1,215,000 American Depositary Shares Representing 2,430,000 Ordinary Shares

BIOFRONTERA AG

This is an initial public offering of 1,215,000 American Depositary Shares, or ADSs, each representing two ordinary shares, nominal value €1.00 per share, of Biofrontera AG, a German stock corporation. Separate from this offering, we have completed a concurrent preemptive rights offering of our ordinary shares pursuant to German law to our existing holders of ordinary shares, under which we will be issuing a total of 3,399,034 ordinary shares. The price per share at which our shares were offered in the German preemptive rights offering was €4.00, which is the same as the initial public offering price per ADS being offered in the U.S. offering (adjusting for the euro/U.S. dollar exchange rate and the ratio of ordinary shares to ADSs), or $9.88. As described below, have also offered our underwriters an over-allotment option to purchase up to an additional 85,483 ADSs in this offering (or 170,966 ordinary shares).

We are offering a maximum of 6,000,000 ordinary shares in the combined offering of the German preemptive rights offering and this U.S. offering of ADSs (including if the underwriters exercise in full their over-allotment option).

Prior to this offering, there has been no public market in the United States, or U.S., for our ordinary shares or ADSs. Our ordinary shares are listed on the Frankfurt Stock Exchange under the symbol "B8F", and we have been approved for the listing of the ADSs on The NASDAQ Capital Market under the symbol "BFRA". On February 8, 2018, the closing price of our ordinary shares on the Frankfurt Stock Exchange was €5.15 ($ 6.39, based upon the noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018, which was €1.00 to $1.24).

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012 and as such, will be subject to reduced public company reporting requirements for this prospectus and future filings.

Investing in our securities involves risk. See "Risk Factors" beginning on page 16 to read about factors you should consider before buying our ADSs.

None of the U.S. Securities and Exchange Commission, any U.S. state securities commission or any foreign securities commission has approved or disapproved of these securities or passed upon the accuracy or adequacy of this prospectus. Any representation to the contrary is a criminal offense.

	Per ADS	Total
Initial public offering price	$ 9.88	$ 12,004,200
Underwriting discount and commissions[(1)]	$ 0.79	$ 960,366
Proceeds, before expenses, to Biofrontera	$ 9.09	$ 11,043,864

The underwriters have the option to purchase up to an additional 85,483 ADSs at the same price per ADS as paid for the ADSs offered hereby, for 45 days after the date of this prospectus, to cover over-allotments, if any.

The underwriters expect to deliver the ADSs against payment in New York, New York on February 16, 2018.

The Benchmark Company, LLC is acting as representative for the underwriters in connection with this offering. An affiliate and a principal of The Benchmark Company, LLC holds a position as a member of the supervisory board of our company. Therefore, The Benchmark Company, LLC is deemed to have a "conflict of interest" under Rule 5121(f)(5) of the Financial Industry Regulatory Authority, Inc. ("FINRA"). Accordingly, this offering will be conducted in accordance with the applicable provisions of Rule 5121, which requires, among other things, that a "qualified independent underwriter" participate in the preparation of, and exercise the usual standards of "due diligence" with respect to, the registration statement and this prospectus. Dawson James Securities, Inc. has agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering.

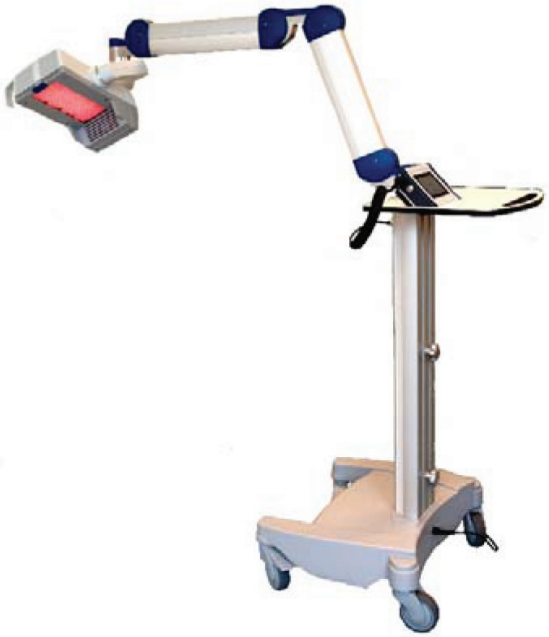
Benchmark

Dawson James Securities, Inc. **Lake Street Capital Markets**

Prospectus dated February 13, 2018.

(1) See "Underwriting (Conflicts of Interest)" for additional information regarding underwriting compensation.


Ameluz® 78 mg/g Gel
5-Aminolävulinsäure
Biofrontera
Zur Anwendung auf de
Ameluz® 78 mg/g Gel
5-Aminolävulinsäure
Zur Anwendung auf der Haut 2g



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You should rely only on the information contained in this prospectus and any related free-writing prospectus that we authorize to be distributed to you. We and the underwriters have not authorized any person to provide you with information different from that contained in this prospectus or any related free-writing prospectus that we authorize to be distributed to you. This prospectus is not an offer to sell, nor is it seeking an offer to buy, these securities in any state or other jurisdiction where the offer or sale is not permitted. The information in this prospectus speaks only as of the date of this prospectus unless the information specifically indicates that another date applies, regardless of the time of delivery of this prospectus or of any sale of the securities offered hereby.

Unless otherwise indicated, all references in this prospectus to "Biofrontera", "we", "us", or "company" refer to Biofrontera AG and its consolidated subsidiaries, Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH, Biofrontera Neuroscience GmbH, Biofrontera Development GmbH and Biofrontera Inc.

No action is being taken in any jurisdictions outside the United States to permit a public offering of the American Depositary Shares, or ADSs, or possession or distribution of this prospectus in such jurisdictions. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to this offering and the distribution of the prospectus applicable to such jurisdictions.

Until March 10, 2018 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.

TRADEMARKS

We own or have rights to trademarks and trade names that we use in connection with the operation of our business, including our corporate name, logos, product names and website names. Other trademarks and trade names appearing in this prospectus are the property of their respective owners. Solely for your convenience, some of the trademarks and trade names referred to in this prospectus are listed without the® and TM symbols, but we will assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor, to our trademarks and trade names.

PRESENTATION OF FINANCIAL INFORMATION

Unless otherwise indicated, the consolidated financial statements and related notes included in this prospectus have been presented in euros, or €, and also comply with the International Financial Reporting Standards, or IFRS, as issued by the International Accounting Standards Board, or IASB. None of the consolidated financial statements in this prospectus were prepared in accordance with United States generally accepted accounting principles. For any of our subsidiaries that use a functional currency that is not euros, the assets and liabilities have been translated at the closing exchange rate as of the relevant balance sheet date (six months ended June 30, 2017: 1.14227 U.S. dollars to 1 euro; June 30, 2016: 1.11038 U.S. dollars to 1 euro), while the income and expenses have been translated at the average exchange rates (six months ended June 30, 2017: 1.08200 U.S. dollars to 1 euro; June 30, 2016: 1.11603 U.S. dollars to 1 euro) applicable to the relevant period. 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. Transactions realized in currencies other than euros 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 arising from such currency translations are recognized in income. See "Summary of Significant Accounting Policies — Translation of Amounts in Foreign Currencies" in the notes to our consolidated financial statements included elsewhere in this prospectus for more information.

Certain information in this prospectus is expressed in U.S. dollars. The noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018 was €1.00 to $1.24. We make no representation that the euro or U.S. dollar amounts referred to in this prospectus could have been converted into U.S. dollars or euros, as the case may be, at any particular rate or at all. See "Risk Factors — Our international operations may pose currency risks, which may adversely affect our operating results and net income." We use the symbol "$" to refer to the U.S. dollar and use the symbol "€" to refer to the euro herein.

PROSPECTUS SUMMARY

This summary highlights selected information contained elsewhere in this prospectus and is qualified in its entirety by the more detailed information and consolidated financial statements and the related notes thereto included elsewhere in this prospectus. This summary does not contain all the information you should consider before investing in our ADSs. You should read this entire prospectus carefully, including "Risk Factors", "Management's Discussion and Analysis of Financial Condition and Results of Operations", and our consolidated financial statements and the related notes thereto included elsewhere in this prospectus, before making an investment decision.

Overview

Our Company

We are an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Our approved products focus on the treatment in the U.S. and Europe of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of basal cell carcinoma in the EU. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots. Because of their location and appearance, actinic keratoses are often cosmetically unappealing.

Our principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy, or PDT, which we sometimes refer to as Ameluz® PDT. Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. A major advantage of treating actinic keratosis and basal cell carcinoma with photodynamic therapy (as opposed to other common treatments such as simple curettage and cryotherapy) is that it is a non-invasive alternative that can have better cosmetic results, *i.e.*, removal of tumors without leaving clearly visible scarring.

In addition, we have developed our own PDT lamp, BF-RhodoLED®, for use in combination with Ameluz®. Our BF-RhodoLED® lamp was approved as a medical device in the EU in November 2012 and is approved for sale in all EU countries, although the use of our BF-RhodoLED® lamp is not required to be used in combination with Ameluz® in the EU or Switzerland.

In May 2016, we received approval from the U.S. Food and Drug Administration, or the FDA, to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016.

We currently sell Ameluz® in the U.S., in 11 countries in Europe and in Israel.

Dermatological Conditions and Diseases that are Treated by Our Products

Ameluz® PDT is approved for the treatment of actinic keratosis on the face and scalp in the U.S. and Europe and certain types of basal cell carcinoma in the EU. It is an alternative to more invasive treatments, such as cryotherapy or simple curettage.

Actinic keratoses are superficial, potentially pre-cancerous skin lesions caused by chronic sun exposure that may, if left untreated, develop into a form of potentially life-threatening skin cancer called squamous cell carcinoma. Actinic keratosis is more common in men than women, and much more common in people over 40 years of age. Actinic keratoses are more likely to develop in people with fair skin and a history of sunburn. They are especially prevalent in geographical areas with sunny climates.

According to The Skin Cancer Foundation (SCF), if left untreated, up to 1% of actinic keratosis lesions develop into squamous cell carcinomas every year. Squamous cell carcinoma has been the second most common form of skin cancer, but its incidence has been rapidly increasing. According to the SCF, more than one million cases of squamous cell carcinoma are diagnosed each year in the U.S., and it has been estimated that as many as 8,800 people die from the disease each year in the U.S. Incidence of the disease has increased by 200 percent in the past three decades in the U.S. and it has recently matched the incidence of basal cell carcinoma in the Medicare fee-for-service population, which had been the most common form of human cancers.

Because actinic keratosis can develop into squamous cell carcinomas, actinic keratosis is classified by The European Academy of Dermatology and Venereology and other international treatment guidelines as a tumor that requires treatment, 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.

Squamous cell carcinoma is an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers (the epidermis). Squamous cell carcinomas often appear as scaly red patches, open sores, elevated growths with a central depression, or warts; and they may crust or bleed. They can become disfiguring and sometimes deadly if allowed to grow.

Basal cell carcinomas are abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the deepest layer of the epidermis (the outermost layer of the skin). Basal cell carcinomas often appear as open sores, red patches, pink growths, shiny bumps or scars and are typically caused by accumulated sun exposure. Basal cell carcinomas are the most common invasive tumors affecting humans, accounting for approximately 80 percent of all non-melanoma skin cancers worldwide. More than 4 million cases of basal cell carcinoma are diagnosed in the U.S. each year. Although basal cell carcinoma rarely spreads to other parts of the body and becomes life-threatening, it can be disfiguring if not treated promptly.

The Limitations of Competing Treatment Regimes

Actinic keratoses are treated using a wide range of methods. The traditional methods of treating actinic keratoses are:

- cryotherapy, or the deep freezing of skin;
- self-applied topical prescription products;
- combination of medication with photodynamic therapy; and
- simple curettage, or the surgical removal of tissue by means of scraping with a curette.

Although any of these methods can be effective, each has limitations and can result in significant side effects.

Cryotherapy is non-selective (i.e., it cannot target specific tissues, but affects all tissues in the area of application), can be painful at the site of freezing, and can cause blistering and loss of skin pigmentation, leaving temporary or permanent white spots. In addition, because there is no standardized treatment protocol, results are not uniform and can depend on the skill or technique of the doctor treating the patient.

Topical prescription products include 5-fluorouracil cream, or 5-FU, which can be irritating and requires twice-a-day application by the patient for approximately 2 to 4 weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment, up to several weeks of healing may be required. Imiquimod or diclofenac, other topical prescription products, require extended applications of cream, lasting up to 3 or 4 months, during which the skin is often very red and inflamed. Treatment with ingenol mebutate is faster, requiring application for only a few days, but side effects can be long-lasting and this drug has been labeled with a black-box warning by the FDA (a warning that appears on a prescription drug's label and is designed to call attention to serious or life-threatening risks).

Simple curettage is generally most useful for one or a few individual lesions, but not for a large number of lesions, and it leaves permanent scars.

Other approved drugs used in combination with photodynamic therapy (PDT) are Levulan® in the U.S. and Metvix®/Metvixia® and AlaCare® in the EU. Levulan® and AlaCare® contain 5-aminolevulinic acid (5-ALA) as its active ingredient and Metvix®

contains methylesther as its active ingredient. Metvix is metabolized to 5-ALA in the tissue, after which the method of action is identical to Levulan. In the U.S., Levulan PDT is approved for treatment of minimally to moderately thick actinic keratosis of the face and scalp in combination with PDT with a blue light source, and, in the EU, Metvix PDT is approved for treatment of actinic keratosis with a red light source. AlaCare® is a 2x2 cm medicated plaster, which is also approved for treatment of actinic keratosis with red light. As with Ameluz®, in the treatment of moderately thick actinic keratosis of the face and scalp, both Levulan and Metvix are used in a PDT treatment once, and the PDT treatment is repeated after several weeks if residual lesions remain. AlaCare® is approved for single use treatment of mild actinic keratosis lesions with a maximum diameter of 1.8 cm on the face and scalp (hairless area).

In the U.S., our approved treatment method involves applying Ameluz® gel to individual or entire fields of actinic keratosis lesions, followed three hours later with exposure to our red light BF-RhodoLED® lamp for approximately ten minutes. In the EU, Ameluz® is also indicated for field cancerization and for superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. In our Phase III trials, our treatment produced varying degrees of pain during light treatment, but the therapy was generally well tolerated. The resulting redness and/or inflammation resolved within 1 to 4 days in most cases; in some cases, however, it persisted for 1 to 2 weeks or even longer.

We believe Ameluz® PDT is a preferable treatment for actinic keratosis compared to non-PDT competing treatment regimes for a number of reasons, including: (i) Ameluz® PDT does not result in significant scarring (as compared to cryotherapy or simple curettage), (ii) skin appearance is typically improved for at least 12 months after treatment and (iii) a patient's healing is typically completed within 1-2 days of treatment.

The most common treatment for basal cell carcinoma in the EU and U.S. is surgical removal. In many European countries, dermatology specialists are hospital-based and, as a result, basal cell carcinoma is most commonly treated in European countries by hospital surgery, which is rarely the case for actinic keratosis. The treatment of basal cell carcinoma by a surgical procedure can result in high cost and clearly visible scarring. But thin, non-aggressive basal cell carcinomas can also be treated with photodynamic therapy, such as Ameluz® PDT. The advantage of treating basal cell carcinoma with photodynamic therapy is that it is a non-invasive alternative that can have better cosmetic results, *i.e.*, removal of tumors without leaving clearly visible scarring. It is also available for patients who are at risk of surgery-related morbidity.

Our Strategy

Our principal objectives are to obtain regulatory approvals for the marketing of Ameluz® PDT for additional indications and in additional countries, and to increase the sales of our approved products. The key elements of our strategy include the following:

- geographic expansion of Ameluz® sales worldwide, including by:
    - expanding our sales in the U.S. of Ameluz® in combination with our BF-RhodoLED® light device for the treatment of actinic keratosis and positioning Ameluz® to be a leading photodynamic therapy product in the U.S., by growing our dedicated sales and marketing infrastructure in the U.S.;
    - expanding our sales in the EU of Ameluz® by marketing it for the treatment not only of actinic keratosis, but also for the treatment of field cancerization (larger skin areas containing potentially pre-cancerous cells and multiple actinic keratosis lesions) and basal cell carcinoma, indications for which we recently obtained approval; and
    - expanding our sales of Ameluz® in other countries where it is an approved product by entering into arrangements with distribution partners;
- extending the approved indications for Ameluz® photodynamic therapy, including by:
    - seeking to extend the approved label for actinic keratosis to include actinic keratosis lesions located other than on the head or scalp and increase the maximal size of the treatment field;
    - seeking to extend the approved indications in the U.S. for Ameluz® in combination with our BF-RhodoLED® light device for the treatment of basal cell carcinoma;

- seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy, or exposure to sunlight, an indication for which we have recently applied in the EU and which we believe may increase the market potential of Ameluz® in such region (since Ameluz® could be used without doctor's office procedures, which procedures can render photodynamic therapy treatment in European markets commercially unattractive due to lack of reimbursement); and

- seeking to extend the approved indications in the EU and U.S. for Ameluz® to additional indications, such as squamous cell carcinoma *in situ*, actinic cheilitis, acne, warts, wound healing, and/or cutaneous leichmania; all of which would require further clinical trials, and other research and development activities.

We also plan to develop additional drug candidates and seek partnerships or other opportunities for drug development collaborations, such as our collaboration and partnership agreement with Maruho Co., Ltd., or Maruho, that is an affiliate of Maruho Deutschland GmbH, a major shareholder of our company, and to continue to develop and expand marketing and sales of our cosmetic skin care products.

Risk Factors

Our business is subject to numerous risks and uncertainties, including those highlighted in "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and that we may never sustain profitability.

- If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our products and product candidates.

- Our existing and any future indebtedness could adversely affect our ability to operate our business.

- Certain of our important patents will expire in 2019. Although the process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors, generic versions of Ameluz® could enter the market after expiration of these patents. If this happens, we may need to reduce the price of Ameluz® significantly and may lose significant market share.

- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our products or product candidates, which could make it difficult for us to sell our products.

- To date, we have engaged in only limited sales of our products, primarily in Germany and Spain and, more recently, in the U.S.

- We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance. We have recently lost market share in Germany to daylight PDT products, an indication for which we have applied but for which Ameluz® is not currently approved.

- We depend on a single unaffiliated contract manufacturer to manufacture Ameluz® and two unaffiliated contractors to produce 5-aminolevulinic acid, the active pharmaceutical ingredient in Ameluz®, for us. If we fail to maintain our relationship with these suppliers or if these suppliers are unable to continue to produce product for us, our business could be materially harmed.

- Even if we obtain regulatory approvals for our products and product candidates, they may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community.

- With respect to our already approved products, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

- A recall of our drug or medical device products, or the discovery of serious safety issues with our drug or medical device products, could have a significant negative impact on us.

- We will need to grow the size of our organization and we may experience difficulties in managing this growth.
- Our international operations may pose currency risks, which may adversely affect our operating results and net income.
- Our business depends substantially on the success of our principal product Ameluz®. If we are unable to successfully commercialize Ameluz®, to obtain and maintain regulatory approvals or reimbursement for Ameluz® for existing and additional indications and/or in additional countries, or if we experience significant delays in realizing any of those commercialization or product development objectives, our business may be materially harmed.
- Clinical drug development is expensive and involves uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If one or more future Phase III clinical trials for Ameluz® were unsuccessful, or significantly delayed, we could be required to abandon development, we may suffer reputational harm and our business will be materially harmed.
- We will be subject to ongoing regulatory requirements in every market where we engage in business and we may face future development, manufacturing and regulatory difficulties.
- If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.
- We may be involved in lawsuits to defend or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Corporate History and Information

Our company was formed in 1997 by Professor Hermann Lübbert, Ph.D., who currently serves as chairman of our management board and our chief executive officer, as a limited liability company (*Gesellschaft mit beschränkter Haftung* or *GmbH*) under German law and under the name "BioFrontera Laboratories GmbH" to provide services to the pharmaceutical industry.

In September 1997, the company was renamed "BioFrontera Pharmaceuticals GmbH" and commenced its current operations, which include the development, marketing, sales, manufacturing and distribution of drugs and medical devices, cosmetics, and other dermatology-related products. On August 24, 2000, our company was converted into a German stock corporation (*Aktiengesellschaft or AG*), and on November 27, 2003, our company was renamed "Biofrontera AG".

Our company's principal executive offices are located at Hemmelrather Weg 201, D-51377 Leverkusen, Germany and our telephone number is 011 49 214 876 00. Our website address is *www.biofrontera.com*. Information contained on our website is not incorporated by reference into this prospectus, and you should not consider information contained on our website to be part of this prospectus or in deciding whether to purchase our ADSs. Our agent for service of process in the U.S. is Biofrontera Inc., 201 Edgewater Dr., Wakefield, Massachusetts 01880, U.S. Our ordinary shares have been listed on the Stock Exchange in Düsseldorf since 2006 and on the Frankfurt Stock Exchange under the ticker symbol "B8F" since 2012.

Implications of Being a Foreign Private Issuer

We will qualify as a "foreign private issuer" as defined in Section 405 of the Securities Act of 1933, as amended, or the Securities Act. As a foreign private issuer, we are exempt from certain rules under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that impose disclosure requirements as well as procedural requirements for proxy solicitations under Section 14 of the Exchange Act. In addition, our officers, directors and principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act. Moreover, we are not required to file periodic reports and financial statements with the U.S. Securities and Exchange Commission, or the SEC, as frequently or as promptly as a company that files as a domestic issuer whose securities are registered under the Exchange Act, nor are we generally required to comply with the SEC's Regulation FD, which restricts the selective disclosure of material non-public information. We intend to take advantage of these exemptions as a foreign private issuer. See "Risk Factors — As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of ADSs."

