

# Biofrontera – Creating Added Value.

Annual Report 2018



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Biofrontera AG Annual Report 2018

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# Key figures and highlights 2018

Biofrontera AG is an international biopharmaceutical company specializing in the development and commercialization of dermatological medications and medical cosmetics.

The Leverkusen-based company with around 150 employees worldwide develops and markets innovative products for healing, protecting and caring for the skin. One of its most important products is Ameluz®, a prescription-only medication for the treatment of non-melanoma skin cancer and its precursors. Ameluz® has been marketed in the EU since 2012 and in the United States since May 2016.

In addition, the company distributes the dermocosmetic series Belixos®, a modern active cosmetic product specially developed for sensitive and irritated skin. Biofrontera is the first German founder-managed pharmaceutical company to receive centralized European and US approval for a medication it has developed itself. The Biofrontera Group was founded in 1997 by today's CEO Prof. Hermann Lübbert. Biofrontera AG is listed on the Frankfurt Stock Exchange (Prime Standard) and on the US NASDAQ Capital Market.

	Results and development 2018	Forecast 2019
Sales revenue	<b>EUR 21.1 million</b>	EUR <b>35 to 40 million</b>
	compared to EUR 12.0 million in 2017	
Results from operations	<b>EUR -18.5 million</b>	EUR <b>-7 to -9 million</b>
	compared to EUR -13.9 million in 2017	
Result before income tax	<b>EUR -19.3 million</b>	EUR <b>-9 to -11 million</b>
	compared to EUR -16.1 million in 2017	

Listing on the US-stock exchange **NASDAQ** in February 2018 in connection with a **capital increase**

**Approval** of Ameluz® in combination with **daylight PDT** by the European Commission in March 2018

Patient recruitment for a **phase III trial** for Ameluz® for the treatment of superficial **basal cell carcinoma** in the **U.S.** in September 2018

Conduct of a **phase III trial** for Ameluz® for the treatment of actinic keratoses on the **extremities** and trunk/neck (successful completion in early 2019)

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# Sustainable corporate strategy

Sustainability forms an integral part of Biofrontera's business activities – after all, improving patients' health is at the heart of our business model. Only by consistently implementing a long-term and clearly defined Group strategy, we can live up to this claim.

In 2018, we successfully reached further milestones of our corporate strategy and thus created further stakeholder value.

We added value for patients by making our drug available for further application in the form of daylight PDT. With our strategy we have also come a step closer to our goal of making photodynamic therapy with Ameluz® accessible to all patients with field cancerization and actinic keratoses. As daylight PDT in Germany is reimbursed by public health insurance, even more people have been able to enjoy access to this highly effective treatment option since 2018.

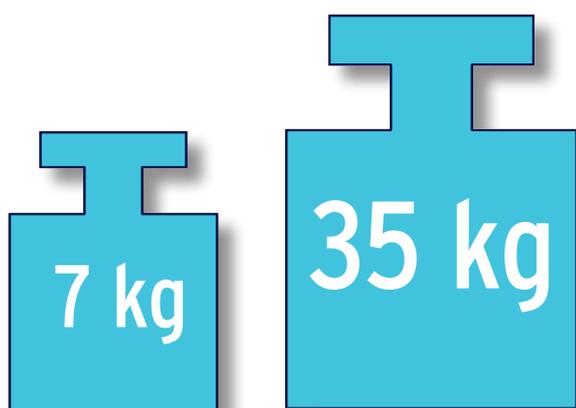
We have also created added value for our customers – dermatologists – by ensuring the long-term security of supply and quality of our drug. We changed our manufacturer of the active ingredient and increased our production batches from 7 kg to 35 kg in 2018. Both projects are subject to high regulatory requirements by the EMA and FDA, on which we worked intensively for two years. The scaling of the manufacturing process also leads to an improvement of our gross margin.

And, of course, we created added value for our investors by boosting our commercial and financial potential through our own sales structures and efficiency enhancement measures. In 2018, we further expanded our sales activities in the USA. The strategic decision to market Ameluz® with our own sales force in our largest market enables us to respond quickly and efficiently to market conditions and thereby achieve the greatest possible market penetration.



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## 2018 production batch upscaling



## CORPORATE FINANCE: NASDAQ LISTING

At the beginning of the year, we improved our financial position through a capital increase in conjunction with our listing on NASDAQ and gained access to the world's largest and most important capital market. However, the move to NASDAQ was above all a major strategic step for us: the listing enhances our visibility with our customers – US dermatologists – strengthens our credibility and thereby supports our sales and marketing activities. In addition, all our shareholders benefit from the increased transparency that goes hand in hand with stringent SEC disclosure requirements. In the course of the Nasdaq listing, the share price recorded a rapid increase from EUR 4.29 on 10 January 2018 (Xetra closing price on the day prior to publication of the intention to list) to EUR 6.25 on 19 February 2018 (Xetra closing price on the day the new shares were entered in the company register). Despite a share price correction experienced during the course of the year, our share price is stable at a level well above its pre-listing price.

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## Development of the market capitalization of Biofrontera AG



# Responsibility

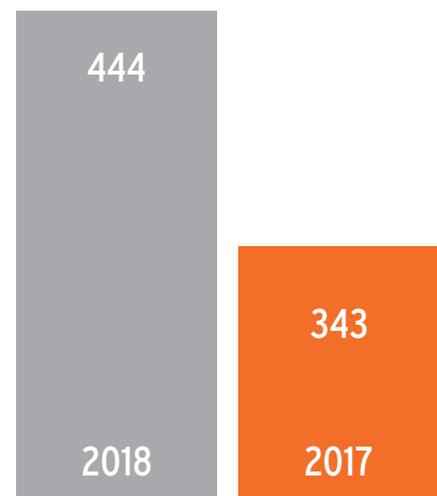
Doctors and patients should be able to trust Ameluz®, which is why drug safety and quality management are our top priorities. As a medium-sized company, we have to meet the same high quality standards as a pharmaceutical giant.

Employee qualification is one of the pillars of a functioning quality management system. New employees at Biofrontera are familiarized with Standard Operating Procedures (SOPs) as part of an extensive onboarding process. They receive training for our quality management system, which is based on the principles of good manufacturing practice (GMP), good clinical practice (GCP) and good distribution practice (GDP).

The SOPs describe in detail the manufacturing and handling procedures for our drug, as well as all quality-relevant processes within the company, which are subject to strict ethical and regulatory standards. Our Quality Assurance Department uses an annual inspection plan to monitor all processes in our own departments, as well as at our contract manufacturers and contract research institutes, in both internal and external audits, and provides the necessary evidence for the respective authorities. Our documentation systems help us identify deviations immediately and respond to them in a controlled manner.



**Ongoing improvement of the quality management processes**  
**SOPs: valid prescribed and controlled workflows**





## Quality management 2018 / 2017



## REGULATORY REQUIREMENTS: FALSIFIED MEDICINES DIRECTIVE

The Falsified Medicines Directive came into force in Europe on 9 February 2019. Since then, solely prescription medicinal products that fulfil certain safety requirements may be distributed in the market. As a prescription drug now has to undergo an authenticity check before being administered to the patient, each drug package requires its own serial number. Something that sounds as straightforward as this is actually a very complex process. In order to ensure that each serial number is assigned only once, a constant exchange of data with the contract manufacturer and suitable software for randomizing the serial numbers is required. The serial numbers must be transferred to the national serialization databases to which pharmacies and wholesalers are also connected. On delivery, the pharmacist scans the package and receives feedback from the system as to whether it is an original or falsified product.

The implementation of the directive proved to be a great challenge for us. As the rules apply equally to all prescription drugs, this means even more effort for a small company like us than for large pharmaceutical companies. As early as 2017, we started the implementation with a team of several departments, including IT, Quality Management and Logistics, in order to meet all the requirements of the new directive.

While we have largely established the system in Europe, we still have a lot of implementation work to do in the US. There, the DSCSA Act will further tighten the regulatory requirements for medicine safety by 2021.

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# Appreciation

Our highly qualified and dedicated employees are a key factor for our success. We offer them a supportive environment where they can work with confidence and develop their skills.

Our employees' satisfaction plays a crucial role in our success of retaining them long-term. For this reason, we offer our staff a wide range of opportunities for professional and personal development. In addition to internal and external training measures within the various departments, and interdisciplinary topics such as regulatory affairs and data protection, our employees regularly attend conferences and seminars. In the 2018 financial year, our employees attended 13 professional development events of the German Medicines Manufacturers' Association (BAH) where they were trained on topics such as drug safety, the German Pharmaceutical Advertising Act and changes in regulatory requirements.

We attach great importance to the compatibility of professional development and personal life planning as well as the promotion of equal opportunities within our company. For several years now, we have been offering our employees a trust-based working time model and, since 2019, a company-wide Mobile Office Policy that enables employees to work flexibly. Part-time and home office models enable smooth reintegration after parental leave and make work and family life more compatible.



## EMPLOYEE DEVELOPMENT: SALES, REGULATORY AND CUSTOMER SERVICE STRUCTURE

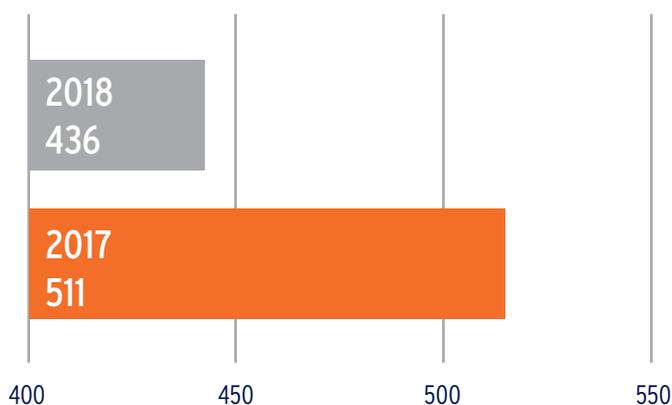
In 2018, the number of our employees grew significantly from 123 to 157, an increase of 28%. The size of our workforce now reflects the resources we need for the future challenges of our growing company. First and foremost, we have strengthened our sales, regulatory and customer service departments. In May, we established a sales team in the UK and now sell Ameluz® through our own sales force in four countries – following Germany, Spain and the USA.

In the regulatory area, we face new regulatory requirements with each indication expansion. As the approval holder, we are obliged to meet the relevant requirements in every country in which Ameluz® is marketed. Those requirements range from notifying the authorities about a change of address to making officially prescribed changes on the packaging or in the product information, to indication extensions such as basal cell carcinoma or daylight-PDT. Our Regulatory Affairs team is responsible for coordinating all these processes with regulators.

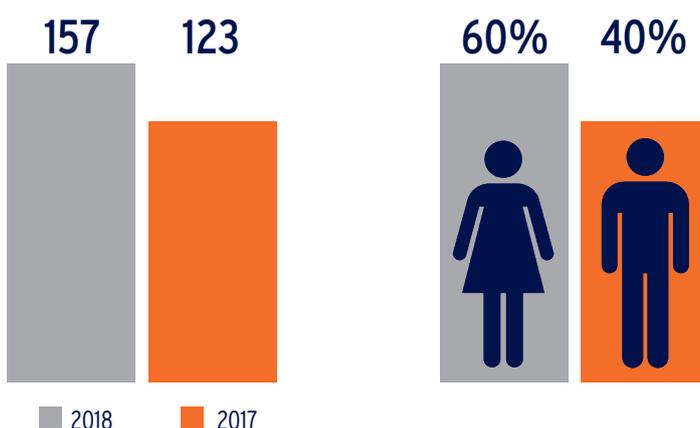
In the USA, we have invested in establishing structures to support doctors in billing their services. Customer orientation and a high understanding of the needs of dermatologists are crucial for their satisfaction and contribute significantly to the success of Ameluz® in the USA. The good work of our account managers in 2018 was honored with the prestigious silver Stevie® Award for outstanding customer service in early 2019.



### Expenses for training and education in EUR per employee



### Employees



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# Future

We have accomplished a lot in the past. We are proud of having achieved most of our goals, some of which were very ambitious. However, we are looking to the future, as we aim to fully leverage the great potential that lies in our drug Ameluz® and in our nanoemulsion.

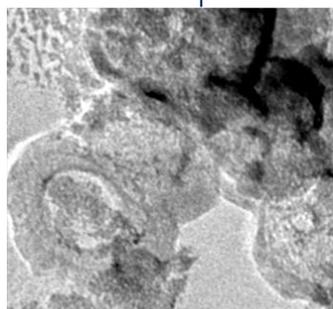
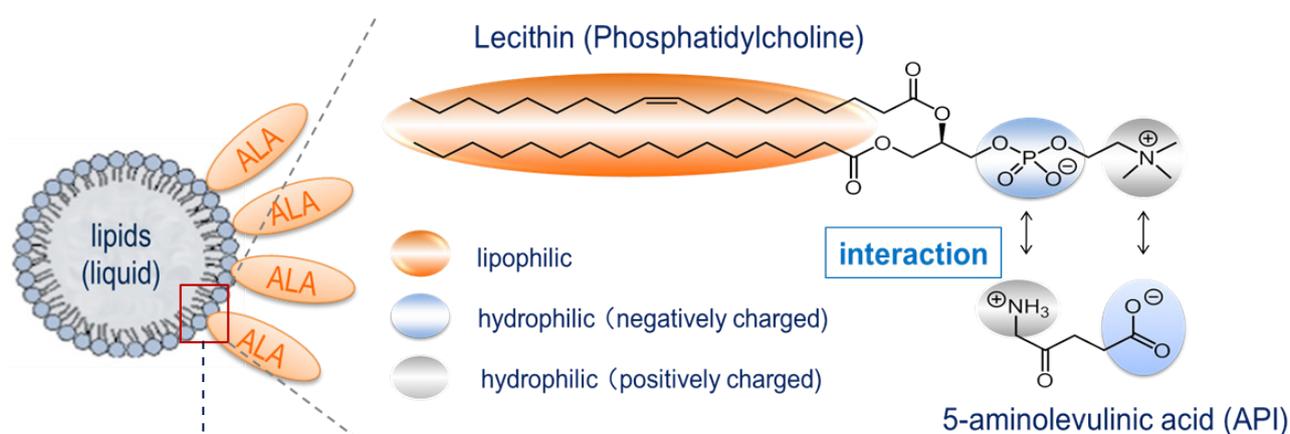
In recent years, we have gradually optimized strategic market positioning of our product. The continuous development and expansion of the application possibilities of our drug Ameluz® are key for our future growth. The market for actinic keratoses alone is estimated at over 2 million prescriptions per year in the EU and over 12 million prescriptions per year in the USA. However, PDT treatments currently account for only 5% of all prescriptions in the EU and only 3% in the USA.

Our goal is to increase the attractiveness of PDT for physicians and patients and thus, significantly boost our sales. For example, if dermatologists in the USA were to treat just one percent of actinic keratosis patients with Ameluz® instead of cryotherapy in the future, this would represent additional sales of Ameluz® worth more than USD 30 million.. With the new billing codes in the USA and the introduction of daylight PDT in Europe, we have already successfully reached important milestones on the road to profitable growth.

However, the treatment options with PDT are not limited to light skin cancer alone. Research suggests a positive effect on acne, wound healing, warts and cervical cancer, for example. We believe in the great future potential for Ameluz®, which we intend to leverage.



## Nanoemulsion – the bearer of future



Great potential also lies in our proprietary and patented nanoemulsion technology. It offers the possibility to stabilize various active substances and is consequently perfectly suited as a basis for new drug formulations. As in the case of Ameluz®, the unique improved skin penetration can lead to greater clinical efficacy.

## FURTHER DEVELOPMENTS: TWO PHASE III TRIALS

In 2018, we launched two further Phase III trials, one of which we completed in the first quarter of 2019. The study was conducted at six study sites in Germany evaluating the safety and efficacy of conventional PDT with Ameluz® and the BF-RhodoLED® lamp for the treatment of actinic keratoses on the extremities as well as the trunk and neck. The preliminary results of the trial's primary endpoint demonstrate the superiority of Ameluz® with an average lesion healing rate of 86% compared to 33% for placebo ( $p > 0.0001$ ). These results will be utilized for the filing of the indication extension with the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA), which Biofrontera plans to submit in the third quarter of 2019.

The second Phase III trial is conducted at 12 clinical centers in the USA. Patient recruitment started in September 2018. The study will investigate Ameluz® in combination with the BF-RhodoLED® lamp for superficial basal cell carcinoma. In Europe, we have already received approval for this indication and we expect a further approval in the USA to significantly expand our market opportunities. Doctors and patients in the USA would then also have a highly effective treatment option with good cosmetic results for superficial basal cell carcinoma.

## Letter to the shareholders

Dear shareholders,

the year 2018 was marked by major operational successes, in particular the approval of daylight PDT in the EU, as well as the approval of the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) of our new active ingredient manufacturer as well as the production of larger manufacturing batches. In the USA, significant improvements were achieved in the reimbursement of Ameluz®. We almost doubled our product revenues in 2018, with total revenues in excess of EUR 21 million, representing 76% growth over the previous year. The listing of our shares on Nasdaq has significantly increased the visibility and credibility of our company in the USA.

In the USA - our largest market accounting for over 70% of our revenues - our sales team and medical sales force have largely reached their planned size and are fully functional. As a result of this and the growing awareness of our clinical data and improved reimbursement, our revenues in this market grew by 136% in 2018 and we expect continued growth over the coming years. We are currently conducting a Phase III trial of Ameluz® for the treatment of superficial basal cell carcinoma (BCC) to further improve our medium-term growth opportunities in the US market. We started recruiting patients in September 2018 and expect the first trial results in the first half of 2020. If successfully approved by the FDA, Ameluz® would be the only drug in the USA to apply photodynamic therapy (PDT) to treat superficial BCC, with patients and physicians thereby also benefiting from an efficient treatment option with excellent cosmetic results.

In Europe, too, we achieved a significant increase in revenues of 41% in 2018. The approval of Ameluz® in combination with daylight PDT in March 2018 significantly improved the positioning of PDT for the treatment of actinic keratosis (AK). When used with daylight PDT, Ameluz® is now reimbursed by statutory health insurance in Germany. In particular, we stimulated growth in our largest sales market in the EU and increased our share of the PDT market to over 60%. Daylight PDT has a particularly positive effect in the usually weak summer months, which was already evident in 2018.

We expect further impetus for Ameluz® from a Phase III trial that has already been completed to evaluate the efficacy of Ameluz® - PDT in the treatment of actinic keratoses on the extremities, trunk and neck. The recently published results will be used to extend the EMA and FDA approvals of Ameluz® to the treatment of actinic keratoses and field cancerizations throughout the body.

At the beginning of 2018, our share was listed on Nasdaq, which has already brought significant benefits to our company. Listing on a US stock exchange is particularly important in light of our presence in the pharmaceutical market in the USA. The reputation of a Nasdaq-listed company with the stringent publication obligations of the SEC gives us solid credibility not only on the capital market, but also among American dermatologists. In addition, the capital inflow has enabled us to expand our sales and marketing activities and has taken our company an enormous strategic step forward. In the course of the Nasdaq listing, the share price recorded a rapid increase from EUR 4.29 on 10 January 2018 (Xetra closing price on the day prior to publication of the intention to list) to EUR 6.25 on 19 February 2018 (Xetra closing price on the day the new shares were entered in the company register). Although a correction occurred in the course of the year, our share price is stable well above the pre-listing price.

In March 2018, we were informed of an intended acquisition offer by Deutsche Balaton AG to acquire up to just under 30% of the shares of Biofrontera AG (according to German law, from 30% a mandatory offer must be made for the entire company). After this offer was initially not approved by the German Federal Financial Supervisory Authority (BaFin), Deutsche Balaton Biotech AG made a similar offer to the shareholders of Biofrontera AG in May 2018. In this context, demands were formulated by the bidder which, in our view, would have severely disrupted Biofrontera's further successful development and growth. The Management and Supervisory boards of Biofrontera AG explained this in detail in their statements. In this context, we would like to thank our employees once again for their support and trust, having rejected the offer unanimously in their own statement. It was precisely the efforts, passion and creativity of our staff that made the company's great success possible. We see great growth potential in Biofrontera, which can be leveraged by a sustainable corporate strategy, and are therefore very grateful that you as shareholders have also clearly confirmed our corporate management and strategy by rejecting the offer.

For more than ten years, we have been expanding and improving treatment options for non-melanoma skin cancer through our research and development activities. We are now setting standards in photodynamic therapy and are continuously expanding our range of Ameluz® therapies. As a result of our sales efforts over the past two years, we are now becoming increasingly visible in the market as a young pharmaceutical company.

We have already surmounted many hurdles: Milestones such as the granting of a specific reimbursement code for Ameluz® and the improvement of PDT in medical billing compared to cryotherapy in the USA are examples of this. Where we market Ameluz® ourselves, we have now established powerful sales structures that have enabled us to raise awareness of the Ameluz® brand through increased market penetration.

Biofrontera pursues a clearly defined corporate strategy, which it has successfully implemented step by step over the past few years. We will continue in the future to consistently follow the path we have set ourselves. We would like to thank you for believing in Biofrontera, in our product Ameluz®, as well as in the people behind this company, and for placing your trust in us to act in your interest and to sustainably increase the value of the company.

Kind regards



Prof. Dr. Hermann Lübbert



Christoph Dünwald



Thomas Schaffer

Management Board of Biofrontera AG

## Investor Relations

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

### Key data on shares, ADSs and other financial instruments

Key data of the registered shares (no par value)	
Stock exchange	Frankfurt Stock Exchange
Other trading platforms	XETRA, Berlin, Düsseldorf, Munich, Stuttgart, Tradegate
Transparency level	Prime Standard
Shares in issue as of 31/12/2018	44,632,674
Share capital	EUR 44,632,674
ISIN	DE0006046113
WKN (German Securities Identification Number)	604611
Ticker symbol	B8F
Designated Sponsor	Lang & Schwarz Broker GmbH
52-week high* (19/03/2018)	EUR 7.19
52-week low* (02/01/2018)	EUR 4.16
Market capitalization as of 31/12/2018	EUR 223.6 million
Average daily trading volume on XETRA (52 weeks as of 31/12/2018)	89,448 shares per day

\* Price data based on XETRA closing price

Key data of the ADS	
Stock exchange	Nasdaq
CUSIP	09075G105
ADS ISIN	US09075G1058
Ratio	1 ADS : 2 ORDs
Symbol	BFRA
Custodian	BNY Mellon
Further trading platform	Stuttgart
WKN (German Securities Identification Number)	A2JEEX
Symbol	BFRA

Key data for the 2017-2022 Convertible Bond	
Stock exchange	Düsseldorf
WKN (German Securities Identification Number)	A2BPDE
ISIN	DE000A2BPDE6
Term, final maturity date	5 years, 31 December 2021
Coupon	6 %
Par/denomination	EUR 100.00
Total volume	EUR 4,999,000
of which converted as of 31/12/2018	EUR 2,403,700
Initial conversion price	EUR 3.50
Conversion price from 01/04/2017	EUR 4.00
Conversion price from 01/01/2018	EUR 5.00, since 03/03/2018 EUR 4.75

## Biofrontera share price performance

In 2018, the German equity market faced a difficult and highly volatile environment. After a positive start to the year, market uncertainty increased significantly, especially during the second half of the year, leading to marked price losses. The turbulent year-end phase was marked by concerns about the economy and interest rates as well as the budget dispute in the USA and associated significant price losses accompanied by high volatility.

Moreover, the price of the Biofrontera share was considerably influenced by its corporate news flow. At the beginning of the year, the share recorded a rapid increase of 62.3% within one month and reached its first high of EUR 6.41 on 1 February 2018. This occurred against the backdrop of the announced listing on the US Nasdaq Stock Market and associated capital increase of over 6,000,000 new shares as well as the promising news regarding daylight PDT, for which the Committee for Medicinal Products for Human Use (CHMP) had issued a positive vote to the EMA regulator.

After sharp price fluctuations during the offer phase, driven above all by substantial price losses accompanied by rising volatility on US stock exchanges - the Dow Jones index suffered a loss of more than 1,100 points on 6 February 2018, its highest daily loss in its history in terms of points - the share commenced a further rally from 14 February 2018, its first trading day on Nasdaq. Within one month, it reached its high for the year of EUR 7.19 on 13 March 2018. Among other factors, the share price benefited from the European Commission's approval of the extended indication for daylight PDT at the beginning of March and the superior efficacy of Ameluz® over the reference drug demonstrated during the follow-up period of the Phase III trial.

The share price subsequently consolidated before incurring price losses at the end of June. However, thanks to positive corporate news, it recovered quickly to stand again at EUR 6.41 by 29 August 2018. In July 2018, for example, product sales doubled in the first half of the year, and a five-year contract was signed with the US Department of Veterans Affairs in August.

