biofrontera AG

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Prof. Dr. Hermann Lübbert Chief Executive Officer

Thomas Schaffer Chief Financial Officer