Implications of Being an Emerging Growth Company

We are an "emerging growth company" as that term is defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of specified reduced reporting requirements that are otherwise applicable generally to public companies. These reduced reporting requirements include:

- an exemption from compliance with the auditor attestation requirement on the effectiveness of our internal controls over financial reporting;
- reduced disclosure about our executive compensation arrangements; and
- an exemption from the requirements to obtain a non-binding advisory vote on executive compensation or stockholder approval of any golden parachute arrangements.

We have elected to take advantage of the scaled disclosure requirements and other relief described above in this prospectus and may take advantage of these exemptions for so long as we remain an emerging growth company. We will remain an emerging growth company until the earliest to occur of: (i) the last day of the fiscal year following the fifth anniversary of this offering; (ii) the last day of the fiscal year in which our annual gross revenue is $1,070,000,000 or more; (iii) the date on which we have, during the previous three-year period, issued more than $1,000,000,000 in non-convertible debt securities; or (iv) as of the end of any fiscal year in which the market value of our ordinary shares held by non-affiliates is $700,000,000 or more as of the end of the second quarter of that fiscal year. We may choose to take advantage of some, but not all, of the available benefits under the JOBS Act. Accordingly, the information contained herein may be different than the information you receive from other public companies in which you hold stock. See "Risk Factors — We are an emerging growth company, and we cannot be certain that the reduced reporting requirements applicable to emerging growth companies will not make our ADSs less attractive to investors."

Recent Developments

Set forth below is certain limited unaudited financial information as of and for the three months and nine months ended September 30, 2017. In connection with our listing on the Frankfurt Stock Exchange, we published substantially all of this financial information in an announcement issued on November 26, 2017. This financial information has been prepared under IFRS as adopted by the EU. No material differences are believed to exist between the presented financial information in accordance with IFRS as adopted by the EU and IFRS as issued by the IASB.

Key figures

	For the Nine Months ended September 30,		For the Three Months ended September 30,	
In €thousands (unless stated otherwise)	**2017**	**2016**	**2017**	**2016**
Sales revenue	7,334.0	2,881.4	2,327.6	1,172.8
Research and development costs	(3,232.9)	(3,358.4)	(1,047.5)	(1,506.4)
Sales costs	(12,586.1)	(4,937.4)	(4,310.8)	(2,105.1)
General administrative costs	(3,625.9)	(2,080.8)	(1,930.3)	(708.4)
Profit/loss for the period	(13,730.1)	(7,163.1)	(5,589.4)	(3,691.5)
Cash flows used in operational activities	(12,313.7)	(6,885.0)	(4,226.8)	(4,374.3)
Cash flows provided by financing activities	10,740.7	8,867.1	6,136.1	(0.3)
Cash and cash equivalents	13,307.3	5,733.3	13,307.3	5,733.3
Employees (number, end of period)	125	81	125	81
Shares outstanding (number, end of period)	38,416,503	30,347,813	38,416,503	30,347,813
Share price (closing Xetra, end of period in EUR)	3.51	3.02	3.51	3.02

As compared with the nine-month period ended September 30, 2016, our sales revenue increased by 154.5% to €7.3 million, driven primarily by the successful market launch of Ameluz® in the U.S. During the first nine months of 2017, we expanded our marketing efforts in the U.S. by expanding our U.S. team from 24 to 45 staff in the areas of field sales, medical and support

and management. In August, we integrated our marketing and sales support areas into Biofrontera Inc., which we believe will enable us to offer our customers cost-efficient support at a high level. In September, we appointed Jeffrey Holm, an experienced marketing manager with a broad network in the U.S. dermatology market, to be Vice President Marketing. Our U.S. customer base currently includes over 500 dermatology practices. We expect the process of claiming reimbursement for Ameluz® will become easier since the permanent J-code for Ameluz® became effective in January 2018, and we expect this will have a positive effect on our sales and revenue.

Based on the preliminary unaudited information currently available to management, we expect to report revenues of between €12.0 and €12.2 million in the year ended December 31, 2017, of which revenues attributed to the United States are expected to be between €6.3 and €6.4 million. As of the date of this prospectus, we cannot estimate other major captions of our statement of comprehensive income as we have not yet finalized our accounting records for the 2017 fiscal year. Therefore, we cannot speak as to any trends for such captions beyond anticipated revenues. Our revenues increased significantly in the quarter ended December 31, 2017 as compared to the prior quarter, primarily due to increases in revenues attributable in the U.S. This is attributable to the completion of training of our sales personnel resulting in an increase in sales and marketing activity. Further, we noted an increase in customer orders in anticipation of the unique, product-specific billing code (J-code) for Ameluz® assigned by the U.S. Center for Medicare and Medicaid Services (CMS) to us in November 2017 (see "Business — Recent Achievements" on page 77 of this prospectus). As the U.S. market continues to develop with planned further investment in sales force and marketing efforts, we anticipate future periods to exhibit similar trends.

Our actual results remain subject to the completion of management's final review, or subsequent events, as well as the completion of the audit of these final results. Accordingly, you should not place undue reliance on our preliminary financial results, which may differ from actual results.

Results of operations

Sales revenue

We generated total sales revenue of €7.3 million in the first nine months ended September 30, 2017, representing an increase of 154.5% year-on-year. Sales revenue in Germany amounted to €1.7 million, reflecting a slight rise of €185 thousand compared with nine months ended September 30, 2017. Revenue generated outside of Germany performed well in the first nine months of 2017, driven primarily by increased sales in the U.S. amounting to €3.4 million. In Europe, sales revenue increased by 61% to €1.2 million. Development projects with Maruho generated sales revenue of €1.1 million in the nine months ended September 30, 2017 as compared with €613 thousand in the nine months ended September 30, 2016.

Operating costs

Research and development costs for the nine months ended September 30, 2017 were €3.2 million, a decrease of €125 thousand, or 4%, as compared with nine months ended September 30, 2016.

Sales costs for the nine months ended September 30, 2017 were €12.6 million, an increase €7.7 million, or 155%, compared with the nine months ended September 30, 2016. This increase was driven primarily by increased marketing and sales expenses in the U.S.

General administrative costs for the nine months ended September 30, 2017 were €3.6 million, an increase of €1.6 million, or 74%, as compared with the nine months ended September 30, 2016. The increase reflects not only higher financing costs incurred on our credit facility with the European Investment Bank, or EIB, but also an increase in expenses for legal advice in connection with shareholder litigation.

Other income and expenses

Other income for the nine months ended September 30, 2017 was €169 thousand, as compared with other income of €2.3 million for the nine months ended September 30, 2016. This decrease was mainly due to the non-recurring repayment in the nine months ended September 30, 2016 of our FDA submission fee in the amount of €2.1 million.

Other expenses in the nine months ended September 30, 2017 were €1 million, an increase of €1 million compared to the nine months ended September 30, 2016. This increase chiefly reflects currency differences due to the U.S. dollar's appreciation to the euro and a significant increase in our expenses denominated in U.S. dollars, resulting from our increased marketing and sales activities in the U.S.

Consolidated net result

The total loss for the nine months ended September 30, 2017 was €(13.7 million), significantly greater than loss of €(7.2 million) for the nine months ended September 30, 2016 and predominantly reflecting the aforementioned trends in operating expenses and other income.

Financial Position

Share capital; capital measures

Our fully paid in share capital was €38.4 million as of September 30, 2017 and was divided into 38,416,503 registered shares with a nominal value of €1.00 each. Our registered share capital amounted to €37.7 million as of December 31, 2017 and was increased by €694 thousand during the nine months ended September 30, 2017 through the exercise of conversion rights from the 2016/2021 convertible bond as well as from the 2017/2022 convertible bond.

Liquidity

Cash flow from operating activities decreased year-on-year from €(6.9 million) in the nine months ended September 30, 2016 to €(12.3 million) for the nine months ended September 30, 2017.

Capital expenditure increased by €31 thousand in the nine months ended September 30, 2017, as compared with the nine months ended September 30, 2016. Given this, cash flow from investing activities decreased from €(208) thousand in the nine months ended September 30, 2016 to €(246) thousand in the nine months ended September 30, 2017, as compared with the nine months ended September 30, 2016.

Cash flow from financing activities in the nine months ended September 30, 2017 was €10.7 million, compared with €8.9 million in the nine months ended September 30, 2016. In the nine months ended September 30, 2016, we received €9.3 million in proceeds from the issuance of new shares, whereas in the nine months ended September 30, 2017 we received €5.0 million in proceeds from the issuance of our 2017/2022 convertible bond and €10 million from our drawing of the first two tranches under our EIB credit facility. Short-term financial debt reduced by €3.6 million in the nine months ended September 30, 2017 as compared to the nine months ended September 30, 2016, driven primarily by our early repayment of the 2009/2017 warrant bond in August 2017.

Cash and cash equivalents were €13.3 million as of September 30, 2017, a decrease of €1.8 million as compared with December 31, 2016.

Biofrontera AG
Condensed consolidated balance sheet
(in EUR thousands)

Assets

	September 30, 2017	December 31, 2016
Non-current assets		
Tangible assets	672.3	644.7
Intangible assets	800.6	1,251.9
Total Non-current assets	1,472.9	1,896.6
Current assets		
Current financial assets		
Trade receivables	1,266.2	1,624.0
Other financial assets	1,009.9	1,376.9
Cash and cash equivalents	13,307.3	15,126.1
Total Current financial assets	15,583.4	18,127.0
Other current assets		
Inventories		
Raw materials and supplies	1,510.9	1,350.3
Unfinished products	463.5	477.1
Finished products and goods	1,972.7	1,818.9
Income tax reimbursement claims	51.7	33.0
Other assets	117.2	175.8
Total Other current assets	4,116.0	3,855.1
Total Current Assets	19,699.4	21,982.1
Total assets	21,172.3	23,878.7

Liabilities

in €'000	September 30, 2017	December 31, 2016
Equity		
Subscribed capital	38,416.4	37,722.4
Capital reserve	100,715.4	98,676.8
Capital reserve from foreign currency conversion adjustments	730.1	(154.2)
Loss carry forward	(120,402.9)	(109,823.7)
Net loss of the year	(14,614.3)	(10,579.2)
Total equity	4,844.7	15,842.1
Long-term liabilities		
Long-term financial liabilities	12,745.4	3,596.9
Current liabilities		
Current financial liabilities		
Trade payables	931.4	2,093.2
Short-term financial debt	131.1	274.4
Other financial liabilities	100.1	58.4
Total current liabilities	1,162.6	2,426.0
Other current liabilities		
Other provisions	2,040.6	1,823.7
Other current liabilities	379.0	190.0
Total Other current liabilities	2,419.6	2,013.7
Total liabilities	3,582.2	4,439.7
Total Equity and liabilities	21,172.3	23,878.7

Condensed consolidated statement of comprehensive income

in€'000	First nine months of 2017	First nine months of 2016	Third quarter 2017	Third quarter 2016
Sales revenue	7,334.0	2,881.4	2,327.6	1,172.8
Cost of sales	(899.7)	(1,028.8)	(264.4)	(265.2)
Gross profit from sales	6,434.3	1,852.6	2,063.2	907.6
Operating expenses				
Research and development costs	(3,232.9)	(3,358.4)	(1,047.5)	(1,506.4)
General administrative costs	(3,625.9)	(2,080.8)	(1,930.3)	(708.4)
thereof financing costs	(1,490.5)	(485.0)	(979.7)	(112.6)
Sales costs	(12,586.2)	(4,937.4)	(4,310.9)	(2,105.0)
Loss from operations	(13,010.7)	(8,524.0)	(5,225.5)	(3,412.2)
Interest expenses	(703.9)	(904.0)	(374.3)	(309.5)
Interest income	4.9	2.4	0.8	0.5
Other expenses	(1,074.0)	(35.5)	(333.1)	(21.4)
Other income	169.4	2,297.3	54.4	51.1
Profit/loss before income tax	(14,614.3)	(7,163.8)	(5,877.7)	(3,691.5)
Income tax	0.0	0.0	0.0	0.0
Profit or loss for the period	(14,614.3)	(7,163.8)	(5,877.7)	(3,691.5)
Expenses and income not included in profit/loss				
Items which may in future be regrouped into the profit and loss statement under certain conditions	884.2	0.7	288.3	0.0
Translation differences resulting from the conversion of foreign business operations				
Other income total	884.2	0.7	288.3	0.0
Total profit/loss for the period	(13,730.1)	(7,163.1)	(5,589.4)	(3,691.5)
Basic/diluted earnings per share	(0.38)	(0.24)	(0.15)	(0.12)

Condensed consolidated cash flow statement

in €'000	First nine months of 2017	First nine months of 2016	Third quarter 2017	Third quarter 2016
Cash flows from operations				
Profit/loss for the period	(14.614.3)	(7.163.8)	(5.887.7)	(3.691.5)
Adjustments to reconcile profit/loss for the period to cash flow into operations				
Financial result	699.0	901.7	373.6	308.9
Depreciation	674.1	606.7	230.3	202.4
(Gains)/losses from disposal of assets	0.0	4.8	0.0	0.0
Non-cash expenses and income	3.455.1	88.5	114.2	42.2
Changes in operating assets and liabilities				
Trade receivables	357.9	379.5	(64.1)	(2.7)
Other assets and income tax assets	406.9	(990.3)	34.5	(651.7)
Inventories	(300.9)	(1.049.8)	(112.7)	(907.5)
Trade payables	(1.161.7)	(306.0)	482.9	(260.7)
Long-term and current financial liabilities	(2.357.7)	0.0	194.0	0.0
Provisions	297.2	659,9	231.1	576.8
Other liabilities	230.7	(16.2)	167.1	9.5
Net cash flow into operational activities	(12.313.7)	(6.885.0)	(4.226.8)	(4.374.3)
Cash flows from investment activities				
Purchase of intangible and tangible assets	(260.2)	(229.5)	(56.5)	(74.9)
Interest received	4.7	2.3	3.0	0.6
Revenue from sale of intangible and tangible assets	9.7	19.2	0.0	9.5
Net cash flow into investment activities	(245.8)	(208.0)	(53.5)	(64.8)
Cash flows from financing activities				
Proceeds from the issue of shares	0.0	9.303.2	0.0	0.0
Proceeds from conversions of option bond 2011/2016	4.999.0	0.0	0.0	0.0
Interest paid	(622.2)	(436.1)	(227.8)	(0.3)
Increase/(decrease) in long-term financial debt	10.000.0	(8.280.7)	10.000.0	(110.6)
Increase/(decrease) in short-term financial debt	(3.636.1)	8.280.7	(3.636.1)	110.6
Net cash flows from financing activities	10.740.7	8.867.1	6.136.1	(0.3)
Net increase (decrease) in cash and cash equivalents	(1.818.8)	1.774.1	1.855.8	(4.439.4)
Cash and cash equivalents at the beginning of the period	15.126.1	3.959.2	11.451.5	10.172.7
Cash and cash equivalents at end of the period	13.307.3	5.733.3	13.307.3	5.733.3
Composition of financial resources at the end of the period				
Cash and cash equivalents	13.307.3	5.733.3	13.307.3	5.733.3

The Offering

The shares being offered by this prospectus are part of a combined offering relating to up to 6,000,000 newly issued ordinary shares, or shares, of our company. The combined offering consists of (i) a rights offering to existing holders of our shares under German law under which 3,399,034 ordinary shares were subscribed and (ii) this initial public offering of ADSs in the United States. We are offering up to 5,829,034 newly issued shares in the combined offering, or 6,000,000 shares if the underwriters exercise their over-allotment option to purchase additional ADSs in full. The initial per share offering price to the public for the ADSs sold in this offering, $9.88, is the same as the per share price for the ordinary shares sold in the German preemptive rights offering (adjusting for the euro/U.S. dollar exchange rate and the ratio of shares to ADSs).

American Depositary Shares offered by Biofrontera AG . . . . . We are offering 1,215,000 ADSs (or 1,300,483 ADSs if the underwriters exercise their over-allotment option to purchase additional ADSs in full) in the United States, which we refer to as "this offering" or the "U.S. offering". As described below, we have completed a separate preemptive rights offering under German law, or the German preemptive rights offering, for an aggregate amount of 3,399,034 ordinary shares (or the equivalent of approximately 1,699,517 ADSs).

German preemptive rights offering. . . . . On May 24, 2017, our shareholders authorized our management board with the approval of our supervisory board to increase the Company's capital by 6,000,000 shares, equivalent to 3,000,000 ADSs. In order to carry out the capital increase, we were required by German law and the terms of our authorized capital to make a preemptive rights offering to our existing shareholders. In the German preemptive rights offering we offered holders of our shares the right to subscribe for newly issued shares in proportion to their holdings of ordinary shares.

The German preemptive rights offering commenced on January 30, 2018 and expired on February 12, 2018. A total of 3,399,034 ordinary shares were subscribed in the German preemptive rights offering.

American Depositary Shares to be outstanding immediately after this offering. . . . . 1,215,000 ADSs (or 1,300,483 ADSs if the underwriters exercise their over-allotment option to purchase additional ADSs in full).

Ordinary shares to be outstanding immediately after this offering. . . . . 44,245,462 shares (or 44,416,428 shares if the underwriters exercise their over-allotment option to purchase additional ADSs in full).

Note: all descriptions of shares outstanding immediately after closing of this offering assume completion of the temporary share loan arrangement under German law in connection with closing and issuance of new shares related to this offering (see "— Share Loan" and "Certain Relationships and Related Party Transactions — Share Loan Agreement" and exclude 548,960 ordinary shares issuable upon the exercise of convertible bonds outstanding as of February 8, 2018, with conversion prices of €5.00 and exclude the issuance of any ordinary shares pursuant to the exercise of any exercisable stock options.

Over-allotment option	As part of the offering, we have granted the underwriters a 45-day option to purchase up to an additional 85,483 ADSs to cover over-allotments, if any.
Use of Proceeds	We intend to use the net proceeds from this offering, and the German preemptive rights offering, to expand our marketing and sales organization in the U.S. We also intend to use the net proceeds of the offering, and the German preemptive rights offering, to continue to fund clinical trials of Ameluz® and to make regulatory filings for marketing approval of Ameluz®, both for geographical expansion and the extension of the indications for Ameluz®. We will use the remainder of the net proceeds of the combined offering for general corporate purposes. See "Use of Proceeds".
Offering price	The offering price of each ADS is $9.88. Separate from this offering, we have completed a concurrent preemptive rights offering of our ordinary shares pursuant to German law to our existing holders, under which we will be issuing 3,399,034 ordinary shares. The price per share at which our shares were offered in the German preemptive rights offering was €4.00, which is the same as the initial public offering price per ADS being offered in the U.S. offering (adjusting for the euro/U.S. dollar exchange rate and the ratio of ordinary shares to ADSs). In determining the offer price, we considered, among other things, current market conditions, the trading price and volume of trading in our ordinary shares on the XETRA electronic trading platform of the Frankfurt Stock Exchange and the results of the bookbuilding process for the ADSs to be offered in this offering. See "Underwriting—Pricing of the Offering" for a discussion of factors considered in determining the price to the public of the ADSs. On February 8, 2018, the closing market price for our ordinary shares on the XETRA electronic trading platform of the Frankfurt Stock Exchange was €5.15 per share, equivalent to approximately $12.77 per ADS (based upon the noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018, which was €1.00 to $1.24) and a ratio of two ordinary shares for each ADS.
The ADSs	Each ADS represents two ordinary shares. The depositary will hold the ordinary shares underlying your ADSs. You will have rights as provided in the deposit agreement. You may surrender your ADSs and withdraw the underlying ordinary shares. The depositary will charge you fees for, among other acts, any surrender for the purpose of withdrawal. Except in certain limited instances described in the deposit agreement, we may amend or terminate the deposit agreement without your consent. If you continue to hold your ADSs, you agree to be bound by the terms of the deposit agreement then in effect. To better understand the terms of the ADSs, you should carefully read "Description of American Depositary Shares" (which contains a summary of the material terms of the deposit agreement) in this prospectus. You should also read the deposit agreement, which is an exhibit to the registration statement that includes this prospectus.

Voting Rights	Holders of ADSs must follow specific procedures to exercise the voting rights of the ordinary shares underlying the ADSs and will not be able to exercise those rights unless we request the Depositary to solicit voting instructions from ADS holders. We discuss these voting rights and procedures further in the sections of this prospectus entitled "Description of Share Capital — Shareholders' Meeting and Voting Rights" and "Description of American Depositary Receipts — Voting Rights".
Dividend Policy	We have not paid any dividends on our shares in the past and do not intend to pay dividends on our shares or ADSs for the foreseeable future.
Lock-Up Agreements	We will agree with the underwriters that, on or before August 12, 2018, we will, subject to certain exceptions, (a) not directly or indirectly, offer, sell or otherwise dispose of any shares of our capital stock or any other securities which are convertible into or exchangeable for shares of our capital stock, (b) not exercise any authorization pursuant to our articles of association to increase our capital other than for the purpose of issuing ordinary shares to the beneficiaries of our existing stock option plans and convertible bonds, warrant bonds or warrants upon the exercise of options or conversion rights, and (c) not propose a capital increase to our shareholders other than a proposal for authorized capital or for contingent capital, in each case except with the prior written consent of The Benchmark Company, LLC. Certain exceptions apply for share issuances of securities upon the exercise of any options or warrants or the conversion of any outstanding securities, issuances of options or shares under equity compensation plans, issuances of rights or shares pursuant to the German preemptive rights offering and the issuance of securities in this offering or in connection with any capital increase in connection with settlement of the over-allotment option. See "Underwriting (Conflicts of Interest)". Our chief executive officer will agree with the underwriters that, except with the prior written consent of The Benchmark Company, LLC, on or before August 12, 2018, he will not, directly or indirectly, sell or otherwise dispose of any of our shares or any other securities which are convertible into or exchangeable for our shares or enter into similar transactions to this effect. See "Underwriting (Conflicts of Interest)".
Conflict of Interest	The Benchmark Company, LLC is acting as representative for the underwriters in connection with this offering. An affiliate and a principal of The Benchmark Company, LLC holds a position as a member of the supervisory board of our company. Therefore, The Benchmark Company, LLC is deemed to have a "conflict of interest" under Rule 5121(f)(5) of the Financial Industry Regulatory Authority, Inc. ("FINRA"). Accordingly, this offering will be conducted in accordance with the applicable provisions of Rule 5121, which requires, among other things, that a "qualified independent underwriter" participate in the preparation of, and exercise the usual standards of "due diligence" with respect to, the registration statement and this prospectus. Dawson James Securities, Inc. ("Dawson") has agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering. We have agreed to indemnify Dawson against liabilities incurred in connection with acting as qualified independent underwriter, including liabilities under the Securities Act. Dawson will undertake the legal responsibilities and liabilities of an underwriter under the Securities Act, specifically including those inherent in Section 11 thereof. Dawson will not receive any additional fees for serving as a "qualified independent underwriter" in connection with this offering.