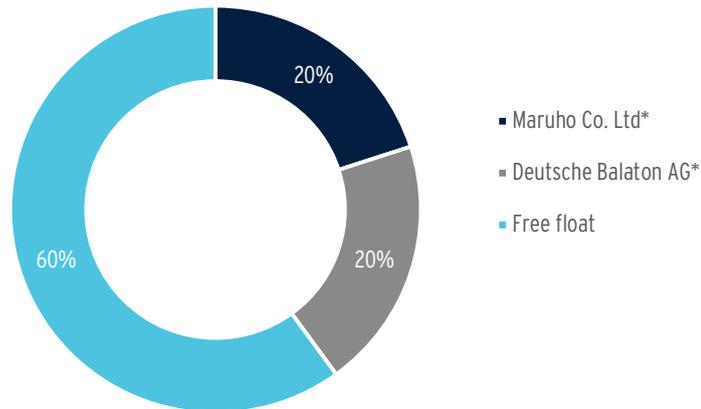
In the fourth quarter, the share price performed in line with market conditions and was subject to wide fluctuations despite encouraging corporate developments such as the very good results with daylight PDT in Europe, further progress in the potential applications of Ameluz® through the completion and start of two patient recruitment for two Phase III trials, respectively, and a forecast upgrade thanks to strong overall revenue growth. On 27 December 2018, the share reached its low for the second half of the year and fell to EUR 4.88 per share. On the last trading day of the year the price recovered again slightly to end the year at 5.01 EUR. The Biofrontera share thereby posted a respectable price appreciation of 20.7% compared to the end of the previous year (EUR 4.15). Following the end of the financial year under review, the share price continued to outperform. In January, the share broke through the EUR 6.00 mark again before subsequently consolidating just below this level.

## Share price chart



## Shareholder structure

The shareholder structure of Biofrontera AG as of 31 December 2018, based on the most recent mandatory disclosures, is as follows:



## Investor relations work

Biofrontera sets great store by active, comprehensive and continuous communication with investors and analysts. The aim at all times is to provide information about the company on a basis that is reliable, open and prompt.

Road shows and conferences offer the Biofrontera management the opportunity to conduct extensive and personal discussions with institutional investors (both equity and debt investors) and analysts. Such discussions were conducted on many days during the 2018 financial year, including at capital market centers in the USA and many important European cities. Biofrontera participated mainly at international conferences oriented to the healthcare sector in 2018, but was also represented at events with a more specific focus.

Along with quarterly statements for the first and third quarters and the half-year financial report, Biofrontera informed investors, analysts and further interested capital market participants at a total of 8 press releases and 39 IR releases. The Management Board held telephone conferences to comment on the Group's published results and report on significant developments and current activities. The annual analysts' conference occurred as part of the Equity Capital Forum in Frankfurt on 26 November 2018.

The Ordinary Annual General Meeting of Biofrontera AG was held on 11 July 2018 in Leverkusen. A total of 63 percent of the voting capital of Biofrontera AG comprising 44,506,980 shares as of this date were represented there. The presence thereby improved considerably compared with the previous year. In their presentations, the Management Board members emphasized the company's rapidly increasing sales and regulatory success in Europe and the USA as well as the company's enhanced visibility in the USA thanks to the IPO on Nasdaq. The shareholders approved all of the company's agenda items listed, including the election of Mr. Eyring as a new member of the Supervisory Board, with a clear majority. All of the shareholders rejected the supplementary motions previously submitted by Deutsche Balaton AG with a very large majority.

On 29 January 2018, Biofrontera approved a capital increase from the Authorized Capital created by the Annual General Meeting on 24 May 2017. This capital increase was implemented in February 2018 in connection with a listing on the US Nasdaq Stock Market. The company's share capital was increased by EUR 6,000,000 by way of a capital increase against cash capital contributions through the issue of 6,000,000 new registered shares with a pro rata amount of the share capital of EUR 1.00 each ("New Shares"). The shareholders were granted statutory subscription rights, subject to the exclusion of fractional amounts. The New Shares also served as the basis for the creation of ADSs publicly offered in the USA. Each ADS securitizes two ordinary shares in the company. ADSs were offered for purchase to investors in the USA subject to shareholders' subscription rights to the New Shares. A total of 1,300,483 ADSs were placed, including the full exercise of the over-allotment option. The subscription price for the New Shares was set at EUR 4.00 per share on 9 February 2018. The net proceeds of the capital measure amounted to EUR 21.6 million. Biofrontera's shares have been listed on the US Nasdaq Stock Market since 14 February 2018. All ordinary shares of Biofrontera AG can be traded without restriction on German stock exchanges, and as ADS on Nasdaq.

In March 2018, the company announced the early repayment of its 2016/21 convertible bond as of 30 April 2018.

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. A further tranche of EUR 5.0 million can be drawn after certain milestones have been reached. Each tranche must be paid back within five years after it has been made available.

## Analyst coverage

The following analysts cover Biofrontera:

Broker	Analyst
The Benchmark Company, LLC	Bruce D. Jackson
Dawson James	Robert Wasserman
Lake Street Capital Markets	Thomas Flaten
sc-consult GmbH	Dipl. Kfm. Holger Steffen

## Conferences

Date	Conference
8-11 January 2018	JP Morgan 36th Annual Healthcare Conference (San Francisco)
15 May 2018	Spring Conference (Frankfurt)
13 September 2018	Lake Street Capital Markets 2018 Best Ideas Growth (BIG) Conference (New York)
24-27 September 2018	Baader Investment Conference, Munich
1-3 October 2018	Cantor Fitzgerald 2018 Global Healthcare Conference (New York)
29-30 October 2018	Dawson James Securities 4th Annual Small Cap Growth Stock Conference (Jupiter)
26 November 2018	Equity Capital Forum (Frankfurt)
29 November 2018	The Benchmark Company Discovery One-on-One Conference (Chicago)
4-6 December 2018	11th Annual LD Micro Main Event (Bel-Air)

# Corporate governance declaration pursuant to Sections 289f, 315d HGB (corporate governance report) for the 2018 financial year

## I. Disclosure pursuant to Sections 289 f (2) subsection 1, 315 d HGB (corporate governance declaration)

The Management and Supervisory boards issued the following compliance statement in December 2018:

### Statement by the Management and Supervisory boards of Biofrontera AG (the company) concerning the German Corporate Governance Code, pursuant to Section 161 of the German Stock Corporation Act (AktG)

Pursuant to Section 161 of the German Stock Corporation Act (AktG), the Management and Supervisory boards of Biofrontera AG are obligated to state each year that the recommendations of the "Government Commission on the German Corporate Governance Code" ("Code"), as published by the Federal Ministry of Justice in the official section of the electronic Federal Gazette (Bundesanzeiger), have been and are being complied with, or which recommendations were not or are not being adhered to and why such is the case ("compliance statement"). The compliance statement must be made permanently accessible to the shareholders. The Management and Supervisory boards hereby issue the following compliance statement:

Since the submission of its annual compliance statement in December 2017 as well as its amendment during the year in April 2018, Biofrontera AG has complied with the recommendations of the Code in the version specified therein taking into account the exceptions therein stated, and will comply with the version dated 7 February 2017, with the following exceptions:

#### Deductibles in respect of the D&O insurance (No. 3.8 subsection 3)

The company has taken out D&O insurance cover, which provides no deductible for Supervisory Board members. In the company's view, such a deductible is not required to ensure the Supervisory Board members' motivation and sense of responsibility. A deductible would, however, probably undermine the company's aspirations to attract outstanding people from Germany and abroad to serve on its Supervisory Board. The Supervisory Board has consequently been expressly exempted from the new provisions regarding the deductible in the German Act regarding the Appropriateness of Management Board Remuneration (VorstAG) (Section 116 AktG).

#### General limit to be specified for the term of office on the Supervisory Board (No. 5.4.1)

As part of its diversity goals, the Supervisory Board should specify a general limit for the term of office on the Supervisory Board. In the company's case, however, specifying a general limit for the term of office is not considered to be appropriate from the current perspective. This is because, in the Supervisory Board's opinion, it is not possible to abstractly determine a length of time that could usefully be specified as a general maximum limit for the term of office. Instead, each case should be assessed individually as to whether the existing length of membership on the Supervisory Board might conflict with proper and impartial fulfilment of the mandate.

#### Structure of remuneration for the Supervisory Board (No. 5.4.6)

The amount of the remuneration of the members of the Supervisory Board is regulated in the Articles of Association. The Chairman receives twice and the Deputy Chairman one and a half times the remuneration to be paid to an ordinary member. The company does not take committee membership into consideration when remunerating the Supervisory Board members. Given the close coordination in the six-member Supervisory Board, a differentiation of the Supervisory Board remuneration according to committee membership is not required at present, especially as the members generally have around the same workloads resulting from membership of the various committees.

## Reporting (No. 7.1.2)

Financial reports, half-yearly reports and interim reports are published within the statutory periods.

Leverkusen, December 2018



Prof. Dr. Hermann Lübbert  
Management Board of Biofrontera AG

Thomas Schaffer

Christoph Dünwald

Dr. Ulrich Granzer  
Chairman of the Supervisory Board

## II. Corporate Governance Report

The current corporate governance report is available on the company's website at [www.biofrontera.com](http://www.biofrontera.com) in the section "Investors", sub-section "Corporate Governance".

# Report of the Supervisory Board of Biofrontera AG for the 2018 financial year



Dear Shareholders

the 2018 financial year proved to be another very successful year for Biofrontera AG and its subsidiaries. After 2017 was dominated by the expansion of our sales activities in the USA, we exceeded the sales revenue level of EUR 20 million in the Group for the first time in 2018. And we did this very dynamically: our sales revenue in the USA increased by around 136% and in Europe by around 41%. In particular, business in the USA, our most important sales market, recorded a very positive trend. In the Supervisory Board's opinion, the employees of the Biofrontera Group and the management deserve special recognition for this. As a small German company, they have succeeded in establishing the company's own powerful and successful sales organization in the USA within a relatively short time.

We also made further good progress in expanding indications for Ameluz®. In March 2018, the European Commission granted approval for Ameluz® in combination with photodynamic daylight therapy (Daylight PDT), so that in the future Ameluz® can be utilized without special lamps. The approval for Daylight PDT has significantly increased the market potential for Ameluz® in Europe and improved the drug's reimbursement status in Germany.

In February 2018, Biofrontera AG reached a very special milestone: the listing on the US NASDAQ Stock Market with a simultaneous successful capital increase. This has laid the financial foundation for the company's further successful development and growth.

## Supervision and consultation

The Supervisory Board discharged the responsibilities incumbent upon it according to the law, the company's articles of association, the German Corporate Governance Code (Code), and its rules of business procedure. The Supervisory Board's activities included supervising and consulting with the Management Board concerning the management of the company and the Group. In the reporting year, the Supervisory Board monitored the Management Board's activities and discussed future business decisions and plans with it.

The Management Board provided the Supervisory Board with regular, timely and comprehensive reports. The Supervisory Board was continuously informed by the Management Board, both during and outside meetings, about the company's current performance. Based on the Management Board's written and verbal reports, the Supervisory Board comprehensively discussed business developments and the company's situation at its meetings. Furthermore, the Chief Executive Officer and the Supervisory Board Chairman regularly exchanged information and ideas. In particular, the Supervisory Board was consulted about decisions of fundamental significance for the company. In particular, the Supervisory Board also reviewed the legality, propriety and expediency of measures proposed by the company's management team, as well as the economic feasibility of such measures. Deviations in business performance from the plans were explained to the Supervisory Board by the Management Board and discussed with it. Additionally, the Supervisory Board examined the extent to which its decisions, proposals and recommendations were subsequently taken into account and implemented by the Management Board in running the company.

If Management Board decisions required Supervisory Board approval or if the Management Board sought approval in relation to particular measures, the Supervisory Board was briefed in advance by way of information and documents of relevance for the decision. Approval was subsequently granted after discussion at meetings of the Supervisory Board or by means of decisions taken by circulation or in telephone conferences.

## Consultations and areas of focus

In fulfilling its responsibilities, the Supervisory Board held six meetings during the reporting year. It also passed resolutions outside the scope of meetings.

In the telephone conference on 1 March 2018, the Management Board reported to the Supervisory Board on current sales trends in individual markets. The Supervisory Board discussed and approved the corporate targets for 2018 and coordinated the further planning process with the Management Board.

The meeting on 25 April 2018 concerned the financial statements. The auditor reported on the timing, structure and results of the audit for the 2017 financial year. After discussing the separate financial statements for 2017, the consolidated financial statements and the combined management report for the company and the Group, the Supervisory Board approved the auditor's reports, raised no reservations on the basis of the results of its own audit, and approved both the separate and consolidated financial statements. It thereby followed the recommendation of its Audit Committee. The financial statements of Biofrontera Aktiengesellschaft for the 2017 financial year were adopted as a consequence. The Management Board reported on the successful capital increase implemented in February 2018 and on the updated financial preview for 2018. The Management Board also reported on current sales and market trends as well as on progress in the research and development area. The Supervisory Board's Nomination Committee and Personnel Committee reported on the results of their meetings. A decision was taken to change the composition of the Supervisory Board committees. In addition, a decision was taken to dissolve the R&D & Market Access Committee, as the Supervisory Board was of the opinion that this committee was no longer required. Furthermore, the Supervisory and Management boards discussed the announcements of a voluntary purchase offer with regard to shares of Biofrontera AG, initially by Deutsche Balaton AG and subsequently by Deutsche Balaton Biotech AG (Deutsche Balaton AG, Deutsche Balaton Biotech AG as well as parties acting jointly with them are hereinafter referred to as "**Deutsche Balaton-Group**").

During the telephone conference on 4 July 2018, the Supervisory Board received reports on current developments in reimbursement matters in the USA and on production issues.

At the meeting on 10 July 2018, the Management Board reported on the preliminary half-year results, current sales trends and current developments in the areas of research, development and approvals. The legal dispute in the USA with competitor DUSA Pharmaceuticals was also discussed. Furthermore, the Management Board reported on the legal disputes with the Deutsche Balaton Group and the public tender offer of Deutsche Balaton Biotech AG for shares of Biofrontera AG.

In the telephone conference held on 25 September 2018, the Management Board initially reported on current business trends. A focus here again was on sales development and sales activities as well as on the further development of the application scope of Ameluz®. The legal disputes with DUSA Pharmaceuticals and the Deutsche Balaton Group were discussed.

At the meeting on 14 December 2018, the Management Board reported in detail on business trends during the first nine months of 2018 and provided an outlook on the annual result for 2018. The Management Board also reported on current developments in the areas of sales, research & development and regulatory affairs. The Supervisory Board also concerned itself with the budget planning for 2019, which it approved. The corporate targets for 2019 were set. The legal disputes with DUSA Pharmaceuticals and the Deutsche Balaton Group were discussed again. The declaration of compliance in accordance with Section 161 of the German Stock Corporation Act (AktG) was adopted.

## Supervisory Board committees

At present, the Supervisory Board has formed an Audit Committee, a Nomination Committee and a Personnel Committee. The Supervisory Board appoints a Supervisory Board member as committee chair in each case. Pursuant to the rules of procedure for the Supervisory Board, the Supervisory Board chair is expected to chair the committees that handle Management Board contracts and prepare Supervisory Board meetings. The Supervisory Board chair should not be the Audit Committee chair too. These requirements were taken into account when making appointments. The committee chairs report to the Supervisory Board on the committees' work.

All the committee members participated in all the committee meetings in 2018.

### Audit Committee

The Audit Committee focuses particularly on issues relating to financial accounting and risk management, the auditor's mandatory independence and the issuing of the audit mandate to the auditor, as well as overseeing the audit of the company's annual financial statements. At companies as defined in Section 264d of the German Commercial Code (HGB), which includes Biofrontera Aktiengesellschaft, the Supervisory Board's nomination for the selection of the auditor must be based on the Audit Committee's recommendation. Furthermore, at companies as defined in Section 264d HGB, at least one member of the Supervisory Board must possess expertise in the financial accounting or auditing areas and be a member of the Audit Committee. The following persons were members of the Audit Committee in the reporting period: Jürgen Baumann, John Borer and Hansjörg Plaggemars. In March 2019, Mr. Plaggemars was dismissed by the court as a member of the Supervisory Board and thus also left

from the Audit Committee (see below the section "*Dismissal of a Supervisory Board member by the court*"). Mr. Reinhold Eyring was appointed as the third member of the Audit Committee on 28 March 2019. Mr. Baumann is the current chair. The committee met once during the reporting year: with the auditor in order to prepare for the Supervisory Board's financial statements meeting on 25 April 2018.

## Personnel Committee

The Personnel Committee prepares decisions for the Supervisory Board regarding the appointment and dismissal of Management Board members. Unlike in the past, the plenum is now assigned responsibility for remuneration decisions, as a result of changes in the German Act on the Appropriateness of Management Board Remuneration (VorstAG), so the Personnel Committee now performs only preparatory work. The following persons are currently members of the Personnel Committee: Jürgen Baumann, John Borer and Dr. Ulrich Granzer. Mr. Baumann is the current chair. The committee met on 25 April 2018. The topics discussed included the achievement of targets by members of the Management Board in 2017 and the issuance of options to Management Board members.

## Nomination Committee

In addition to the chair, the Nomination Committee includes two further Supervisory Board members who are elected to the committee. The Nomination Committee's task is to propose suitable candidates for the Supervisory Board's election proposals to the AGM. Here, the Nomination Committee considers the balance and variety of knowledge, skills and experience of all the Supervisory Board members, and prepares candidate profiles. The Nomination Committee is also to make proposals to the Supervisory Board concerning, and communicate results from, a regular assessment of the knowledge, capabilities and experience of both the members individually as well as the Supervisory Board in its entirety. In the course of performing its duties, the Nomination Committee can draw on company resources it deems appropriate and also on external consultants within the necessary framework. The Nomination Committee is currently composed of the following members: John Borer, Dr. Ulrich Granzer and Reinhard Eyring (since 25 April 2018). Dr. Granzer occupies the chair. Until 25 April 2018, Mr. Hansjörg Plaggemars was a member of the Nomination Committee in place of Mr. Eyring. The committee met on 25 April 2018. A decision was taken to propose to the 2018 Annual General Meeting that Mr. Eyring be elected to the Supervisory Board, having initially been court-appointed to the Supervisory Board.

## Individualized disclosure of the participation of Supervisory Board members in Supervisory Board and committee meetings in the 2018 financial year

Supervisory Board members	Supervisory Board and committee meetings	Participation	Attendance
Jürgen Baumann	8	8	100%
John Borer	9	9	100%
Reinhard Eyring	7	5	71%
Dr. Ulrich Granzer	8	8	100%
Hansjörg Plaggemars	7	7	100%
Kevin Weber	6	5	83%

Mr. Weber was unable to attend the telephone conference on 1 March 2018. Due to a professional stay abroad, Mr. Eyring was unable to attend the telephone conference scheduled for 4 July 2018 and the meeting on 10 July 2018.

## Separate and consolidated financial statements for 2018

The audit firm Warth & Klein Grant Thornton AG, Düsseldorf, was appointed Group auditor for the 2018 financial year by the Annual General Meeting on 11 July 2018 and was subsequently awarded the corresponding mandate by the Supervisory Board. The auditor's statement of independence was obtained. Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft audited the separate and consolidated financial statements of Biofrontera Aktiengesellschaft, which the Management Board prepared, and the combined management report for the 2018 financial year, and issued unqualified audit opinions for them. Furthermore, the auditor noted that the Management Board had established an appropriate information and monitoring system which was suitable, both in terms of its design and operation, to identify at an early stage any developments that might jeopardize the company as a going concern.

The consolidated financial statements were prepared in accordance with International Financial Reporting Standards (IFRS).

The financial statement documents were discussed in the Audit Committee on 25 April 2018 in the presence of the auditor. The Audit Committee dealt in particular with the key audit matters described in the respective auditor's report (key audit matters), including the audit procedures performed. At the subsequent meeting of the Supervisory Board to approve the financial statements on the same day, the financial statement documents were discussed in detail in the presence of, and after a report by, the auditor. All Supervisory Board members received the financial statements documents and the audit reports drawn up by the auditor in good time before the financial statements meeting and studied the documents thoroughly. At the financial statements meeting, the separate and consolidated financial statements were discussed extensively with the Management Board. The auditor reported on the audit, commented on the main audit topics, and was at the Supervisory Board's disposal to answer questions and provide information. The auditor reported on the scope, focus and key findings of its audit, in particular key audit matters and the audit procedures performed. The auditor was available to the Supervisory Board to answer questions and provide further information. All questions posed by the Supervisory Board were answered in full by the Management Board and the auditor. The auditor also provided information about its findings on internal controlling and risk management with regard to the accounting process.

The Supervisory Board took note of the audit reports, the separate and consolidated financial statements and the combined management report for the company and the Group. After discussing the separate financial statements, the consolidated financial statements and the combined management report for the company and the Group, the Supervisory Board approved the auditor's reports and the results of the audit, expressed no reservations on the basis of the results of its own audit, and approved both the separate and the consolidated financial statements. The annual financial statements of Biofrontera Aktiengesellschaft were adopted as a consequence.

This Supervisory Board report was adopted at the financial statements meeting on 25 April 2018, as well as the corporate governance declaration.

### Auditor responsible

Since the 2018 financial year, Mr. Michael Gottschalk has served Biofrontera AG as the company's mandated independent auditor in the auditing of the financial statements.

## Corporate governance and compliance declaration pursuant to Section 161 AktG

Further information on corporate governance is available in the annual report and online at [www.biofrontera.com](http://www.biofrontera.com), under "Investors" / "Corporate Governance", as well as in the corporate governance declaration. Details of the Supervisory Board's objectives regarding its composition and the status of implementation are also published there.

## Conflicts of interest in the Supervisory Board

In accordance with the recommendation of the German Corporate Governance Code, any conflicts of interest that have arisen and their treatment should be reported in the report of the Supervisory Board. Biofrontera AG has not declared any deviation in this respect.

Mr. John Borer is a senior staff member, but not a shareholder of The Benchmark Company, LLC. Along with two further investment banks, The Benchmark Company, LLC, advised Biofrontera AG as part of its US stock market listing in early 2018. Mr. Borer was not involved in coordination regarding the question of mandating The Benchmark Company, LLC, all of which occurred in 2017. No events occurred in 2018 relating to The Benchmark Company, LLC, that could have created a conflict of interest.

Mr. Hansjörg Plaggemars was a member of the Management Board of DELPHI Unternehmensberatung (hereinafter "DELPHI") until 13 April 2018. DELPHI is a company of the Deutsche Balaton Group and holds a majority interest in Deutsche Balaton AG. According to his own statements, Mr. Plaggemars achieved in 2018 and continues to generate a major part of his income from activities for companies of the Deutsche Balaton Group. As described above, the Supervisory Board dealt with legal disputes between Biofrontera AG on the one hand and the Deutsche Balaton Group on the other hand in the year under review. In addition, the Supervisory Board discussed the announcements of Deutsche Balaton AG and Deutsche Balaton Biotech AG to make a voluntary purchase offer for shares of Biofrontera AG. In the following the Supervisory Board dealt with the voluntary purchase offer of Deutsche Balaton Biotech AG for shares of Biofrontera AG.

Mr. Plaggemars did not participate in sections of meetings of the Supervisory Board or telephone conferences in which legal disputes with the Deutsche Balaton Group, as well as the acquisition offer and its announcements were discussed. Information was exchanged and opinions formed in the Supervisory Board without his presence. The Supervisory Board did not pass any resolutions with regard to the legal disputes with the Deutsche Balaton Group. Insofar as the Supervisory Board was required to

submit comments on the acquisition offer of Deutsche Balaton Biotech AG and its amendment pursuant to § 27 WpÜG, Mr. Plaggemars participated in the votes on the adoption of the comments in the following circulation procedure. However, it was disclosed in the statements that Mr. Plaggemars was working for companies of the Deutsche Balaton Group at the time of the adoption of the statements. In addition, the voting results of the resolutions adopted by the Supervisory Board were communicated in the statements. As a result, every reader of the statements was in a position to appreciate the result of the resolution in view of the contents communicated.

In the future, the Supervisory Board intends to proceed in such a way that members subject to a conflict of interest do not participate in the exchange of information and consultations within the Supervisory Board. This applies in principle in the same way to the participation in voting of the Supervisory Board.

## Dismissal of a Supervisory Board member by the court

Pursuant to Section 103 (3) AktG, the competent local court must dismiss a member of the Supervisory Board at the request of the Supervisory Board if there is an important reason in his person. In January 2019, the Supervisory Board filed an application with the Cologne Local Court to dismiss Mr. Plaggemars as a member of the Supervisory Board of Biofrontera AG. The background to this is that Mr. Plaggemars has submitted a written statement in proceedings pending before the Regional Court of Cologne in which DELPHI applied for the appointment of a special auditor for Biofrontera AG pursuant to Section 142 (2) AktG. This legal proceeding was initiated by DELPHI in January 2018, when Mr. Plaggemars was still a member of the Management Board of DELPHI. The Supervisory Board would have been responsible for submitting a statement in the proceedings as a body pursuant to Section 142 (5) AktG, but not an individual member, with the result that the submission of the statement violates the statutory competence regulations. In the statement, Mr. Plaggemars also disclosed information which, in the opinion of the remaining members of the Supervisory Board, is subject to the consulting secrecy of the Supervisory Board pursuant to Section 116 AktG and of which DELPHI thus also gained knowledge. Following an application by the Supervisory Board, the Cologne Local Court (Amtsgericht) dismissed Mr. Plaggemars as a member of the Supervisory Board of Biofrontera AG in accordance with § 103 (3) AktG for cause. The resolution was issued on 22 March 2019 and came to the knowledge of the company on 26 March 2019. The ruling for dismissal is effective immediately. However, an appeal can be filed within one month, which has been done. In the case of a successful appeal, Mr. Plaggemars would be reinstated as a member of the Supervisory Board.

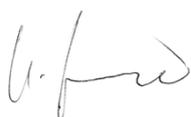
## Further personnel changes on the Supervisory Board

Mr. Mark Reeth relinquished his mandate as a member of the Supervisory Board with effect as at 31 October 2017. In early 2018, the Cologne District Court appointed Mr. Reinhard Eyring, resident in Kronberg, Taunus, lawyer and partner in the Ashurst LLP legal practice in Frankfurt am Main, as Mr. Reeth's successor as a member of the company's Supervisory Board pursuant to Section 104 (1) and (2) of the German Stock Corporation Act (AktG). The Annual General Meeting on 11 July 2018 subsequently elected Mr. Reinhard Eyring to the Supervisory Board as Mr. Reeth's successor, subject to the proviso that his term of office end at the conclusion of the Annual General Meeting that resolves on the formal approval of the actions of the Supervisory Board for the financial year ending on 31 December 2020.

Once again, we would like to thank you, our shareholders, for your commitment and trust. Ultimately, the financial resources you have made available have formed the basis for your company to develop so well, and to successfully position itself as a specialist in the photodynamic therapy area.

The Supervisory Board would like to thank the Management Board and the staff of both Biofrontera Aktiengesellschaft and the Biofrontera Group for their great commitment, dedication and outstanding performance during the past financial year.

Leverkusen, 25 April 2019



Dr. Ulrich Granzer  
Chairman of the Supervisory Board

# Combined management report for parent company and Group as of 31 December 2018

## Basis of the Group

### Group structure

As of 31 December 2018, the Biofrontera Group (hereinafter also referred to as "Biofrontera" or "Biofrontera Group") consists of a parent company, Biofrontera AG, a branch office in Spain and five wholly owned subsidiaries, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc. Biofrontera Inc. is headquartered in Wakefield, Massachusetts, USA. All the other companies are based at the parent company's head office in Leverkusen, Germany.

### Business model

The public entity, Biofrontera AG, performs the function of a holding company within the group of companies. It is responsible for Biofrontera's management, strategic planning and internal control and monitoring, it also ensures the necessary financing needs are met. Biofrontera Bioscience GmbH undertakes the research and development tasks for the Group and is the holder of patents and approvals for Ameluz®. Based on a license agreement with Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH (which is also the holder of the CE certificate for BF-RhodoLED®) is responsible for the manufacturing and also the further licensing and marketing of the Biofrontera Group's approved products. Biofrontera Inc. is responsible for the marketing of the Biofrontera Group's approved products in the US.

For all of the markets Biofrontera serves, Ameluz® is produced by a contract manufacturer in Switzerland. The PDT lamp is produced at Biofrontera's headquarters in Leverkusen, Germany.

Biofrontera Development GmbH and Biofrontera Neuroscience GmbH were established as additional wholly owned subsidiaries of Biofrontera AG in December 2012. The purpose of both companies is to pursue the development of pipeline products that do not form part of Biofrontera's core business and consequently cannot be sufficiently financed as part of normal business development. The product BF-derm1, which is intended for the treatment of severe chronic urticaria, is now the responsibility of Biofrontera Development GmbH, while the product BF-1, which is intended for the prophylactic treatment of migraines, is the responsibility of Biofrontera Neuroscience GmbH. This outsourcing of development candidates has created a structure through which the financing of the further development of these two products could be detached from the normal Biofrontera Group financing.

### Group strategy

The Biofrontera Group's strategic objective is to optimize the positioning and market potential of Ameluz® while becoming a leading specialty pharmaceutical company in dermatology. Focus areas of activity currently include further expanding sales of our products, as well as extending the approvals of Ameluz® to include further indications to enhance its brand potential.

Biofrontera has received centralized approval for a completely self-developed drug marketed under the Ameluz® brand. Since the market launch in February 2012, Biofrontera has been deploying its own sales force to market Ameluz® among dermatologists in Germany, as well as in Spain since March 2015. Ameluz® has been available in the United Kingdom for several years, but has only been actively promoted by Biofrontera's own sales team since May 2018. This is due to the particularly important indication extensions in this market to include field cancerization (2016), basal cell carcinoma (BCC) (2017) and daylight PDT for actinic keratosis (2018). Licensing partners distribute the drug in several other European Union countries, as well as in Israel and Switzerland.

A U.S. subsidiary, Biofrontera Inc., based in Wakefield, Massachusetts, has been set up in order to market in the USA. The U.S. subsidiary has established all functions and obtained all licenses required for a sales and marketing company in the pharmaceuticals and medical products sector. All further Biofrontera Group functions necessary for a pharmaceutical company, such as regulatory approvals, production, IT, clinical trials etc. continue to be covered exclusively by the German companies with worldwide responsibility.

## Products

Further milestones for a successful future for Biofrontera were achieved in 2018. In March 2018, the European Commission approved the application of Ameluz® in combination with daylight PDT - an important application for the European market - and has been actively marketing this product since April. In September 2018, this approval was also granted in Switzerland.

Although the potential of Ameluz® is far from being exhausted (Biofrontera is currently pursuing the development for basal cell carcinoma in the USA, and the efficacy of PDT for some further indications has also already been shown), the company has already succeeded in positioning the product excellently in the market in both Europe and the USA.

After two years, the USA has already become the most important market for Ameluz®. In 2018, around 70% of sales revenues were generated in the USA, and this share will presumably increase further. For this reason, it is reasonable that Biofrontera focuses increasingly on the USA market. Moreover, this factor partly accounts for the decision to also go public on a stock exchange in our largest market, and thereby strengthen our profile and credibility among American customers and investors. For this reason, Biofrontera listed the company's shares on the NASDAQ in February 2018.

As a consequence, 2018 once again proved to be a very decisive and successful time for Biofrontera, which was characterized by further growth indicators. Against this backdrop and the associated challenges, the Biofrontera Group has also strengthened its employee base. During the reporting period, the number of employees grew from 123 to 157, with 62 already being employed in the USA.

### Ameluz®

Ameluz® 78 mg/g Gel ("Love the Light" - development name: BF-200 ALA) received a first centralized European approval for the treatment of mild and moderate actinic keratoses (AK) on the face and scalp in December 2011. Its significant superior effect compared to its direct competitor product Metvix® was proven for this indication during Phase III development. Actinic keratoses are superficial forms of skin cancer, and a risk exists that they can spread to deeper layers of skin, and thereby form potentially fatal spinal cell carcinoma. The combination of Ameluz® with light treatment is an innovative approach that constitutes a form of photodynamic therapy (PDT). The product information approved by the European Medicines Agency (EMA) explicitly mentions the significant superiority of Ameluz® for removing all of a patient's keratoses compared to its direct competitor product.

In the pivotal Phase III trials, Ameluz® showed excellent healing rates and demonstrated marked and statistically significant superiority compared to the approved comparator product tested in parallel. In the first Phase III trial, in which the drug was combined with an LED lamp, in 87% of patients treated with Ameluz® all keratoses were completely removed, and in terms of the number of individual keratosis lesions as many as 96% were completely eradicated (all the values stated are ITT - intent to treat - values). In the second Phase III approval trial, the effectiveness of Ameluz® was tested in comparison with the approved standard medication. Based on the average for all lamps, Ameluz® resulted in the complete healing of actinic keratoses in 78% of patients, whereas the approved competitor product achieved a significantly inferior healing rate of 64%. With LED lamps, the healing rates increased to 85% for Ameluz® and 68% for the competitor product. The side effect profile was very similar in both products and was characterized by localized pain during 10-minute illumination and sunburn-like skin changes in the first days after PDT.

As the approval in the USA requires a combination of drug and lamp, Biofrontera has developed its own PDT lamp, BF-RhodoLED®, and has had it CE-certified in the EU, which also required the entire company to be certified pursuant to the ISO 9001 and ISO 13485 standards. The ISO certification went through a regular renewal process in 2018. In preparation for the approval in the USA, a Phase III trial was performed with a combination of Ameluz® and BF-RhodoLED®. With this combination, keratoses were completely eradicated from 91% of patients, and in terms of the number of individual lesions, 94% were completely removed after treatment (99.1% of mild and 91.7% of moderate lesions).

Since this study was the very first Phase III study of PDT in which the drug was applied over a large area (field therapy), the cosmetic result could be determined without considering the disappearance of the keratotic lesions. All skin ageing parameters that were tested improved significantly as a result of the treatment. An improvement in the UV-induced skin ageing of patients treated with Ameluz® observed immediately after PDT continued to develop during the follow-up period. Before PDT, only 14.8% of patients had no impairments to the surface of the skin. Whereas twelve weeks after the last PDT, 63% of patients were already free of such cosmetic damage, this percentage rose after a year to 72.2%. Similar results were also observed for pigment disorders. Before PDT, hyperpigmentation occurred in 59.3% and hypopigmentation in 46.3% of patients, with 48.1% exhibiting irregular pigmentation. Twelve weeks after PDT with Ameluz®, these rates initially fell to 42.6%, 29.6% and 29.6%, respectively, and decreased over the course of a year to 24.1%, 11.1% and 18.5%, respectively. These results clearly show the long-lasting skin

rejuvenation effect achieved by using photodynamic therapy with Ameluz®. The skin repair processes triggered by the therapy remain active for at least 12 months.

Based on the Phase III trial for field therapy, the European Commission, after a positive vote, approved Ameluz® for treatment of field cancerization, and the results relating to an improvement in skin appearance were included in the official product information in the EU.

Two of the Phase I trials required by the U.S. Food and Drug Administration (FDA), were also already completed in 2015. These clinical trials were initiated with a total of approximately 240 patients or test persons to add the safety data required for registration in the USA to the European approval package for Ameluz®. Specifically, one of the trials was a sensitization study, which determines the potential of Ameluz® to trigger allergies, and the other was a maximal usage trial, which tests the absorption in the blood of the active ingredient in Ameluz®, aminolaevulinic acid, and the light-activated metabolite protoporphyrin IX in cases of treatment with the maximum quantity, in other words, the application of a complete tube onto the defective skin. No safety concerns were identified in either of the trials.

Based on the aforementioned trials, Biofrontera received approval for Ameluz® in the USA in May 2016. The approved indication relates to "lesion- and field-directed PDT for mild and moderate actinic keratosis on the face and scalp".

Actinic keratosis is classified as treatable precancer that requires treatment, and the international treatment guidelines list photodynamic therapy as the gold standard for the removal of actinic keratoses, particularly for patients with large keratotic areas ("field cancerization"). The latest statistics show that actinic keratosis is becoming a widespread disease, with up to 8 million people affected in Germany alone, with an upwards trend. Risk factors include, above all, significant exposure to sunlight and UV radiation, as well as a higher age: in the over 60s, actinic keratoses should be detectable in more than 40%, and from the age of 75 even in more than 50%. A total of even as many as 58 million individuals are estimated to suffer from actinic keratosis in the USA. In particular, subclinical and mild actinic keratoses can develop into life-threatening squamous cell carcinomas, and this occurs to the relevant lesions within two years on average. The increasing seriousness of actinic keratosis is illustrated by the recognition of actinic keratosis as an occupational disease in Germany in the summer of 2013. Since then, occupational insurance associations have been obligated to cover the treatment costs of patients who have mainly worked outdoors for a long time and who fulfil certain criteria, for the duration of these patients' lives. The related payment modalities were set in March 2016, with PDT being included as a treatment method. PDT can be used to treat actinic keratosis in the context of an occupational disease, and can be billed accordingly.

At present, actinic keratoses are treated using a wide range of methods. Lesions are treated, sometimes for weeks, with topical creams, which are often ineffective, or the diseased skin may be removed by mechanical intervention (curettage) or freezing (cryotherapy), which very often leads to the formation of scars or permanent pigment disorders, besides offering little efficacy.

The market for topical creams continues to report constant growth, and medicinally and legally questionable PDT formulations continue to be used in Germany. As the leading drug used by independent dermatologists in Germany in the PDT, Ameluz® can and must see a significant increase in sales in the aforementioned sectors can and must.

The AK patients treated in the Phase III trial were observed by the trial doctors for a year after the final treatment. Here, the long-term nature of the pharmaceutical effect of Ameluz® was analyzed in terms of effectiveness, safety and cosmetic result. In the three trials, patients who had received Ameluz® PDT with an LED lamp had recurrence rates between 22% and 40% after 12 months. The recurrence rate is defined in this context as the percentage of patients exhibiting at least one AK again after 12 months. These figures lie considerably below the recurrence rates for all other AK therapies described in the literature.

The overall advantages of Ameluz® in terms of effectiveness, handling, user-friendliness and skin rejuvenation effects, 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 over the next few years. This will be supported by the indication expansion in 2017 to include basal cell carcinoma, as the vast majority of PDT treatments are conducted for this indication, particularly in the UK and Spain.

Biofrontera has conducted a Phase III trial for the extension of the European approval to include the BCC indication. BCCs are the most common invasive tumors that affect humans and account for approximately 50% to 80% of all skin cancers. Around 30% of all Caucasians develop at least one BCC in their lifetime, and cases are increasing rapidly worldwide due to increased exposure to UV light. Surgical removal is the most frequent treatment currently used especially in the USA but this can lead to clearly visible scarring, whereas treatment with PDT, which is an alternative particularly in the treatment of thin BCCs, achieves excellent cosmetic results. In the pivotal Phase III trial, a total of 278 patients were treated. This trial was under the clinical

management of Prof. Colin Morton (UK) and Prof. Markus Szeimies (Germany) and was conducted at 27 clinical trial centers in England and Germany. In the clinical trial, the effectiveness and safety of Ameluz® were compared with that of Metvix®, a drug already approved in the EU for the treatment of BCC. Non-aggressive (superficial and nodular) BCCs with a thickness of up to 2 mm were included in the trial. The trial results have been available since January 2016 and confirm the company's positive expectations. Ameluz® achieved the complete elimination of all BCCs from the patient in 93.4% of cases compared to 91.8% with Metvix®. Greater differences occurred with thicker BCCs. For example, 89.3% of nodular carcinomas were removed entirely with Ameluz®, and just 78.6% with Metvix®. Recurrence rates after 12 months were higher for Metvix® than for Ameluz®.

Based on the results of this Phase III trial, Biofrontera applied to the European regulator in July 2016 for approval to treat BCC with Ameluz®, which the European Commission issued in January 2017.

Daylight-PDT enables reimbursement for PDT to patients with public health insurance in Germany, and to compete directly with topical drugs that patients apply themselves. In order to obtain regulatory approval, actinic keratosis patients were treated with Ameluz® in combination with daylight-PDT compared to Metvix® as part of a Phase III clinical trial between June and September 2016. This comparative, randomized, observer-blind multicenter trial was conducted at seven trial centers in Spain and Germany with a total of 52 patients. The clinical endpoint of the trial was the total healing rate for all lesions on each treatment side 12 weeks after treatment. The secondary clinical endpoints included determining medication safety and additional efficacy parameters. The trial was jointly directed by Dr. Susana Puig, Research Director at the Biomedical Research Institute August Pi I Sunyer and professor at the University of Barcelona as the main research director in Spain, and Prof. Thomas Dirschka, founder of the private dermatology practice CentroDerm as the main research director in Deutschland. Each patient had between 3 and 9 mild to moderate actinic keratoses (Olsen grades 1 and 2) on each of two comparable treatment areas on the face and/or scalp. The selection of medication for the respective treatment side was random. The last patient completed the clinical phase of the trial in December 2016. The trial's results proved the non-inferiority (relevant from a regulatory standpoint) of Ameluz® compared with Metvix®. All relevant secondary endpoints produced comparable or higher cure rates for Ameluz® in relation to Metvix®.

While the difference in the healing rates between the two products was only indicative after three months, statistically significant differences were evident during the one-year follow-up period. Three months after the one-off treatment with daylightPDT, 79.8% of Ameluz® and 76.5% of Metvix® patients were fully clinically healed. One year after treatment, however, 19.9% of lesions were recurring after treatment with Ameluz® PDT and 31.6% with Metvix® PDT ( $p < 0.01$ ). The recurrence rates for lesions that are more difficult to treat, such as moderately thick lesions (Olsen II) or lesions on the scalp, amounted to 20.5% and 23.4%, respectively for Ameluz® and 34.3% and 43.7%, respectively for Metvix® ( $p < 0.01$ ). Ameluz® is thereby also significantly superior to its European competitor in daylight-PDT.

In 2017, Biofrontera submitted an application for the approval of Ameluz® in combination with daylight-PDT and in March 2018 received approval from the European Commission to treat actinic keratosis and field cancerization with daylightPDT. Daylight-PDT comprises a favorable and relatively pain-free alternative to the conventional PDT treatment with a special lamp. Here, the topically applied medication is activated by natural or artificial daylight. As treatment in daylight-PDT does not need to be administered at a physician's practice, it competes directly with the self-applied topical medications that are much more widely disseminated in Europe, and is consequently also reimbursed by public healthcare insurance in Germany. It is anticipated that the significantly superior efficacy one year after treatment compared with Metvix® will support better market penetration with Ameluz®.

### BF-RhodoLED®

BF-RhodoLED® 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® 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® has been CE-certified since November 2012 and is distributed throughout the EU. For marketing in the USA, the final assembly of the PDT lamp was relocated to Biofrontera's premises where the final assembly of the lamps has been done since July 2016. Consequently, from the point of view of the regulatory authorities, this makes Biofrontera the responsible manufacturer.

### Belixos®

Belixos® is a modern active cosmetic product specially developed for sensitive and irritated skin. Biofrontera's patented biocolloid technology, which optimizes epidermal penetration, makes the products unique: pure herbal biocolloids combine with

medicinal plant extracts to form an extraordinary combination of active ingredients with a proven depth effect that combines the best of nature and science.

The Belixos® Creme rapidly and reliably soothes itching and is the ideal basic treatment for inflamed, reddened and flaky skin. It soothes the skin, reduces scratching and allows the skin to regenerate naturally. Belixos® Creme, which has been available since 2009, has consequently proved particularly useful as an effective basic treatment for atopic dermatitis and psoriasis.

Over the past two years, other specialist regenerative cosmetic products for skin problems have been developed. The typical deep yellow color is the unmistakable mark of quality. This is derived from the traditional medicinal plant extract obtained from the roots of Mahonia aquifolium. Belixos® products use only natural active substance extracts with clinically proven effects.

**belixos® Liquid** is an innovative scalp tonic with a practical pipette for dosing, which soothes scalps irritated by psoriasis or eczema, for example, and restores their balance. For itchy and flaky scalps, a combination of anti-inflammatory mahonia, moisturizing oats, irritation-relieving panthenol and a special zinc PCA complex is used.

**belixos® Gel** is specially cosmetically formulated for skin that is inflamed, reddened and prone to skin blemishes, providing an effective treatment for rosacea and acne. The gel texture is formulated to be extra grease-free, has a complex of active substances consisting of anti-inflammatory mahonia and Sepicontrol A5, is antibacterial, removes hardened skin and regulates sebum.

**belixos® Protect** is a modern daily care product specially developed for sun-damaged skin. With its skin-regenerative properties deriving from highly concentrated niacinamide, it leaves skin smooth and helps repair damaged skin. It also contains UVA and UVB broad spectrum protection with SPF15 to protect against further light-induced skin ageing and hyperpigmentation.

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

## Sales and markets

### USA

Biofrontera launched Ameluz® in the US market in October 2016. Marketing in the USA is being realized through the company's wholly owned subsidiary, Biofrontera Inc., which was founded for this purpose in March 2015. All important key positions in the USA were filled locally and the development of sales structures was continued in the year under review. By now our U.S. sales team has grown to nearly forty employees. Our sales team is supported by six scientific consultants, our Market Access and Managed Markets Team, as well as a Customer Service Team. Since its launch, we have sold more than EUR 20 million of Ameluz® in the USA and thereby established the product in the market.

### Germany and Europe

With its central European approval, Ameluz® can be sold and distributed in all EU countries, as well as in Norway, Iceland and Liechtenstein. In many European countries, however, price and reimbursement status have to be defined before market launch, which can be a very prolonged process. The drug is available in these countries at a pharmacy retail price of between EUR 150 and approximately EUR 220 per 2g tube.

In Europe, Ameluz® and BF-RhodoLED® have been promoted by our own sales forces in Germany (since 2012), Spain (since 2015) and the UK (since May 2018). In other European countries, sales are made with the help of licensing partners: Denmark, Sweden, Norway, Austria, Switzerland, Liechtenstein and Israel. It was necessary to undergo an independent approval process in these countries, which was conducted by the distribution partners in collaboration with Biofrontera. The contracts with the licensing partners were concluded in such a way that Biofrontera has received no down payment, or only a modest down payment, and the regional partners purchase Ameluz® from Biofrontera at a price that is linked to their respective sales price. Biofrontera's share of the sales price varies considerably depending on the market conditions in each country, ranging from 35% to 55% of net sales. Overall, however, marketing with Biofrontera's own sales teams has proved to be much more successful in recent years, with the result that sales with distribution partners now account for only a small proportion of total sales.

## Research and development projects

All research and development activities of the Biofrontera Group are located in Biofrontera Bioscience GmbH, which is responsible for clinical studies, as well as regulatory activities, such as the granting, maintenance and expansion of our approvals. Responsibility for the project management of all development activities is assumed internally; monitoring, data management and statistics are partially or completely outsourced. The number of employees at Biofrontera Bioscience GmbH rose from 13 in 2017 to 18 in 2018.

### Research collaboration

In July 2016, the company signed a research partnership with Maruho Co., Ltd. ("Maruho"), a Japanese company specializing in dermatology, in which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology were to be researched. Ameluz® was developed with a similar strategy. The nanoemulsion technology stabilized the active substance and improved skin penetration, leading to greater clinical efficacy. As part of Phase 1 of the collaboration, which was completed on 31 March 2018, Biofrontera and Maruho tested possible formulations for various other generic compounds. Stable compounds were developed for some, but not all, substances and combinations that were tested. Maruho paid all research and development costs incurred as part of Phase 1 of the partnership. The companies have agreed that the newly developed intellectual property (IP) of Phase 1 shall be the joint ownership of Biofrontera and Maruho and the pre-existing IP, including in particular Biofrontera's patented nanoemulsion, will remain the property of the respective companies. Although Biofrontera can use the research results independently of Maruho, the reverse would only be possible with Maruho obtaining an additional license agreement for the nanoemulsion technology from us.

## Patent and trademark development

The company maintains four 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, 5-aminolevulinic acid nanoemulsions, 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, which are pending, in Brazil, Paraguay, the United Arab Emirates, Uruguay, and the U.S. Patent applications in Paraguay and Uruguay were dropped in 2018.

### Nanoemulsions with 5-aminolevulinic acid

We have been issued composition of matter patents for our technology relating to nanoemulsion of 5-aminolevulinic acid in Australia, Canada, the EU (for Germany and Switzerland), Israel, and the U.S. Patent protection in these jurisdictions will expire on November 12, 2019.

Protection for this patent family, which describes the combination of nanoemulsions with aminolaevulinic acid hydrochloride, the active ingredient in Ameluz®, expires on 12 November 2019. Upon expiration of this patent family, we will not be able to rely on the expired patents to prevent competitors from copying, making, or selling the active ingredient used in Ameluz®. The additional patent application on the specific nanoemulsion developed for Ameluz® would extend the protection until December 21, 2027. This additional patent has been granted in many countries but has not yet been (and may never be) granted in the U.S. 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®, another patent application was already filed in 2018.

### Migraine prophylaxis BF-1

We have been issued composition of matter patents for our technology relating to derivatives of 4-(Thio- or Seleno-xanthene-9-ylidene)-Piperidine or Acridine and its use as a selective 5-HT<sub>2B</sub> receptor in Australia, Canada, China, the European Union (for Denmark, France, Germany, Italy, Netherlands, Spain, Sweden, Switzerland, Turkey, and the UK), India, Japan, Russia, South Africa, South Korea, and the U.S. Patent protection in these jurisdictions will expire on October 23, 2022. These patents relate to our developmental migraine prophylaxis product candidate BF-1. Since it will not be possible to bring these compounds to market prior to the patent expiry date, we dropped the patent in 2018.

Instead, we have filed an international patent application regarding anti-migraine compounds and their use through the World Intellectual Property Organization, and national phases have commenced in the EU and the U.S. The U.S. patent has been granted, expiring in January 2034.

## Photodynamic therapy

A new Patent Cooperation Treaty (PCT) application "Improved Photodynamic Therapy" was filed with the European Patent Office (EPO) on 23 August 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.

### Utility model

In addition, we have applied for a (German) utility model for our technology for pharmaceutical and / or cosmetic compositions for skin treatment. The utility model is valid for a maximum period of ten years after filing the application and expires on 9 April 2020.

## Personnel matters

### Management Board

The Management Board consists 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	63	Chair	2000	31/10/2020
Christoph Dünwald	German	51	Sales & Marketing	2016	30/11/2020
Thomas Schaffer	German	56	Finance	2013	30/11/2020

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 provided 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.