Depositary	The Bank of New York Mellon
Custodian	The Bank of New York Mellon SA/NV
Share Loan	To facilitate the orderly closing of this offering of ADSs, and because of timing considerations related to the technical issuance and registration of new ordinary shares under German law, the shares underlying the ADSs immediately prior to and concurrent with the consummation of this offering and the time of delivery of the ADSs will be shares (referred to as the "Borrowed Shares") loaned by Maruho Deutschland GmbH to Lang & Schwarz Broker GmbH, acting as a service provider for us pursuant to a separate mandate agreement, for deposit with the custodian for the Depositary under the ADS facility (the "Share Loan"). In order to repay and satisfy the Share Loan, we will undertake the registration of a capital increase with the commercial register of the local court of Cologne. The Borrowed Shares will be retained by the custodian for the Depositary. We will receive the full net proceeds of this offering only upon registration of the capital increase with the commercial register. If for any reason we fail to complete registration of the capital increase, then we will not retain any proceeds from this offering. See "Risk Factors — Risks Related to the Offering and Ownership of our ADSs — We will rely on a Share Loan arrangement in order to facilitate the orderly closing of this offering of ADSs. If the Share Loan arrangement is not completed (for example, if registration of the capital increase relating to this offering fails), we will not receive the proceeds of this offering, which would have a material adverse effect on our financial position, liquidity and results of operations" and "Certain Relationships and Related Party Transactions — Share Loan Agreement".
Listing and Quotation	Our ordinary shares are listed on the Frankfurt Stock Exchange under the Symbol B8F; International Securities Identification Number (ISIN) DE0006046113; German securities code (WKN) 604611. We have been approved for listing of the ADSs on The NASDAQ Capital Market under the symbol "BFRA."

RISK FACTORS

You should carefully consider the risks described below and all other information contained in this prospectus before making an investment decision. If any of the following risks actually occur, our business, financial condition and results of operations could be materially and adversely affected. In that event, the trading price of the ADSs could decline, and you may lose part or all of your investment. This prospectus also contains forward-looking information that involves risks and uncertainties. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of many factors, including the risks described below and elsewhere in this prospectus.

Risks Related to Our Financial Position and Capital Requirements

We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and that we may never sustain profitability.

We have incurred losses in each year since inception. Our net loss for the fiscal years ended December 31, 2015 and December 31, 2016 was €11.2 million and €10.6 million, respectively. Our net loss for the nine months ended September 30, 2017 and September 30, 2016 was €14.6 million and €7.2 million, respectively. As of September 30, 2017, we had an accumulated deficit of €135.0 million.

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

If we fail to obtain additional financing, we may be unable to complete the development and commercialization of our products and product candidates.

Our operations have consumed substantial amounts of cash since inception. We expect to continue to spend substantial amounts to pursue additional indications for which our products and product candidates may be commercialized, and to continue the clinical development of our product candidates, including further Phase III clinical trials. We also require significant additional funds in order to commercialize Ameluz® in the U.S.

We believe that our existing cash and cash equivalents, the credit facilities available to us under the EIB credit facility, the anticipated net proceeds from this offering, and revenue from product sales and future milestone or license payments will be sufficient to enable us to fund our operating expenses and to advance our commercialization strategy in the U.S. for the next 12 months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. After the next 12-month period, we may require additional capital for the further development and commercialization of our products. We may need substantial additional funds to fully develop, manufacture, market and sell our other potential products. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the timing, costs and results of clinical trials for our product Ameluz®;
- the outcome, timing and cost of regulatory approvals by the FDA, the European Medicines Agency, or EMA, and comparable foreign regulatory authorities, including the potential for the FDA, EMA or comparable foreign regulatory authorities to require that we perform more studies than those that we currently expect;
- the cost of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effects of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities; and
- the cost of establishing sales, marketing and distribution capabilities for Ameluz® PDT in the U.S. and in such other regions in which we are approved to market it and in which we choose to commercialize it.

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

Any of the above events could significantly harm our business, prospects, financial condition and/or results of operations and could cause the price of our shares or ADSs to decline.

Our existing and any future indebtedness could adversely affect our ability to operate our business.

In May 2017, we entered into a finance contract with the European Investment Bank, or EIB, under which EIB agreed to provide us with loans of up to €20 million in the aggregate. Our finance contract with EIB, which we refer to as the EIB credit facility, is unsecured, is guaranteed by certain of our subsidiaries, and is available to be drawn in tranches during a two year period. Future tranches require the achievement of certain milestones. Each tranche must be repaid five years after drawdown. The EIB credit facility contains undertakings by our company regarding the use of proceeds and limitations on debt, liens, mergers, acquisitions, asset sales, dividends and other restrictive covenants. As of the date of this prospectus, we have borrowed €10 million under the EIB credit facility. On July 6, 2022, we will be required to repay this €10 million principal amount, plus €3 million in deferred interest and an additional amount of performance participation interest determined by reference to the change in our market capitalization between disbursement and maturity of the loan. Under the EIB credit facility, we are not permitted to incur additional third-party debt in excess of €1 million without the prior consent of the EIB (subject to certain exceptions, such as for ordinary course deferred purchase arrangements and, subject to maximum amounts, various types of leases).

In addition, in November 2016 we issued convertible bonds in the aggregate initial principal amount of €5.0 million maturing on January 1, 2021 of which €4.9 million has already been converted into shares. In January 2017, we issued convertible bonds maturing on January 1, 2022 in the aggregate initial principal amount of €5.0 million of which €2.3 million has already been converted into shares. The convertible bonds provide the holders of those bonds with the right to convert them into our ordinary shares at set conversion prices, depending upon time of conversion. The convertible bonds we issued in December 2016 provide the holders with the right to convert them, at any time, in whole but not in part, into our ordinary shares, at a conversion price per share equal to: €4.00 per share from January 1, 2017 until December 31, 2018 and €5.00 per share from January 1, 2018 until maturity. The convertible bonds we issued in January 2017 provide the holders of those bonds with the right to convert them, at any time, in whole but not in part, into our ordinary shares, at a conversion price per share equal to: €4.00 per share from April 1, 2017 until December 31, 2018 and €5.00 per share from January 1, 2018 until maturity. If all of the remaining bonds were converted, we would be required to issue up to 548,960 additional ordinary shares, which would result in additional dilution to shareholders.

Our indebtedness could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash to the payment of interest and principal, reducing money available for working capital, capital expenditure, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- increasing the risk of dilution to the holders of our shares or ADSs in the event any of these bonds are exercised for or converted into our ordinary shares;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete; and
- placing us at a competitive disadvantage to competitors that are better capitalized than we are.

We may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under our existing debt obligations, in particular the minimum €13 million payment that we must make on July 6, 2022. Failure to make payments or comply with other covenants under our existing debt could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender or lenders accelerate the amounts due, we may not be able to make accelerated payments, and such lenders could file suit against us to collect the amounts due under such obligations or pursue other remedies. In addition, the covenants under our existing debt obligations could limit our ability to obtain additional debt financing.

Risks Related to Our Business and Strategy

Certain of our important patents will expire in 2019. Although the process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors, generic versions of Ameluz® could enter the market after expiration of these patents. If this happens, we may need to reduce the price of Ameluz® significantly and may lose significant market share.

The patent family that protects aminolevulinic acid hydrochloride, an active ingredient in Ameluz®, against copying by competitors will expire on November 12, 2019. This patent family includes U.S. Patent No. 6,559,183, which is listed in the FDA Orange Book and identified as covering aminolevulinic acid hydrochloride, the active ingredient in Ameluz®. Patent No. 6,559,183 serves as a significant barrier to entry into the market by generic versions of Ameluz®. Although the process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors, once this patent expires, generic versions of Ameluz® may not be prevented from entering the market and competing with Ameluz®. This may cause a significant price drop and, therefore, a significant drop in our profits. We may also lose significant market share for Ameluz.

Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our products or product candidates, which could make it difficult for us to sell our products.

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

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

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

The pricing of prescription pharmaceuticals is subject to governmental control in some of the countries in which we have received and/or seek to receive approval to commercialize certain of our products. We are approved to market certain of our products in the EU and the U.S., and we intend to seek approval to market our product candidates in selected other jurisdictions. If we obtain approval in one or more foreign jurisdictions for our product candidates, we will be subject to rules and regulations in those jurisdictions. In some countries, particularly those in the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after obtaining marketing approval for a product candidate. In addition, market acceptance and sales of our product candidates will depend significantly on the availability of adequate coverage and reimbursement from government or other third party payors for our product candidates and may be affected by existing and future health care reform measures. Without adequate levels of reimbursement by government health care programs and private health insurers, the market for our products will be limited. While we continue to support efforts to improve reimbursement levels to physicians and plan to work to improve coverage for our products, if our efforts are not successful, a broader adoption of our products and sales of our products could be negatively impacted.

Healthcare legislative changes may have a material adverse effect on our business and results of operations.

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

The Affordable Care Act is a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of healthcare spending, enhance remedies against fraud and abuse, add new transparency requirements for healthcare and the health insurance industry, impose new taxes and fees on the healthcare industry and impose additional health policy reforms. This law revises the definition of "average manufacturer price" for reporting purposes, which could increase the amount of Medicaid drug rebates to states once the provision is effective. Further, the law imposes a significant annual fee on companies that manufacture or import branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may require us to modify our business practices with healthcare practitioners. While the U.S. Supreme Court upheld the constitutionality of most elements of the Affordable Care Act in 2012, other legal challenges are still pending final adjudication in several jurisdictions. In addition, Congress has also proposed a number of legislative initiatives, including possible repeal of the Affordable Care Act. At this time, there remains a significant amount of uncertainty related to the future of the Affordable Care Act, and whether there will be changes to certain provisions or its entirety. We can provide no assurance that the Affordable Care Act, as currently enacted or as amended in the future, will not adversely affect our business and financial results, and we cannot predict how future federal or state legislative or administrative changes relating to healthcare reform will affect our business.

Other legislative changes have been proposed and adopted in the U.S. since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2012 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions of Medicare payments to providers up to 2 percent per fiscal year. The American Taxpayer Relief Act of 2012, or the ATRA, among other things, reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Recently there has been increased government scrutiny regarding the manner in which manufacturers set prices for and market commercial products. If we become the subject of any government investigation with respect to our drug pricing, marketing, or other business practices, we could incur significant expense and could be distracted from operation of our business and execution of our strategy. Any such investigation could also result in reduced market acceptance and demand for our products, could harm our reputation and our ability to market our products in the future, and could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

There have been, and likely will continue to be, legislative and regulatory proposals at the U.S. federal and state levels directed at broadening the availability of healthcare and containing or lowering the cost of healthcare. We cannot predict the initiatives that may be adopted in the future. Additionally, third party payors, including governmental payors, managed care organizations and private health insurers, are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our product candidates, if we obtain regulatory approvals;
- our ability to set a price or obtain reimbursement that we believe is fair for our products;

- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

Any denial or reduction in reimbursement from Medicare or other programs or governments may result in a similar denial or reduction in payments from private payors, which may adversely affect our future profitability.

To date, we have engaged in only limited sales of our products, primarily in Germany and Spain and, more recently, in the U.S.

We have engaged in only limited sales of our products to date. In Germany, the majority of our sales have been generated in the private dermatology offices sector. Historically, our sales partners in European countries outside of Germany have experienced difficulty in selling Ameluz® because that process involves selling both drug combined with a procedure, an area in which our sales partners generally have little experience. We launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016 and have a limited history of marketing our products there. Our products may never gain significant acceptance in the European or U.S. marketplace and, therefore, may never generate substantial revenue or profits for us. We must establish a larger market for our products and build that market through marketing campaigns to increase awareness of, and confidence by doctors in, our products. If we are unable to expand our current customer base and obtain market acceptance of our products, our operations could be disrupted and our business may be materially adversely affected. Even if we achieve profitability, we may not be able to sustain or increase profitability.

Competing products and technologies based on traditional treatment methods may make our products or potential products noncompetitive or obsolete.

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

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

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

We cannot guarantee that new drugs or future developments in drug technologies will not have a material adverse effect on our business. Increased competition could result in price reductions, lower levels of government or other third party reimbursements, failure to achieve market acceptance and loss of market share, any of which could adversely affect our business, results of operations and financial condition. Further, we cannot give any assurance that developments by our competitors or future competitors will not render our technologies obsolete or less advantageous.

We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance. We have recently lost market share in Germany to daylight PDT products, an indication for which we have applied but for which Ameluz® is not currently approved.

The pharmaceutical and medical device industry is characterized by intense competition and rapid innovation. Our competitors may be able to develop other products that are able to achieve similar or better results for the treatment of actinic keratosis. We expect that our future competitors will include mostly established pharmaceutical companies, such as Sun Pharma and Galderma. Most of our competitors have substantially greater financial, technical and other resources, such as larger research and development staffs and experienced marketing and manufacturing organizations and well-established sales forces. Competition

may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries.

Our competitors may succeed in developing, acquiring or licensing products that are more effective or less costly than our products and product candidates. Metvix® has also recently been approved in the EU for use in daylight photodynamic therapy for which it is sold by Galderma under the brand name Luxerm® in Germany and Luxera® in other European countries. This gives that drug a competitive advantage compared to Ameluz®, as Ameluz® is not yet approved to be used in daylight photodynamic therapy to treat actinic keratosis. In recent months, the market share of Ameluz® of photodynamic therapy drugs for treatment of actinic keratosis dispensed by German public pharmacies has fallen from over 75% to approximately 60%, a decline which we believe resulted primarily from the introduction to the German market of Luxerm® in 2016. We believe that daylight photodynamic therapy products will play an increasingly important role in Europe in the future and will begin to be prescribed as an alternative to less effective, self-applied, topical prescription product creams (which have historically been market leaders in the EU in treating actinic keratosis). We have applied to extend our indication for Ameluz® to daylight photodynamic therapy in the EU to better compete with Metvix® and Luxerm®, and in January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. There can be no assurance, however, that we will receive the extended indication. If we fail to obtain this extended indication, then we may continue to lose market share to Metvix® and Luxerm® and any other products that receive approval for daylight photodynamic therapy in the EU in the future.

In addition, our products compete with other therapies, such as simple curettage and, particularly in the U.S., cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

If we are not able to compete effectively with the competitors and competing therapies discussed above, we may lose significant market share in the relevant markets, which could have a material adverse effect on our revenue, results of operations and financial condition.

If we are unable to establish effective marketing and sales capabilities or enter into agreements with third parties to market and sell our products, we may be unable to generate revenues.

In order to commercialize our products, we must further build our marketing, sales and distribution capabilities, in particular in the U.S. The establishment, development and training of our sales force and related compliance plans to market our products are expensive and time consuming and can potentially delay the commercial success of our products. In the event we are not successful in developing our marketing and sales infrastructure, we may not be able to successfully commercialize our products, which would limit our ability to generate product revenues.

We depend on a single unaffiliated contract manufacturer to manufacture Ameluz® and two unaffiliated contractors to produce 5-aminolevulinic acid, the active pharmaceutical ingredient in Ameluz®, for us. If we fail to maintain our relationship with these suppliers or if these suppliers are unable to continue to produce product for us, our business could be materially harmed.

We depend on a single unaffiliated contract manufacturer located in Switzerland to manufacture Ameluz® and two unaffiliated contractors to produce 5-aminolevulinic acid, the active pharmaceutical ingredient in Ameluz®, for us. The initial terms of our contracts with these suppliers begin to expire in June 2020, and the contracts renew automatically for one- or two-year periods, as applicable, until they are terminated. For more information on the terms of our contracts with these suppliers, see "Business—Commercial Partners and Agreements". If we fail to maintain our relationship with these parties, we may be unable to obtain an alternative manufacturer of Ameluz® or suppliers of 5-aminolevulinic acid that could deliver the quantity of the product at the quality and cost levels that we require. Even if acceptable alternative suppliers could be found, we may experience delays in transitioning the manufacturing from our existing suppliers to our new suppliers (in particular with respect to our manufacturer of Ameluz®). Problems of this kind could cause us to experience order cancellations and loss of market share. The failure of the suppliers to supply Ameluz® or 5-aminolevulinic acid that satisfies our quality, quantity and cost requirements in a timely manner could impair our ability to deliver Ameluz® and could increase our costs, particularly if we are unable to obtain Ameluz® or 5-aminolevulinic acid from alternative sources on a timely basis or on commercially reasonable terms. In addition, our suppliers are regulated by the FDA and must comply with applicable laws and regulations, including home-country laws. If the suppliers fail to comply, this could harm our business.

If we fail to manufacture Ameluz® or BF-RhodoLED® or other marketed products and product candidates in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or cGMP, or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of our products, breach obligations to our licensing partners or be unable to meet market demand, and lose potential revenues.

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

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

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

Because of a lack of comprehensive public data regarding the market for actinic keratosis treatments in the U.S., the U.S. market size for Ameluz® for the treatment of actinic keratosis may be smaller than we have estimated.

Because of a lack of comprehensive public data regarding the market for actinic keratosis treatments in the U.S., some of our estimates and judgments are based on various sources which we have not independently verified and which potentially include outdated information, or information that may not be precise or correct, potentially rendering the U.S. market size for treatment of actinic keratosis with Ameluz® smaller than we have estimated, which may reduce our potential and ability to increase sales of Ameluz® and revenue in the U.S. Although we have not independently verified the data obtained from these sources, we believe that such data provide the best available information relating to the present market for actinic keratosis treatments in the U.S., and we often use such data for our business and planning purposes. We are responsible for the inclusion of such data in this prospectus.

If we face allegations of noncompliance with the law and encounter sanctions, our reputation, revenues and liquidity may suffer, and our products could be subject to restrictions or withdrawal from the market.

Any government investigation of alleged violations of the law could require us to expend significant time and resources in response and could generate negative publicity. Any failure to comply with ongoing regulatory requirements may significantly and adversely affect our ability to commercialize and generate revenues from our products. If regulatory sanctions are applied or if regulatory approval is withdrawn, the value of our company and our operating results will be adversely affected. Additionally, if we are unable to generate revenues from our product sales, our potential for achieving profitability will be diminished and the capital necessary to fund our operations will be increased.

Even if we obtain regulatory approvals for our products and product candidates, they may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community.

In May 2016, we received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016. Even after obtaining regulatory approval for our products or extending their indications, our products may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community. Market acceptance of any of our products and product candidates for which we receive approval depends on a number of factors, including:

- the clinical indications for which they are approved, including any restrictions placed upon the product in connection with its approval, such as patient registry or labeling restriction;
- the product labeling, including warnings, precautions, side effects, and contraindications that the FDA or other regulatory authorities approve;
- the potential and perceived advantages of our product candidates over alternative products or therapies;
- relative convenience and ease of administration;
- the effectiveness and compliance of our sales and marketing efforts;
- acceptance by major operators of hospitals, physicians and patients of the product candidate as a safe and effective treatment;
- the prevalence and severity of any side effects;
- product labeling or product insert requirements of the FDA or other regulatory authorities;
- any Risk Evaluation and Mitigation Strategy that the FDA might require for our drug product candidates;
- the timing of market introduction of our product candidates as well as competitive products;
- the perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative products; and
- the availability of adequate reimbursement and pricing by third party payors and government authorities, including any conditions for reimbursement required by such third party payors and government authorities.

If our products and product candidates are approved, but fail to achieve market acceptance among physicians, patients, payors, or others in the medical community, we will not be able to generate significant revenues, which would have a material adverse effect on our business, prospects, financial condition and results of operations.

With respect to our already approved products, we may be subject to healthcare laws, regulation and enforcement. Our failure to comply with those laws could have a material adverse effect on our results of operations and financial condition.

We may be subject to additional healthcare regulation and enforcement by the U.S. federal government and by authorities in the U.S., the EU and other jurisdictions in which we conduct our business. In certain jurisdictions outside of the U.S. where we currently commercialize certain of our products, we are already subject to such regulation and enforcement. Such U.S. laws include, without limitation, state and federal anti-kickback, federal false claims, privacy, security, financial disclosure laws, anti-trust, Physician Payment Sunshine Act reporting and fair trade regulation and advertising laws and regulations. Many states and other jurisdictions have similar laws and regulations, some of which are broader in scope. If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject to penalties, including, but not limited to, civil and criminal penalties, damages, fines, the curtailment or restructuring of our operations, the exclusion from participation in federal, state or other healthcare programs and imprisonment, any of which could adversely affect our ability to operate our business and our financial results.