### Employees

As of 31 December 2018, 157 employees worked for the Biofrontera Group (previous year: 123). Of these, 31 were employed at Biofrontera AG (previous year: 23), 18 at Biofrontera Bioscience GmbH (previous year: 13) and 49 at Biofrontera Pharma GmbH including the Spanish office (previous year: 39). No staff are employed at Biofrontera Development GmbH or Biofrontera Neuroscience GmbH. Biofrontera Inc. employed a total of 62 staff (previous year: 48). The growth in the number of employees in the Biofrontera Group is primarily attributable to the further expansion of sales and marketing activities.

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

As a result of the resolution passed by the Annual General Meeting held on 31 May 2016, the Supervisory Board has been comprised of the following members since 31 May 2016, with these members acting as representatives of the shareholders:

Name	Nationality	Age	Position	Date of first appointment	Term
Dr. Ulrich Granzer	German	58	Chair	12/05/2006	2021
Jürgen Baumann	German	64	Deputy Chair	24/05/2007	2021
John Borer	USA	61	Member	31/05/2016	2021
Reinhard Eyring **)	German	60	Member	07/02/2018	2021
Hansjörg Plaggemars *)	USA	48	Member	31/05/2016	2021
Kevin Weber	USA	60	Member	31/05/2016	2021

\* Hansjörg Plaggemars was removed from his position as a member of the Supervisory Board of Biofrontera AG by the Cologne District Court on 22 March 2019.

\*\* Mr. Reinhold Eyring was initially appointed to the Supervisory Board as Mark Reeth's successor on 7 February 2018 and subsequently confirmed at the Annual General Meeting on 11 July 2018.

## Internal controls

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

The key figures are calculated on a monthly basis, while the budget planning for the current financial year is revised and updated quarterly. In addition, medium-term, comprehensive planning is prepared once a year. A detailed cost analysis is carried out 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, sales revenue, reported by region, is the key performance indicator. On a consolidated basis, revenues include sales to wholesalers, as well as physicians and clinics, sales to our licensing partners, and revenue from research contracts.

Due to the increase in sales revenues from EUR 12,025 thousand in 2017 to EUR 21,107 thousand in 2018, the result from operating activities has been increasingly used as a relevant control parameter metric. It measures the operating earning power of the company independently of its financial structure and local taxation, allowing the indicator to be used for international comparisons with other companies.

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

## Non-financial performance indicators

The number and qualifications of employees are the key non-financial performance indicators. This internal control system is applied on a consolidated basis so the entire Group is managed according to one standard.

The employees of Biofrontera are an important success factor and consequently, represent a central control parameter. In the recruitment of personnel, the company focuses primarily on staff possessing the requisite qualifications and expertise to reach the objectives that are set in the operative and administrative areas. We therefore measure the annual expenditure on training and further education, as well as the number of training courses. Personnel costs are always monitored in line with the salary level customary in the industry sector.

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 expansion of regulatory approvals for our drug and the number of external and internal audits are important non-financial control parameters for the company.

# Economic and business report for the 2018 financial year

## Business performance

As in the previous financial year, Biofrontera again succeeded in almost doubling product revenues in 2018. This illustrates the enormous potential that continues to arise for Ameluz® and our red-light LED lamp, BF-RhodoLED®. For the first time, we were able to sell more than 100,000 tubes of our drug worldwide in one year.

A major focus of our work in 2018 in the U.S. was to ensure the successful and correct reimbursement of Ameluz®. As Ameluz® - as a so-called "buy-and-bill" drug - is purchased directly by the physician, the reimbursement risk, as well as the additional work entailed in the reimbursement without a special billing code remains with the physician. This initially reduced willingness to stock up with larger volumes of the new drug. The individual reimbursement code (J-Code) for Ameluz® requested by Biofrontera in January 2017 was granted after the normal application deadlines in January 2018. Biofrontera has thereby cleared another hurdle for the regular reimbursement of Ameluz®. However, the responsible authorities and insurance companies need to update their systems to ensure smooth reimbursement, which also takes time. In the third quarter, we temporarily had to deal with an erroneous restriction on the reimbursement for Ameluz®. However, this restriction was corrected retroactively to 1 July 2018 through our intervention at the Center for Medicare and Medicaid Services (CMS). The last hurdle for a smooth reimbursement of our drug was the publication of the average selling price. Although Biofrontera has reported this average price to the responsible authority (CMS) every quarter since it was launched, it was published for the first time in January 2019. We consequently assume that the main problems with reimbursement have finally been resolved.

Our customers benefited from the increase in reimbursement for the work performed by the physician in connection with PDT treatment. This reimbursement, the so-called CPT codes, has been significantly increased and the physician-relevant codes now exceed the reimbursement for cryotherapy, the treatment of choice for actinic keratoses in the USA. This improved reimbursement will help us to better position PDT as a treatment method in the market.

After two years on the American market, we raised the price of Ameluz® in line with inflation for the first time on 1 October 2018. The price increase was generally accepted by our customers, but led to some extraordinary stockpiling by some doctors and consequently to increased sales in September 2018.

We estimate that the market share of Ameluz® in the U.S. - PDT drug segment is now about 18% (previous year: about 8%) and expect to further increase our market share in the future.

In Germany, the largest European market for Ameluz®, the market share of Ameluz® in the segment of PDT drugs sold by German public pharmacies, was approximately 66% in 2018, compared to approximately 59% in the previous year. With the introduction of daylight-PDT, Ameluz® has once again established itself as a strong market leader in the PDT market compared to competing products. We estimate that in the future daylight-PDT will gain further market share, which to date had been reserved for self-applied topical creams. What is particularly interesting is that Ameluz® is finally reimbursed by the public health insurance funds when prescribed for daylight-PDT. The number of patients who have access to treatment with Ameluz® multiplied in 2018. Biofrontera has used this to reposition itself in the German dermatology market. We have invested in marketing & sales and were able to increase prescriptions for Ameluz® in Germany by about 50% last year.

In Spain, too, the approval of daylight-PDT has led to significant growth. After an approval and reimbursement process lasting almost 18 months, the Spanish authorities have also granted approval to market Ameluz® for basal cell carcinoma (BCC) (we have been able to do this in Germany since the beginning of 2017). However, we had to accept a 27% reduction in our sales price in Spain as of 1 July 2018. We now have to compensate for this margin decrease by boosting volumes and are optimistic that we will be able to do so with our very efficient sales team.

Earnings before income tax for the Biofrontera Group amounted to EUR -19,269 thousand in the 2018 financial year after EUR -16,102 thousand in the previous year. The revenue growth in 2018 did not yet have a positive effect on the business result, in particular due to higher legal and consulting costs and the further expansion of the sales structure in the USA. In addition to the successful expansion of the workforce, the focus in 2018 continued to be on employee training and development.

Biofrontera AG reports a net loss for the year of EUR -9,072 thousand (previous year: EUR -3,995 thousand) in its single-entity financial statements under German commercial law (HGB). The higher net loss for the year is due in particular to the significant increase in legal and consulting costs in connection with the patent litigation in the U.S.

## Biofrontera Group financial position and performance

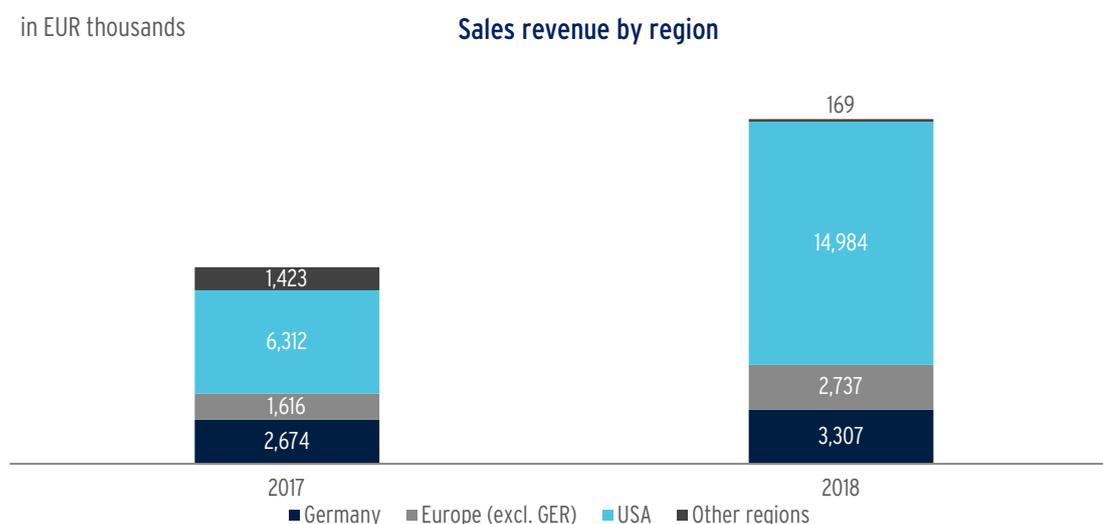
As of 31 December 2018, the scope of consolidation of the Biofrontera Group has not changed compared to 31 December 2017. In addition to Biofrontera AG, the consolidated financial statements as at 31 December 2018 include the subsidiaries Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc.

### Results of operations of the Biofrontera Group

in EUR thousands	2018	2017
Sales revenue	21,107	12,025
Gross profit on sales	16,656	10,310
Research and development costs	(4,427)	(4,225)
General administrative costs	(12,963)	(3,097)
Sales costs	(17,744)	(16,922)
Loss on operations	(18,478)	(13,934)
Interest expenses	(1,784)	(1,133)
Interest income	24	38
Other expenses	(332)	(1,333)
Other income	1,301	260
Loss before income tax	(19,269)	(16,102)
Income tax	10,391	0
Loss after income tax	(8,878)	(16,102)

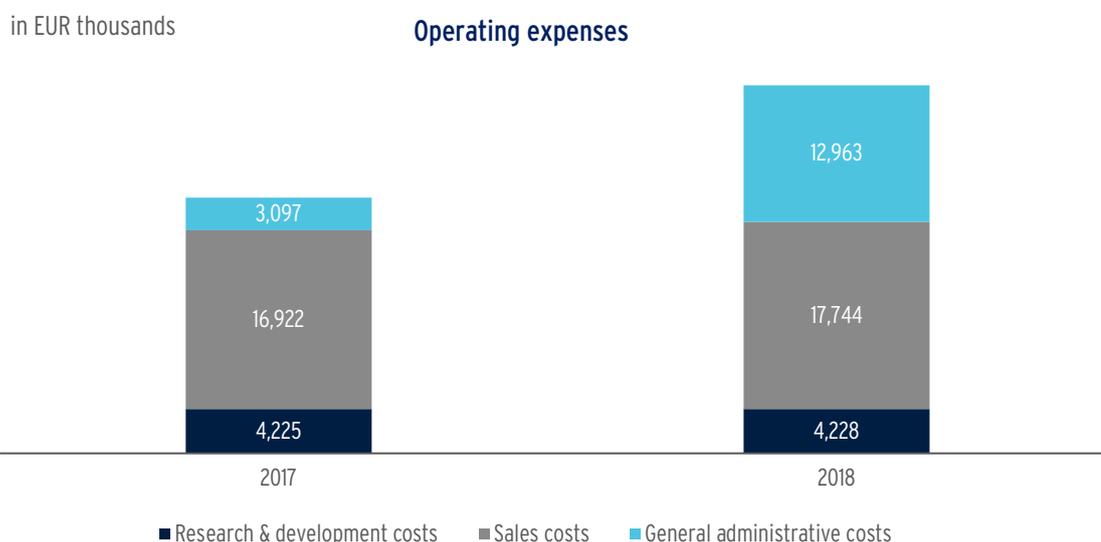
### Sales revenue

The Biofrontera Group generated total revenue of EUR 21,107 thousand in the 2018 reporting year, equivalent to an increase of more than 76% compared to the previous year (previous year: EUR 12,025 thousand). Revenues from product sales almost doubled compared to the previous year (EUR 20,938 thousand; previous year: EUR 10,602 thousand). Sales in the USA continued to develop very positively in the 2018 financial year. US sales increased by 136%, or EUR 8,582 thousand, to a total of EUR 14,894 thousand (previous year: EUR 6,312 thousand). This growth was driven by the further expansion of our sales structures and improvements in the reimbursement of PDT for dermatologists in the USA. Sales revenues in Germany improved by EUR 634 thousand, or 24%, year-over-year to reach EUR 3,307 thousand. In other European countries, sales revenue increased by 69% to reach EUR 2,737 thousand (previous year: EUR 1,616 thousand). The sales revenue growth in Europe is especially due to the introduction of the daylight-PDT, which was approved in March. Sales revenues from other regions amounted to EUR 169 thousand (previous year: EUR 1,423 thousand), which were mainly based on revenue from the development partnership with Maruho.



## Gross profit on sales

In the 2018 reporting year, gross profit on sales increased by EUR 6,346 thousand, to reach EUR 16,656 thousand, compared with EUR 10,310 thousand in the prior-year period. The gross margin fell from 86% in 2017 to 79% in 2018. The decrease in our gross margin was due to the one-off costs included in cost of sales for the introduction of larger production lots and the reduction in sales revenue from other regions.



## Research and development costs

Research and development costs were at the previous year's level and include costs for clinical studies, as well as expenses for regulatory activities, such as the granting, maintenance and expansion of our approvals. Research and development costs remained well below the original forecast of EUR 6 million to EUR 7 million for 2018. This is mainly due to lower costs for clinical trials.

## General administrative costs

General administrative costs amounted to EUR 12,963 thousand in the 2018 financial year and thereby increased by EUR 9,866 thousand to EUR 12,963 thousand (previous year: EUR 3,097 thousand), which was in particular due to higher legal and consulting costs. Additionally, the administrative expenses in the USA increased.

## Sales and marketing costs

Sales and marketing costs totaled EUR 17,744 thousand in the 2018 financial year, thereby rising only slightly compared with the previous year (EUR 16,922 thousand). Sales and marketing costs include the costs of our own sales teams in Germany, Spain, the UK and the USA, as well as marketing expenses. The higher level of sales activities in the USA is reflected both in sales and marketing costs, as well as administrative costs in the USA.

## Loss on operations

Research and development costs, sales and marketing costs, and general administrative costs totaled EUR 35,134 thousand in the 2018 financial year. This corresponds to an increase of TEUR 10,890 or 45% over the previous year of TEUR 24,244. As a result of the unexpectedly high increase in general administrative costs - in particular due to high legal and consulting costs - the result from operations of EUR -18,478 thousand (previous year: EUR -13,934 thousand) was below the level of the previous year despite the significant increase in gross profit from sales.

## Interest expenses

Interest expenses increased by EUR 651 thousand and amounted to EUR 1,784 thousand (previous year: EUR 1,133 thousand), mainly due to interest expenses on the 2017/2022 convertible bonds placed in 2017 and the EIB loan granted in July 2017.

## Other income and expenses

This item mainly includes expenses and income from currency translation.

## Income taxes

Income taxes of EUR 10,391 thousand were reported in the 2018 financial year (previous year: EUR 0 thousand), which are mainly attributable to the initial recognition of deferred tax assets on tax loss carryforwards. These relate in particular to the deferred tax assets on loss carryforwards for Biofrontera Pharma GmbH to be recognized for the first time as at 31 December 2018. The subsidiary has already generated profits in the second half of 2018 due to the increased business volume and it can be assumed that Biofrontera Pharma GmbH will continue to generate positive results in the future and thus use its tax loss carryforwards.

## Net assets of the Biofrontera Group

in EUR thousands	31/12/2018	31/12/2017
Non-current assets	11,546	1,394
Current financial assets	23,642	13,215
Other current assets	3,945	5,238
<b>Total assets</b>	<b>39,133</b>	<b>19,847</b>
Equity	16,356	3,381
Non-current liabilities	15,007	12,355
Current financial liabilities	2,000	1,810
Other current liabilities	5,770	2,301
<b>Total equity and liabilities</b>	<b>39,133</b>	<b>19,847</b>

## Non-current assets

The increase in non-current assets is mainly attributable to the first-time recognition of deferred tax assets on tax loss carryforwards at Biofrontera Pharma GmbH in the amount of the expected positive earnings trend. Deferred tax assets amount to EUR 10,400 thousand (previous year: EUR 0 thousand).

## Current financial assets

The increase in current financial assets reflects liquidity of EUR 19,451 thousand (previous year: EUR 11,083 thousand). Trade receivables amounted to EUR 3,397 thousand as of 31 December 2018, compared to EUR 1,561 thousand in the 2017 financial year. The increase in the 2018 financial year is due to increased sales revenue from product sales.

## Other current assets

Other current assets mainly include inventories amounting to EUR 3,177 thousand (previous year: EUR 3,733 thousand).

## Equity

The Biofrontera Group has equity amounting to EUR 16,356 thousand based on IFRS accounting principles. Equity increased particularly as a result of the issue of new shares in February 2018 with gross proceeds totaling EUR 24,000 thousand, as well as allocations to capital reserves from the conversion of employee options in the amount of EUR 433 thousand and from the exercise of conversion rights from the 2016/2021 and 2017/2022 convertible bonds in the amount of EUR 77 thousand.

## Non-current liabilities

Non-current liabilities include financial liabilities of EUR 13,462 thousand (previous year: EUR 12,355 thousand) and the formation of long-term provisions for legal costs of EUR 1,545 thousand (previous year: EUR 0 thousand), the current portion of which is shown under other current liabilities. A total of EUR 3,184 thousand was accrued in 2018 for the litigation cost risk in connection with the patent litigation in the USA. Of this amount, EUR 1,545 thousand is reported under non-current provisions and EUR 1,639 thousand under current provisions.

## Current financial liabilities

At EUR 2,000 thousand (previous year: EUR 1,811 thousand), current financial liabilities are slightly above the level of the previous year.

## Other current liabilities

Other current liabilities amounted to EUR 5,770 thousand (previous year: EUR 2,301 thousand) and increased in particular due to the above-mentioned formation of provisions for litigation costs in the 2018 financial year in the amount of EUR 1,639 thousand (previous year: EUR 0 thousand).

## Financial position of the Biofrontera Group

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

in EUR thousands	2018	2017
<b>Statement of cash flows</b>		
Cash flow from operating activities	-13,434	-13,119
Cash flow from investing activities	-511	-375
Cash flow from financing activities	22,274	9,451
Cash and cash equivalents	19,451	11,083
Non-current financial liabilities	13,462	12,355
Current financial debt	165	170
Net liquidity	5,824	-1,442

Net cash flow from operating activities amounted to EUR -13,434 thousand and thereby remained almost unchanged at the level of the previous year.

Net cash flow from investing activities decreased by EUR 136 thousand to EUR -511 thousand.

Net cash flow from financing activities increased year-over-year to EUR 22,274 thousand (previous year: EUR 9,451 thousand), in particular from proceeds from the issue of new shares with gross issue proceeds totaling EUR 24,000 thousand compared with financial year 2017.

Cash and cash equivalents increased due to the proceeds from the capital increase in February 2018 and amounted to EUR 19,451 thousand as of 31 December 2018 (previous year: EUR 11,083 thousand). From today's perspective, the company has sufficient liquidity to implement Biofrontera's strategy.

The non-current liabilities have a term until 2022 and consist of the 2017/2022 Convertible Bond and the loan from the European Investment Bank.

The EIB loan is unsecured and guaranteed by our main 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 million, with a further tranche of EUR 5 million being drawn down after the reporting date in February 2019. A further tranche of EUR 5 million can be drawn after certain milestones have been reached. Each tranche must be paid back within five years after it has been made available. The loan contains three different interest components. A variable interest component, entailing quarterly interest payments on the outstanding amounts based on 3-month EURIBOR plus a risk premium; a fixed component at 6% per annum which is due at term-end; and 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.

## Biofrontera AG financial position and performance

### Results of operations of Biofrontera AG

in EUR thousands	2018	2017
Sales revenue	3,019	2,598
Other operating income	897	45
Cost of materials	(2,899)	(2,502)
Personnel costs	(3,028)	(2,429)
Depreciation and amortization	(31)	-36
Other operating expenses	(8,030)	(2,761)
Other interest and similar income	2,676	2,282
Interest and similar expenses	(1,676)	(1,191)
Other taxes	(1)	(1)
Net loss for the year	(9,073)	(3,995)

The revenues reported in the single-entity financial statements under German commercial law mainly comprise revenues from services provided within the Biofrontera Group. In line with the higher revenues, the costs of purchased services increased.

As part of the further development of business activities, additional employees were hired and resulted in higher personnel expenses in the reporting period.

The increase in operating expenses by EUR 5,269 thousand is mainly due to higher legal and consulting costs. 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 loan provided by the EIB.

### Net assets of Biofrontera AG

in EUR thousands	31 December 2018	31 December 2017
Non-current assets	32,270	32,283
Receivables due from affiliated companies	80,605	67,838
Cash and balances with banks	16,147	8,113
Other assets	367	426
<b>Total assets</b>	<b>129,389</b>	<b>108,661</b>
Equity	110,408	94,491
Provisions	4,732	744
Bonds	2,595	2,745
Liabilities to banks	10,990	10,380
Other liabilities	664	301
<b>Total equity and liabilities</b>	<b>129,389</b>	<b>108,661</b>

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 increased due to the capital increase in February 2018 from EUR 8,113 thousand to EUR 16,147 thousand. For further details on the financial position, please refer to the presentation of the consolidated financial position.

Biofrontera AG has equity of EUR 110,408 thousand as of 31 December 2018 on the basis of accounting policies pursuant to the German Commercial Code (HGB) (previous year: EUR 94,491 thousand).

The increase in provisions is mainly due to the formation of provisions for legal costs in the amount of EUR 3,489 thousand (previous year: EUR 0 thousand).

The bonds include the 2017/22 Convertible Bond. The decrease results from the exercised conversions and the early repayment of the 2016/21 Convertible Bond.

The increase in liabilities to banks results from the interest payable at maturity on the loan provided by the EIB.

## Assessment of the financial position

As a result of the cash inflows from the capital increase carried out in February 2018 and the inflow of a further tranche of EUR 5.0 million from the EIB loan, the company has sufficient funds at its disposal to continue financing its business activities.

## Comparison of actual and forecast business performance

The Biofrontera Group showed a solid financial performance in the reporting year 2018. Detailed comparisons of projected targets and actual results are shown in the table below:

Key figures	Forecast 2018	Revised Forecast 2018	Target achievement as of 31/12/2018
Group sales revenue	EUR 16 to 20 million	EUR 19 to 22 million	EUR 21 million
Research and development costs	EUR 6 to 7 million		EUR 4 million
General administrative costs	EUR 7 to 8 million		EUR 13 million
Sales and marketing costs	EUR 18 to 20 million		EUR 18 million
Loss before income tax	EUR -15 to -16 million		EUR -19 million
Loss after income tax	EUR -15 to -16 million	EUR -8 to -10 million	EUR -9 million

## Assessment of the course of business by the Management Board

The 2018 financial year was an exceptionally successful year for Biofrontera. In particular, the strong sales revenue growth in the USA contributed to the strong performance. The approval extension to daylight-PDT in the EU had a positive effect on sales growth in Europe. As a result, we not only achieved the originally forecast revenue target for 2018, but also significantly exceeded it with more than EUR 21 million.

Research and development costs remained well below the original forecast. This is mainly due to lower costs for clinical trials.

General administrative expenses were higher than forecast. This is due to rising costs for legal advice in connection with the lawsuits filed by Deutsche Balaton and, above all, legal disputes with our competitor Dusa Pharmaceuticals Inc. in the U.S.

In 2018, Biofrontera continued to invest in marketing and sales activities in the EU and the U.S. and hired additional employees as planned, with employee growth significantly slower than in the previous year. Sales and marketing costs in the 2018 financial year were in line with our guidance.

In an ad hoc announcement dated 10 October 2018, the company announced a revised forecast for sales revenue and the net result for 2018. The adjustment took into account a charge against earnings from the recognition of provisions for future legal costs, which includes the estimated costs for legal disputes with Dusa Pharmaceuticals Inc. and the Deutsche Balaton Group, in each case until a ruling in the next instance.

An improvement in the consolidated net result derives from the deferred tax assets on loss carryforwards of Biofrontera Pharma GmbH to be reported for the first time as of 31 December 2018. The subsidiary has already generated profits in the second half of 2018 thanks to the increased business volume and it can be assumed that Biofrontera Pharma GmbH will continue to generate positive results in the future, and thereby be able to utilize its tax loss carryforwards. At EUR -9 million, the consolidated net result was in line with the revised forecast.

The lower than expected result in Biofrontera AG's single-entity financial statements under German commercial law (HGB) is mainly due to the increased costs for legal advice.

## Outlook and forecast

### Framework conditions

Health expenditure worldwide will continue to grow. People are living to an increasingly advanced age thanks to improved medical care, with the proportion of the ageing population thereby steadily increasing. In addition, lifestyle and old age diseases - mostly chronic diseases - are playing an increasing role, many of them also due to lifestyle changes. The sharp increase in the occurrence of sun-induced non-melanoma skin cancer, as well as the associated medical treatment and prophylaxis are consequences of this. With PDT, the company considers itself to be excellently positioned in both Europe and the USA.