A recall of our drug or medical device products, or the discovery of serious safety issues with our drug or medical device products, could have a significant negative impact on us.

The FDA, the EMA and other relevant regulatory agencies have the authority to require or request the recall of commercialized products in the event of material deficiencies or defects in design or manufacture or in the event that a product poses an unacceptable risk to health. Manufacturers may, under their own initiative, recall a product. A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to produce our products in a cost-effective and timely manner.

Further, under the FDA's medical device reporting, or MDR, regulations, we are required to report to the FDA any event which reasonably suggests that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction of the same or similar device marketed by us were to recur, would likely cause or contribute to death or serious injury. The FDA also requires reporting of serious, life-threatening, unexpected and other adverse drug experiences and the submission of periodic safety reports and other information. Product malfunctions or other adverse event reports may result in a voluntary or involuntary product recall and other adverse actions, which could divert managerial and financial resources, impair our ability to manufacture our products in a cost-effective and timely manner and have an adverse effect on our reputation, financial condition and operating results. Similar reporting requirements exist in Europe and other jurisdictions.

Any adverse event involving our products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract management from operating our business and may harm our reputation and financial results as well as threaten our marketing authority for such products.

Our medical device product, the BF-RhodoLED® lamp, is subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.

The medical device industry is regulated extensively by governmental authorities, principally the FDA and corresponding state and European and other foreign governmental agencies. The regulations are very complex and are subject to rapid change and varying interpretations. Regulatory restrictions or changes could limit our ability to carry on or expand our operations or result in higher than anticipated costs or lower than anticipated sales. The FDA and other U.S. or European or other foreign governmental agencies regulate numerous elements of our business, including:

- product design and development;
- pre-clinical and clinical testing and trials;
- product safety;
- establishment registration and product listing;

- distribution;
- labeling, manufacturing and storage;
- pre-market clearance or approval;
- advertising and promotion;
- marketing, manufacturing, sales and distribution;
- relationships and communications with health care providers;
- adverse event reporting;
- market exclusivity;
- servicing and post-market surveillance; and
- recalls and field safety corrective actions.

Before we can market or sell a new regulated product or a significant modification to an existing product in the U.S., we must obtain either marketing clearance under Section 510(k) of the Federal Food, Drug and Cosmetic Act, or FDCA, or approval of a Pre-Market Approval, or PMA, application from the FDA, unless an exemption from premarket clearance and approval applies. In the 510(k) clearance process, the FDA must determine that a proposed device is "substantially equivalent" to a device legally on the market, known as a "predicate" device, with respect to intended use, technology and safety and effectiveness, in order to clear the proposed device for marketing. Clinical data are sometimes required to support a finding of substantial equivalence. The PMA pathway requires an applicant to demonstrate the safety and effectiveness of the device based on extensive clinical data. The PMA process is typically required for devices that are deemed to pose the greatest risk, such as life-sustaining, life-supporting or certain implantable devices or products that do not have an adequate predicate product. The PMA process can be lengthy, expensive, and carries uncertainty of approval. Products that are approved through a PMA application generally need FDA approval before they can be modified. Similarly, some modifications made to products cleared through a 510(k) premarket notification submission may require a new 510(k) submission, including possibly with clinical data. Before we can offer our device products to any of the 31 nations within the EU and the European Free Trade Association, we must first satisfy the requirements for CE Mark clearance, a conformity mark that signifies a product has met all criteria of the relevant EU directives, especially in the areas of safety and performance. The process of obtaining regulatory clearances or approvals to market a medical device can be costly and time-consuming, and we may not be able to obtain these clearances or approvals on a timely basis, or at all for our products or proposed products. We obtained CE Mark clearance for our BF-RhodoLED® lamp in November 2012 and FDA approval for it, to be used in connection with Ameluz® gel, in May 2016.

The FDA can delay, limit or deny clearance or approval of a device for many reasons, including:

- our inability to demonstrate that our products are safe and effective for their intended uses or substantially equivalent to a predicate device;
- the data from our clinical trials may not be sufficient to support clearance or approval; and
- the manufacturing process or facilities we use may not meet applicable requirements.

In addition, the FDA and other regulatory authorities may change their respective clearance and approval policies, adopt additional regulations or revise existing regulations, or take other actions which may prevent or delay approval or clearance of our products under development or impact our ability to modify our currently cleared or approved products on a timely basis.

Any delay in, or failure to receive or maintain, clearance or approval for our products under development could prevent us from generating revenue from these products or achieving profitability. Additionally, the FDA and comparable foreign regulatory authorities have broad enforcement powers. Regulatory enforcement or inquiries, or other increased scrutiny of us, could dissuade some customers from using our products and adversely affect our reputation and the perceived safety and efficacy of our products.

Failure to comply with applicable regulations could jeopardize our ability to sell our products and result in enforcement actions such as fines, civil penalties, injunctions, warning letters, Form 483 reports, recalls of products, delays in the introduction of products into the market, refusal of the FDA or other regulators to grant future clearances or approvals, and the suspension or withdrawal of existing approvals by the FDA or other regulators. Any of these sanctions could result in higher than anticipated costs or lower than anticipated sales and have a material adverse effect on our reputation, business, financial condition and operating results.

Furthermore, we may evaluate international expansion opportunities in the future for our medical device products. As we expand our operations outside of the U.S. and Europe, we are, and will become, subject to various additional regulatory and legal requirements under the applicable laws and regulations of the international markets we enter. These additional regulatory requirements may involve significant costs and expenditures and, if we are not able comply with any such requirements, our international expansion and business could be significantly harmed.

Modifications to our medical device products, such as our BF-RhodoLED® lamp in Europe, may require reclassifications, new CE marking processes or may require us to cease marketing or recall the modified products until new CE marking is obtained.

A modification to our medical devices such as our BF-RhodoLED® lamp, which is approved for sale in Europe, could lead to a reclassification of the medical device and could result in further requirements (including additional clinical trials) to maintain the product's CE marking. If we fail to comply with such further requirements we may be required to cease marketing or to recall the modified product until we obtain clearance or approval, and we may be subject to significant regulatory fines or penalties.

We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may be unable to successfully implement our business strategy.

Our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with specialized scientific and technical skills. We are highly dependent on our management, scientific, medical and operations personnel, including Prof. Hermann Lübbert, Ph.D., chairman of our management board and chief executive officer; Thomas Schaffer, member of our management board and chief financial officer and Christoph Dünwald, member of our management board and chief commercial officer. Our company does not maintain "key man" insurance for any of our officers. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations.

Despite our efforts to retain valuable employees, members of our management, scientific and development teams may terminate their employment with us on short notice. Although we have employment agreements with our key employees, these employees could leave our employment at any time, with certain notice periods. We do not maintain "key man" insurance policies on the lives of these individuals or the lives of any of our other employees. Our success also depends on our ability to continue to attract, retain and motivate highly skilled junior, mid-level and senior managers as well as junior, mid-level and senior scientific and medical personnel and sales representatives.

Many of the other biotechnology and pharmaceutical companies that we compete against for qualified personnel have greater financial and other resources, different risk profiles and a longer history in the industry than we do. They may also provide more diverse opportunities and better chances for career advancement. Some of these characteristics may be more appealing to high quality candidates than what we can offer. If we are unable to continue to attract and retain high quality personnel, our ability to advance the development of our product candidates, obtain regulatory approval and commercialize our product candidates will be limited.

Our employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA or EMA regulations, provide accurate information to the FDA or EMA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices in the U.S. and Europe as well as in other jurisdictions where we conduct our business. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer

incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, inability to obtain product approval and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

We will need to grow the size of our organization and we may experience difficulties in managing this growth.

As of September 30, 2017, we had 125 employees. As our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating additional employees;
- managing our internal development efforts effectively, including the clinical and FDA and EMA review process for our product candidates, while complying with our contractual obligations to contractors and other third parties; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize our products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. To date, we have used the services of outside vendors to perform tasks including clinical trial management, statistics and analysis and regulatory affairs. Our growth strategy may also entail expanding our group of contractors or consultants to implement these tasks going forward. Because we rely on numerous consultants, effectively outsourcing many key functions of our business, we will need to be able to effectively manage these consultants to ensure that they successfully carry out their contractual obligations and meet expected deadlines. However, if we are unable to effectively manage our outsourced activities or if the quality or accuracy of the services provided by consultants is compromised for any reason, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for our product candidates or otherwise advance our business. There can be no assurance that we will be able to manage our existing consultants or find other competent outside contractors and consultants on economically reasonable terms, or at all. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to further develop and commercialize our products and product candidates that we develop and, accordingly, may not achieve our research, development and commercialization goals.

We may encounter difficulties growing our sales force.

Our initial estimate of the size of the required sales force may be materially different from the size of the sales force actually required to effectively commercialize our product candidates. As such, we may be required to hire substantially more sales representatives to adequately support the commercialization of our products and product candidates or we may incur excess costs as a result of hiring more sales representatives than necessary. With respect to certain geographical markets, we may enter into collaborations with other entities to utilize their local marketing and distribution capabilities, but we may be unable to enter into such agreements on favorable terms, if at all. If our future collaborators do not commit sufficient resources to commercialize our future products, if any, and we are unable to develop the necessary marketing capabilities on our own, we will be unable to generate sufficient product revenue to sustain our business. We may be competing with companies that currently have extensive and well-funded marketing and sales operations.

Certain of our employees and patents are subject to foreign laws.

A majority of our employees work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between us and our employees or former employees pertaining to alleged non-adherence to the provisions of this act that may be costly to defend and take up our management's time and efforts whether we prevail or fail in any such dispute. There is a risk that the compensation we provided to employees who assign patents to us may be deemed to be insufficient and we may be required under German law to

increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to us, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, our results of operations could be adversely affected.

We believe that our success depends, in part, upon our ability to protect our intellectual property throughout the world. However, the laws of some foreign countries, including Germany, may not be as comprehensive as those of the U.S. and may not be sufficient to protect our proprietary rights. In addition, we generally do not pursue patent protection in all jurisdictions because of cost and confidentiality concerns. Accordingly, our international competitors could obtain foreign patent protection for, and market overseas, products and technologies for which we are seeking patent protection in the U.S.

A variety of risks associated with commercializing our products and product candidates internationally could materially adversely affect our business.

We, or our licensing partners, may seek regulatory approval for our product candidates outside of the U.S. and EU and, accordingly, we expect that we will be subject to additional risks for our products and product candidates related to operating in foreign countries if we obtain the necessary approvals, including:

- differing regulatory requirements in foreign countries;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- unexpected changes in tariffs, trade barriers, price and exchange controls and other regulatory requirements;
- economic weakness, including inflation, or political instability in particular foreign economies and markets;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- foreign taxes, including withholding of payroll taxes;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenues, and other obligations incident to doing business in another country;
- difficulties staffing and managing foreign operations;
- workforce uncertainty in countries where labor unrest is more common than in Germany or the U.S.;
- potential liability under the Foreign Corrupt Practices Act of 1977 or comparable foreign regulations;
- challenges enforcing our contractual and intellectual property rights, especially in those foreign countries that do not respect and protect intellectual property rights to the same extent as in the EU or the U.S.;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism.

These and other risks associated with our or our licensing partners' international operations may materially adversely affect our ability to attain or maintain profitable operations.

Our business and operations would suffer in the event of system failures.

Despite the implementation of security measures, our internal computer systems and those of our current and future clinical research organizations, or CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or

security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our products and product candidates could be delayed.

If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our products.

We face an inherent risk of product liability as a result of the clinical testing of our products and face an even greater risk if we commercialize our products on a larger scale. For example, we may be sued if our products allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing; defects in design; a failure to warn of dangers inherent in the product, negligence, strict liability; and a breach of warranties. Claims could also be asserted under state consumer protection acts. In Europe, medical products and medical devices may, under certain circumstances, be subject to no-fault liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products and product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

- costs to defend litigation and other proceedings;
- a diversion of management's time and our resources;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- initiation of investigations by regulators;
- product recalls, withdrawals or labeling, marketing or promotional restrictions;
- loss of revenue;
- substantial monetary awards to trial participants or patients;
- exhaustion of any available insurance and our capital resources;
- the inability to commercialize our products; and
- a decline in our share or ADS price.

We currently maintain product liability insurance. If such insurance is not sufficient, or if we are not able to obtain such insurance at an acceptable cost in the future, potential product liability claims could prevent or inhibit the commercialization of our products and the products we develop. A successful claim could materially harm our business, financial condition or results of operations. Additionally, we cannot guarantee that continued product liability insurance coverage will be available in the future at acceptable costs.

Our international operations may pose currency risks, which may adversely affect our operating results and net income.

Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. In general, we conduct our business, earn revenues and incur costs in the local currency of the countries in which we operate. In 2016, 80% of our revenue was generated and approximately 71% of our costs were incurred in euros (54% and 47%, respectively, for the nine months ended September 30, 2017). Although currency exchange rate fluctuations have not had an impact on our operations to date, as we execute our strategy to expand in the U.S. and internationally, our exposure to currency risks will increase. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies, the dollar and the euro will affect our revenues, cost of goods sold, and operating margins, and could result in exchange losses in any given reporting period.

We incur currency transaction risks whenever we enter into either a purchase or a sale transaction using a different currency from the currency in which we report revenues. In such cases we may suffer an exchange loss because we do not currently engage in currency swaps or other currency hedging strategies to address this risk.

Given the volatility of exchange rates, we can give no assurance that we will be able to effectively manage our currency transaction risks or that any volatility in currency exchange rates will not have an adverse effect on our results of operations.

Failure to comply with the U.S. Foreign Corrupt Practices Act or other applicable anti-corruption legislation could result in fines, criminal penalties and an adverse effect on our business.

We operate in a number of countries throughout the world. We are committed to doing business in accordance with applicable anti-corruption laws. We are subject, however, to the risk that our officers, directors, employees, agents and collaborators may take action determined to be in violation of such anti-corruption laws, including the U.S. Foreign Corrupt Practices Act of 1977, the U.K. Bribery Act 2010 and the European Union Anti-Corruption Act, as well as trade sanctions administered by the U.S. Office of Foreign Assets Control and the U.S. Department of Commerce. Any such violation could result in substantial fines, sanctions, civil and/or criminal penalties or curtailment of operations in certain jurisdictions, and might adversely affect our results of operations. In addition, actual or alleged violations could damage our reputation and ability to do business.

Global economic, political and social conditions have adversely impacted our sales and operations and may continue to do so.

The uncertain direction and relative strength of the global economy, difficulties in the financial services sector and credit markets, continuing geopolitical uncertainties and other macroeconomic factors all affect spending behavior of potential end-users of our products. The prospects for economic growth in Europe, the U.S. and other countries remain uncertain and may cause end-users to further delay or reduce purchases of drugs or therapies that are not fully reimbursed by governmental or other third party payors. In particular, a substantial portion of our sales are made to customers in countries in Europe, which is experiencing a significant economic crisis. If global economic conditions remain volatile for a prolonged period or if European economies experience further disruptions, our results of operations could be adversely affected. The global financial crisis affecting the banking system and financial markets has resulted in a tightening of credit markets, lower levels of liquidity in many financial markets and extreme volatility in fixed income, credit, currency and equity markets.

Our products may become obsolete prior to the end of their anticipated useful lives, and we may be required to dispose of existing inventory or write off the value or accelerate the depreciation of those assets, each which would materially and adversely impact our results of operations.

We focus on continual product innovation and product improvement. While we believe this provides a competitive edge, it also results in the risk that our products will become obsolete prior to the end of their anticipated useful lives. If we introduce new products or next generation products prior to the end of the useful life of a prior generation, we may be required to dispose of existing inventory, or write off the value of these assets, each of which would materially and adversely impact our results of operations.

Our business involves environmental risks and we may incur significant costs complying with environmental laws and regulations.

We are subject to federal, state, local and foreign laws and regulations which govern the use, manufacture, storage handling and disposal of hazardous materials and specific waste products. We believe that we are in compliance in all material respects with currently applicable environmental laws and regulations. However, we cannot guarantee that we will not incur significant costs to comply with environmental laws and regulations in the future. We also cannot guarantee that current or future environmental laws or regulations will not materially adversely affect our operations, business or financial condition. In addition, although we believe our safety procedures for handling and disposing of these materials comply with federal, state, local and foreign laws and regulations, we cannot completely eliminate the risk of accidental contamination or injury from these materials. In the event of such an accident, we could be held liable for any resulting damages, and this liability could exceed our resources.

Risks Related to the Clinical Development and Regulatory Approval of Our Products

Our business depends substantially on the success of our principal product Ameluz®. If we are unable to successfully commercialize Ameluz®, to obtain and maintain regulatory approvals or reimbursement for Ameluz® for existing and additional indications and/or in additional countries, or if we experience significant delays in realizing any of those commercialization or product development objectives, our business may be materially harmed.

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

- successful completion of further clinical trials;
- receipt of further regulatory approvals, including for the marketing of Ameluz® for additional indications and/or in additional countries;
- obtaining adequate reimbursement from governments and other third party payors for Ameluz®;
- maintaining regulatory compliance for our contract manufacturing facility and sales force;
- manufacturing sufficient quantities in acceptable quality;
- achieving meaningful commercial sales of our products;
- sourcing sufficient quantities of raw materials used to manufacture our products;
- successfully competing with other products;
- continued acceptable safety and effectiveness profiles for our products following regulatory approval and marketing;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our intellectual property rights.

If we do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our products, which would materially harm our business and we may not be able to earn sufficient revenue and cash flows to continue our operations.

Our ability to generate future revenues depends heavily on our success in:

- maintaining and extending U.S., EU and/or other foreign regulatory approvals for our products;
- manufacturing commercial quantities of our products at acceptable costs;
- successfully commercializing our products, and
- achieving broad market acceptance of our products and product candidates in the medical community and with the government and other third party payors and patients.

Clinical drug development is expensive and involves uncertain outcomes, and results of earlier studies and trials may not be predictive of future trial results. If one or more future Phase III clinical trials for Ameluz® were unsuccessful, or significantly delayed, we could be required to abandon development, we may suffer reputational harm and our business will be materially harmed.

If the results of our clinical trials for our current products or product candidates or clinical trials for any future product candidates do not achieve their primary efficacy endpoints or raise unexpected safety issues, the prospects for approval of our product candidates or the extension of indications for our products will be materially adversely affected. Moreover, preclinical

and clinical data are often susceptible to varying interpretations and analyses and many companies that believed their product candidates performed satisfactorily in preclinical studies and clinical trials have failed to achieve similar results in later clinical trials, or have ultimately failed to obtain regulatory approval of their product candidates. Many products that initially showed promise in clinical trials or earlier stage testing have later been found to cause undesirable or unexpected adverse effects that have prevented their further development and regulatory approval. Our ongoing trial for basal cell carcinoma may not produce the results that we expect or that are required to achieve FDA approval.

In addition, we may experience numerous unforeseen events that could cause our clinical trials to be delayed, suspended or terminated, or which could delay or prevent our ability to receive regulatory approval or commercialize our product candidates, including that:

- clinical trials of our products and product candidates may produce negative, inconclusive or inconsistent results, and we may decide, or regulators may require us, to conduct additional clinical trials or implement a clinical hold;
- we may elect or be required to suspend or terminate clinical trials of our products and product candidates, including based on a finding that the participants are being exposed to unacceptable health risks;
- regulators or institutional review boards may not authorize us or our investigators to commence or continue a clinical trial, or may require additional data before allowing clinical trials to commence, continue or proceed from one phase to another, or conduct, or continue a clinical trial at a prospective trial site;
- our third party contractors may fail to comply with regulatory requirements, such as good clinical practice requirements, fail to follow approved study protocols, or fail to meet their contractual obligations to us in a timely manner, or at all;
- the cost of clinical trials for our products and product candidates may be greater than we anticipate;
- changes in government regulation or administrative actions;
- the supply of materials necessary to conduct clinical trials of our products and product candidates may be insufficient or inadequate; and
- our products and product candidates may have undesirable adverse effects or other unexpected characteristics.

If we experience delays in the completion of, or termination of, any clinical trial of our products and product candidates, the commercial prospects of our products and product candidates will be materially harmed, and our ability to generate product revenues from any of these products and product candidates, if any, will cease or be delayed. We may have to repeat or redesign clinical trials, which could delay the regulatory approval process. In addition, any termination of, or delays in completing, our clinical trials will increase our costs, slow down our product development and approval process and jeopardize our ability to commence product sales and generate revenue. Any of these occurrences may significantly harm our business, financial condition and prospects. In addition, many of the factors that cause, or lead to a delay in the commencement or completion of or early termination of, clinical trials may also ultimately lead to the denial of regulatory approval of our products and product candidates.

We will be subject to ongoing regulatory requirements in every market where we engage in business and we may face future development, manufacturing and regulatory difficulties.

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

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

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

- issue warning letters or Form 483 (or similar) notices requiring us to modify certain activities or correct certain deficiencies;
- require product recalls or impose civil monetary fines;
- mandate modifications to promotional materials or require us to provide corrective information to healthcare practitioners;
- require us or our potential future collaborators to enter into a consent decree or permanent injunction;
- impose other administrative or judicial civil or criminal actions, including monetary or other penalties, or pursue criminal prosecution;
- withdraw regulatory approval;
- refuse to approve pending applications or supplements to approved applications filed by us or by our potential future collaborators;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products.

Risks Related to Our Dependence on Third Parties

We rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval for or commercialize our product candidates and our business could be substantially harmed.