The sales structure in the U.S. subsidiary is largely complete. The elimination of reimbursement problems for physicians in the USA, our most important market, and the receipt of the regulatory approval for Ameluz® in combination with daylight-PDT in the EU, should exert a positive impact on business performance in the 2019 financial year. Biofrontera will continue to be present at the most important American dermatology conferences and will aim for broad-based reporting about white skin cancer and Ameluz® among physicians and the general public. In Europe, we expect a significant growth spurt from the growing acceptance of daylight- PDT.

In addition, the agreed or currently negotiated cooperation projects with Maruho Co. Ltd. in Japan will offer the company both economic and strategic advantages.

The table below summarizes the company's guidance for the 2019 financial year without taking the acquisition of Cutanea Life Sciences, Inc. into consideration:

Key figures	Forecast 2019
Group sales revenue	EUR 35 to 40 million
Research and development costs	EUR 5 to 7 million
General administrative costs	EUR 10 to 12 million
Sales and marketing costs	EUR 20 to 22 million
Loss on operations	EUR -7 to -9 million
Loss before income tax	EUR -9 to -11 million

### Forecast of key financial figures

For the 2019 financial year, the company expects revenue from product sales to be in the range between EUR 35 million and EUR 40 million. Despite the positive trend in overall conditions, it remains very difficult to plan sales revenue growth, thereby leading to a considerable fluctuation range in achievable sales revenues.

Under the aforementioned conditions, the Biofrontera Group will achieve a result before income tax of approximately EUR -7 million to EUR -9 million and a consolidated net result of around EUR -9 million to EUR -11 million in 2019. The achievement of this result depends significantly on sales revenue trends. During the course of the year, we expect to reach the operating break-even point in the fourth quarter.

From today's perspective, the Biofrontera has sufficient liquidity to implement its strategy, even taking into account the further utilization of a further tranche of the EIB loan amounting to EUR 5.0 million at the beginning of 2019.

Biofrontera expects a further slight increase in the number of employees in 2019 in order to continue the appropriate acceleration and support of the company's growth.

For the individual financial statements of Biofrontera AG, we continue to expect a net loss for the year in 2019, which, however, will be significantly lower than in 2018.

### Planned regulatory progress

Patient recruitment for the Phase III trial to obtain U.S. regulatory approval for the BCC indication began in September 2018. We expect recruitment to be completed during the first half of 2020. The Phase III trial for actinic keratoses of the trunk and extremities was completed in the first quarter of 2019. Initial results and an application for approval extension are expected during the course of the year.

## Forecast of further key financial figures

Biofrontera will also continue to invest in the expansion of Ameluz's indications. In addition, as in the past, considerable costs will be incurred for maintaining the existing approvals. In total, Biofrontera expects research and development costs of approximately EUR 5 million to EUR 7 million.

Sales and marketing costs represent by far the largest operative cost block. We expect another slight increase in such costs in 2019, principally because of the staff hired during the course of last year. The related costs will be expensed on a full-year basis in 2019. Besides this, we will occasionally hire further staff and invest to a greater extent in conferences and marketing activities. We expect that sales and marketing costs will be between EUR 20 million and EUR 22 million.

Administrative costs will remain largely unchanged compared to 2018 and will be between approximately EUR 9 million and EUR 11 million.

## Cooperation with Maruho and acquisition of Cutanea Life Sciences, Inc.

Sales and development costs of less than EUR 1.0 million are expected from the research cooperation with Maruho agreed in March 2019.

This forecast does not include any effects of the Cutanea Life Sciences, Inc. ("Cutanea") acquisition on the balance sheet or income statement. However, it is assumed that in 2019 this will not lead to any negative changes in the result from operating activities and also no negative effects on the Biofrontera Group's liquidity position. The sale of the new products Aktipak® and Xepi™ is expected to generate sales revenue in the mid-single digit million range, which are not included in the aforementioned forecast. Additional marketing costs incurred in 2019 for the commercialization of the products acquired as part of the Cutanea acquisition will be pre-financed by Maruho and will consequently not affect total sales costs in 2019.

## 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 2018 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 decision-making processes, thereby forming an integral element of planning and controlling processes Group-wide. Risk management and control mechanisms are coordinated with each other. These ensure that risks of relevance to 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 are involved in Group-wide risk policy 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 and all the processes relevant to the preparation of the financial statements.

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

## 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.

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.

## Liquidity, profitability and access to capital markets

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.

In this connection, the company's continued existence 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 currently has sufficient liquidity available due to the issuance of subordinated convertible bonds in January 2017, the drawdown of several tranches totaling EUR 15 million from the European Investment Bank loan, as well as especially due to the proceeds from the capital increase completed in February 2018.

However, the risk still exists that Biofrontera's profitability cannot be achieved or cannot be achieved sustainably, and that its self-financing potential would consequently prove insufficient. On the basis of its previous, invariably successful experience with capital measures, the Management Board assumes that it can continue to secure the liquidity it requires for its business activities. Should – contrary to expectations – these valid estimates not be realized, a going concern risk would ensue.

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 liquidity planning in order to be able to take any necessary measures in good time to achieve our targets. To ensure payment security, liquid funds are kept available so that all the Group's scheduled payment obligations can be fulfilled on their respective due dates. The level of this liquidity reserve is reviewed regularly and adjusted to current circumstances where necessary.

On 25 March 2019, Biofrontera Inc., through its wholly owned subsidiary Biofrontera Newderm LLC, USA entered into an agreement with Maruho for the acquisition of all shares in Cutanea Life Sciences, Inc. Our acquisition of Cutanea Life Sciences, Inc. may not be successful, which could adversely affect our ability to develop and commercialize products and product candidates, impact our cash position, increase our expense and present significant distractions to our management. We mitigate this risk by monitoring monitoring the integration of Cutanea Life Sciences, Inc.

## 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.

## 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 currently has only one approved drug, Ameluz®, which it markets in Europe and the USA. A risk exists that Ameluz® may not be established sufficiently or sustainably on the market.

It is possible that the product Ameluz® will not prove to be successful in competition with other treatment options for actinic keratosis or BCC. Despite the greater effectiveness of Ameluz®, doctors may resort to other products more often than expected because of the higher treatment costs associated with PDT, for which they frequently do not obtain any, or only insufficient, remuneration from the healthcare systems.

Competitive disadvantages over its competitors are also possible due to advantages with regard to the indication spectrum of competing products.

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.

## 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 intervening period 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.

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 drug side effects 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.

## Sales 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.

Reorientations in the respective healthcare systems and changes in the reimbursement behavior of drug reimbursors as well as market barriers in the relevant markets may result in the risk of insufficient or unsustainable market penetration. Ameluz's competitive position may also be adversely affected by product characteristics that are not optimally perceived in the respective market in comparison with competing products.

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 & 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® lamp to reduce our dependence on suppliers in this area, too.

## 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.

## 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 can influence the structures relevant for Biofrontera in the respective healthcare sector.

On 23 June 2016, the electorate in the United Kingdom voted in favor of leaving the European Union, commonly referred to as Brexit. On 29 March 2017, the country formally notified the European Union of its intention to withdraw from 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, Brexit 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, Brexit 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.

## 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.

## 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.

## 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.

Opportunities include the expansion of Ameluz® indications for BCC in the USA and acne, the exploitation of market potential, and the research collaboration with Maruho in preparation for the clinical development of Tacrolimus in Biofrontera's nanoemulsion.

On 19 March 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.

Further, at the time of publication of the annual report, Maruho and Biofrontera are negotiating a cooperation on the research and development of further indications for Ameluz® for the treatment of acne. On 19 March 2019, Maruho and Biofrontera signed a (non-binding) term sheet in this regard. Currently, a proof of concept trial and maximal use pharmacokinetic-trial are planned, the costs of which will be borne by Maruho in an amount yet to be specified. These trials will possibly be followed by additional clinical trials required for US market approval of further indications. Under the term sheet, it is also envisaged that Biofrontera will grant Maruho a license for marketing Ameluz® in parts of Asia and Oceania, the terms and conditions of which have yet to be negotiated.

Additionally, the company sees further opportunities through the acquisition of Cutanea Life Sciences, Inc. The opportunities consist of advantages to compete more effectively insofar as Cutanea's products and expertise supplement Biofrontera's existing core business. The expansion of the U.S. product portfolio with two FDA-approved drugs represented an opportunity to accelerate the company's growth.

On 25 March 2019, Biofrontera Inc., through its wholly owned subsidiary Biofrontera Newderm LLC, USA ("Biofrontera"), which was founded on 20 March 2019, entered into an agreement with Maruho for the acquisition of all shares in Cutanea Life Sciences, Inc., USA ("Cutanea"). Cutanea has been marketing AKTIPAK®, a prescription gel for the treatment of acne, as well as Xepi™, a prescription cream for the treatment of impetigo, since November 2018. The objective of the acquisition of Cutanea by Biofrontera is to effectively exploit the sales potential of AKTIPAK® and Xepi™ in the USA in order to strengthen Biofrontera's US market presence. 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 restructured business activities (start-up costs). A purchase price equal to the start-up costs actually incurred must be paid to Maruho by 2023. Subsequently, 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 operating costs that may be incurred

during the first three months after completion of the transaction. Maruho will also indemnify Biofrontera and Cutanea against all liabilities relating to or resulting from the period prior to the transaction.

## Overall opportunity and risk situation at Biofrontera

The Management Board of the Biofrontera Group considers the overall risks to be controllable and does not consider the continued existence of the company to be jeopardized. The Management Board trusts the effectiveness of the risk management system with regard to the positive and negative changes in the environment and the requirements of current business. The assessment is based on various factors, which are summarized below:

- The Management Board of the Biofrontera Group considers the company to be well positioned to take advantage of opportunities, as well as to successfully manage any adverse events that may occur.
- To date, the Group has been able to meet its payment obligations at all times. Thanks to the capital increase carried out in the year under review in the course of the U.S. IPO, the provision of a further tranche of the EIB in February 2019 and the higher sales revenue growth, the liquidity position improved significantly compared to previous years.
- Having already received regulatory approval for BCC in Europe in 2017, we further strengthened our market position in the EU with the approval of Ameluz® in combination with daylight-PDT in the year under review. We hope to see a further increase in the market potential of Ameluz® from our recently completed study for the treatment of actinic keratoses on the extremities, trunk and neck with photodynamic therapy. To further enhance our growth opportunities in the U.S. market, we are currently conducting a study on the treatment of superficial basal cell carcinoma (BCC) with Ameluz® in combination with our red-light lamp BF-RhodoLED® in the U.S., for which we started recruiting patients in September 2018.
- In the year under review, the sales organization in the U.S. was further expanded. Thanks to this and by improving the reimbursement options for PDT with Ameluz®, market penetration was significantly improved. This enabled us to make better leverage our opportunities in the past financial year and continue to achieve strong growth in our sales revenue and reputation.
- 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.

## 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® in the USA. 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 believes that these claims lack merit and intend to defend against them vigorously, the company 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. Although the court made a preliminary finding that DUSA is reasonably likely to prevail on its non-patent claims, the court's ruling is not final and Biofrontera continues to vigorously contest DUSA's allegations. 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 may incur significant costs in defending these claims. In addition to internal human resources, we also mandate U.S. lawyers to defend the claims. The costs incurred by Biofrontera as a result would not be reimbursed by the plaintiff in the event of a positive outcome of the proceedings, due to the characteristics of the U.S. legal system.

In July 2018, Biofrontera Inc. brought a lawsuit against DUSA Pharmaceuticals Inc. 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. The court has allowed Biofrontera's tortious

interference claims to proceed to discovery. Biofrontera has filed an amended complaint with additional allegations for its sampling and pricing claims. DUSA has moved to dismiss Biofrontera's amended complaint, and DUSA's motion remains pending.

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 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, and remains pending. Deutsche Balaton AG, Wilhelm Konrad Thomas Zours and Delphi Unternehmensberatung AG are among our major shareholders—see "Item 7—Major Shareholders and Related Party Transactions" for more information on their shareholdings.

In June 2017, the company was served with a claim for rescission and nullity brought by the shareholder Deutsche Balaton AG, in which it sued for the nullity of certain resolutions of the Annual General Meeting on May 24, 2017. The claim was dismissed by the Regional Court of Cologne in December 2017. In response to Deutsche Balaton AG's appeal, the Cologne Higher Regional Court upheld the claim in November 2018. The Cologne Higher Regional Court did not allow the Federal Supreme Court to review the ruling. As the Company considers the judgment of the Cologne Higher Regional Court to be incorrect, it has filed an appeal for non-admission with the Federal Supreme Court. A decision of the Federal Court of Justice has not yet been issued.

Deutsche Balaton AG has filed 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 already rejected by the Cologne Regional Court in November 2017 without hearing the company. Deutsche Balaton AG has filed an appeal against this. The appeal has been submitted to the Cologne Higher Regional Court for decision. 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 will have ruled on the appeal by Deutsche Balaton AG. Delphi Unternehmensberatung AG had already filed a request for a special audit with the same content at the company's Annual General Meeting on May 24, 2017, which was rejected. The company considers the allegations made in the special audit motions to be insubstantial; from the company's point of view, they serve solely to discredit the Executive Board and Supervisory Board of Biofrontera AG.

Deutsche Balaton AG has further brought a claim for rescission and nullity against the negative resolutions of the Annual General Meeting of 11 July 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.

## 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 2018 financial year and the total accumulated number of stock options issued to the Management Board were as follows as of 31 December 2018:

	Prof. Dr. Hermann Lübbert	Thomas Schaffer	Christoph Dünwald
Non-performance-based salary component 2018	EUR 366 thousand	EUR 241 thousand	EUR 264 thousand
Non-performance-based salary component 2017	EUR 366 thousand	EUR 241 thousand	EUR 242 thousand
Performance-based salary component 2018	EUR 80 thousand	EUR 70 thousand	EUR 50 thousand
Performance-based salary component 2017	EUR 76 thousand	EUR 67 thousand	EUR 48 thousand
Income from the exercise of stock options 2018	EUR 94 thousand	EUR 83 thousand	-
Income from the exercise of stock options 2017	-	-	-
Stock options (31/12/2018)	276,850	140,000	140,000
Fair value when granted (2018)	EUR 423 thousand	EUR 230 thousand	EUR 230 thousand
Stock options (31 December 2017)	236,850	125,000	90,000
Fair value when granted (2017)	EUR 299 thousand	EUR 145 thousand	EUR 112 thousand
thereof granted 2018	80,000	50,000	50,000
thereof granted 2017	70,000	40,000	40,000

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. The measurement factors are set at the end of each financial year for the following financial year in a mutually agreed 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 Management Board members 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. In 2010, the Chief Executive Officer was granted 35,000 options, and the other Management Board member was granted 20,000 options, and in 2011, the Chief Executive Officer was granted 30,000 options and the other Management Board member was granted 20,000 options on this basis. In 2012, a further 40,000 options were granted to the Chief Executive Officer, and an additional 25,000 options were granted to the other Management Board member. In the 2013 financial year, the Chief Executive Officer was granted 30,000 options, and the other Management Board member was granted 15,000 options, and in the 2014 financial year, 16,850 options were granted to the Chief Executive Officer, and 20,000 options were granted to the other Management Board member. No options were granted to the Management Board members in 2015. In the 2016 financial year, 80,000 options were granted to the Chief Executive Officer, and the other Management Board members were each granted

50,000 options. In the 2017 financial year 70,000 options were granted to the Chief Executive Officer, and the other Management Board members were each granted 40,000 options. In fiscal year 2018, 80,000 options were granted to the Chairman of the Management Board and 50,000 options each to the other members of the Management Board.

Options granted in the 2010 financial year forfeited in November 2016 and options granted in the 2100 financial year forfeited in September 2017.

## 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 31 December 2018 on the basis of the mandatory disclosures by the shareholders can be found in the notes to the consolidated financial statements under item 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 item 5. *Subscribed capital, capital reserve, authorized capital*.

### Share capital

The detailed presentation of share capital as at 31 December 2018 is provided in the notes to the consolidated financial statements under item 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 item 5. *Subscribed capital, capital reserve, authorized capital*.

### Authorized capital

The company's share capital was conditionally increased by up to EUR 4,116,855 by the issuing of up to 4,116,855 new ordinary registered no par value shares (Authorized Capital I). The purpose of the conditional capital increase is (i) to ensure the granting of warrant rights and the agreement of warrant obligations in accordance with the bond conditions and (ii) to ensure the fulfilment of conversion rights and the fulfilment of conversion obligations in accordance with the bond conditions, which are issued, agreed and guaranteed by the company or its direct or indirect majority-owned subsidiaries (affiliated companies) in the period up to 27 August 2020, based on the authorization of the Annual General Meeting held on 28 August 2015. The conditional capital increase is to be implemented only in the event that financial instruments are issued based on the authorization of the Annual General Meeting held on 28 August 2015, and only insofar as the holders or creditors of financial instruments issued by the company exercise their warrant or conversion rights or fulfil their warrant or conversion obligations. The new shares carry dividend rights from the start of the financial year in which they are issued. The Management Board is authorized to determine the further details of the implementation of the conditional capital increase, subject to the approval of the Supervisory Board. The Supervisory Board is authorized to amend Section 7 of the bylaws in accordance with the use of conditional capital, and after the expiry of all warrant and conversion periods.

The company's share capital is conditionally increased by EUR 346,900 by the issuing of up to 346,900 no par value registered shares (Authorized Capital III). The purpose of the conditional capital increase is solely to fulfil the warrants granted up to 1 July 2015 on the basis of the authorization of the Annual General Meeting held on 2 July 2010. The conditional capital increase is implemented only insofar as holders of the issued warrants exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay cash settlement in order to fulfil the warrants. The new shares are dividend-entitled from the start of the financial year in which they are issued by the exercise of warrants.

The company's share capital is conditionally increased by EUR 1,814,984 by the issuing of up to 1,814,984 no par value registered shares (Conditional Capital V). The purpose of the conditional capital increase is solely to fulfil the warrant rights granted up to 27 August 2020 on the basis of the authorization of the Annual General Meeting held on 28 August 2015. The conditional capital increase is to be implemented only insofar as holders of the issued warrants exercise their right to purchase shares in the company, and the company does not grant any of its own shares or pay cash settlement in order to fulfil the warrants. The new shares are dividend-entitled from the start of the financial year in which they are issued by the exercise of warrants. The Supervisory Board is authorized to amend Section 7 of the bylaws in accordance with the use of conditional capital and after the expiry of all warrant and conversion periods.

## 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 [www.biofrontera.com](http://www.biofrontera.com) in the section "Investors", subsection "Corporate Governance".

Leverkusen, 25 April 2019  
Biofrontera AG



Prof. Dr. Hermann Lübbert  
Chief Executive Officer



Christoph Dünwald  
Chief Sales and Marketing Officer



Thomas Schaffer  
Chief Financial Officer

## 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's financial position, cash flows and results of operations, and that the combined management report for both the company and the Group presents the business performance, including the business results and the position of the Biofrontera Group and of Biofrontera AG, in such a way that a true and fair view is conveyed, and that the main opportunities and risks relating to the anticipated performance of the Biofrontera Group and Biofrontera AG are described.

Leverkusen, 25 April 2019  
Biofrontera AG



[Signed] Prof. Dr. Hermann Lübbert



[signed] Thomas Schaffer



[signed] Christoph Dünwald

# Consolidated financial statements as of 31 December 2018

## Consolidated balance sheet as of 31 December 2018

### Assets

in EUR thousands		31 December 2018	31 December 2017
<b>Non-current assets</b>			
Tangible assets	(1)	794	746
Intangible assets	(1)	352	648
Deferred taxes	(8)	10,400	-
<b>Total non-current assets</b>		<b>11,546</b>	<b>1,394</b>
<b>Current assets</b>			
<b>Current financial assets</b>			
Trade receivables	(3)	3,397	1,561
Other financial assets	(4)	794	571
Cash and cash equivalents	(7)	19,451	11,083
<b>Total current financial assets</b>		<b>23,642</b>	<b>13,215</b>
<b>Other current assets</b>			
Inventories	(2)		
Raw materials and supplies		1,098	1,516
Unfinished products		320	485
Finished products and goods		1,759	1,732
<b>Total inventories</b>		<b>3,177</b>	<b>3,733</b>
Income tax reimbursement claims	(6)	53	52
Other assets	(5)	715	1,454
<b>Total other current assets</b>		<b>3,945</b>	<b>5,239</b>
<b>Total current assets</b>		<b>27,587</b>	<b>18,454</b>
<b>Total assets</b>		<b>39,133</b>	<b>19,848</b>

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

## Equity and liabilities

in EUR thousands		31 December 2018	31 December 2017
<b>Equity</b>	(9)		
Subscribed capital		44,632	38,417
Capital reserve		117,109	100,769
Capital reserve from foreign currency conversion		(2)	700
Loss carried forward		(136,505)	(120,403)
Loss for the period		(8,878)	(16,102)
<b>Total equity</b>		<b>16,356</b>	<b>3,381</b>
<b>Non-current liabilities</b>			
Non-current financial debt	(10)	13,462	12,355
Other non-current provisions	(12)	1,545	-
<b>Total non-current liabilities</b>		<b>15,007</b>	<b>12,355</b>
<b>Current liabilities</b>			
<b>Current financial liabilities</b>			
Trade payables	(11)	1,806	1,621
Current financial debt	(10)	165	170
Other financial liabilities		29	20
<b>Total current financial liabilities</b>		<b>2,000</b>	<b>1,811</b>
<b>Other current liabilities</b>			
Other provisions	(12)	2,891	562
Other current liabilities	(13)	2,879	1,739
<b>Total other current liabilities</b>		<b>5,770</b>	<b>2,301</b>
<b>Total current liabilities</b>		<b>7,770</b>	<b>4,112</b>
<b>Total equity and liabilities</b>		<b>39,133</b>	<b>19,848</b>

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

## Consolidated statement of comprehensive income for the financial years 2018 and 2017

in EUR thousands		2018	2017
Sales revenue	(15)	21,107	12,025
Cost of sales	(16)	(4,451)	(1,715)
<b>Gross profit from sales</b>		<b>16,656</b>	<b>10,310</b>
<b>Operating expenses</b>			
Research and development costs	(17)	(4,427)	(4,225)
General administrative costs	(19)	(12,963)	(3,097)
Sales costs	(18)	(17,744)	(16,922)
<b>Loss from operations</b>		<b>(18,478)</b>	<b>(13,934)</b>
Interest expenses	(20)	(1,614)	(1,048)
Effective interest expenses	(20)	(170)	(85)
Interest income	(20)	24	38
Other expenses	(21)	(332)	(1,333)
Other income	(21)	1,301	260
<b>Loss before income tax</b>		<b>(19,269)</b>	<b>(16,102)</b>
Income tax	(22)	10,391	-
<b>Loss for the period</b>		<b>(8,878)</b>	<b>(16,102)</b>
<b>Expenses and income not included in</b>			
Items which may in future be regrouped into the profit and loss statement under certain conditions		(702)	854
Translation differences resulting from the conversion of foreign business operations			
<b>Other income total</b>		<b>(702)</b>	<b>854</b>
<b>Total loss for the period</b>		<b>(9,580)</b>	<b>(15,248)</b>
Basic/diluted earnings per share	(23)	(0,20)	(0,42)

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

## Consolidated statement of changes in equity for the financial years 2018 and 2017

(in EUR thousands except for share information)	Ordinary shares	Subscribed capital	Capital reserve	Capital from foreign currency conversion adjustments (OCI)	Accumulated loss	Total
<b>Balance as of 1 January 2017</b>	<b>37,722,433</b>	<b>37,722</b>	<b>98,677</b>	<b>(154)</b>	<b>(120,403)</b>	<b>15,842</b>
Conversion from convertible bond 2016/2021	26,700	27	74	-	-	101
Conversion from convertible bond 2017/2022	667,695	668	1,837	-	-	2,505
Foreign currency conversion adjustment	-	-	-	854	-	854
Increase in capital reserve from the stock option program	-	-	181	-	-	181
Loss for the period	-	-	-	-	(16,102)	(16,102)
<b>Balance as of 31 December 2017</b>	<b>38,416,828</b>	<b>38,417</b>	<b>100,769</b>	<b>700</b>	<b>(136,505)</b>	<b>3,381</b>
Capital Increase	6,000,000	6,000	18,000	-	-	24,000
Costs of equity procurement	-	-	(2,432)	-	-	(2,432)
Conversion from convertible bond 2016/2021	6,874	7	26	-	-	33
Conversion from convertible bond 2017/2022	13,472	13	51	-	-	64
Conversion of stock options from the stock option program	195,500	195	433	-	-	628
Foreign currency conversion adjustment	-	-	-	(702)	-	(702)
Increase in capital reserve from the stock option program	-	-	262	-	-	262
Loss for the period	-	-	-	-	(8,878)	(8,878)
<b>Balance as of 31 December 2018</b>	<b>44,632,674</b>	<b>44,632</b>	<b>117,109</b>	<b>(2)</b>	<b>(145,383)</b>	<b>16,356</b>

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

## Consolidated cash flow statement for the financial years 2018 and 2017

in EUR thousands	01.01.-31.12.2018	01.01.-31.12.2017
<b>Cashflows from operations</b>		
Loss before income tax	(19,269)	(16,102)
Adjustments to reconcile loss before income tax to cash flow into operations		
<b>Income tax</b>	(9)	-
<b>Financial result</b>	1,784	1,094
<b>Depreciation</b>	754	884
<b>Other non-current provisions</b>	1,545	-
<b>Losses from disposal of assets</b>	5	-
<b>Non-cash (income) and expenses</b>	(328)	1,080
Changes in operating assets and liabilities		
Trade receivables	(1,836)	63
Other assets and income tax assets	(149)	173
Inventories	368	(86)
Trade payables	185	(1,010)
Provisions	2,366	711
Other liabilities	1,150	74
<b>Net cash flow used in operational activities</b>	<b>(13,434)</b>	<b>(13,119)</b>
<b>Cash flow from investment activities</b>		
Purchase of intangible and tangible assets	(513)	(397)
Interest received	-	6
Proceeds from sale of intangible and tangible assets	2	16
<b>Net cash flow used in investment activities</b>	<b>(511)</b>	<b>(375)</b>
<b>Cashflows from financing activities</b>		
Proceeds from the issue of shares	24,000	-
Costs of equity procurement	(1,768)	(664)
Proceeds from issuing convertible bonds 2017/2022	-	4,999
Proceeds from exercise of employee stock options	628	-
Proceeds from drawing down EIB loans	-	10,000
Cash outflow for EIB loan procurement costs	-	(650)
Interest paid	(536)	(598)
Repayment of warrant bond 2009/2017	-	(5,226)
Proceeds from repayment of option bonds 2009/2017	-	1,590
Repayment of convertible bond 2016/2021	(50)	-
<b>Net cash flows provided by financing activities</b>	<b>22,274</b>	<b>9,451</b>
Net increase/(decrease) in cash and cash equivalents	8,329	(4,043)
Changes from exchange rate differences	39	-
Cash and cash equivalents at the beginning of the period	11,083	15,126
<b>Cash and cash equivalents at the end of the period</b>	<b>(27)</b>	<b>11,083</b>

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

# Notes to the consolidated financial statements as of 31 December 2018

## 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 Wakefield, Massachusetts, U.S., research, develop and market dermatological products.