We have engaged third party CROs in connection with our Phase III clinical trials for our products and product candidates and will continue to engage such CROs in the future. We will rely heavily on these parties for proper execution of our clinical trials, and we will control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal and regulatory requirements, and scientific standards, and our reliance on our CROs does not relieve us of our regulatory responsibilities. We and our CROs will be required to comply with current Good Clinical Practices, or cGCP requirements, which are a collection of regulations enforced by the FDA or comparable foreign regulatory authorities for products and product candidates in clinical development in order to protect the health, safety and welfare of patients and assume the integrity of clinical data. These requirements are also intended to protect the health, safety and welfare of study subjects through requirements such as informed consent. The FDA enforces good clinical practices through periodic inspections of trial sponsors, principal investigators and trial sites. In Phase I, the initial introduction of the drug into human subjects, the drug is typically tested to assess the pharmacological actions and side effects associated with increasing doses. Phase II usually involves clinical trials in a limited patient population to determine the effectiveness of the drug for a particular indication or indications, dosage tolerance and optimum dosage and to identify common adverse effects and safety risks. If a drug demonstrates evidence of effectiveness and an acceptable safety profile in Phase II, Phase III clinical trials are undertaken to obtain additional information about clinical efficacy and safety in a larger number of patients. Throughout this process, regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these CROs fail to comply with applicable cGCP regulations or record-keeping requirements at any point during the clinical trial process, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or EMA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications or, in some instances, require us to suspend operations. We cannot assure you that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, for drugs, our clinical trials must be conducted with products produced under cGMP regulations and will require a large number of test subjects. For our devices, clinical trials must use product manufactured in compliance with design controls under the QSR. Our failure or any failure by our CROs to comply with these regulations or to recruit a sufficient number of

patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, we may be implicated if any of our CROs violate federal, state, local or foreign fraud and abuse or false claims laws and regulations, or healthcare privacy and security laws.

The CROs will not be employed directly by us and, except for remedies available to us under our agreements with such CROs, we cannot control whether they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other product development activities, which could affect their performance on our behalf. If the CROs do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval for or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our products and product candidates would be harmed, our costs could increase and our ability to generate revenues could be delayed.

Switching or adding CROs involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays may occur, which can materially impact our ability to meet our desired clinical development timelines. Although we plan to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a material adverse impact on our business, prospects, financial condition and results of operations.

We rely on third parties for the supply of raw materials and manufacture of our principal product.

We rely on third parties for the timely supply of raw materials and for the manufacture of Ameluz®. Although we actively manage these third party relationships to provide continuity and quality, some events which are beyond our control could result in the complete or partial failure of these goods and services. Any such failure could have a material adverse effect on our financial condition and operations.

We currently license the commercialization rights for some of our products outside of the U.S., Germany, Spain and the UK, which exposes us to additional risks of conducting business in international markets.

Markets outside the U.S. and Germany are an important component of existing commercialization strategy for our existing marketed products as well as part of our growth strategy for Ameluz®. We have entered into commercial supply agreements for Ameluz® and BF-RhodoLED® lamps pursuant to which we exclusively supply and our partners exclusively purchase the products from us in their respective territories, as described in greater detail under "Business — Commercial Partners and Agreements." Our agreements require us to timely supply products that meet the agreed quality standards and require our customers to purchase products from us, in some cases in specified minimum quantities. If we fail to maintain these agreements and agreements with other partners or to enter into new distribution arrangements with selling parties, or if these parties are not successful, our revenue-generating growth potential will be adversely affected. Moreover, international business relationships subject us to additional risks that may materially adversely affect our ability to attain or sustain profitable operations, including:

- efforts to enter into distribution or licensing arrangements with third parties in connection with our international sales, marketing and distribution efforts may increase our expenses or divert our management's attention from the development of product candidates;
- changes in a specific country's or region's political and cultural climate or economic condition;
- differing requirements for regulatory approvals and marketing internationally;
- difficulty of effective enforcement of contractual provisions in local jurisdictions;
- potentially reduced protection for intellectual property rights;
- potential third party patent rights in countries outside of the U.S. or the EU;
- unexpected changes in tariffs, trade barriers and regulatory requirements;
- economic weakness, including inflation, or political instability;

- compliance with tax, employment, immigration and labor laws for employees traveling abroad;
- the effects of applicable foreign tax structures and potentially adverse tax consequences;
- foreign currency fluctuations, which could result in increased operating expenses and reduced revenue and other obligations incidental to doing business in another country;
- workforce uncertainty in countries where labor unrest is more common than in the U.S. or Germany;
- the potential for so-called parallel importing, which is what happens when a local seller, faced with high or higher local prices, opts to import goods from a foreign market (with low or lower prices) rather than buying them locally;
- failure of our employees and contracted third parties to comply with U.S. Office of Foreign Asset Control rules and regulations and the U.S. Foreign Corrupt Practices Act or comparable foreign regulations;
- production shortages resulting from any events affecting raw material supply or manufacturing capabilities abroad; and
- business interruptions resulting from geo-political actions, including war and terrorism, or natural disasters, including earthquakes, volcanoes, typhoons, floods, hurricanes and fires.

These and other risks may materially adversely affect our ability to attain or sustain revenue from international markets.

We may form or seek strategic alliances in the future and we may not realize the benefits of such alliances.

We may form or seek strategic alliances, create joint ventures or collaborations or enter into licensing arrangements with third parties that we believe will complement or augment our development and commercialization efforts with respect to our products and any future products that we may develop. Any of these relationships may require us to incur non-recurring and other charges, increase our near- and long-term expenditures, issue securities that dilute our existing holders of our shares or ADSs or disrupt our management and business. In addition, we face significant competition in seeking appropriate strategic partners and the negotiation process is time-consuming and complex. Moreover, we may not be successful in our efforts to establish a strategic partnership or other alternative arrangements for our product candidates because they may be deemed to be at too early of a stage of development for collaborative effort and third parties may not view our product candidates as having the requisite potential to demonstrate safety and efficacy. If we license products or businesses, we may not be able to realize the benefit of such transactions if we are unable to successfully integrate them with our existing operations and company culture and vice versa. We cannot be certain that, following a strategic transaction or license, we will achieve the revenue or specific net income that justifies such transaction. Any delays in entering into new strategic partnership agreements related to our products or product candidates could delay the development and commercialization of our products or product candidates in certain geographies or for certain indications, which would harm our business prospects, financial condition and results of operations.

Risks Related to Our Intellectual Property

If our efforts to protect the proprietary nature of the intellectual property related to our technologies are not adequate, we may not be able to compete effectively in our market.

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

In addition, the patent applications that we own or that we may license may fail to result in issued patents in the U.S., the EU or in other countries or jurisdictions. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the issued patents and patent applications we hold with respect to our products is threatened, it could dissuade companies from collaborating with us to develop, and threaten our ability to commercialize, our products. Further, if we encounter delays in our clinical trials, the period of time

during which we could market our products under patent protection would be reduced. Since patent applications in the U.S. and most other countries are confidential for a period of time after filing, we cannot be certain that we were the first to file any patent application related to our product candidates. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a "first to file" system in the U.S. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

In addition to the protection afforded by patents, we seek to rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we require all of our employees to assign their inventions to us to the extent permitted by law, and require all of our employees, consultants, advisors and any third parties who have access to our proprietary know-how, information or technology to enter into confidentiality agreements, we cannot be certain that our trade secrets and other confidential proprietary information will not be disclosed or that competitors will not otherwise gain access to our trade secrets or independently develop substantially equivalent information and techniques. Furthermore, the laws of some foreign countries do not protect proprietary rights to the same extent or in the same manner as the laws of the U.S. or the EU. As a result, we may encounter significant problems in protecting and defending our intellectual property both in the U.S., in the EU and in other countries. If we are unable to prevent unauthorized material disclosure of our intellectual property to third parties, we may not be able to establish or maintain a competitive advantage in our market, which could materially adversely affect our business, operating results and financial condition.

Third party claims of intellectual property infringement may prevent or delay our product discovery and development efforts.

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

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

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

We may be involved in lawsuits to defend or enforce our patents, which could be expensive, time-consuming and unsuccessful.

Competitors may infringe upon our patents. To counter infringement or unauthorized use, we may be required to file infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that one or more of our patents is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of our patents at risk of being invalidated, held unenforceable, or interpreted narrowly and could put our patent applications at risk of not issuing. Defense of these claims, regardless of their merit, would involve substantial litigation expense and would be a substantial diversion of employee resources from our business. In the event of a successful claim or counterclaim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, obtain one or more licenses from third parties, pay royalties or redesign our infringing products, which may be impossible or require substantial time and monetary expenditure.

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome could require us to cease using the related technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if the prevailing party does not offer us a license on commercially reasonable terms. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distract our management and other employees. We may not be able to prevent misappropriation of our trade secrets or confidential information, particularly in countries where the laws may not protect those rights as fully as in the U.S. or the EU.

Furthermore, because of the substantial amount of discovery that could be required in connection with intellectual property litigation, there is a risk that some of our confidential information could be compromised by disclosure during this type of litigation. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our shares and ADSs.

Obtaining and maintaining our patent protection depends on compliance with various procedures, document submission requests, fee payments and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for noncompliance with these requirements.

Periodic maintenance fees on any issued patent are due to be paid to the USPTO and patent agencies in other jurisdictions in several stages over the lifetime of the patent. The USPTO and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent application process. While an inadvertent lapse can in many cases be cured by payment of a late fee or by other means in accordance with the applicable rules, there are situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. Noncompliance events that could result in abandonment or lapse of a patent or patent application include, but are not limited to, failure to respond to official actions within prescribed time limits, non-payment of fees and failure to properly legalize and submit formal documents. In such an event, our competitors might be able to enter the market, which would have a material adverse effect on our business.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on all of our products and product candidates throughout the world would be prohibitively expensive. Competitors may use our technologies in jurisdictions where we have not obtained patent protection to develop their own products and, further, may export otherwise infringing products to territories where we have patent protection, but where enforcement is not as strong as that in the U.S. and the EU. These products may compete with our products in jurisdictions where we do not have any issued patents and our patent claims or other intellectual property rights may not be effective or sufficient to prevent them from so competing.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries, particularly certain developing countries, do not favor the enforcement of patents and other intellectual property protection, particularly those relating to biopharmaceuticals, which could make it difficult for us to stop the infringement of our patents or marketing of competing products in violation of our proprietary rights generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial cost and divert our efforts and attention from other aspects of our business.

Our trade secrets are difficult to protect.

Confidentiality agreements with employees and others may not adequately prevent disclosure of our trade secrets and other proprietary information and may not adequately protect our intellectual property.

Our success depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our partners, licensors and contractors. Because we operate in a highly competitive technical field of drug development, we rely in part on trade secrets to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality agreements with our corporate partners, employees, consultants, sponsored researchers and other advisors. These agreements typically require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party by us during the course of the receiving party's relationship with us. Our agreements also provide that any inventions made based solely upon our technology are our exclusive property, and we enter into assignment agreements that are recorded in patent, trademark and copyright offices around the world to perfect our rights.

These confidentiality and assignment agreements may be breached and may not effectively assign intellectual property rights to us. Our trade secrets also could be independently discovered by competitors, in which case, we would not be able to prevent use of such trade secrets by our competitors. The enforcement of a claim alleging that a party illegally obtained and was using our trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. In addition, courts outside the U.S. or the EU may be less willing to protect trade secrets. There exists a risk that we may not be able to detect when misappropriation of our trade secrets has occurred or where a third party is using our trade secrets without our knowledge. The failure to obtain or maintain meaningful trade secret protection could adversely affect our competitive position.

Generic manufacturers may launch products at risk of patent infringement.

If other manufacturers launch products to compete with our products or product candidates in spite of our patent position, these manufacturers would likely erode our market and negatively impact our sales revenues, liquidity and results of operations.

Risks Related to the Offering and Ownership of our ADSs

An active trading market for our ADSs may not develop or be sustained.

Prior to the offering contemplated by this prospectus, there has been no public market for our ADSs in the U.S. An active trading market for our ADSs may not develop or be sustained. If an active market for our ADSs does not develop or continue, it may be difficult for the holders to sell our ADSs without depressing the market price for our ADSs or to sell our ADSs at or above the prices at which they acquired our ADSs or to sell our ADSs at the time they would like to sell. The initial public offering price of our ADSs will be determined through negotiations between us and the underwriters. The initial public offering price may not be indicative of the market price of our ADSs after the offering. Any inactive trading market for our ADSs may also impair our ability to raise capital to continue to fund our operations by selling our ADSs and may impair our ability to acquire other companies or technologies by using our ADSs as consideration.

There has been varying trading volume for our ordinary shares.

Each ADS represents two ordinary shares of our company. Even though our ordinary shares have been listed on the Stock Exchange in Düsseldorf since 2006 and the Frankfurt Stock Exchange since 2012, there has been limited liquidity in such markets for our ordinary shares from time to time, which could make it more difficult for holders to sell our ordinary shares. We do not intend to directly list our ordinary shares on a U.S. trading market and, therefore, do not expect that a trading market will develop for our ordinary shares.

There can be no assurance that an active trading market for our ADSs will develop or be sustained.

In addition, the stock market generally has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of listed companies. Broad market and industry factors may negatively affect the market price of our ordinary shares or ADSs, regardless of our actual operating performance. The market price and liquidity of the market for our ordinary shares or ADSs that will prevail in the market may be higher or lower than the price you pay and may be significantly affected by numerous factors, some of which are beyond our control.

The price of our ordinary shares or ADSs may be volatile, and you could lose all or part of your investment.

The trading price of our shares or ADSs is likely to be highly volatile and could be subject to wide fluctuations in response to various factors, some of which are beyond our control, including limited trading volume. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this prospectus, these factors include:

- adverse results or delays in clinical trials;
- our failure to commercialize our products or product candidates;
- actual or anticipated variations in our operating results and our financial position;
- our failure to meet the estimates and projections of the investment community or that we may otherwise provide to the public and the publication of research reports about us or our industry;
- adverse regulatory decisions or changes in laws or regulations;
- introduction of new products or services offered by us or our competitors;
- our inability to obtain adequate product supply;
- our inability to establish collaborations, if needed;
- departures of key scientific or management personnel;
- our ability to successfully manage our growth and enter new markets;
- disputes or other developments relating to proprietary rights, including patents, litigation matters and our ability to obtain patent protection for our technologies;

- significant lawsuits, including patent or shareholder litigation; and
- other events or factors, many of which are beyond our control.

In addition, the stock market in general, and The NASDAQ Capital Market and pharmaceutical companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Broad market and industry factors may negatively affect the market price of our shares or ADSs, regardless of our actual operating performance. If the market price of our ADSs does not exceed your purchase price, you may not realize any return on your investment in us and may lose some or all of your investment. In the past, securities class action litigation has often been instituted against companies following periods of volatility in the market price of a company's securities. This type of litigation, if instituted, could result in substantial costs and a diversion of management's attention and resources, which would harm our business, operating results or financial condition.

We have broad discretion to determine how to use the funds raised in this offering and may use them in ways that may not enhance our operating results or the price of our ADSs.

Our management will have broad discretion over the use of proceeds from this offering, and we could spend the proceeds from this offering in ways the holders of our ADSs may not agree with or that do not yield a favorable return, if any. We intend to use the net proceeds of this offering for the purposes described in the "Use of Proceeds" section of this prospectus. However, our use of these proceeds may differ substantially from our current plans. You will not have the opportunity, as part of your investment decision, to assess whether proceeds are being used appropriately. You must rely on the judgment of our management regarding the application of the net proceeds of this offering. If we do not invest or apply the proceeds of this offering in ways that enhance our business, we may fail to achieve expected financial results, which could cause the price of our ADSs to decline.

We will rely on a Share Loan arrangement in order to facilitate the orderly closing of this offering of ADSs. If the Share Loan arrangement is not completed (for example, if registration of the capital increase relating to this offering fails), we will not retain the proceeds of this offering, which would have a material adverse effect on our financial position, liquidity and results of operations.

To facilitate the orderly closing of this offering of ADSs, and because of timing considerations related to the technical issuance and registration of new ordinary shares under German law, the shares underlying the ADSs immediately prior to and concurrent with the consummation of this offering and the time of delivery of the ADSs will be Borrowed Shares loaned by Maruho Deutschland GmbH to Lang & Schwarz Broker GmbH, acting as our service provider pursuant to a separate mandate agreement, for deposit with the custodian for the Depositary under the ADS facility. In connection with the consummation of this offering, we will initially receive proceeds equal to one-quarter of the nominal value of the ordinary shares underlying the ADSs sold in this offering (i.e., €0.25 per ordinary share). Upon receipt of the partial proceeds of the offering and the subscription certificate, we will initiate the registration of a capital increase for the number of shares underlying the ADSs sold in this offering with the commercial register of the local court of Cologne. Although we expect to complete the registration process within approximately one week, it is possible that registration of the capital increase may take as long as three weeks. The time required to complete registration of the capital increase is determined by the schedule of the local court. Once the capital increase has been registered, newly issued ordinary shares of our company equal to the number of shares underlying the ADSs sold in this offering will be delivered to Lang & Schwarz Broker GmbH, which will return the shares to Maruho Deutschland GmbH in repayment and satisfaction in full of the Share Loan. The Borrowed Shares will be retained by the custodian for the Depositary. We will receive the full net proceeds of this offering only upon registration of the capital increase with the commercial register. If for any reason we fail to complete registration of the capital increase we will not retain any proceeds from this offering, which would have a material adverse effect on our financial position, liquidity and results of operations. If we do not retain the proceeds of this offering, it may constitute a secondary offering.

We are an emerging growth company, and the reduced reporting requirements applicable to emerging growth companies may make our ADSs less attractive to investors.

We are an emerging growth company, as defined in the JOBS Act. For as long as we continue to be an emerging growth company, we may take advantage of exemptions from various reporting requirements that are applicable to other public companies that are not emerging growth companies, including not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act, reduced disclosure obligations regarding executive compensation in this prospectus and our periodic reports and exemptions from the requirements of holding nonbinding advisory votes on executive compensation and shareholder approval of any golden parachute payments not previously approved. We could be an emerging growth company

until the earliest of the end of the fiscal year corresponding with the fifth anniversary of our initial public offering, the date on which we qualify as a "large accelerated filer" under U.S. securities laws, the end of the fiscal year in which our annual revenue is $1,070,000,000 or more, or the date on which we issue more than $1,000,000,000 in non-convertible debt during any prior three-year period. Our investors may find our ADSs less attractive because we may rely on these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ADS price may be more volatile.

Under the JOBS Act, an emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We currently prepare our financial statements in accordance with IFRS as issued by the IASB, which do not have separate provisions for publicly traded and private companies. However, in the event we convert to generally accepted accounting principles in the U.S., or U.S. GAAP, while we are still an emerging growth company, we may be able to take advantage of the benefits of this extended transition period.

We have no present intention to pay dividends on our ordinary shares in the foreseeable future and, consequently, your only opportunity to achieve a return on your investment during that time is if the price of our ADSs appreciates.

We have no present intention to pay dividends on our ordinary shares in the foreseeable future. Any recommendation by our supervisory and management boards to pay dividends will depend on many factors, including our financial condition, results of operations, legal requirements and other factors. In addition, under the EIB credit facility we are not permitted to pay dividends to shareholders without the prior consent of EIB. Accordingly, if the price of our ADSs declines in the foreseeable future, you will incur a loss on your investment, without the likelihood that this loss will be offset in part or at all by potential future cash dividends.

As a new investor, you will experience substantial dilution as a result of this offering.

The public offering price per ADS will be substantially higher than the as adjusted net tangible book value per ADS before giving effect to this offering. Accordingly, if you invest in the ADSs in this offering, you will incur immediate substantial dilution of approximately $8.17 per ADS (based on the net tangible book value per share underlying the ADSs as of June 30, 2016). Furthermore, if the underwriters exercise their over-allotment option to purchase additional ADSs or if outstanding options or convertible bonds are subsequently exercised or converted, you could experience further dilution. This dilution is due in large part to the fact that our earlier investors paid substantially less than the assumed public offering price when they purchased their ordinary shares. For further information regarding the dilution resulting from this offering, please see the section of this prospectus entitled "Dilution".

Raising additional capital may cause additional dilution of the percentage ownership of the holders of our ADSs, restrict our operations, require us to relinquish rights to our technologies, products or product candidates and could cause our ADS price to fall.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting clinical trials, commercialization efforts, expanded research and development activities and costs associated with operating a public company in the U.S. and Germany. To raise capital, we may sell ordinary shares, ADSs, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. If we sell ordinary shares, ADSs, convertible securities or other equity securities, investors may be materially diluted by subsequent sales. Such sales may also result in material dilution to our existing holders of ADSs, and new investors could gain rights, preferences and privileges senior to the holders of our ordinary shares or ADSs. If we raise additional funds through strategic partnerships and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, products or product candidates, or grant licenses on terms unfavorable to us.

We have created four sets of "contingent capital" (*bedingtes Kapital*) which, under German corporate law, means ordinary shares that we have been approved to issue, in the future, upon the exercise or conversion of specified outstanding options, warrants, convertible bonds or other convertible securities, totaling up to 6,994,985 ordinary shares, of which we expect to use 542,400 ordinary shares to cover issuances of ordinary shares pursuant to our 2010 employee stock option plan and 1,814,984 ordinary shares to cover issuances of ordinary shares pursuant to our 2015 employee stock option plan. We expect up to 246,515 shares would be used to cover issuances of ordinary shares pursuant to our 2009/2017 warrant bond, which was repaid in full on August 3, 2017. The remaining 4,137,601 ordinary shares from contingent capital may be used by our company for the issuance of shares to holders of convertible bonds if the repayment price is covered by issuing shares. Our management board, with the approval of our supervisory board, can increase our capital by these amounts and issue new ordinary shares in a

corresponding amount without additional shareholder approval and can, to a limited extent, exclude subscription rights of our shareholders in connection therewith (see "Description of Share Capital"). If beneficiaries exercise their options or additional ordinary shares are issued under any of our authorized capital or our contingent capital, you may experience additional dilution, which could cause our ADS price to fall.

We have also created one set of authorized capital (genehmigtes Kapital) which, under German law, enables our management board, with prior approval of the supervisory board, to issue up to 6,000,000 of our ordinary shares.

Substantial future sales of our ordinary shares or ADSs in the public market, or the perception that these sales could occur, could cause the price of the ADSs to decline.

Additional sales of our ordinary shares or ADSs in the public market after this offering, or the perception that these sales could occur, could cause the market price of the ADSs to decline. Upon completion of this offering and the German preemptive rights offering (assuming no exercise or conversion of any of our outstanding convertible bonds or stock options), we will have outstanding approximately 44,245,462 ordinary shares (based on 38,416,428 ordinary shares outstanding as of February 8, 2018), or 44,416,428 if the underwriters exercise their over-allotment option in full. All ADSs sold in this offering will be freely transferable without restriction or additional registration under the Securities Act, except for any ADSs sold to our "affiliates" (subject to the terms of the lock-up agreements referred to below, as applicable). Neither Maruho Deutschland GmbH nor any of our other major shareholders will be subject to any lock-up agreements and may sell their shares at any time. Our chief executive officer will be subject to a lock-up agreement that provides that any ordinary shares or ADSs held by him will be available for sale upon the expiration of a lock-up period, which will expire 180 days after the date of this prospectus. Any or all of these ordinary shares or ADSs may be released prior to expiration of the lock-up period with the prior written consent of The Benchmark Company, LLC. To the extent ordinary shares or ADSs are released before the expiration of the lock-up period and these ordinary shares or ADSs are sold into the market, the market price of the ADSs could decline. See "Shares and ADSs Eligible for Future Sale" for" and "Underwriting (Conflicts of Interest)" for a more detailed description of the terms of these "lock-up" arrangements.

Unstable market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

As widely reported, global credit and financial markets have experienced extreme disruptions in the past several years, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates and uncertainty about economic stability. There can be no assurance that further deterioration in credit and financial markets and confidence in economic conditions will not occur. Our general business strategy may be adversely affected by any such economic downturn, volatile business environment or continued unpredictable and unstable market conditions. If the current equity and credit markets deteriorate, or do not improve, it may make any necessary debt or equity financing more difficult, more costly, and more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could have a material adverse effect on our growth strategy, financial performance and ADS price and could require us to delay or abandon clinical development or commercialization plans. In addition, there is a risk that one or more of our current service providers, manufacturers and other partners may not survive these difficult economic times, which could directly affect our ability to attain our operating goals on schedule and on budget.

At September 30, 2017, we had approximately €13.3 million of cash and cash equivalents. While we are not aware of any downgrades, material losses, or other significant deterioration in the fair value of our cash equivalents since September 30, 2017, no assurance can be given that further deterioration of the global credit and financial markets would not negatively impact our current portfolio of cash equivalents or our ability to meet our financing objectives. Furthermore, our ADS price may decline due in part to the volatility of the stock market and the general economic downturn.

We could be subject to securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because pharmaceutical companies have experienced significant share price volatility in recent years. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

If securities or industry analysts cease publishing research, or publish inaccurate or unfavorable research about our business, our ADS price and trading volume could decline.

The trading market for our ADSs will depend in part on the research and reports that securities or industry analysts publish about us or our business. If one or more of the analysts who covers us downgrades our shares or ADSs or publishes inaccurate or unfavorable research about our business, our share and ADS price may decline. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, demand for our shares and ADSs could decrease, which might cause our share and ADS price and trading volume to decline.

As a foreign private issuer, we are exempt from a number of rules under the U.S. securities laws and are permitted to file less information with the SEC than U.S. companies. This may limit the information available to holders of ADSs.

We are a "foreign private issuer," as defined in the rules and regulations of the U.S. Securities and Exchange Commission, or SEC, and, consequently, we are not subject to all of the disclosure requirements applicable to companies organized within the U.S. For example, we are exempt from certain rules under the U.S. Securities Exchange Act of 1934, or the Exchange Act, that regulate disclosure obligations and procedural requirements related to the solicitation of proxies, consents or authorizations applicable to a security registered under the Exchange Act. In addition, members of our supervisory board and management board and our principal shareholders are exempt from the reporting and "short-swing" profit recovery provisions of Section 16 of the Exchange Act and related rules with respect to their purchases and sales of our securities. Moreover, we are not required to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. public companies. Accordingly, there may be less publicly available information concerning our company than there is for U.S. public companies.

As a foreign private issuer, we will file an annual report on Form 20-F within four months of the close of each year ended December 31 and furnish reports on Form 6-K relating to certain material events promptly after we publicly announce these events. However, we are not required to issue quarterly financial information because of the above exemptions for foreign private issuers, and holders of our ADSs will not be afforded the same protections or information generally available to investors holding shares in public companies organized in the U.S.

As we are a "foreign private issuer" that follows, and intends to continue to follow, certain home country corporate governance practices, holders of our ADSs may not have the same protections afforded to shareholders of companies that are subject to all The NASDAQ Capital Market corporate governance requirements.

As a foreign private issuer, we have the option to follow certain German corporate governance practices rather than those of The NASDAQ Capital Market, except to the extent that such laws would be contrary to U.S. securities laws, and provided that we disclose the requirements we are not following and describe the home country practices we follow instead. We intend to rely on this "foreign private issuer exemption" with respect to The NASDAQ Capital Market's shareholder approval requirements in respect of equity issuances and equity-based compensation plans, the requirement to have independent oversight on our director nominations process and the quorum requirement for meetings of our shareholders. In addition, we intend to rely on the "foreign private issuer exemption" in the future with respect to The NASDAQ Capital Market requirement, once effective, to have a formal charter for the compensation committee. We may in the future elect to follow home country practices in Germany with regard to other matters. As a result, holders of our ADSs may not have the same protections afforded to shareholders of companies that are subject to all The NASDAQ Capital Market corporate governance requirements. See "Management — Differences between Our Corporate Governance Practices and the Rules of The NASDAQ Capital Market."

We may lose our foreign private issuer status in the future, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

We are currently a foreign private issuer and, therefore, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We would lose our foreign private issuer status if, for example, more than 50% of our assets are located in the U.S. and we continue to fail to meet additional requirements necessary to maintain our foreign private issuer status. As of September 30, 2017, a portion of our assets were located in the United States, although this may change as we expand our operations in the U.S.

A foreign private issuer must determine its status on the last business day of its most recently completed second fiscal quarter. If a foreign private issuer no longer satisfies these requirements, it will become subject to U.S. domestic reporting requirements on the first day of its fiscal year immediately succeeding such determination. If we lost this status, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed

and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance practices in accordance with various SEC and The NASDAQ Capital Market rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members to our management board and supervisory board.

Your rights as a shareholder in a German corporation may differ from your rights as a shareholder in a U.S. corporation.

We are organized as a stock corporation (*Aktiengesellschaft* or *AG*) under the laws of Germany, and by participating in this offering you will become a holder of ADSs of a German stock corporation. You should be aware that the rights of shareholders of a German stock corporation under German law differ in important respects from those of shareholders of a U.S. corporation. These differences include, in particular:

- Under German law, certain important resolutions, including, for example, capital decreases, measures under the German Transformation Act, such as mergers, conversions and spin-offs, the issuance of convertible bonds or bonds with warrants attached and the dissolution of the German stock corporation apart from insolvency and certain other proceedings, require the vote of a 75% majority of the capital present or represented at the relevant shareholders' meeting (*Hauptversamlung*). Therefore, the holder or holders of a blocking minority of 25% or, depending on the attendance level at the shareholders' meeting, the holder or holders of a smaller percentage of the shares in a German stock corporation may be able to block any such votes, possibly to our detriment or the detriment of our other shareholders.

- As a general rule under German law, a shareholder has no direct recourse against the members of the management board (*Vorstand*) or supervisory board (*Aufsichtsrat*) of a German stock corporation in the event that it is alleged that they have breached their duty of loyalty or duty of care to the German stock corporation. Apart from insolvency or other special circumstances, only the German stock corporation itself has the right to claim damages from members of either board. A German stock corporation may waive or settle these damages claims only if at least three years have passed and the shareholders approve the waiver or settlement at the shareholders' meeting with a simple majority of the votes cast, provided that a minority holding, in the aggregate, 10% or more of the German stock corporation's share capital does not have its opposition formally noted in the minutes maintained by a German civil law notary.

- By subscribing or purchasing ADSs you will not become a shareholder of the Company.

For more information, we have provided summaries of relevant German corporation law and of our articles of association under "Management" and "Description of Share Capital."

We may qualify as a passive foreign investment company, or "PFIC," for U.S. federal income tax purposes which could result in adverse U.S. federal income tax consequences to U.S. holders of our ADSs.

In general, we will be treated as a PFIC for any taxable year in which either (1) at least 75% of our gross income (looking through certain corporate subsidiaries) is passive income (this is known as the "income test") or (2) at least 50% of the average value of our assets (looking through certain corporate subsidiaries) is attributable to assets that produce, or are held for the production of, passive income (this is known as the "asset test"). In the event we are treated as a PFIC, U.S. holders (as defined in "Taxation — U.S. Taxation of ADSs and Ordinary Shares") of our ADSs could be subject to adverse U.S. federal income tax consequences. These consequences include the following: (i) if our ADSs are "marketable stock" for purposes of the PFIC rules and a U.S. holder makes a mark-to-market election with respect to its ADSs, the U.S. holder will be required to include annually in its U.S. federal taxable income an amount reflecting any year-end increase in the value of its ADSs; (ii) if a U.S. holder does not make a mark-to-market election, it may incur significant additional U.S. federal income taxes on income resulting from distributions on, or any gain from the disposition of, our ADSs, as such income generally would be allocated over the U.S. holder's holding period for its ADSs and subject to tax at the highest U.S. federal income taxation rate in effect for such years, with an interest charge then imposed on the resulting taxes in respect of such income; and (iii) dividends paid by us would not be eligible for reduced individual rates of U.S. federal income tax. In addition, U.S. holders that own an interest in a PFIC are required to file additional U.S. federal tax information returns. A U.S. holder may in certain circumstances mitigate adverse

tax consequences of the PFIC rules by filing an election to treat the PFIC as a qualified electing fund, or a QEF. However, in the event that we are or become a PFIC, we do not intend to comply with the reporting requirements necessary to permit U.S. holders to elect to treat us as a QEF. See "Taxation — U.S. Taxation of ADSs and Ordinary Shares — Additional U.S. Federal Income Tax Consequences — PFIC Rules."

We expect to be treated as a publicly traded corporation for purposes of the PFIC rules with respect to the current taxable year. In such case, the value of our assets for purposes of the asset test will generally be determined by reference to the market price of our shares. Fluctuations in the market price of our shares may cause us to become a PFIC for the current taxable year or later taxable years. In addition, the composition of our income and assets will be affected by how, and how quickly, we use our liquid assets and the cash raised in this offering. If we were unable to deploy significant amounts of cash for active purposes, our risk of being classified as a PFIC would substantially increase. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for the current taxable year or any future taxable year. We urge U.S. holders to consult their own tax advisors regarding the possible application of the PFIC rules. See "Taxation — U.S. Taxation of ADSs and Ordinary Shares — Additional U.S. Federal Income Tax Consequences — PFIC Rules."

Exchange rate fluctuations may reduce the amount of U.S. dollars you receive in respect of any dividends or other distributions we may pay in the future in connection with your ADSs.

Under German law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our unconsolidated annual financial statements prepared under the German Commercial Code in accordance with accounting principles generally accepted in Germany. Exchange rate fluctuations may affect the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. Such fluctuations could adversely affect the value of our ADSs and, in turn, the U.S. dollar proceeds that holders receive from the sale of our ADSs.

As a holder of ADSs, you may not have the same voting rights as the holders of our ordinary shares and may not receive voting materials in time to be able to exercise your right to vote.

Except as described in this prospectus and the deposit agreement, holders of our ADSs will not be able to exercise voting rights attaching to the ordinary shares evidenced by our ADSs on an individual basis. Under the terms of the deposit agreement, holders of the ADSs may instruct the depositary or its nominee to exercise the voting rights attaching to the ordinary shares represented by the ADSs. Pursuant to the deposit agreement and in light of the fact that pursuant to German law and our articles of association, one whole ordinary share represents one vote, voting instructions can be given only in respect of a number of ADSs representing a whole number of ordinary shares. You may not receive voting materials in time to instruct the depositary to vote, and it is possible that you, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote.

The value of the ADSs may not track the price of our ordinary shares.

Our ordinary shares currently trade on the Frankfurt Stock Exchange under the Symbol B8F; International Securities Identification Number (ISIN) DE0006046113; German securities code (WKN) 604611. Active trading volume and pricing for our ordinary shares on the Frankfurt Stock Exchange will usually, but not necessarily, act as predictors of similar characteristics in respect of the ADSs. In addition, the terms and conditions of our agreement with our depositary may result in less liquidity or lower market value of the ADS than for our ordinary shares. Since the holders of the ADSs may surrender the ADSs to take delivery of and trade our ordinary shares (a characteristic that allows investors in ADSs to take advantage of price differentials between different markets), an illiquid market for our ordinary shares may result in an illiquid market for the ADSs. Therefore, the trading price of our ordinary shares may not be correlated with the price of the ADSs.

Your right as a holder of ADSs to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

We may, from time to time, distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make any such rights available to the ADS holders in the U.S. unless we register such rights and the securities to which such rights relate under the Securities Act or an exemption from the registration requirements is available. In addition, the deposit agreement provides that the depositary bank will not make rights available to you unless the distribution to ADS holders of both the rights and any related securities are either registered under the Securities Act or exempted from registration under

the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. Accordingly, you may be unable to participate in our rights offerings and may experience dilution in your holdings.

As a holder of ADSs, you may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Under the terms of the deposit agreement, the Depositary has agreed to pay to you the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. You will receive these distributions in proportion to the number of our ordinary shares your ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to take any other action to permit the distribution of the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that, as a holder of ADSs, you may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to you. These restrictions may have a material adverse effect on the value of your ADSs.

Exchange rate fluctuations may reduce the amount of U.S. dollars you receive in respect of any dividends or other distributions we may pay in the future in connection with your ADSs.

Under German law, the determination of whether we have been sufficiently profitable to pay dividends is made on the basis of our unconsolidated annual financial statements prepared under the German Commercial Code in accordance with accounting principles generally accepted in Germany. Exchange rate fluctuations may affect the amount in U.S. dollars that our shareholders receive upon the payment of cash dividends or other distributions we declare and pay in euros, if any. Such fluctuations could adversely affect the value of our ADSs and, in turn, the U.S. dollar proceeds that holders receive from the sale of our ADSs.

You may be subject to limitations on the transfer of your ADSs.

Your ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when it deems doing so expedient in connection with the performance of its duties. The depositary may close its books from time to time for a number of reasons, including in connection with corporate events such as a rights offering, during which time the depositary needs to maintain an exact number of ADS holders on its books for a specified period. The depositary may also close its books in emergencies, and on weekends and public holidays. The depositary may refuse to deliver, transfer or register transfers of our ADSs generally when our share register or the books of the depositary are closed, or at any time if we or the depositary thinks that it is advisable to do so because of any requirement of law or of any government or governmental body, or under any provision of the deposit agreement, or for any other reason in accordance with the terms of the deposit agreement. As a result, you may be unable to transfer your ADSs when you wish.

U.S. investors may have difficulty enforcing civil liabilities against our company or members of our supervisory and management boards and the experts named in this prospectus.

Certain members of our supervisory and management boards and the experts named in this prospectus are non-residents of the U.S., and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may not be possible, or may be very difficult, to serve process on such persons or us in the U.S. or to enforce judgments obtained in U.S. courts against them or us based on civil liability provisions of the securities laws of the U.S. In addition, awards of punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in Germany. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time. Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities

laws against us, certain members of our supervisory and management boards and the experts named in this prospectus. The U.S. and Germany do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters, though recognition and enforcement of foreign judgments in Germany is possible in accordance with applicable German laws.

We will incur significant increased costs as a result of operating as a company whose ADSs are publicly traded in the U.S. and whose ordinary shares are publicly traded on the Frankfurt Stock Exchange, and our management will continue to be required to devote substantial time to new compliance initiatives.

As a company whose ADSs will be trading on The NASDAQ Capital Market in the U.S. and whose ordinary shares will be trading on the Frankfurt Stock Exchange in Germany, we will incur significant legal, accounting, insurance and other expenses that we did not previously incur. In addition, the Sarbanes-Oxley Act, the U.S. Dodd-Frank Wall Street Reform and Consumer Protection Act and related rules implemented by the SEC and The NASDAQ Capital Market have imposed various requirements on public companies, including requiring establishment and maintenance of effective disclosure and financial controls. These costs will increase at the time we are no longer an emerging growth company eligible to rely on exemptions under the JOBS Act from certain disclosure and governance requirements. Our management and other personnel will need to devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. These laws and regulations could also make it more difficult and expensive for us to attract and retain qualified persons to serve on our supervisory board or its committees or on our management board. Furthermore, if we are unable to satisfy our obligations as a public company, we could be subject to delisting of the ADSs, fines, sanctions and other regulatory action and potentially civil litigation.

As a result of becoming a public company in the U.S., we will become subject to additional regulatory compliance requirements, including Section 404 of the Sarbanes-Oxley Act, and if we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

As a public company listed on The NASDAQ Capital Market, the Sarbanes-Oxley Act will require, among other things that we assess the effectiveness of our internal control over financial reporting at the end of each fiscal year. We anticipate being first required to issue management's assessment of internal control over financial reporting pursuant to Section 404(a) of the Sarbanes-Oxley Act in connection with issuing our consolidated financial statements as of and for the fiscal year ending December 31, 2018.

We have started the process of designing, implementing and testing our internal control over financial reporting required to comply with Section 404(a) of the Sarbanes-Oxley Act. This process is time-consuming, costly and complicated. Our management may not be able to effectively and timely implement controls and procedures that adequately respond to the increased regulatory compliance and reporting requirements that will be applicable to us as a public company listed on The NASDAQ Capital Market. If we fail to maintain internal control over financial reporting adequate to meet the demands that will be placed upon us as a public company listed in the U.S., our business and reputation may be harmed, the accuracy and timeliness of our financial reporting may be adversely affected, and the price of our ADSs may decline.

In addition, our independent registered public accounting firm will be required to attest to the effectiveness of our internal controls over financial reporting beginning with our annual report following the date on which we are no longer an "emerging growth company," which may be up to five fiscal years following the date of this offering.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus includes forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, included in this prospectus regarding our strategy, future operations, regulatory process, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. The words "believe", "anticipate", "intend", "expect", "target", "goal", "estimate", "plan", "assume", "may", "will", "predict", "project", "would", "could" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

The forward-looking statements in this prospectus include, but are not limited to, statements about:

- our ability to achieve and sustain profitability;
- our ability to compete effectively in selling our products;
- our ability to expand, manage and maintain our direct sales and marketing organizations;
- our actual financial results may vary significantly from forecasts and from period to period;
- our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing;
- our ability to market, commercialize, achieve market acceptance for and sell our products and product candidates;
- market risks regarding consolidation in the healthcare industry;
- the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third party payors for procedures using our products significantly declines;
- our ability to adequately protect our intellectual property and operate our business without infringing upon the intellectual property rights of others;
- the regulatory and legal risks, and certain operating risks, that our international operations subject us to;
- the fact that product quality issues or product defects may harm our business;
- any product liability claims; and
- the progress, timing and completion of our research, development and preclinical studies and clinical trials for our products and product candidates.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly the factors described in the "Risk Factors" section of this prospectus, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make.

You should read this prospectus and the documents that we have filed as exhibits to the registration statement of which this prospectus is a part, completely and with the understanding that our actual future results may be materially different from what we expect. We have based these forward-looking statements on our current expectations and projections about future events. These forward-looking statements are subject to risks, uncertainties and assumptions about us, including those listed in the sections of this prospectus entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in this prospectus.

We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

EXCHANGE RATES

The following table shows, for the years and dates indicated, certain information concerning the rate of exchange of euro per U.S. dollar based on the Noon Buying Rates quoted by the Federal Reserve Bank of New York for euros expressed in U.S. dollars for one Euro. No representation is made that the euro or the U.S. dollar amounts referred to herein could have been or could be converted into U.S. dollars or euros, as the case may be, at any particular rate.

	U.S. dollar for one Euro			
Period	**High**	**Low**	**Period Average[1]**	**Period End**
Nine months ended September 30, 2017	1.2041	1.0416	1.1242	1.1813
Six months ended June 30, 2017	1.1420	1.0416	1.0924	1.1411
2016	1.1516	1.0375	1.1072	1.0552
2015	1.2015	1.0524	1.1096	1.0859
2014	1.3927	1.2101	1.3297	1.2101
2013	1.3816	1.2774	1.3779	1.3281
2012	1.3463	1.2062	1.2859	1.3186

(1) The average of the Noon Buying Rates on the last business day of each full month during the relevant period.

The high and low exchange rates for the euro for each month during the previous 12 months is set forth below:

	U.S. dollar for one Euro	
Month	**High**	**Low**
January 2017	1.0794	1.0416
February 2017	1.0802	1.0551
March 2017	1.0882	1.0514
April 2017	1.0941	1.0606
May 2017	1.1236	1.0869
June 2017	1.1420	1.1124
July 2017	1.1826	1.1336
August 2017	1.2025	1.1703
September 2017	1.2041	1.1747
October 2017	1.1847	1.1580
November 2017	1.1936	1.1577
December 2017	1.2022	1.1725

The noon buying rate for the euro on January 31, 2018 was quoted by the Federal Reserve Bank of New York at 1.24 U.S. dollars for one euro.