## Summary of significant accounting policies

### Basis for preparation of the consolidated financial statements

The consolidated financial statements for Biofrontera AG for the financial year from 1 January 2018 to 31 December 2018 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.

Biofrontera AG is the parent company, which prepares consolidated financial statements for the group companies. The consolidated financial statements as at 31 December 2018 are presented in euros (EUR) or thousands of euros. Rounding differences can arise in the tables due to commercial rounding.

On 25 April 2019, the Management Board approved the consolidated financial statements for the financial year ending 31 December 2018 for publication and forwarding to the Supervisory Board.

### Changes in accounting standards

The accounting policies applied are consistent with those applied on 31 December 2017, with the exception of the new and revised standards and interpretations described below that were applied for the first time starting with the 2018 financial year.

Standard	Description	Mandatory application for Biofrontera	Effects
Amendment to IFRS 2	Classification and Measurement of Share-based Payment Transactions	1 January 2018	No effects
Amendment to IFRS 4	Applying IFRS 9 Financial Instruments with IFRS 4 Insurance Contracts	1 January 2018	No effects
IFRS 9	Financial Instruments	1 January 2018	See below
IFRS 15	Revenue from Contracts with Customers	1 January 2018	See below
Amendment to IFRS 15	Effective date of IFRS 15	1 January 2018	See below
Amendment to IFRS 15	Clarifications to IFRS 15	1 January 2018	See below
Amendment to IAS 40	Transfers of Investment Property	1 January 2018	No effects
IFRIC 22	Foreign Currency Transactions and Advance Consideration	1 January 2018	No effects
Annual Improvements to IFRSs	Annual Improvements to IFRSs Cycle 2014-2016 (IFRS 1 and IAS 28)	1 January 2018	No effects

## First-time application of IFRS 9

For the 2018 financial year, Biofrontera applied the new standard IFRS 9 "Financial Instruments" for the first time. The standard replaces the previous provisions of IAS 39 on the recognition and measurement of financial instruments. The impact of the new regulations on Biofrontera is as follows:

- Biofrontera holds financial assets mainly in the form of cash, cash equivalents and trade receivables. The assets were allocated to the "Loans and receivables" category under IAS 39. Under the new categorization rules, they are categorized as "held at amortized cost". The new impairment model for debt instruments, which applies to trade receivables in the form of the simplified approach, leads in some cases to earlier recognition of impairments. At Biofrontera, this did not result in any changes to the valuation as of 1 January 2018 compared with 2017.
- In the case of financial liabilities, which primarily consist of bank borrowings and bond liabilities, as well as trade payables, the first-time application of the new standard has no effect on recognition and measurement. This applies in particular to the EIB loan, which for accounting purposes continues to be split between the original loan liability and the performance component embedded as a derivative.
- The new rules of IFRS 9 on hedge accounting are of no significance for Biofrontera, as the company has not designated any hedging relationships.

Biofrontera has made use of the option to simplify the first-time application of IFRS 9. Accordingly, the financial instruments held as of 31 December 2017 were reclassified with effect from 1 January 2018 as shown below. No effects arose for the valuation methods applied and the carrying amounts.

### Reconciliation of the carrying amounts of financial assets

Financial assets in EUR thousands	IAS 39 as at 31.12.2017			IFRS 9 as at 01/01/2018	
	Carrying amount	Measurement category	Remeasurement adjustment	Carrying amount	Measurement category
Cash and cash equivalents	11,083	LaR	0	11,083	AC
Trade receivables	1,561	LaR	0	1,561	AC
Other financial assets	571	LaR	0	571	AC

LaR: Loans and Receivables (financial assets measured at amortized cost)

AC: Amortized Cost (held - financial assets measured at amortized cost)

### Reconciliation of impairments relating to 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. Based on the experience of Biofrontera in the past, no value adjustment for expected credit losses as at 1 January 2018 had to be recognized.

As of 1 January 2018, Biofrontera waived the recognition of valuation allowances for expected credit losses for reasons of materiality. Due to the consistently good creditworthiness of Biofrontera's customers and the relatively short term of the receivables, the default risk is low in absolute terms. Historically, outstanding receivables have been received within the agreed upon payment terms.

## Reconciliation of the carrying amounts of financial liabilities

Financial liabilities in EUR thousands	IAS 39 as at 31.12.2017		Remeasur- ment adjustment	IFRS 9 as at 01/01/2018	
	Carrying amount	Measurement category		Carrying amount	Measurement category
Trade payables	1,621	FLAC	0	1,621	AC
Financial liabilities	11,973	FLAC	0	11,993	AC
Other financial liabilities	20	FLAC	0	20	AC
Financial liabilities	552	FVTPL	0	552	FVTPL

FLAC: Financial liabilities at amortized cost (other liabilities at amortized cost)

AC: Amortized cost (financial liabilities measured at amortized cost)

FVTPL: Fair value through profit or loss (financial liabilities at fair value through profit or loss)

### First-time adoption of IFRS 15 Revenue from Contracts with Customers

Since the 2018 financial year, the timing and amount of revenues to be reported in the consolidated income statement have been determined in accordance with IFRS 15 "Revenue from Contracts with Customers". Revenue recognition follows a five-step process. After assessing whether a contract with a customer exists (step 1), a decision has to be taken as to whether the agreement should be split into separate performance obligations, which should be assessed separately for the purposes of recognizing revenue (step 2). In this case, the total consideration expected by the entity must be determined (step 3) and allocated appropriately to the identified benefit performance (step 4). Revenue is recognized when and to the extent that the performance obligations have been performed. To this end, upon transfer of control to the customer of the agreed goods or services is when revenue is to be recognized.

Control is expressed in the ability to direct the use of goods and services and to appropriate the benefits associated with them. It can be transferred to the customer at a certain point in time or over a period of time. The performance obligations assumed by Biofrontera in customer contracts are fulfilled almost without exception by the transfer of goods and consequently at a certain point in time.

Biofrontera applied the new revenue recognition standard for the first time on 1 January 2018 using the modified retrospective method. For this purpose, customer contracts not yet fully performed as of 1 January 2018 were treated as if IFRS 15 had been applied to them from the outset. Changes to existing contracts or other matters, which would have required a different revenue recognition compared to the principles applied so far, did not exist. Accordingly, the transition to the new revenue recognition rules did not result in any adjustment to retained earnings. The comparative information for the previous year has not been adjusted. The new standard also had no impact on Biofrontera's consolidated balance sheet and consolidated income statement in the 2018 financial year.

IFRS 15 may lead to changes in the presentation of financial information in the balance sheet. Contract assets are to be recognized if the due date of the consideration for a fulfilled performance obligation is not only dependent on the passage of time. Payments by customers for goods or services still to be transferred and unconditional obligations by customers to make payments before the transfer of goods or services result in the recognition of a contractual liability. As of 1 January 2018, no contract assets or contract liabilities required recognition. Accordingly, revenues for the 2018 financial year do not include any amounts recognized as contract liabilities on the first-time adoption date. Revenues from performance obligations fulfilled in previous financial years were also recognized to only an insignificant extent.

Apart from expanded disclosure requirements, the first-time adoption of IFRS 15 resulted in no effects.

## Future changes in accounting standards

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

Standard	Description	Mandatory application for Biofrontera	Expected effects
Amendment to IFRS 3*	Definition of a Business	1 January 2020	No effects
Amendment to IFRS 9	Early repayment regulations with negative compensation	1 January 2019	No effects
IFRS 16	Leases	1 January 2019	See below
Amendment to IAS 19	Plan Amendment, Curtailment or Settlement	1 January 2019	No effects
Amendment to IAS 28	Investments in Associates and Joint Ventures	1 January 2019	No effects
IFRIC 23	Uncertainties over Income Tax Treatments	1 January 2019	No effects
Annual Improvements to IFRSs	Annual Improvements to IFRSs Cycle 2015-2017	1 January 2019	No effects
Amendment to IAS 1, IAS 8*	Definition of Material	1 January 2020	No effects
Amendments to References to the Conceptual Framework*	References to the Conceptual Framework	1 January 2020	No effects
IFRS 17*	Insurance Contracts	1 January 2021	No effects

\* Adoption by the EU still pending

### IFRS 16 Leases

For financial years beginning on or after 1 January 2019, IFRS 16 requires the application of a new lease standard. Contrary to the previous accounting guidance, 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 reflected in the balance sheet, is therefore no longer applicable. The lease liability to be carried as a liability is calculated as the present value of the expected future payments to be made to the lessee. They are updated using the effective interest method. The right to use the underlying asset to be recognized in return is to be recognized at cost at the inception of the lease. In addition to the leasing payments, any initial direct costs of the lessee and disposal costs are included in the calculation. Incentive payments granted by the lessor are to be deducted. The capitalized right of use must be amortized and tested for impairment if indications of impairment exist. The new accounting guidance for lessors is consistent to the previous accounting guidance. Finally, changes have been made to the disclosure of leases and to the reporting in the notes to the financial statements.

The leasing contracts concluded by Biofrontera as lessee mainly relate to buildings and vehicles used for operational and administrative purposes. The company will apply the new accounting standard under the modified retrospective method to leases with a remaining term of more than one year as of 1 January 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 expedients available 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.

According to current estimates, management expects the transition to the new lease accounting to lead to the following changes in the consolidated balance sheet

- an increase in non-current assets due to the capitalization of rights of use in the amount of EUR 2,335 thousand;
- an increase in balance sheet liabilities due to the recognition of leasing liabilities in the amount of EUR 2,302 thousand;
- a decrease in the loss carried forward in the amount of EUR 26 thousand.

The actual impact could result in a higher or lower value.

Effects on the consolidated income statement are expected in the form of higher depreciation (an expected increase of EUR 262 thousand) and higher interest expenses (an expected increase of EUR 25 thousand). Offsetting this, leasing expenses recorded under other operating expenses will be reduced.

The above information does not take into account leases that take effect or are concluded after 1 January 2019.

Biofrontera will not report the rights of use and leasing liabilities separately on the balance sheet, but will include them in line items containing comparable assets and liabilities.

The exercise of the contractual option under the operating lease agreements for lamps (BF-RhodoLED® PDT lamp) was only exercised to a minor extent. Therefore, the first-time application of the new leasing standard will not have any material impact on Biofrontera as a lessor.

## 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:

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., Wakefield, Massachusetts, U.S., with a direct interest of 100%

The basis for the consolidation of the companies included in the consolidated financial statements are the financial statements (or HBII pursuant to IFRS) of these companies prepared for 31 December 2018 pursuant to uniform principles. The consolidated financial statements as of 31 December 2018 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 inter-company balances and income and expenses have been eliminated on consolidation. Results of intra-group transactions have been eliminated.

## Reclassification of prior year figures

Deferred liabilities, which had been disclosed as of December 31, 2017 in the balance sheet under the line item "Other provisions" have been reclassified as of December 31, 2018 to the balance sheet line items "Trade payables" and "Other current liabilities", respectively. As their underlying positions have a significantly lower degree of estimation uncertainty than the provisions disclosed as of December 31, 2018, this reclassified presentations provides a reliable and more relevant information (IAS 8.14 (b)). The previous year's figures were reclassified to conform to the current year presentation. As a result, the line item "Other provisions" now being presented as of December 31, 2017 was reduced by a total amount of EUR 1,973 thousand, while the line items "Trade payables" increased by EUR 537 thousand and "Other current liability" by EUR 1,436 thousand, respectively.

## Translation of amounts in foreign currencies

The consolidated financial statements as of 31 December 2018 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 (2018: 1.1445 USD/EUR, previous year 1.2022 USD/EUR). Income and expense items are translated applying the average exchange rates applicable to the relevant period (2018: 1.1818 USD/EUR, prior year: 1.1301 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 (EUR -702 thousand, previous year EUR 854 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 650 thousand (previous year: EUR -1,291 thousand).

## Application of estimates

The preparation of the consolidated financial statements for 31 December 2018 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 discretion are the measurement of provisions, stock options, convertible bonds, EIB loans and income taxes and the determination of the useful lives of non-current assets. Estimates are also made as part of fair value measurement pursuant to IFRS 13. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary 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

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 1 January 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.

## 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 20 years.

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

No intangible assets exist with indefinite useful lives.

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

## Impairment of 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.

## 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 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 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). These financial liabilities were allocated to the category "Financial liabilities measured at amortized cost". The financial liabilities of the performance component measured at fair value are allocated to the category "Financial liabilities at fair value through profit or loss". Due to the short terms of the trade payables and trade receivables, the carrying amounts of such items correspond to their fair values. The remaining receivables and liabilities are classified to the "Hold" category. The financial liabilities are measured applying the effective interest method.

## 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.

## 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 measured at amortized cost.

## 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.

## 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.

## Convertible bonds

Convertible bonds comprise compound financial instruments which are to be allocated to a debt component (bond) and an equity component (conversion right) on initial recognition. The debt component (bond) is to be recognized at fair value when the contract is concluded. The fair value in this context is calculated by discounting the contractually determined future payments applying a standard market interest rate for a comparable bond without a conversion right. The issuer's default risk is also to be taken into consideration. The equity component (conversion right) is calculated as the difference between the issue proceeds and the present value of the liability (equity derivative, residual value method).

The following distinction is made as part of subsequent recognition of the convertible bond: The debt component is subsequently measured at amortized cost applying the effective interest method. The equity component is not subject to any subsequent measurement.

## 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. A further tranche of EUR 5.0 million can be drawn after certain milestones have been reached. 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. This is discounted to the measurement cut-off date applying a market interest rate.

## 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® is sold exclusively through pharmaceutical wholesalers or directly to hospitals in Germany, as well as directly to pharmacies and hospitals in other European countries. In the U.S., Ameluz® is reimbursed as a so-called "buy-and-bill drug" and consequently marketed directly to physicians. Revenue is recognized when the products are delivered to the respective customers. Additionally, in 2018 sales revenue was achieved through passing costs on to Maruho Co. Ltd as part of the development partnership that has been agreed.

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

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

Revenues are recognized less revenue-based trade taxes and sales deductions. Expected sales deductions, for example rebates and discounts, are recognized based on estimated values at revenue recognition. Payment terms for Ameluz® include short-term payment terms with a possibility for sales rebates.

## 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.

The research and development costs relating to the medication Ameluz®, which has been approved in Europe and the U.S., and to the company's other research and development projects, are consequently expensed in the period in which they are incurred.

Intangible assets under development relate to the further development of BF-RhodoLED®, as this will generate future economic benefits.

## Notes to the consolidated balance sheet

### 1. Intangible and tangible assets

The additions to intangible assets and to tangible assets in the reporting period arise mainly from the purchase of software (EUR 5 thousand; previous year: EUR 15 thousand), right-of-use assets connected with the prototype of the PDT lamp (EUR 10 thousand; previous year: EUR 90 thousand), from the capitalization of the costs of developing a new prototype of the PDT lab (EUR 258 thousand; previous year: EUR 9 thousand), as well as further laboratory devices (EUR 115 thousand; previous year: EUR 194 thousand) and other fixtures and equipment (EUR 125 thousand; previous year: EUR 83 thousand). The asset disposals with acquisition/manufacturing costs totaling EUR 5,336 thousand (previous year: EUR 16 thousand) result mainly from intangible assets and relate in particular to the now fully depreciated right of use for the active ingredient ALA (aminolaevulinic acid) in the amount of EUR 5,068 thousand and the scrapping and discarding of tangible assets that are no longer usable in the amount of EUR 255 thousand (previous year: EUR 0 thousand).

## Consolidated statement of changes in non-current assets in 2018

in EUR thousands	Cost						Accumulated depreciation and amortization					Carrying amounts	
	1 Jan. 18	Currency translation	Additions	Transfers	Disposals	31 Dec. 18	1 Jan. 18	Currency translation	Additions	Disposals	31 Dec. 18	31 Dec. 18	1 Jan. 18
<b>I. Tangible assets</b>													
Operating and business equipment	4,089	5	240	-	230	4,104	3,343	1	194	229	3,309	795	746
<b>II. Intangible assets</b>													
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	1,100	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
	<b>10,735</b>	<b>5</b>	<b>513</b>	<b>-</b>	<b>5,335</b>	<b>5,918</b>	<b>9,341</b>	<b>1</b>	<b>755</b>	<b>5,326</b>	<b>4,771</b>	<b>1,147</b>	<b>1,394</b>

## Consolidated statement of changes in non-current assets in 2017

in EUR thousands	Cost						Accumulated depreciation and amortization					Carrying amounts	
	1 Jan. 17	Currency Translation	Additions	Transfers	Disposals	31 Dec. 17	1 Jan. 17	Currency translation	Additions	Disposals	31 Dec. 17	31 Dec. 17	1 Jan. 17
<b>I. Tangible assets</b>													
Operating and business equipment	3,834	(7)	278	-	16	4,089	3,189	(2)	167	11	3,343	746	645
<b>II. Intangible assets</b>													
1. Software and licenses	444	(1)	15	-	-	458	304	-	124	-	428	30	140
2. Right-of-use assets	6,089	-	99	-	-	6,188	4,977	-	593	-	5,570	618	1,112
	6,533	(1)	113	-	-	6,646	5,281	-	717	-	5,998	648	1,252
	<b>10,367</b>	<b>(8)</b>	<b>392</b>	<b>-</b>	<b>16</b>	<b>10,735</b>	<b>8,470</b>	<b>(2)</b>	<b>884</b>	<b>11</b>	<b>9,341</b>	<b>1,394</b>	<b>1,897</b>

## 2. Inventories

Inventories as of balance sheet date are EUR 3,177 thousand (previous year: EUR 3,732 thousand). Inventories are comprised of finished products, work in progress, and raw materials and supplies at the sales companies.

In 2018, inventories were written down by EUR 187 thousand (previous year: EUR 0 thousand).

## 3. Trade receivables

Trade receivables are mainly attributable to the sale of Ameluz®, the PDT lamp BF-RhodoLED® and the medical cosmetics product Belixos®. It is expected that all trade receivables will be settled within twelve months of the balance sheet date. Value adjustments for doubtful receivables have not been applied since no receivables existed that were significantly aged as of 31 December 2018. For 31 December 2017, no value adjustments were recognized as in the previous year.

## 4. Other financial assets

The other financial assets comprise mainly prepayments rendered for studies (EUR 614 thousand; previous year: EUR 446 thousand) and the depositing of collateral, mainly for credit cards and leased vehicles (EUR 164 thousand; previous year: EUR 96 thousand). As in the previous year, no individual value adjustments were applied during the reporting year.

## 5. Other assets

Other assets mainly comprise of prepaid expenses (EUR 664 thousand; previous year: EUR 1,393 thousand). In the previous year, this item also included the deferred costs for equity procurement measures offset against capital reserves in connection with the IPO on the NASDAQ Capital Market on 14 February 2018.

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

## 6. Income tax reimbursement claims

These consist of claims for tax refunds relating to withheld capital gains tax, plus the Solidarity Surcharge (EUR 53 thousand; previous year: EUR 52 thousand).

## 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 19,451 thousand (previous year: EUR 11,083 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

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 31 December 2018. The subsidiary has already generated profits in the second half of 2018 thanks to the increased business volume 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 loss carryforwards within Biofrontera AG amounting to EUR 188 thousand were capitalized to the extent that they are offset by deferred tax liabilities in the same amount.

The following table shows changes in the Group's existing deferred tax assets deriving, as a matter of principle, from tax loss carryforwards:

in EUR thousands	31.12.2018		31.12.2017	
	Loss carried forward	Deferred tax assets	Loss carried forward	Deferred tax assets
Corporation tax including Solidarity Surcharge	131,928	20,884	119,725	18,947
Business tax	118,548	19,703	107,962	17,949
U.S. corporation tax	14,452	3,613	8,026	2,007
<b>Total</b>		<b>44,200</b>		<b>38,903</b>

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 up to 31 December 2017, and from 1 January 2018 they can be deducted indefinitely.

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 regarding the remaining deferred tax assets deriving, as a matter of principle, from loss carryforwards (EUR 33,526 thousand; previous year EUR 38,903 thousand) and deferred tax assets of EUR 782 thousand (previous year EUR 321 thousand) were not recognized on the balance sheet, in accordance with IAS 12.34.

in EUR thousands	31.12.2018		31.12.2017	
	Deferred tax assets	Deferred tax liabilities	Deferred tax assets	Deferred tax liabilities
Loss carryforwards	10,674	-	-	-
Non-current assets				
- Intangible assets	-	(87)	-	-
- Tangible assets	-	-	-	-
- Financial assets	-	-	-	-
Current assets				
-Receivables and other assets	59	-	-	-
Non-current liabilities				
- Provisions	-	(82)	-	-
Current liabilities				
-Provisions	-	(152)	-	-
-Liabilities and other	-	(12)	-	-
<b>Total</b>	<b>10,733</b>	<b>(333)</b>	<b>-</b>	<b>-</b>
Netting of deferred tax assets and liabilities	(333)	333	-	-
<b>As recognized on balance sheet</b>	<b>10,400</b>	<b>-</b>	<b>-</b>	<b>-</b>

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:

in EUR thousands	31.12.2018	31.12.2017
Consolidated earnings before tax	(19,269)	(16,102)
<b>Expected income tax reimbursement at the tax rate of the parent company</b>	<b>6,252</b>	<b>5,226</b>
Differences arising from different tax rates	(685)	586
Adjustment of deferred taxes due to tax rates	-	(121)
- from temporary differences	-	(1,014)
- from loss carryforwards		
Tax increases due to non-deductible expenses	(100)	(646)
Changes in unrecognized deferred tax assets		
- from active temporary differences	(895)	(194)
- from loss carryforwards	5343	(4,161)
Other effects	475	323
Income taxes as per statement of comprehensive income	10,390	-

## 9. Equity

### Share capital

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 44,632,674 on 31 December 2018. It was divided into 44,632,674 registered shares with a nominal value of EUR 1.00 each. On 31 December 2018, the share capital amounted to EUR 38,416,828.

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 3 June 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 13 February 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.

As part of a subscription rights offer to all existing shareholders and a simultaneous public offering to investors in the U.S., a total of 6,000,000 new shares with a notional nominal value of EUR 1.00 per share were offered and successfully placed at a subscription price of EUR 4.00 per share. The subscription price per ADS amounted to USD 9.88.

The numbers of shares held by the shareholders on 31 December 2018, based on the most recent mandatory disclosures, are as follows:

	31.12.2018	31.12.2017
Maruho Deutschland Co., Ltd., Osaka Japan The total share of voting rights is assigned to Maruho Co., Ltd, Osaka, through the company Maruho Deutschland GmbH, Düsseldorf, which is controlled by the former.	8,891,843	7,631,586
Wilhelm Konrad Thomas Zours The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours:		
<ul style="list-style-type: none"> <li>• DELPHI Unternehmensberatung AG</li> <li>• VV Beteiligungen AG</li> <li>• Deutsche Balaton AG</li> <li>• Deutsche Balaton Biotech AG</li> <li>• Prisma Equity AG</li> </ul>	8,935,384	3,400,907
Liechtensteinische Landesbank AG (LLB), Vienna, Austria (previously: Semper Constantia Invest GmbH)	-	1,165,212
Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany The share of voting rights is attributed to Universal-Investment GmbH through the company FEHO Vermögensverwaltungsgesellschaft.	-	799,463
Free float	26,805,447	25,419,660
<b>Total</b>	<b>44,632,674</b>	<b>38,416,828</b>

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 capital

The authorized capital consisted of three share capital amounts.