USE OF PROCEEDS

Our management board, with approval of our supervisory board, has the authority to issue up to 6,000,000 ordinary shares in the combined offering. Our estimated use of proceeds below assumes: (a) the issuance of 2,430,000 ordinary shares (or 1,215,000 ADSs) in this offering and an additional 170,966 ordinary shares (or 85,483 ADSs) if the underwriters' over-allotment option is exercised in full, based on the estimated initial public offering price per ADS of $9.88, (b) the issuance of 3,399,034 ordinary shares in the German preemptive rights offering, and (c) for amounts expressed in U.S. dollars, an exchange rate of €1.00 to $1.2355 based upon the prevailing exchange rate reported by Bloomberg and used by the parties as of the date hereof.

Based on the assumptions set forth above, we estimate that the net proceeds to us from this offering will be approximately $9.31 million, or $10.09 million if the underwriters' over-allotment option is exercised in full, and the net proceeds to us from the German preemptive rights offering will be approximately €13.60 million (or $16.80 million), for a total net proceeds to us from the combined offering of $26.11 million, or $26.89 million if the underwriters' over-allotment option is exercised in full, in each case after deducting underwriting discounts and commissions of approximately $0.96 million, or approximately $1.0 million if the underwriters' over-allotment option is exercised in full, and estimated offering expenses payable by us, of approximately $1.73 million (assuming, in each case, completion of the temporary share loan arrangement in connection with and issuance of new shares related to this offering as described in "Certain Relationships and Related Party Transactions — Share Loan Agreement").

We intend to use approximately $15.00 million of the net proceeds from the combined offering to increase our marketing and sales organization in the U.S. We also intend to use approximately $6.00 million of the net proceeds of the combined offering to continue to fund the following clinical trials of Ameluz® (and to make regulatory filings for marketing approval of Ameluz®, both for geographic expansion and the extension of the indications for Ameluz®): (i) our clinical trial comparing the efficacy of Ameluz® PDT with PDT using just the vehicle that is used to deliver the active ingredient in Ameluz®, in combination with photodynamic therapy when using our BF-RhodoLED® lamp, in the treatment of superficial basal cell carcinoma, (ii) our clinical trial investigating the field-directed treatment of actinic keratosis on the extremities and the trunk with Ameluz®, (iii) our clinical trial evaluating the safety and efficacy of Ameluz® versus placebo in the treatment of Bowen's disease (squamous cell carcinoma *in situ*) with photodynamic therapy when using our BF-RhodoLED® lamp and (iv) our clinical trial evaluating the safety and efficacy of Ameluz® at an application thickness of 1 mm versus application of a thin layer of Ameluz® in the treatment of mild to severe actinic keratosis on the face and/or scalp with photodynamic therapy when using our BF-RhodoLED® lamp. We expect to be able to complete all of these clinical trials and the related regulatory filings and marketing approval processes with the proceeds from this offering and our other available sources of liquidity (including the proceeds from our concurrent German preemptive rights offering). We will use the remainder of the net proceeds of the combined offering, if any, for general corporate purposes.

The amounts and timing of our actual expenditures will depend on numerous factors, the timing and success of any clinical trials and preclinical studies we may commence in the future, the timing of regulatory submissions, the status of our sales and marketing efforts, the amounts of proceeds actually raised in this offering and the amount of cash generated by our operations. Because we operate in a very dynamic and highly competitive industry, the actual use of proceeds may differ substantially from the ranges indicated above. Our management will have broad discretion to allocate the net proceeds from this offering.

Pending our use of the net proceeds, we intend to invest them in short-term and medium-term interest-bearing instruments.

DIVIDEND POLICY AND LIQUIDATION PROCEEDS

We have never declared or paid any dividends on our ordinary registered shares. Under German corporate law, we currently have no ability to pay dividends because of our past losses. If we were to earn annual net income, we currently plan to retain such annual net income for the foreseeable future to finance business development and internal growth. In addition our EIB credit facility generally restricts the payment of dividends by us. We, therefore, do not anticipate paying dividends in the foreseeable future.

Under German law, Biofrontera may pay dividends only from retained earnings *(Bilanzgewinn)* reflected in its unconsolidated financial statements (as opposed to the consolidated financial statements for Biofrontera and its subsidiaries) prepared in accordance with the principles set forth in the German Commercial Code (*Handelsgesetzbuch*) and as adopted and approved by the management board (*Vorstand*) and the supervisory board (*Aufsichtsrat*). In determining the retained earnings that may be distributed as dividends, under our articles of association, the management board and the supervisory board may allocate to earnings reserves (*Gewinnrücklagen*) our remaining net income (*Jahresüberschuss*) for the fiscal year after deducting amounts to be allocated to legal and statutory reserves and losses carried forward in whole or in part. An amount of more than half of the remaining net income may only be allocated to earnings reserves, if the earnings reserves after allocation would exceed half of the registered capital.

Our shareholders, in their resolution on the appropriation of retained earnings, may carry forward distributable retained earnings in part or in full and may allocate additional amounts to earnings reserves. Profits carried forward will be automatically incorporated in the retained earnings of the next fiscal year. Amounts allocated to the earnings reserves are available for dividends only if and to the extent the earnings reserves have been dissolved by the management board when preparing the financial statements, thereby increasing the retained earnings.

Our shareholders may declare dividends at an ordinary general shareholders' meeting, which must be held within the first eight months of each fiscal year. Dividends approved at an ordinary general shareholders' meeting are payable promptly after the meeting, unless otherwise decided at the meeting. Because all of our shares are in book-entry form represented by one or more global certificates deposited with Clearstream Banking AG in Frankfurt am Main, Germany, shareholders receive dividends through Clearstream Frankfurt for credit to their deposit accounts.

Apart from liquidation as a result of insolvency proceedings, Biofrontera may be liquidated (*liquidiert*) only with a majority of three-quarters of the share capital present or represented at a shareholders' meeting at which the vote is taken. In accordance with the German Stock Corporation Act (*Aktiengesetz*), upon a liquidation of Biofrontera, any liquidation proceeds remaining after paying off all of our liabilities would be distributed among the shareholders in proportion to the number of ordinary shares held by each shareholder.

Dividends are subject to German withholding tax. See "Certain Material U.S. Federal Income and German Tax Considerations — German Taxation of ADSs — Withholding Tax Refund for U.S. Treaty Beneficiaries".

TRADING MARKETS

Our shares are currently traded on the Frankfurt Stock Exchange under the symbol “B8F”.

Prior to the offering, there has been no public market in the U.S. for our shares or the ADSs. We have been approved for listing of the ADSs on The NASDAQ Capital Market under the symbol “BFRA”.

The table below sets forth for the periods indicated the high and low closing prices in euro of our shares as reported by the XETRA electronic trading platform of the Frankfurt Stock Exchange:

	High (€)	Low (€)
2013:		
First quarter	4.95	3.75
Second quarter	4.90	3.27
Third quarter	4.00	3.25
First quarter	3.65	3.29
2014:		
First quarter	4.08	3.20
Second quarter	3.35	2.80
Third quarter	2.86	2.18
Fourth quarter	3.00	2.29
2015:		
First quarter	2.69	1.84
Second quarter	2.70	2.04
Third quarter	2.30	2.00
Fourth quarter	2.30	1.60
2016:		
First quarter	2.26	1.85
Second quarter	3.69	2.29
Third quarter	3.21	2.61
Fourth quarter	3.41	2.88
2017:		
First quarter	4.82	3.14
Second quarter	4.46	3.58
Third quarter	4.06	3.51
Fourth quarter	4.21	3.16
Previous six months:		
August 2017	4.06	3.73
September 2017	3.96	3.51
October 2017	3.69	3.53
November 2017	3.94	3.16
December 2017	4.21	3.93
January 2018	6.21	4.16

The average daily volume of our shares traded on the XETRA electronic trading platform of the Frankfurt Stock Exchange for the years 2016, 2015, and 2014 was 50,987, 37,960 and 17,898, respectively. In the first nine months of 2017, the average daily volume of our shares traded on XETRA was 54,888.

On February 8, 2018, the closing price of our shares on the Frankfurt Stock Exchange was €5.15.

We were also listed on the AIM Market of the London Stock Exchange from June 3, 2014 until February 18, 2015. Trading and liquidity however on that stock exchange was very limited and, as a result, we informed the London Stock Exchange of our intent to terminate such listing, which was effectuated on February 18, 2015.

CAPITALIZATION

The following table sets forth our capitalization and cash and cash equivalents, debt and total capitalization of our company as of June 30, 2017:

- on an actual basis in accordance with IFRS;
- as adjusted to give effect to the following: (a) the issuance of 5,829,034 ordinary shares in the combined offering consisting of this offering of 1,215,000 ADSs (but excluding any exercise of the underwriters' over-allotment option) at $9.88 per ADS and the 3,399,034 ordinary shares issued in the German preemptive rights offering, at €4.00 per ordinary share, and after deducting underwriting discounts and commissions of $0.96 million and estimated offering expenses of approximately $1.73 million payable by us, (b) the draw down of the first tranche of €10.0 million from the European Investment Bank in July 2017 and (c) the repayment of the 2009/2017 bond for a total cash payment of €3.7 million (principal of €5.2 million, net of holdings of its own bonds with a nominal value of €1.5 million) in August 2017.

The actual and as adjusted information below is illustrative only, and following the completion of this offering will be adjusted based on the actual offering price and other terms of our offering determined at pricing. You should read this table in conjunction with the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes included elsewhere in this prospectus.

	As of June 30, 2017			
	Actual		As adjusted[1][3]	
(amounts in thousands, except per share data)	$[4]	€	$[5]	€
Cash and cash equivalents	13,054	11,451	52,809	42,588
Debt				
Long-term debt, net of current portion	3,026	2,654	15,617	12,594
Capital lease obligations, net of current portion	—	—	—	—
Total debt, net of current portion	3,026	2,654	15,617	12,594
Total debt, including current portion	10,213	8,959	18,976	15,303
Shareholders' Equity				
Ordinary shares, with no par value (notional par value of €1 per share), (38,416,428 shares issued and outstanding at June 30, 2017; 44,245,462 shares issued and outstanding as adjusted for the combined offering)[2]	43,794	38,416	54,864	44,245
Additional paid-in capital	115,268	101,112	144,360	116,420
Subscribed shares	—	—	—	—
Accumulated other comprehensive loss	—	—	—	—
Accumulated deficit[6]	(147,218)	(129,139)	(160,279)	(129,257)
Total equity	11,843	10,389	38,945	31,408
Total capitalization	22,056	19,348	57,921	46,711

(1) If the underwriters fully exercise their over-allotment option to purchase additional ADSs, the amount of cash and cash equivalents, total equity and total capitalization would increase by €0.7 million ($0.8 million). The as adjusted information is illustrative only.

(2) The actual number of ordinary shares shown as issued and outstanding exclude 548,960 ordinary shares issuable upon the exercise of convertible bonds outstanding as of February 8, 2018, with conversion prices of €5.00 and excludes the issuance of any ordinary shares pursuant to the exercise of any exercisable stock options.

(3) Assumes completion of the temporary share loan arrangement in connection with the issuance of new shares related to this offering. See "Certain Relationships and Related Party Transactions — Share Loan Agreement."

(4) Translated solely for convenience into U.S. dollars at an assumed exchange rate of €1.00 per $1.14, which was the exchange rate of such currencies based on the noon buying rate of the Federal Reserve Bank of New York on June 30, 2017.

(5) Translated solely for convenience into U.S. dollars at an assumed exchange rate of €1.00 per $1.24, which was the exchange rate of such currencies based on the noon buying rate of the Federal Reserve Bank of New York on January 31, 2018.

(6) Includes loss carry-forward and accumulated losses.

DILUTION

If you invest in our ADSs in this offering, your interest will be immediately diluted to the extent of the difference between the initial public offering price per ADS in this offering and the net tangible book value per ADS after the combined offering consisting of this offering of ADSs and the German preemptive rights offering. Dilution results from the fact that the initial public offering price per ADS is substantially in excess of the net tangible book value per ADS. As of June 30, 2017, we had a historical net tangible book value of €0.24 per ordinary share, which would be equivalent to $0.61 per ADS (based on the noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018, which was €1.00 to $1.24, and two ordinary shares per ADS). Our net tangible book value per share represents total consolidated tangible assets less total consolidated liabilities, all divided by the number of shares outstanding on June 30, 2017.

After:

(i) giving effect to the sale of 5,829,034 ordinary shares in the combined offering consisting of this offering of ADSs, at the initial public offering price of $9.88 per ADS, and the ordinary shares to be issued in the German preemptive rights offering, at a price of €4.00 per ordinary share, and after deducting the underwriting discounts and commissions and estimated offering expenses, and assuming completion of the temporary share loan arrangement in connection with the issuance of new shares related to this offering as described in "Certain Relationships and Related Party Transactions — Share Loan Agreement", and

(ii) assuming the underwriters have not exercised their over-allotment option,

our as adjusted net tangible book value at June 30, 2017, would have been €0.69 per ordinary share, or $1.71 per ADS (assuming the exchange rate listed above and two ordinary shares per ADS). This represents an immediate increase in as adjusted net tangible book value of €0.45 per ordinary share to existing shareholders and an immediate dilution of $8.17 per ADS to new investors. The following table illustrates this dilution per ADS:

Initial public offering price per ADS	$	9.88
Historical net tangible book value per ADS as of June 30, 2017[1][2]	$	0.61
Increase in pro forma net tangible book value per ADS attributable to new investors in the combined offering[1][3]	$	1.10
Pro forma net tangible book value per ADS after the combined offering[1][3]	$	1.71
Dilution per ADS to new investors participating in the U.S. offering[3]	$	8.17

(1) Translated solely for convenience into U.S. dollars at an exchange rate based upon the noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018 which was €1.00 to $1.24.
(2) Based on the historic net tangible book value per share as of such date.
(3) Assumes completion of the temporary share loan arrangement in connection with the issuance of new shares related to this offering. See "Certain Relationships and Related Party Transactions — Share Loan Agreement."

If the underwriters fully exercise their over-allotment option to purchase additional ADSs, as adjusted net tangible book value after this offering would increase to approximately $1.73 per ADS, and there would be an immediate dilution of approximately $0.02 per ADS to new investors. The as adjusted information is illustrative only.

We may choose to raise additional capital due to market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our equity holders.

The following table shows, as of June 30, 2017, on an as adjusted basis and assuming completion of the temporary share loan arrangement in connection with the issuance of new shares related to this offering as described in "Certain Relationships and Related Party Transactions — Share Loan Agreement", the number of ADSs purchased from us, the total consideration paid to us and the average price paid per share by existing shareholders and by new investors purchasing ADSs in the U.S. offering and ordinary shares in the German preemptive rights offering, excluding any exercise by the underwriters of their over-allotment option:

	ADS[1] Subscribed For/Purchased		Total Consideration		Average Price
	Number	Percent	Amount	Percent	Per ADS
Existing shareholders[2]	19,208,214	86.8%	$ 159,062,000	84.7%	$ 8.281
Investors participating in the U.S. offering and German preemptive rights offering[3]	2,914,517	13.2%	$ 28,807,086	15.3%	$ 9.884
Total	22,122,731	100.0%	$ 187,869,086	100.0%	$ 8.492

(1) Prior issuances of ordinary shares are presented in ADSs solely for purposes of this table. Each ADS represents two ordinary shares.

(2) Translated solely for convenience into U.S. dollars at an assumed exchange rate of €1.00 per $1.14, which was the exchange rate of such currencies based on the noon buying rate of the Federal Reserve Bank of New York on June 30, 2017.

(3) Assumes (i) a public offering price of ordinary shares offered in the German preemptive rights offering of €4.00 per share and an initial public offering price in the U.S. offering of $9.88 per ADS, before deducting the underwriting discounts and commissions and estimated offering expenses payable by us (in thousands, except share and per share amounts and percentages).

The number of shares and ADSs to be outstanding after this offering is based on the number of shares outstanding as of June 30, 2017, and excludes up to 548,960 shares that may be issued upon the conversion of outstanding convertible bonds and shares that may be issued upon the exercise of stock options, and assumes (i) no exercise of the underwriters' over-allotment option to purchase up to 85,483 additional ADSs, and (ii) completion of the temporary share loan arrangement in connection with the issuance of new shares related to this offering as described in "Certain Relationships and Related Party Transactions — Share Loan Agreement".

SELECTED CONSOLIDATED FINANCIAL DATA

The following table sets forth a summary of the consolidated historical financial information of, and for the periods ended on, the dates indicated for Biofrontera AG. We prepare our consolidated financial statements in accordance with IFRS as issued by the IASB. The selected consolidated statement of operations data for the years ended December 31, 2016 and December 31, 2015, and the selected consolidated balance sheet data as of December 31, 2016 and December 31, 2015 have been derived from our audited consolidated financial statements included elsewhere in this prospectus. Our selected consolidated statement of operations data for the six months ended June 30, 2017 and June 30, 2016 and the selected consolidated balance sheet data as of June 30, 2017 have been derived from our unaudited interim condensed consolidated financial statements included elsewhere in this prospectus. The unaudited interim condensed consolidated financial statements have been prepared on the same basis as our audited consolidated financial statements and include all normal recurring adjustments that we consider necessary for a fair statement of our financial position and operating results for the periods presented.

You should read the following summary of consolidated financial information in conjunction with the section of this prospectus entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the related notes contained elsewhere in this prospectus.

	Six Months Ended June 30,		Year Ended December 31,	
	2017	2016	2016	2015
	€	€	€	€
	(amounts in thousands, except share and per share data)			
Statement of operations data:				
Sales Revenue	5,006	1,709	6,130	4,138
Gross Margin	87,31%	55.30%	73.05%	70.14%
Research and development costs	(2,185)	(1,852)	(4,640)	(6,204)
Sales costs	(8,275)	(2,832)	(8,763)	(4,170)
General administrative costs	(1,696)	(1,372)	(2,853)	(2,759)
Loss from operations	(7,785)	(5,112)	(11,779)	(10,231)
Loss before income tax	(8,736)	(3,472)	(10,579)	(11,203)
Per share data:				
Basic and diluted loss per share	(0.23)	(0.12)	(0.36)	(0.48)
Basic and diluted operating loss per share	(0.23)	(0.12)	(0.38)	(0.48)
Shares used in computing basic and diluted loss per share	38,416,428	29,194,771	29,742,634	23,156,343

	At June 30,	At December 31,	
	2017	2016	2015
	€	€	€
	(amounts in thousands)		
Balance sheet data:			
Cash and cash equivalents	11,452	15,126	3,959
Other current financial assets	2,338	3,001	1,625
Other current assets	3,912	3,855	1,639
Non-current Assets	1,647	1,897	2,275
Total assets	19,348	23,879	9,498
Long-term liabilities	2,654	3,597	11,230
Current liabilities	6,305	4,440	3,077
Total shareholders' equity	10,389	15,842	(4,809)

	Six Months Ended June 30,		Year Ended December 31,	
	2017	2016	2016	2015
	€	€	€	€
	(amounts in thousands)			
Other financial data:				
Net cash flow from operational activities	(8,087)	(2,511)	(10,259)	(9,655)
Net cash flow from (into) investment activities	(192)	(143)	(455)	17
Net cash flows from financing activities	4,605	8,867	21,881	5,088

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion of our financial condition and results of operations in conjunction with the audited consolidated financial statements and the notes to our financial statements included elsewhere in this prospectus. This discussion contains forward-looking statements that involve risks, uncertainties and assumptions. As a result of many factors, including those set forth under the section entitled "Risk Factors" and elsewhere in this prospectus, our actual results may differ materially from those anticipated in the forward-looking statements contained in the following discussion and analysis.

Overview

We are an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin.

We were founded in 1997 by Professor Hermann Lübbert, Ph.D., who currently serves as chairman of our management board and our chief executive officer. Our ordinary shares have been listed on the Stock Exchange in Düsseldorf since 2006 and on the Frankfurt Stock Exchange since 2012 under the ticker symbol "B8F" since 2012.

Our principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy, or PDT, which we sometimes refer to as Ameluz® PDT. We are currently selling Ameluz® in the U.S., in 11 countries in Europe and in Israel. In Germany, Spain, the UK, and the U.S., we distribute and sell our products through our own sales force. We have agreements with partners to sell Ameluz® and the BF-RhodoLED® lamp in other European countries and in Israel. We manufacture Ameluz® for worldwide sales using a third party contract manufacturer in Switzerland. We manufacture our BF-RhodoLED® lamp at our corporate headquarters in Leverkusen, Germany.

Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome.

In addition, we have developed our own PDT lamp, BF-RhodoLED®, for use in combination with Ameluz®. Our BF-RhodoLED® lamp was approved as a medical device in the EU in November 2012 and is approved for sale in all EU countries, although the use of our BF-RhodoLED® lamp is not required to be used in combination with Ameluz® in the EU or Switzerland.

In May 2016, we received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016.

We are also seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy (*i.e.*, using natural daylight to activate the drug), which we applied for in the second quarter of 2017. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks.

We intend to further develop and seek approval to commercialize Ameluz® for the treatment of other medical conditions, such as basal cell carcinoma in the U.S. and squamous cell carcinoma *in situ*. See "Business—Recent Achievements" for a summary of recent developments in connection with our efforts to extend the approved indications for Ameluz®.