The conditional increase in the share capital (Authorized Capital I) of EUR 6,434,646 was approved on 28 August 2015, of which is EUR 4,116,855 available as at 31 December 2018. Authorized 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 (Authorized Capital III) of EUR 542,400 was approved on 28 February 2015, of which is EUR 346,900 available as of 31 December 2018, and serves exclusively to fulfill option rights granted on 1 July 2015 on the basis of the AGM of 2 July 2010.

The conditional increase in the share capital (Authorized Capital V) of EUR 1,814,984 approved on 28 February 2015 serves exclusively to fulfill option rights granted on 27 August 2020 on the basis of the annual general Meeting ("AGM") on 28 August 2015.

## Convertible bond 2016/2021

In November 2016, 49,990 subordinated convertible 2016/2021 bonds were issued in a total nominal amount of EUR 4,999,000 ("convertible bond"). Shareholders were granted indirect subscription rights to the bonds. Shareholders were granted statutory subscription rights in a 607:1 ratio at an issue price of EUR 100.00 per bond.

The conversion price amounted initially to EUR 3.00 per share, EUR 4.00 per share from 1 January 2017 and EUR 5.00 per share from 1 January 2018. In the 2018 financial year, further bonds in a nominal amount of EUR 32,700 (previous year: EUR 106,800 thousand) were converted into the company's shares. Pursuant to section 12 of the bonds' terms and conditions, the conversion price was reduced in March 2018 by EUR 0.25 to EUR 4.75.

On 30 April 2018, the 2016/2021 Convertible Bond was repaid early in the amount of EUR 50,300, plus accrued interest.

### Convertible bond 2017/2022

On 23 December 2016, the company's Management Board approved the issue of a further convertible bond, which was placed in full in an amount of EUR 5.0 million in January 2017.

The bond's initial conversion price amounts to EUR 3.50, to EUR 4.00 from 1 April 2017 and to EUR 5.00 from 1 January 2018. Pursuant to section 11 of the bonds' terms and conditions, the conversion price was reduced in March 2018 by EUR 0.25 to EUR 4.75. The bonds carry 6% annual interest on their par value from 1 February 2017. Unless previously converted, the bond is to be repaid in cash on 1 January 2022.

As of 31 December 2018, bonds in a nominal amount of EUR 2,403,700 were converted into the company's shares.

The conditional increase in the share capital (Authorized Capital I) of EUR 6,434,646 was approved on 28 August 2015, of which is EUR 4,116,855 still available as at 31 December 2018.

### 2010 share option program

At the AGM on 2 July 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 24 November 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 30 July 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.

The issue date was 24 November 2010. The granting of options is made without any payment being provided in return. On 24 November 2010, 106,400 options (first tranche) were issued with an exercise price per share of EUR 1.91. On 30 September and 7 October 2011 (second tranche) a further 96,400 options were issued with an exercise price of EUR 2.48 each. On 23 March 2012 and 11 May 2012 (third tranche), 65,000 options were issued with an exercise price of EUR 3.30 each, and 51,500 options were issued with an exercise price of EUR 4.09 each. On 2 September 2013, 179,500 options were issued (fourth tranche) with an exercise price of EUR 3.37 each. On 2 April 2014, 159,350 options were issued with an exercise price of EUR 3.43 each (fifth tranche).

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).

The right to exercise the options ends at the latest six years after the first day of issue. The right to exercise the first options that were issued thus ends on 24 November 2016. If the options have not been exercised by this time, they expire without provision of compensation. In 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). For this reason, the fair value of a share from this share option program with a grant date of 24 November 2010 was determined, on the basis of a binomial model, to have a fair value of EUR 0.57 / share option. The pro rata amounts are recognized in instalments over the vesting period until the end of the vesting period as personnel expenses and as an increase in the capital reserve. Share price volatilities of 45.78% and 51.3% were applied in calculating the fair value of the options granted in 2010 and 2011, volatilities of 53.5% and 65% were applied for the options granted in 2012, volatility of 39.2% was applied for the options granted in 2013, and volatility of 32.3% for the options granted in 2014 (based on the reporting date volatility). A dividend yield of 0% was applied in all cases, as well as risk-free rates of respectively 1.75% and 1.21%, and 0.9% and 0.82% in 2012 as well as 0.71% in 2013 and 0.68% in 2014, and a standard 20% annual beneficiary turnover rate. No share options were issued in financial year 2015. The authorization to issue options under the 2010 share option program ended on 1 July 2015.

The vesting period for the first tranche ran until 24 November 2014, and the vesting period for the second tranche ran until 30 September 2015 or 7 October 2015 respectively. The option rights from the first tranche expired on 24 November 2016 and from the second tranche the option rights expired on 30 September and 7 October 2017, respectively, as the exercise conditions were not met.

The vesting period for the third tranche ran until 23 March 2016 and 11 May 2016 respectively. On 5 March 2018, 40,000 options were converted after fulfilment of the exercise conditions. A further 32,500 options were converted on 2 May 2018. The remaining 19,000 options from this tranche expired on 3 May 2018.

The vesting period for the fourth tranche ended on 2 September 2017. A total of 65,500 options had been exercised from these tranches up to the reporting date.

The vesting period for the fifth tranche ended on 2 April 2018. Of these, 57,500 options had been converted by the balance sheet date.

A total of 153,750 (previous year: 141,750) options were forfeited by employees leaving the company. As of 31 December 2018, 137,850 (previous year: 364,350) option rights were exercisable.

In March 2018, the exercise prices were adjusted pursuant to section 11 of the options' terms and conditions. The exercise price for the third tranche now amounts to EUR 3.02 and EUR 3.81 respectively, for the fourth tranche to EUR 3.093 and for the fifth tranche to EUR 3.15.

The cost expensed in the reporting period amounted to EUR 6 thousand (previous year: EUR 42 thousand).

2010 share option program	31.12.2018	31.12.2017
Outstanding at the beginning of the period	364,350	439,500
Granted during the period	-	-
forfeited during the period	19,000	4,500
Exercised during the period	195,500	-
Expired during the period	12,000	70,650
Outstanding at the end of the period	137,850	364,350
Exercisable at the end of the period	137,850	-
Range of exercise prices for outstanding options	EUR 3.093 - 3.15	EUR 3.26 - 4.05
Weighted average of remaining contractual life	12 months	18 months

The Authorized Capital III for servicing options from this program amounts to EUR 346,900.

In addition, the share capital was increased by EUR 195,500.00, divided into 195,500 registered shares, from the conversion of options from the 2010 employee stock option plan during the 2018 financial year.

### 2015 share option program

At the AGM on 28 August 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 27 August 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 volume of EUR 1,814,984 and a term of five years from the issue date, in other words, until 27 August 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 18 September 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.

The inclusion of a "comparison with a reference index" as performance target instead of "achievement of a minimum reference price of EUR 5.00" as performance target is deemed to be a major difference in the conditions of the 2015 share option program compared to the 2010 share option program. The fair value of each option of this share option program was calculated on the grant date of the first tranche on 18 April 2016 based on a Monte Carlo risk simulation at a fair value of EUR 1.00/option. The fair value of a stock option under this option program was determined at the grant date of 1 December 2016 on the basis of a Monte Carlo risk simulation with a fair value of EUR 1.30/stock option, at the grant date of 28 April 2017 on the basis of a Monte Carlo risk simulation with a fair value of EUR 1.50/stock option, and at the grant date of 28 November 2016 on the basis of a Monte Carlo risk simulation with a fair value of EUR 1.48/stock option, and at the grant date 7 May 2018 on the basis of a Monte Carlo risk simulation with a fair value of EUR 2.35/share option. When measuring the fair value of the options granted in 2016, the volatility of the share price in the 1st tranche was 50.6%, in the 2nd tranche 49.0%, in the 3rd tranche 47%, in the 4th tranche 46%, and in the 5th tranche of 47%. The first tranche is based on daily prices and annualized on the assumption of 250 trading days per year, the second tranche is based on daily prices and annualized on the assumption of 250 trading days per year and the third tranche is based on daily prices and annualized on the assumption of 250 trading days per year, and 7.00% for the 2nd tranche, 7.5% for the 3rd tranche, 7.6% for the 4th tranche and the 5th tranche (based on the Capital Asset Pricing Model (CAPM)) and a total risk-adjusted interest rate of 5.92% for the 1st tranche and 13.26% for the 2nd tranche, 13.94% for the third tranche, 14.05% for the fourth tranche and 14.03% for the fifth tranche, as well as an annual turnover of the beneficiaries of 12% and 9% respectively is assumed for both tranches in the case of the fifth tranche.

On 18 April 2016, 425,000 options (first tranche) were issued with an exercise price per share of EUR 2.49. On 1 December 2016, a further 130,500 option rights (2nd tranche) were issued at an exercise price of EUR 3.28 each. On 28 April 2017, a further 329,000 options (3rd tranche) were issued at an exercise price of EUR 4.02 each and a further 300,500 options (4th tranche) at an exercise price of EUR 3.33 each. On 7 May 2018, 180,000 options were issued with an exercise price of EUR 5.73 each (5th tranche).

A total of 113,000 options were forfeited by employees leaving the company. Due to the vesting period, no options have yet been exercised or forfeited. The cost expensed in the reporting period amounted to EUR 257 thousand (prior-year period: EUR 139 thousand).

In March 2018, the exercise prices were adjusted pursuant to section 13 of the options' terms and conditions. The exercise price now amounts for the first tranche to EUR 2.25, for the second tranche to EUR 3.04, for the third tranche to EUR 3.78 and for the fourth tranche to EUR 3.09.

2015 share option program	31 December 2018	31 December 2017
Outstanding at the beginning of the period	1,143,500	548,000
Granted during the period	180,000	629,500
Forfeited during the period	69,500	34,000
Exercised during the period	-	-
Expired during the period	-	-
Outstanding at the end of the period	1,254,000	1,143,500
Exercisable at the end of the period	-	-
Range of exercise prices for outstanding options	EUR 2.25 - 5.73	EUR 2.49 - 4.02
Weighted average of remaining contractual life	50 months	60 months

## 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 2,432 thousand for the year ended 31. December 2018.

## Capital management

Consolidated equity determined in accordance with IFRS is managed as capital. The company's capital management body regularly reviews the equity facilities available to the Group. The management's 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 company's Management Board ensures that all Group companies have sufficient capital at their disposal in the form of equity and debt funding.

## 10. Financial liabilities

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	31.12.2018				
	2019	2020	2021	2022	Total
<u>Convertible bond 2017/2022:</u>					2,595
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

in EUR thousands	31.12.2017					
	2018	2019	2020	2021	2022	Total
<u>Convertible bond 2016/2021:</u>						
Principal repayment				83		83
Interest payment	5	5	5	5		20
<u>Convertible bond 2017/2022:</u>						
Principal repayment					2,662	2,662
Interest payment	160	160	160	160	80	720
<u>EIB loan</u>						
Principal repayment					10,000	10,000
Interest payment	380	405	433	461	3,926	5,605

### Convertible bond 2016/21

In November 2016, 49,990 subordinated convertible 2016/2021 bonds were issued in a total nominal amount of EUR 4,999,000 ("convertible bond"). The term of the 2016/2021 convertible bond begins on the date of its initial issue ("issue date") and ends on 31 December 2020.

The individual bonds carry 6% annual interest on their par value from 1 January 2017 (inclusive). The interest payments are payable annually subsequently on 1 January of each year, commencing on 1 January 2018. The fair value of the convertible bond was calculated as part of the initial valuation using an interest rate of 7.9%.

The bonds can be converted into the company's ordinary no par value registered shares, each of which has a nominal share of EUR 1.00 in the share capital. The shares are dividend-entitled from the year when the conversion right is exercised.

During the term, the holders of the bonds are entitled to convert all bonds into the company's shares. The initial conversion price is staggered. From the start of the term until 31 December 2016, the initial conversion price amounts to EUR 3.00 per share. From 1 January 2017 until 31 December 2017, the initial conversion price amounts to EUR 4.00 per share. From 1 January 2018, the conversion price amounts to EUR 5.00 per share.

At the end of the term of the convertible bond, the company is entitled to deliver shares instead of repaying the bonds. Moreover, the company is entitled to convert the bonds into shares at any time if the average price of the company shares exceeds EUR 5.00 on one occasion. In both cases, the initial conversion price amounts to EUR 5.00.

As of 30/04/2018, bonds in a nominal amount of EUR 4,948,700.00 were converted into the company's shares. In March 2018, the conversion price was reduced to EUR 4.75 pursuant to section 12 of the bonds' terms and conditions.

On 30 April 2018, the 2016/2021 Convertible Bond was repaid early as only a small volume of approximately EUR 50 thousand was still outstanding, including accrued interest.

## Convertible bond 2017/22

On 23 December 2016, the company's Management Board approved the issue of a further convertible bond, which was placed in full in an amount of EUR 5.0 million in January 2017. The term of the 2017/2022 convertible bond begins on the date of its initial issue ("issue date") and ends on 31 December 2021.

The individual bonds carry 6% annual interest on their par value from 01 February 2017 (inclusive). The interest payments are payable semi-annually subsequently on 1 January of each year, commencing on 1 July 2017. The fair value of the convertible bond was calculated as part of the initial valuation using an interest rate of 7.6%.

The bonds can be converted into the company's ordinary no par value registered shares, each of which has a nominal share of EUR 1.00 in the share capital. The shares are dividend-entitled from the year when the conversion right is exercised.

During the term, the holders of the bonds are entitled to convert all bonds into the company's shares. The initial conversion price is staggered. From the start of the term until 31 March 2017, the initial conversion price amounts to EUR 3.50 per share. From 01 April 2017 until 31 December 2017, the initial conversion price amounts to EUR 4.00 per share. From 1 January 2018, the initial conversion price amounts to EUR 5.00 per share. In March 2018, the conversion price was reduced to EUR 4.75 pursuant to section 11 of the bonds' terms and conditions.

At the end of the term of the convertible bond, the company is entitled to deliver shares instead of repaying the bonds.

As of 31 December 2018, bonds in a nominal amount of EUR 2,403,700 were converted into the company's shares.

## 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 31 December 2018, the carrying amount of the liability component on this basis was EUR 9,887 thousand (previous year: EUR 9,138 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 31 December 2018, the discounted interest payment or fair value of the performance component amounted to EUR 1,080 thousand (previous year: EUR 522 thousand).

## 11. Trade payables

The trade payables (EUR 1,805 thousand; previous year: EUR 1,620 thousand) increased by EUR 185 thousand from the previous year. This item includes liabilities to be accrued for the first time in the amount of EUR 479 thousand (previous year: EUR 360 thousand), which were reported under other provisions in the previous year. The previous year's amount was reclassified accordingly to conform to the current year presentation.

## 12. Other provisions

Current and non-current other provisions report the following changes:

### Other current provisions

in EUR thousands	01.01.2018	Utilization	Released	Added	Translation difference	31.12.2018
Outstanding invoices	393	262	34	840	7	944
Costs for financial statements and auditing	143	141	2	224	-	224
Provisions for litigation costs, current	-	-	-	1,696	-	1,696
Other provisions	26	-	-	1	-	27
<b>Total current provisions</b>	<b>562</b>	<b>403</b>	<b>36</b>	<b>2,761</b>	<b>7</b>	<b>2,891</b>

## Other non-current provisions

EUR thousands	01.01.2018	Utilized	Released	Added	Translation difference	31.12.2018
Provisions for litigation costs, non-current	-	-	-	1,545	-	1,545
<b>Other non-current provisions</b>	-	-	-	<b>1,545</b>	-	<b>1,545</b>

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 and the non-current provisions prospectively within 2 years.

To conform to the current year presentation, the liabilities deferred in the previous year (EUR 1,973 thousand) are no longer recognized under provisions and instead under the respective liabilities.

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.

In 2018, a total of EUR 3,241 thousand was accrued for costs to defend against litigation in connection with pending proceedings in the U.S. and Germany.

In March 2018, DUSA Pharmaceuticals Inc. ("DUSA") filed a lawsuit in the District Court of Massachusetts against Biofrontera AG and its subsidiaries alleging infringement of its patents No. 9,723,991 and No. 8,216,289 by the sale of BF-RhodoLED® in the U.S.. In July 2018, DUSA amended its lawsuit to add claims for misappropriation of trade secrets, unauthorized interference in contractual relationships, and misleading and unfair commercial practices.

Although Biofrontera believes that these claims are unjustified and intend to defend them vigorously, Biofrontera cannot guarantee that we will succeed.

The court largely rejected DUSA's application for an injunction, but ordered Biofrontera not to use documents or documents derived from other documents originating from DUSA. Although the court has made a preliminary determination that DUSA is reasonably likely to prevail over its non-patent claims, the court's ruling is not final and Biofrontera continues to vigorously challenge DUSA's allegations. In addition, Biofrontera filed motions for inter partes review with the Patent Trial and Appeal Board (PTAB) to invalidate the patents. On 26 February 2019, the PTAB issued decisions stating that some of the claims had a sufficient chance of success on nullity arguments, but nevertheless rejected the filing of the review applications as the PTAB disagreed with the remaining claims.

We may incur significant costs in defending these claims. In addition to internal human resources, we also mandate U.S. lawyers to defend the claims. The costs incurred by Biofrontera as a result would not be reimbursed by the plaintiff in the event of a positive outcome of the proceedings, due to the characteristics of the U.S. legal system.

### 13. Other current liabilities

Other current liabilities (in EUR thousands)	31 December 2018	31 December 2017
Other financial liabilities		
Payroll tax	267	184
Social security	13	29
Wages and salaries	141	89
Other	9	16
<b>Total</b>	<b>430</b>	<b>303</b>
Other current liabilities		
Accrual for employee bonuses	2,099	1,162
Accrual for outstanding vacation	315	263
Other accruals	14	0
Accrual for outstanding invoices	21	11
<b>Total</b>	<b>2,449</b>	<b>1,448</b>
<b>Total other current liabilities</b>	<b>2,879</b>	<b>1,739</b>

### 14. 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 31.12.2018	Carrying amount as of 31.12.2018	Fair value as of 31.12.2017	Carrying amount as of 31.12.2017	Net gains (+) or losses (-) 31.12.2018	Net gains (+) or losses (-) 31.12.2017
Category: Held						
Cash and cash equivalents	19,451	19,451	11,083	11,083	(10)	0
Trade receivables	3,397	3,397	1,561	1,561	1	(1)
Other financial assets	794	794	571	571	-	(13)
Financial receivables and assets						
<b>Total</b>	<b>23,642</b>	<b>23,642</b>	<b>13,215</b>	<b>13,215</b>	<b>(9)</b>	<b>(14)</b>

Financial liabilities (EUR thousands)	Fair value as of 31.12.2018	Carrying amount as of 31.12.2018	Fair value as of 31.12.2017	Carrying amount as of 31.12.2017	Net gains (+) or losses (-) 31.12.2018	Net gains (+) or losses (-) 31.12.2017
Financial liabilities at amortized cost						
Financial liabilities, current	165	165	170	170	-	0
Trade payables	1,805	1,805	1,621	1,621	(13)	(48)
Other current financial liabilities	29	29	20	20	-	0
Financial liabilities, non-current	12,382	12,382	11,803	11,803	-	32
<b>Total</b>	<b>14,382</b>	<b>14,382</b>	<b>13,614</b>	<b>13,614</b>	<b>(13)</b>	<b>(16)</b>
Financial liabilities at fair value through profit or loss						
Financial liabilities, non-current	1,080	1,080	552	552	528	(32)
<b>Total</b>	<b>15,462</b>	<b>15,462</b>	<b>14,166</b>	<b>14,166</b>	<b>515</b>	<b>(16)</b>

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

The net gains and losses generally include currency translation effects.

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

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

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

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

Biofrontera has financial instruments at level 3. No reclassifications between the individual fair value hierarchy levels were implemented in the 2018 financial year. In the case of financial liabilities, non-current financial liabilities belong to level 3 (performance component of the EIB loan) (EUR 1.1 million, 31 December 2017: EUR 0.6 million).

## 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:** Interest-rate risk is deemed minor as existing interest-rate modalities for the Biofrontera Group's relevant financing facilities can generally be adapted to market conditions short-term to medium-term. The performance component represents one exception, although this is mitigated by a limit to 4% of the market price risk. No cash flow risk exists in relation to fixed interest warrant bonds. Due to the fixing of interest, no disadvantageous changes can occur to the interest payments. As the liabilities are not recognized at fair value but instead at amortized cost, there is also no fair value 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.

As of 31 December 2018, Biofrontera held no financial positions that were exposed to interest rate risks.

**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 27.0 million (previous year: EUR 13.1 million) A 5% change in the value of financial assets and financial liabilities in foreign currency would result in a change of EUR 1.4 million (previous year: EUR 0.7 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 2018 financial year, no individual value adjustments were made for other financial assets (prior-year period: EUR 0); in addition, no individual value adjustments were applied to trade receivables in the 2018 financial year (prior-year period: EUR 0). Cash and cash equivalents are invested with banks and insurance companies with sufficient deposit protection.

**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.

Biofrontera maintains a liquidity reserve, the amount of which is regularly reviewed and adjusted if necessary, in order to be able to meet all payment obligations throughout the Group when due. In February 2019, the company drew on a further tranche of EUR 5 million from the EIB loan. A further tranche of EUR 5 million can be drawn after certain milestones have been reached. Each tranche must be paid back within five years after it has been made available.

As a result of this loan and other successful capital measures, the company currently has sufficient liquidity at its disposal.

Depending on business trends, in particular on the success in tapping the market potential of the Ameluz® product, the company could be dependent in the medium term on the injection of additional equity or debt from outside sources until a sustainable financing from the operating cash flow is ensured.

See the relevant balance sheet notes on undiscounted payments from financial debt due in the next years.

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 2018 financial year

### 15. Sales revenue

Sales revenue (in EUR thousands)	01.01.-31.12.2018			01.01.-31.12.2017		
	Product revenue	Development revenues	Other	Product revenue	Development revenues	Other
Germany	3,307	-	-	2,674	-	-
Europe	2,737	-	-	1,616	-	-
U.S.	14,894	-	-	6,312	-	-
Other regions	-	129	40	-	1,423	-
<b>Total</b>	<b>20,938</b>	<b>129</b>	<b>40</b>	<b>10,602</b>	<b>1,423</b>	<b>-</b>

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

In the 2018 financial year, we generated EUR 94 thousand of income from operating leases (previous year: EUR 0 thousand). We generated income of EUR 240 thousand from finance leases (previous year: EUR 0 thousand).

### 16. Cost of sales, gross profit

The cost of materials included in the cost of sales amounted to EUR 3,636 thousand for the 2018 financial year (previous year: EUR 1,498 thousand).

The gross profit on sales increased by EUR 6,534 thousand in the 2018 reporting year, to reach EUR 16,656 thousand, compared with EUR 10,310 thousand in the prior-year period.

### 17. Research and development costs

Research and development costs amounted to EUR 4,427 thousand (previous year: EUR 4,225 thousand) and include costs for clinical studies as well as expenses for regulatory activities, i.e. the granting, maintenance and expansion of our approvals.

### 18. Sales and marketing costs

Sales and marketing costs amounted to EUR 17,744 thousand in the 2018 financial year (previous year: EUR 16,922 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.

### 19. General administrative costs

General administrative costs amounted to EUR 12,963 thousand in the 2018 financial year and thus increased by a total of EUR 9,866 thousand compared to the previous year, in particular due to increased legal and consulting costs (EUR 6,230 thousand; previous year: EUR 183 thousand). Administrative costs also include financing costs of EUR 496 thousand (previous year: EUR 583 thousand).

## 20. Interest expenses and income

The financial result essentially comprises ongoing interest expenses calculated using the effective interest method of the convertible bonds 2016/2021 and 2017/2011 placed in 2016 and 2017 (EUR 191 thousand; previous year: EUR 189 thousand) and the EIB loan made available in July 2017 (EUR 1,593 thousand; previous year: EUR 826 thousand).

## 21. Other expenses (income), net

Other expenses reduced by EUR 1,000 thousand to EUR 332 thousand in the 2018 financial year. By contrast, other income increased by EUR 1,042 thousand (EUR 1,302 thousand; previous year: EUR 260 thousand). These changes mainly include expenses and income from currency translation on loans granted by the parent company to the U.S. subsidiary Biofrontera Inc. in US dollars.

## 22. Deferred income tax

As of the balance sheet date, deferred tax assets were capitalized for the first time due to the corporation tax and trade tax loss carryforwards that can currently be carried forward in Germany and the planned future tax profits of Biofrontera Pharma GmbH. Income from deferred tax amounts to EUR 10,400 thousand (previous year: EUR 0 thousand). An amount of EUR 9 thousand from current income taxes was recognized (previous year: EUR 0 thousand).

## 23. 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.

	31.12.2018	31.12.2017
Number of weighted ordinary shares in circulation (on average)	43,695,794	38,076,087
Net loss for the year in EUR thousands	(8,878)	(16,102)
<b>Basic/diluted earnings per share in EUR</b>	<b>(0.20)</b>	<b>(0.42)</b>

## 24. Additional information about the consolidated statement of comprehensive income

The other income only includes conversion adjustments from the conversion of the foreign business entity into the Group's currency.

### Depreciation and amortization expense

Depreciation and amortization of EUR 754 thousand in the 2018 financial year and of EUR 884 thousand in the previous year: is included in the following items in the statement of comprehensive income:

in EUR thousands	31.12.2018	31.12.2017
Research and development costs	595	707
General administrative costs	109	142
Cost of sales	15	17
Sales and marketing	34	18
<b>Depreciation and amortization expense</b>	<b>754</b>	<b>884</b>

### Personnel costs

in EUR thousands	31.12.2018	31.12.2017
Wages and salaries	14,252	11,349
Social security charges	1,973	1,627
Costs for pension schemes	191	66
<b>Total</b>	<b>16,416</b>	<b>13,042</b>

## 25. Staff

In 2018 (2017), the Biofrontera Group had an average of 141 (119) employees worldwide, of whom 122 (106) were full-time employees, 29 (21) of our employees hold an academic degree, 13 (15) of our employees were directly or indirectly involved in production, 4 (2) employees in research and development, 12 (10) employees were involved in clinical and regulatory tasks, another 70 (51) employees were involved in marketing and sales, and 42 (41) of our employees were involved in management, business development, finance, human resources and administration. Of our 141 (119) employees, 75 (69) work in Germany, 56 (44) in the United States, 7 (6) in Spain and 3 in the United Kingdom, compared to 119 employees as of 31 December 2017, 74 employees as of 31 December 2016, 52 employees as of 31 December 2015 and 40 employees as of 31 December 2014. None of our employees are subject to collective wage bargaining. We regard our relationship with our employees as good.

## 26. Other information

Operating leases: The Group companies lease administrative and research facilities, as well as vehicles and equipment, under operating lease contracts. The future minimum commitments from leases are as follows:

in EUR thousands	2018	2017	2018	2017	2018	2017
	± 1 year		1 year to 5 years		> 5 years	
<b>Operating lease commitments</b>						
Building	629	516	2,798	1,780	1,196	1,188
Vehicle leases	420	395	342	390	-	-
Operating and office equipment	14	21	46	16	-	-

Lease-related expenses for the reporting period amounted to EUR 597 thousand (previous year: EUR 516 thousand).

In the U.S., BF RhodoLED® lamps are also offered under leasing agreements. In the first six months, these contracts are accounted for as operating leases. After six months, the lessee has the option to either return or purchase the device. The agreed purchase price can then be paid immediately in full or over a period of another 24 months. If payment is made for a further 24 months, the contracts are accounted for as financing leases. In the 2018 financial year, we generated EUR 94 thousand of income from operating leases (previous year: EUR 0 thousand). We generated income of EUR 240 thousand from finance leases (previous year: EUR 0 thousand). The expected future lease income as of 31 December 2018 is as follows:

in EUR thousands	2018	2017	2018	2017	2018	2017
	± 1 year		1 year to 5 years		> 5 years	
<b>Operating lease income</b>						
Operating lease payments	15	38	-	-	-	-
<b>Finance lease income</b>						
Finance lease interest income	19	-	11	-	-	-
Finance lease payments	121	-	72	-	-	-

## 27. 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 536 thousand (previous year: EUR 598 thousand). Taxes paid amounted to EUR 9 thousand (previous year: EUR 0 thousand). Interest received amounted to EUR 24 thousand (previous year: EUR 38 thousand).

The changes are comprised as follows:

in EUR thousands	31.12.2017	Cash flow	Non-cash changes Addition/ retirement	Fair value change	31.12.2018
Convertible bond 2016/2021	79	(50)	(29)	-	-
Convertible bond 2017/2022	2,530	-	(35)	-	2,495
EIB loan	9,746	-	693	528	10,967
<b>Non-current financial liabilities</b>	<b>12,355</b>	<b>(50)</b>	<b>629</b>	<b>528</b>	<b>13,462</b>
Interest: Convertible Bond 2016/2021,	5	(6)	1	-	-
Interest: Convertible Bond 2017/2022,	80	(158)	156	-	78
Interest: EIB loan	86	(371)	373	-	87
<b>Current financial liabilities</b>	<b>170</b>	<b>(535)</b>	<b>530</b>	<b>-</b>	<b>165</b>
<b>Total financial liabilities</b>	<b>12,525</b>	<b>(585)</b>	<b>1,159</b>	<b>528</b>	<b>13,627</b>

## 28. Members of the Management Board

The Management Board consists of Prof. Dr. Hermann Lübbert (Chief Executive Officer), Mr. Thomas Schaffer (Chief Financial Officer) and Mr. Christoph Dünwald (Chief Commercial Officer).

Name	Nationality	Age	Position	Term
Professor Dr. Hermann Lübbert	German	63	Chair	31/10/2020
Thomas Schaffer	German	56	Finance	30/11/2020
Christoph Dünwald	German	51	Sales & Marketing	30/11/2020

### 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.

### Management Board compensation

	Professor Dr. Hermann Lübbert	Thomas Schaffer	Christoph Dünwald
Non-performance-based salary component 2018	EUR 366 thousand	EUR 241 thousand	EUR 264 thousand
Non-performance-based salary component 2017	EUR 366 thousand	EUR 241 thousand	EUR 242 thousand
Performance-based salary component 2018	EUR 80 thousand	EUR 70 thousand	EUR 50 thousand
Performance-based salary component 2017	EUR 76 thousand	EUR 67 thousand	EUR 48 thousand
Income from the exercise of stock options 2018	EUR 94 thousand	EUR 83 thousand	-
Income from exercise of stock options 2017	-	-	-
Stock options (31.12.2018)	276,850	140,000	140,000
Fair value when granted (2018)	EUR 423 thousand	EUR 230 thousand	EUR 230 thousand
Stock options (31.12.2017)	236,850	125,000	90,000
Fair value when granted (2017)	EUR 299 thousand	EUR 145 thousand	EUR 112 thousand
Thereof granted in 2018	80,000	50,000	50,000
Thereof granted in 2017	70,000	40,000	40,000

All salaries/bonuses are classified as short-term employee benefits as defined in IAS 24.17 (a).

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

Thomas Schaffer Industrial Tracking Systems AG, Fürstentfeldbruck, Germany, Chairman of the Supervisory Board

## 29. Members of the Supervisory Board

Name	Nationality	Age	Position	Data first appointment	Term until
<b>Dr. Ulrich Granzer</b>	<b>German</b>	<b>58</b>	<b>Chair</b>	<b>12.05.2006</b>	<b>2021</b>
Curriculum vitae:	<p>Dr. Ulrich Granzer, Supervisory Board Chairman, is a founder and owner of Granzer Regulatory Consulting &amp; Services, and has been a Supervisory Board member since 2006. 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 approval area.</p> <p>He studied pharmaceuticals at Phillips University Marburg before receiving his doctorate from Tübingen</p>				
<b>Jürgen Baumann</b>	<b>German</b>	<b>64</b>	<b>Deputy Chair</b>	<b>24.05.2007</b>	<b>2021</b>
Curriculum vitae	<p>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.</p> <p>Mr. Baumann studied economic sciences at Wuppertal University.</p>				
<b>John Borer</b>	<b>U.S.</b>	<b>61</b>	<b>Member</b>	<b>31.05.2016</b>	<b>2021</b>
Curriculum vitae	<p>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 &amp; Renshaw and held management positions at Pacific Business Credit as well as at Barclays American Business Credit. His law doctorate was awarded by the Loyola Law School in Los Angeles.</p>				
<b>Reinhard Eyring</b>	<b>German</b>	<b>60</b>	<b>Member</b>	<b>07.02.2018</b>	<b>2021</b>
Curriculum vitae	<p>Reinhard Eyring is a partner and Head of Germany at Ashhurst LLP. Previously he was a partner at Schürmann &amp; Partner for 11 years.</p> <p>Mr. Eyring studied law at the University of Freiburg and subsequently worked as a trainee at the Regional Court of Frankfurt am Main.</p>				
<b>Hansjörg Plaggemars*</b>	<b>U.S.</b>	<b>48</b>	<b>Member</b>	<b>31.05.2016</b>	<b>2021</b>
Curriculum vitae	<p>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.</p> <p>He studied business management at Bamberg University.</p>				
<b>Kevin Weber</b>	<b>USA</b>	<b>60</b>	<b>Member</b>	<b>31.05.2016</b>	<b>2021</b>
Curriculum vitae	<p>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.</p> <p>He holds a degree in management and marketing from Western Michigan University.</p>				

\* Hansjörg Plaggemars was removed from his position as a member of the Supervisory Board of Biofrontera AG by the Cologne District Court on 22 March 2019.

## Supervisory board compensation

in EUR thousands	Compensation 2018	Compensation 2017
Dr. Ulrich Granzer	30	30
Jürgen Baumann	23	23
John Borer	15	15
Reinhard Eyring	14	0
Hansjörg Plaggemars	15	15
Mark Reeth	-	12
Kevin Weber	15	15
<b>Total</b>	<b>112</b>	<b>110</b>

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
Hansjörg Plaggemars	Ming Le Sports AG <sup>1,2</sup>	Supervisory Board	Chair
	Nordic SSW 1000 Verwaltungs AG <sup>1</sup>	Supervisory Board	Chair
	Carus AG <sup>1</sup>	Supervisory Board	Deputy Chair
	Deutsche Balaton Immobilien I AG <sup>1</sup>	Supervisory Board	Member
	Alpha Cleantec AG <sup>1</sup>	Management Board	sole representation authorization
	Balaton Agro Invest AG <sup>1</sup>	Management Board	sole representation authorization
	MARNA Beteiligungen AG <sup>1,2</sup>	Management Board	sole representation authorization
	S&O Agrar AG i.l. <sup>1,2</sup>	Management Board	sole representation authorization
	Snowbird AG i.l. <sup>1,2</sup>	Management Board	sole representation authorization
	Strawtec Group AG <sup>1</sup>	Management Board	sole representation authorization
	Youbisheng Green Paper AG <sup>1,2</sup>	Management Board	sole representation authorization
	OOC CTV Verwaltungs GmbH <sup>1</sup>	Management Board	sole representation authorization
Reinhard Eyring	DESTAG Deutsche Steinindustrie AG	Supervisory Board	Chair

Whereby footnote 1 means: "Group mandate" and footnote 2 means that the company is listed on the stock market.

In the 2018 financial year, compensation paid to Supervisory Board members amounted to EUR 112 thousand (previous year EUR 110 thousand). The compensation transactions are classified as short-term employee benefits as per IAS 24.17(a).

## 30. Related party disclosures

In July 2016, Biofrontera AG signed a research cooperation partnership (a collaboration and partnership agreement) with Maruho Co., Ltd, as part of which possibilities to jointly develop pharmaceutical products based on Biofrontera's proprietary nanoemulsion technology are to be researched. According to this agreement's provisions, Biofrontera, as part of research services, will conduct the requisite work for the exploratory research of these product candidates. Maruho is bearing the related costs. The partnership ended on 31 March 2018.

This development partnership generated revenue of EUR 129 thousand in the 2018 financial year (previous year: EUR 1,423 thousand). Receivables due from Maruho amounted to EUR 0 thousand as of 31 December 2018 (31 December 2017: EUR 124 thousand).

The Benchmark Company, LLC, served as an underwriter in the initial public offering on the Nasdaq Exchange and, in that capacity, received underwriting discounts in the amount of EUR 257 thousand, as well as a non-accountable expense allowance of EUR 102 thousand. John Borer, who is a member of our supervisory board, serves as Senior Managing Director and Head of Investment Banking at The Benchmark Company, LLC.

During 2017, our company availed itself of additional advisory services from supervisory board member Dr. Ulrich Granzer and his consulting company Granzer Regulatory Consulting & Services, which is owned and controlled by Dr. Granzer. These services went beyond the scope of normal supervisory board activities. Dr. Granzer assisted our company with key issues relating to the preparation of the applications for approval submitted to the supervisory authorities in Europe and the U.S. During the fiscal year ending December 31, 2018, no advisory services were provided by Granzer Regulatory Consulting & Services. There are no accounts payable to Granzer Regulatory Consulting & Services on December 31, 2018 (December 31, 2017: €0). The amounts stated here do not include statutory value added tax at the current rate of 19%.

In the 2018 financial year, there were no further reportable transactions or relationships with related parties beyond those described above or in sections 28 and 29, which the members of the Management Board and the Supervisory Board. The Group of related persons and entities is limited to those referred to therein.

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.

In light of the close cooperation between the Group companies, internal offsetting is applied, which is reviewed and adjusted to requirements on an annual basis.

### 31. Auditor's fees and services

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

in EUR thousands	2018	2017
Auditing services	580	360
[of which for the previous year]	[221]	[22]
Other assurance services	85	0
	<b>665</b>	<b>360</b>

Besides the statutory auditing of the separate annual and consolidated financial statements of Biofrontera AG, the auditing services also include the auditor's review of the condensed half-year financial statements and interim management report, as well as the audits of the consolidated financial statements according to PCAOB standards.

Other assurance services included the audit of the revenue guidance and issuance of the comfort letter.

### 32. Events after the reporting date

On 8 January 2019, Biofrontera announced that the US Food and Drug Administration (FDA) and previously also the European Medicines Agency (EMA) had approved an increase in the batch size for the production of Ameluz® from the previous 7 kg to 35 kg. The approval of five times the batch size will ensure a secure supply of Ameluz® to meet the growing demand in all regions.

On 20 March 2019, Biofrontera announced positive preliminary results for the primary endpoint of the Phase III clinical trial on the safety and efficacy of conventional photodynamic therapy (PDT) with Ameluz® and the BF-RhodoLED® lamp for the treatment of actinic keratoses (AK) on the extremities or trunk/neck. The preliminary results of the primary endpoint of the trial demonstrate the superiority of Ameluz® with an average lesion healing rate of 86% compared to 33% for placebo (p>0.0001). These results are expected to form the basis for applications to the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) for an extension of Biofrontera's regulatory filings during the third quarter of 2019.

#### EIB loan

On 4 February 2019, Biofrontera drew down another tranche of EUR 5 million from the EIB loan. Originally, the loan was available in tranches within a two-year period until July 2019. At the beginning of 2019, it has been extended for another year, which makes the last tranche available until May 2020.

## Research cooperation with Maruho

On 19 March 2019, the company signed an agreement to continue its research collaboration with Maruho Co., Ltd., Osaka, Japan ("Maruho") in the field of branded generics. In the new project phase, Biofrontera will prepare the formulation of one of four compounds in Biofrontera's nanoemulsion for clinical trials that were jointly investigated in an earlier project phase (Phase 1).

In addition, on 19 March 2019, the company signed a non-binding key term sheet on a collaboration to research and develop further indications of Ameluz® for the treatment of moderate to severe acne, as well as the negotiation of Maruho's license to market Ameluz® in parts of Asia and Oceania.

## Changes in the composition of the Supervisory Board

By order of the Cologne District Court dated 22 March 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 22 March 2019 and came to the company's attention on 26 March 2019. The ruling regarding the removal from office is effective immediately. However, an appeal may be lodged within one month, which has been done. In the event of a successful appeal, Mr. Plaggemars would reassume his position as a member of the Supervisory Board.

## Acquisition of Cutanea Life Sciences, Inc.

On 25 March 2019, Biofrontera Inc., through its wholly owned subsidiary Biofrontera Newderm LLC, U.S. ("Biofrontera"), which was founded on 20 March 2019, entered into an agreement with Maruho for the acquisition of all shares in Cutanea Life Sciences, Inc., U.S. ("Cutanea"). Cutanea has been marketing AKTIPAK®, a prescription gel for the treatment of acne, as well as Xepi™, a prescription cream for the treatment of impetigo, since November 2018.

The objective of the acquisition of Cutanea by Biofrontera is to effectively exploit the sales potential of AKTIPAK® and Xepi™ in the U.S. in order to strengthen Biofrontera's U.S. market presence.

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 restructured business activities (start-up costs). A purchase price equal to the start-up costs actually incurred must be paid to Maruho by 2023.

Subsequently, 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 operating costs that may be incurred during the first three months after completion of the transaction. Maruho will also indemnify Biofrontera and Cutanea against all liabilities relating to or resulting from the period prior to the transaction.

## Publication of voluntary tender offer by Maruho Deutschland GmbH

On 1 April 2019, Maruho Deutschland GmbH, a 100% subsidiary of Maruho Co., Ltd. (together "Maruho"), has published a notification pursuant to Section 10 WpÜG on Maruho has decided to offer to the shareholders of Biofrontera AG, by way of a voluntary public tender offer in the form of a partial offer, to acquire a total of up to 4,322,530 no-par value registered shares of Biofrontera AG against payment of EUR 6.60 per share in cash. The management board of Biofrontera AG values Maruho as a strategically oriented long-term partner. Biofrontera AG and Maruho have been working together closely and trustfully for many years. Maruho is not only one of the largest single shareholders of Biofrontera, but also a reliable partner in various research and development collaborations. Further, last week Biofrontera has acquired Maruho's U.S. business through the acquisition of Cutanea Life Sciences, Inc. The management board of Biofrontera AG regards Maruho's interest in an increase in its shareholding as an affirmation of the path it has taken to make Biofrontera a leading specialist in dermatology.

On 15 April 2019, Maruho published the notification pursuant to Section 14 (3) Clause 1 No. 2 WpÜG, as well as the offer document for the voluntary public tender offer in the form of a partial offer (cash offer) to the shareholders of Biofrontera AG to acquire a total of up to 4,322,530 no-par value registered shares of Biofrontera AG.

On 10 April 2019, we were requested by Deutsche Balaton AG pursuant to Section 122 (1) AktG to convene an extraordinary shareholders' meeting to discuss Maruho's voluntary public tender offer. The extraordinary shareholder's meeting will be held on 15 May 2019.

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

Leverkusen, 25 April 2019



Prof. Dr. Hermann Lübbert  
Chief Executive Officer



Thomas Schaffer  
Chief Financial Officer



Christoph Dünwald  
Chief Sales and Marketing Officer

# Independent Auditor's Report

To Biofrontera AG, Leverkusen

## Report on the Audit of the Consolidated Financial Statements and of 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 2018, 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 2018 to 31 December 2018, 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 2018 to 31 December 2018. 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] (Corporate Governance Report) 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 2018 and of its financial performance for the financial year from 1 January 2018 to 31 December 2018, and
- the accompanying combined management report as a whole provides an appropriate view of the Group's position. In all material respects, this combined management report is consistent with the consolidated financial statements, complies with German legal requirements and appropriately presents the opportunities and risks of future development. Our audit opinion on the combined management report does not cover the content of the above mentioned Corporate Governance Declaration pursuant to Section 289f and Section 315d HGB.

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

### Basis for the Audit Opinions

We conducted our audit of the consolidated financial statements and of the combined management report in accordance with section 317 HGB and the EU Audit Regulation (No. 537/2014, referred to subsequently as "EU Audit Regulation") and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Our responsibilities under those requirements and principles are further described in the "Auditor's Responsibilities for the Audit of the Consolidated Financial Statements and of the Combined Management Report" section of our auditor's report. We are independent of the group entities in accordance with the requirements of European law and German commercial and professional law, and we have fulfilled our other German professional responsibilities in accordance with these requirements. In addition, in accordance with Article 10 (2) point (f) of the EU Audit Regulation, we declare that we have not provided non-audit services prohibited under Article 5 (1) of the EU Audit Regulation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinions on the consolidated financial statements and on the combined management report.

### Key Audit Matters in the Audit of the Consolidated Financial Statements

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the consolidated financial statements for the financial year from 1 January 2018 to 31 December 2018. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our audit opinion thereon; we do not provide a separate audit opinion on these matters.

In the following we present the key audit matters in our view: Our presentation of the key audit matters has been structured as follows:

- ① Financial Statement Risk
- ② Audit approach
- ③ Reference to related disclosures

## Capitalization of tax loss carryforwards

### ① Financial Statement Risk

In the consolidated balance sheet as of 31 December 2018 of Biofrontera AG, a balance from deferred tax assets in the amount of kEUR 10,733 and deferred tax liabilities amounting to kEUR 333 are recognised under the line item "Deferred taxes".

Of the deferred tax assets, an amount of kEUR 10,486 as at 31 December 2018 relates to tax loss carryforwards of Biofrontera Pharma GmbH capitalised for the first time by the company, which has already generated profits in the second half of 2018 and the executive directors assume 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 total amount of kEUR 33,526 were not recognised.

Whether the deferred tax assets from the loss carryforwards 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 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 significance in our audit.

### ② Audit Approach

As part of our audit of the capitalisation or the omitted capitalisation of deferred tax assets from loss carryforwards we critically assessed the judgement of the executive directors relating to the predictability of future taxable profits of the relevant taxable entities. For this purpose we first analysed the taxable income history as well as the planning for the financial year 2019 submitted by the executive directors of Biofrontera AG and assessed whether the loss carryforwards are resulting from events in the past which are unlikely to recur. For Biofrontera Pharma GmbH we furthermore evaluated the assessment of the executive directors of Biofrontera AG that the positive earnings development of Biofrontera Pharma GmbH in 2018 and in the planning period is expected to be sustainable. In this context we reconciled the taxable income planning of Biofrontera Pharma GmbH with planning of the Biofrontera Group for the financial year 2019 as adopted by the executive directors of Biofrontera AG and approved by the Supervisory Board, and we reconciled the forward projection planning with current and expected conditions in the relevant markets and our understanding of economic environment of the Biofrontera Group. On the basis of the information obtained in this process, we finally evaluated the assessment of the executive directors with regard to evidence leading to the capitalisation of the loss carryforwards at Biofrontera Pharma GmbH and recalculated the tax loss carryforwards as well as 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 financial statements - 8. Deferred income tax" section of the notes to the consolidated financial statements.

## Evaluation of provisions for litigation costs

### ① Financial Statement Risk

The consolidated financial statements as at 31 December 2018 shows provisions for litigation costs in the amount of kEUR 3,241 under the balance sheet item "Other provisions". It includes provisions in the amount of kEUR 3,191 for estimated litigation costs of Biofrontera AG in connection with a lawsuit filed by DUSA Pharmaceuticals Inc. in the District Court of Massachusetts against Biofrontera AG and its subsidiaries alleging infringement of its patents by the sale of BF-RhodoLED® in the U.S.

Biofrontera believes that these claims are unjustified and intends to defend them.

Biofrontera may incur significant costs in defending these claims, as in addition to internal human resources they also mandated U.S. lawyers to defend the claims. The costs incurred by Biofrontera as a result would not be reimbursed by the plaintiff in the event of a positive outcome of the proceedings, due to the characteristics of the U.S. legal system, and therefore a provision was accrued as at 31 December 2018.

The evaluation of the provisions for litigation costs is based on the assessments and assumptions of the executive directors of Biofrontera AG on the costs of the litigation and the length of the proceedings in court and is therefore subject to high estimation uncertainty. Against this background, this matter was of particular significance in our audit.

### ② Audit Approach

As part of our audit we assessed, among other things, the process established by the Company to ensure the recognition, the estimate of the costs of the proceedings, and the accounting presentation of the legal dispute. Additionally, we assessed the appropriateness of material assumptions relating to the recognition and measurement of the provisions recognised for litigation. For this purpose we inspected the underlying documents of the legal dispute and evaluated the directly obtained legal counsel's confirmation. Furthermore, we conducted inquiries of one executive director to obtain an understanding of the current development and the rationale on which the relevant estimates are based. Additionally, a written statement concerning the underlying significant assumptions for the accounting of the provision was obtained from the Company. Within our audit we also assessed the respective disclosures in the notes to the consolidated financial statements.

### ③ Reference to related Disclosures

The disclosures of Biofrontera AG relating to accounting policies with regard to provisions and estimates used are shown in the "Summary of significant accounting policies" section of the notes to the consolidated financial statements and the disclosures relating to provisions in the "Notes to the consolidated financial statements - 12. Other provisions" section of the notes to the consolidated financial statements.

## Other Information

The executive directors 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 regarding the consolidated financial statements and the Responsibility Statement pursuant to Section 315 para.1 sentence 5 HGB regarding the combined management report and
- the remaining parts of the 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 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 Combined Management Report**

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

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with section 317 HGB and the EU Audit Regulation and in compliance with German Generally Accepted Standards for 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 11 July 2018. We were engaged by the supervisory board on 9 October 2018. 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, 25 April 2019

Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft

Prof. Dr. Thomas Senger

Michael Gottschalk

Wirtschaftsprüfer  
[German Public Auditor]

Wirtschaftsprüfer  
[German Public Auditor]

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[www.instinctif.com](http://www.instinctif.com)

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Biofrontera:

2019 Stevie Winner (p. 9, top)

Nanoemulsion (p. 11, top)

U. Granzer (p. 20)

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