In our product pipeline, we are pursuing research and development of up to four branded generic dermatology drugs under a collaboration and partnership agreement with Maruho, a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of our company. See "Business — Our Research and Development Plans — Our Development Collaboration with Maruho" for more information.

We have incurred losses in each year since inception. Our net loss for the fiscal years ended December 31, 2015 and December 31, 2016 was €11.2 million and €10.6 million, respectively. As of September 30, 2017, we had an accumulated deficit

of €135.0 million. Our ability to become profitable depends on our ability to further commercialize Ameluz®. Even if we are successful in increasing our product sales, we may never achieve or sustain profitability. We anticipate substantially increasing our sales and marketing expense as we attempt to exploit the recent regulatory approvals we have received to market Ameluz® in the U.S. and the EU. There can be no assurance that our sales and marketing efforts will generate sufficient sales to allow us to become profitable. Moreover, due to the numerous risks and uncertainties associated with developing and commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

Over the past five years, we have funded our operations primarily through the issuance and sale of equity securities, warrant bonds and convertible bonds. We expect to continue to fund our operations over the next several years primarily through proceeds from the EIB credit facility that we entered into in May 2017, our existing cash resources, and revenues generated from our operating business. If we achieve certain milestones, we may borrow additional amounts under the EIB credit facility and may also, subject to the covenants under our existing debt obligations, enter into other forms of debt financing. Any equity financing, if needed, would likely result in dilution to our existing shareholders and any debt financing, if available, would likely involve significant cash payment obligations and include restrictive covenants that may restrict our ability to operate our business.

Components of Our Results of Operations

Revenue

We generate revenue through the sale of our products Ameluz®, BF-RhodoLED® and Belixos® (our cosmetic skin care product) as well as from payments made by Maruho to us in connection with the development projects we conduct under our collaboration and partnership agreement with it.

In Germany, Spain, the UK and the U.S., we distribute and sell Ameluz® through our own sales force and recognize revenue upon shipment to our customers, such as wholesalers or hospitals or physicians. We have entered into license and distribution agreements with a variety of partners in other European countries and Israel. According to these agreements, we produce our products and sell them to our distribution or commercial partners at a transfer price, which is a defined percentage of the estimated final sales price in the respective country or territory. Such percentages range from 35% to 60%. Since production of Ameluz® is specific for most countries, we typically produce larger lots for our distribution or commercial partners and ship and invoice them. Our distribution or commercial partners hold inventory and subsequently sell stock over time in their applicable country or territory. We recognize revenue upon shipment to such partners. Upon signing of our license and supply agreements, we also typically receive one-time payments from our distribution partners.

Accordingly, the primary factors that determine our revenue derived from our products are:

- the level of orders generated by our sales force in the U.S. and Germany;
- the level of orders from our commercial partners
- the level of prescriptions and institutional demand for our products; and
- unit sales prices.

We also generate revenue from development projects entered into with Maruho. Under a collaboration and partnership agreement we entered into with Maruho, development work for the product candidates will be carried out either by our personnel or by subcontractors that we select. All costs under these projects will be borne by Maruho (subject to a cap of €2.3 million) and invoiced from us to Maruho on a monthly basis. We generated revenue of €1.2 million from this agreement in the fiscal year ended December 31, 2016.

Revenue from the sales of our BF-RhodoLED® photodynamic therapy lamp, which we mainly use our lamp to support sales of Ameluz®, and Belixos®, our over-the-counter line of skin care cosmetics products, are relatively insignificant compared with the revenues generated through our sales of Ameluz®.

Between 2015 and 2016, revenue in Germany decreased by 17% due to lower volume of sales, while revenue in other countries increased by 20%, driven primarily by prices that were on average 45% higher in 2016 (due to a higher volume of sales in countries with higher prices, in particular Spain). This average price increase was partially offset by a volume decrease of (25)%, although the decrease in volumes occurred primarily in countries where we sell to our license partners (from which we receive lower revenues as a result of the transfer price we must pay to the license partners, which on average is approximately 50% of the local average selling price in the relevant country).

For the six months ended June 30, 2017 compared to the six months ended June 30, 2016, revenue in Germany increased by 7%, based on a greater volume of sales, while revenue in other countries increased by 15% driven primarily by (i) a more favorable mix of revenue at higher price points with various license partners and revenue in Spain (where we sell Ameluz® directly, rather than through license partners) and (ii) an increase in volume of 7%.

The following table provides a breakdown of revenue for the past two fiscal years and for the six months ended June 30, 2017 and 2016:

	Six months ended June 30,		Year ended December 31,	
	2017	2016	2016	2015
	€	€	€	€
	(amounts in thousands)			
Germany	1,103	1,034	2,515	3,028
United States	2,386	0	1,153	0
Other International revenues	732	635	1,247	1,040
One time license payments	0	40	40	70
Development Projects	785	0	1,177	0
Total Revenue	5,006	1,709	6,132	4,138

Cost of Goods Sold

Our cost of goods sold is comprised of all direct manufacturing expenses for our products, including any expenses associated with manufacturing and logistics, such as packaging, freight or transportation costs. We further include any costs associated with changes or upgrades in the manufacturing processes at our third party manufacturers which had to be paid by us to fulfill certain post-approval obligations requested by the EMA. All overhead costs associated with manufacturing are also included in our costs of goods sold.

Research and Development Expenses

We incur research and development expenses related to our clinical and drug and medical device development programs. Our research and development expenses consist of expenses incurred in developing, testing and manufacturing drugs and devices for clinical trials, as well as seeking and maintaining regulatory approval of our product candidates, including:

- expenses associated with regulatory submissions, clinical trials and manufacturing;
- payments to third party contract research organizations, or CROs, contract laboratories and independent contractors;
- payments made to regulatory consultants;
- payments made to third party investigators who perform clinical research on our behalf and clinical sites where such testing is conducted;
- personnel related expenses, such as salaries, benefits, travel and other related expenses;
- expenses incurred to obtain and maintain regulatory approvals and licenses, patents, trademarks and other intellectual property; and
- facility, maintenance, and allocated rent, utilities, and depreciation and amortization, and other related expenses.

Research and development costs totaled €4.6 million and €6.2 million for the fiscal years ended December 31, 2016 and December 31, 2015, respectively. From 2014 through 2016, our research and development costs totaled €15.4 million.

The following table summarizes the costs of significant projects and reconciling items to arrive at total research and development expenses for the periods shown (in thousands of euros):

	Six months ended June 30,		Year ended December 31,	
	2017	2016	2016	2015
	€	€	€	€
	(amounts in thousands)			
Clinical studies (external expenses)	750	613	1,356	1,833
FDA and EMA fees	404	85	932	2,072
Other expenses	1,031	1,154	2,352	2,299
Total Research and development expenses	2,185	1,852	4,640	6,204

As we continue our clinical trial program for Ameluz®, both to show effectiveness in comparison to other drugs or therapies and to try to extend the current indications of Ameluz®, we expect to incur similar levels of research and development expenses. In addition, any termination of, or delays in completing, our clinical trials will slow down our product development and approval process, leading to increased costs.

Sales Costs

Sales costs consist primarily of salaries, benefits and other related costs for personnel serving in our sales, marketing and business development functions in Germany, Spain and the U.S. Our sales costs also include costs related to marketing materials as well as sales congresses, industry conferences and similar events conducted to promote our products. Sales costs for the fiscal year ended December 31, 2015 also include marketing expenses in the UK incurred by our former marketing partner Spirit Healthcare, which expenses were reimbursed by us until our contract with Spirit Healthcare terminated in July 2015.

In 2016, we significantly increased our sales costs with the continued commercialization of our products, in particular, to establish and build, after obtaining FDA approval that year, a marketing and sales organization in the U.S. in connection with the launch of commercial sales in the U.S. of Ameluz® and our BF-RhodoLED® lamp in the U.S. Although our revenue increased significantly in the six months ended June 30, 2017, as compared with the six months ended June 30, 2016, our sales costs increased even more significantly. This increase in sales costs related primarily to the hiring of new sales professionals in the U.S. As our presence becomes more established in the U.S. we plan to leverage our sales professionals and will seek to generate more revenue per person so that revenues related to efforts from these salespersons exceed their cost.

We incurred sales costs of €8.8 million and €4.2 million for the fiscal years ended December 31, 2016, and December 31, 2015, respectively.

General and Administrative Expenses

General and administrative expenses consist primarily of compensation for employees in executive and operational functions, including finance, investor relations, information technology and human resources. Other significant costs in this category include facilities costs and professional fees for accounting and legal services, travel, insurance premiums and depreciation. After completion of the offering, we anticipate increases in expenses relating to insurance, legal and accounting services, investor relations and other internal resource requirements arising from additional compliance and reporting obligations imposed by The NASDAQ Capital Market and the U.S. federal securities laws.

We incurred general and administrative expenses of €2.9 million and €2.8 million for the fiscal years ended December 31, 2016, and December 31, 2015, respectively.

Stock Compensation

We grant stock options to members of our management board, senior management, and employees. We recognize compensation expense as a charge to operations over the relevant vesting period of the options, which generally is four years.

The aggregate estimated fair value for options issued during the fiscal year ended December 31, 2016 was approximately €1.5 million, which is being recognized over the vesting periods. Total compensation expense recorded related to options

during the fiscal year ended December 31, 2016, was approximately €0.1 million. From inception through the fiscal year ended December 31, 2016, we have incurred cumulative compensation expense related to stock options of approximately €0.5 million.

Finance Expense

Finance expense consists of interest income and interest expense, and foreign exchange gains (losses). Interest income consists of interest earned on our cash and cash equivalents. The interest expenses were almost entirely the result of interest payments on our two series of warrant bonds outstanding during 2015 and 2016, and of the compounding of interest on those two series of warrant bonds, using the effective interest method. We incurred finance expense of €1.2 million and €1.2 million in the fiscal years ended December 31, 2016 and December 31, 2015, respectively.

Other Income and Expenses

Other income typically consists of creation and reversal of certain accruals, mainly for bonuses and accrued expenses. In 2016, we also recorded the reimbursement of the application fee we had paid to the FDA in 2015 upon submission of our New Drug Application under the U.S. Prescription Drug User Fee Act, or PDUFA fee, in other income. Payment of that fee was made in 2015 and recorded in research and development expenses.

Income Taxes

As a result of the net losses we have incurred in each fiscal year since inception, we have recorded no provision for income taxes during such periods. At December 31, 2016, we had net operating loss carry-forwards for German corporation and trade tax purposes of €120.4 million and at December 31, 2015, we had net operating loss carry-forwards for German corporation and trade tax purposes of €109.8 million. Deferred tax assets are generally determined on the basis of the existing income tax rates in Germany. As a result of the German Company Tax Reform Act 2008, the corporation tax rate is set at 15%. When a solidarity surcharge of 5.5% is included, this results in a combined tax rate of 15.8%.

In addition to the corporate tax rate, our company is also subject to a local business tax rate of 16.6%. As the business taxes are not deductible as an operating expense, the resulting tax rate is 32.4%.

Loss carry forwards have an unlimited carry forward period under current German law.

Effect of Foreign Currency Fluctuations

We publish our consolidated financial statements in euros. Historically, most of our revenues and expenses have also been denominated in euros. Therefore, we have not been subject to any major influences on our net income due to currency exchange effects. Since we have obtained FDA approval and begun to commercialize our products in the U.S., we expect to generate a significant part of our revenues and expenses in U.S. dollars. These revenues and expenses incurred in U.S. dollars will be translated into euros when they are reported in our consolidated financial statements. As a result, any substantial future appreciation or decline of the U.S. dollar against the euro could have a material effect on our revenue and profitability.

Our product, Ameluz®, is manufactured by a third party contract manufacturer in Switzerland. Any invoices by such manufacturer are denominated in Swiss Francs. As our sales and revenue increase, we expect to increase the manufacturing purchases from our Swiss manufacturer and could, therefore, be increasingly subject to currency exchange effects from these Swiss Franc denominated transactions with our Swiss manufacturer.

Results of Operations

Comparison of the six months ended June 30, 2017 to the six months ended June 30, 2016

Total revenue

Total Revenue

	Six months ended June 30,		Increase (decrease)	
	2017	**2016**	**Amount**	**Percentage**
	€ thousands (except percentages)			
Germany	1,103	1,034	69	7%
United States	2,386	0	2,386	n/a
Other International Revenues	732	635	97	15%
One Time License Payments	0	40	(40)	(100)%
Maruho Development Project	785	0	785	n/a
Total Revenue	5,006	1,709	3,297	193%

Revenue for the six months ended June 30, 2017 increased by approximately 193% to €5.0 million from €1.7 million for the six months ended June 30, 2016. This increase was mainly driven by revenue in the U.S. (€2.4 million) and revenue from the Maruho development project (€0.8 million).

During the six months ended June 30, 2017, we recorded €1.1 million of revenue in Germany, which represents an increase of €69 thousand or 7% compared to the six months ended June 30, 2016.

During the six months ended June 30, 2017, we recorded revenue of €0.7 million from the sale of products in other European countries, either to our distribution partners or from our own sales in countries other than Germany. This represents an increase of €97 thousand or 15%.

During the six months ended June 30, 2017, we further recorded €2.4 million revenue in the U.S. During the six months ended June 30, 2016, we had no revenues from the sale of products in the U.S. We commenced commercialization of Ameluz® in the U.S. in October 2016, so the six months ended June 30, 2017 represented the full first half-year period during which we have marketed Ameluz® in the U.S. We expect the sales of Ameluz® in the U.S. to increase in the near term as we continue to develop our sales operations.

Revenue from our development projects with Maruho was €0.8 million during the six months ended June 30, 2017. During the six months ended June 30, 2016, we had no revenue from these projects.

Cost of sales

Cost of Sales

	Six months ended June 30,		Increase (decrease)	
	2017	**2016**	**Amount**	**Percentage**
	€ thousands (except percentages)			
Cost of sales	(635)	(764)	129	(17)%

Cost of sales was €(0.6) million for the six months ended June 30, 2017, compared to €(0.8) million for the six months ended June 30, 2016, a decrease of €129 thousand, mainly due to a reduction in production costs at our pharmaceutical ingredient supplier.

Research and development expenses

Research and Development Expenses

	Six months ended June 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	€ thousands (except percentages)			
Clinical studies (external expenses)	(750)	(613)	137	22%
FDA and EMA Fees	(404)	(85)	319	375%
Other research and development expenses	(1,031)	(1,154)	(123)	(11)%
Total research & development expenses	(2,185)	(1,852)	333	18%

Research and development expenses were €2.2 million for the six months ended June 30, 2017, compared to €1.9 million for the six months ended June 30, 2016, an increase of €333 thousand, or 18%. This increase was mainly due to higher fees paid to regulatory bodies such as the FDA and the EMA.

Sales costs

Sales Costs

	Six months ended June 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	€ thousands (except percentages)			
Personnel expenses	(4,958)	(1,606)	(3,352)	(209)%
Trade shows and marketing material	(469)	(294)	(175)	(60)%
Logistics and other	(2,848)	(932)	(1,916)	(206)%
Total sales costs	(8,275)	(2,832)	(5,443)	(192)%

Sales costs were €8.3 million for the six months ended June 30, 2017, compared with €2.8 million for the six months ended June 30, 2016, an increase of €5.5 million, or 192%.

During the six months ended June 30, 2017, we further invested in building a sales and marketing infrastructure in the U.S., hiring qualified personnel and incurred expenses for marketing activities in the U.S. following the approval by the FDA. The increase in sales costs was mainly due to these investments in the U.S., which we expect to continue to incur. As our presence becomes more established in the U.S. we plan to leverage our sales professionals and will seek to generate more revenue per person so that revenues related to efforts from these salespersons exceed their cost.

General and administrative expenses

General and Administrative Expenses

	Six months ended June 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	€ thousands (except percentages)			
General and administrative expenses	(1,696)	(1,372)	(324)	24%

General and administrative expenses increased by 24%, to €1.7 million for the six months ended June 30, 2017, compared to €1.4 million for the six months ended June 30, 2016. This increase was mainly due to higher cost of financing.

Interest income and expense

Interest Income and Expense

	Six months ended June 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	€ thousands (except percentages)			
Interest Expense	(330)	(594)	264	45%
Interest Income	4	2	2	100%

Interest expense decreased by €264 thousand, to €0.3 million for the six months ended June 30, 2017, compared to €(0.6) million for the six months ended June 30, 2016 due to the repayment of our warrant bond in December 2016.

Other income and (expense), net

Other Income and (Expense), Net

	Six months ended June 30,		Increase (decrease)	
	2017	2016	Amount	Percentage
	€ thousands (except percentages)			
Other income and (expense), net	(626)	2,232	(2,858)	(128)%

Other income (expense), net was €(0.6) million for the six months ended June 30, 2017, compared to income of €2.2 million for the six months ended June 30, 2016. A significant portion of this decrease was attributable to the reimbursement of the €2.1 million PDUFA fee that had a one-time effect in March 2016. An increase of €0.7 million in other expenses was driven mainly by foreign currency exchange movements.

Comparison of Fiscal Years Ended December 31, 2016 and December 31, 2015

Total revenue

Total Revenue

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Germany	2,515	3,028	(513)	(17)%
United States	1,153	0	1,153	n/a
Other International Revenues	1,247	1,040	207	20%
One Time License Payments	40	70	(30)	(43)%
Maruho Development Project	1,177	0	1,177	n/a
Total Revenue	6,132	4,138	1,994	48%

Revenue for the fiscal year ended December 31, 2016 increased by approximately 48%, to €6.1 million, from €4.1 million for the fiscal year ended December 31, 2015.

During the fiscal year ended December 31, 2016, we recorded €2.5 million of revenue in Germany, which represents a decrease of €513 thousand or 17% compared to the fiscal year ended December 31, 2015. This decrease was mainly due to the change of competitive landscape following the introduction in the EU of a drug identical to Metvix® and approved for daylight photodynamic therapy.

During the fiscal year ended December 31, 2016, we recorded revenue of €1.3 million from the sale of products in other European countries, either to our distribution partners or from our own sales in countries other than Germany. This represents an increase of €207 thousand or 20%.

During the fiscal year ended December 31, 2016, we further recorded €1.2 million revenue in the U.S. We launched commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016 and thus earned revenue in the U.S. for only a small part of the year. We expect annual revenue in the U.S. to increase significantly in 2017 as compared to 2016.

Revenue from the development projects with Maruho was €1.2 million during the fiscal year ended December 31, 2016. In 2015 we had no revenue from these projects.

We also recorded €40 thousand in license income during the fiscal year ended December 31, 2016. We received these license payments following the achievements of milestones as set forth in one of our license and supply agreements. We had €70 thousand in license income in the fiscal year ended December 31, 2015.

Cost of sales

Cost of Sales

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Cost of sales	(1,652)	(1,236)	416	34%

Cost of sales was €1.7 million for the year ended December 31, 2016, compared to €1.2 million for the year ended December 31, 2016, an increase of €416 thousand. This increase resulted primarily from a higher volume of products sold during the period.

Research and development expenses

Research and Development Expenses

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Clinical studies (external expenses)	(1,356)	(1,833)	477	(26)%
FDA and EMA Fees	(932)	(2,072)	1,140	(55)%
Other research and development expenses	(2,352)	(2,299)	(53)	2%
Total research & development expenses	(4,640)	(6,204)	1,564	(25)%

Research and development expenses were €4.6 million for the fiscal year ended December 31, 2016, compared to €6.2 million for the fiscal year ended December 31, 2015, a decrease of €1.6 million, or 25%. This decrease was mainly due to a PDUFA fee of €2.1 million that we had to pay to the FDA upon submission of our New Drug Application in 2015. This fee is usually waived for small companies for their initial submission. In consultation with the FDA, Biofrontera lodged an application for a waiver of this fee, but this could not be processed on the filing date as the FDA did not have a process for handling such applications. This fee was refunded by the FDA in March 2016 and was recorded in other income in fiscal year 2016.

Research and development expenses incurred in 2015 and 2016 were related to our clinical and drug and medical device development programs as well as expenses associated with maintaining the European approval dossier, preparing regulatory documentation and filing with regulatory authorities in other regions, in particular with the FDA in the U.S. for Ameluz® and our BF-RhodoLED® lamp. A minor part of our expenses were associated with filing and maintaining our patents and other intellectual property rights.

Sales costs

Sales Costs

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Personnel expenses	(5,063)	(1,965)	(3,098)	(158)%
Trade shows and marketing material	(566)	(670)	104	16%
Logistics and other	(3,134)	(1,535)	(1,599)	(104)%
Total sales costs	(8,763)	(4,170)	(4,593)	(110)%

Sales costs were €8.8 million for the fiscal year ended December 31, 2016, compared with €4.2 million for the fiscal year ended December 31, 2015, an increase of €4.6 million, or 110%.

Sales costs include salaries and other benefits for our sales and marketing teams in Germany and Spain, costs for marketing material such as flyers and promotional materials distributed to physicians, costs for marketing events such as symposia and scientific meetings, as well as marketing expenses incurred in the UK by our contract partner Spirit Healthcare and reimbursed by us until the contract with Spirit Healthcare terminated in July 2015. During the fiscal year ended December 31, 2016, we further invested in building a sales and marketing infrastructure in the U.S., hiring qualified personnel and incurred expenses for marketing activities in the U.S. following the approval by the FDA. The increase in sales costs was mainly due to these investments in the U.S., which we expect to continue to incur.

General and administrative expenses

General and Administrative Expenses

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
General and administrative expenses	(2,853)	(2,759)	94	3%

General and administrative expenses increased by 3%, to €2.9 million for the fiscal year ended December 31, 2016, compared to €2.8 million for the fiscal year ended December 31, 2015. This increase was mainly due to higher financing expenses.

Interest income and expense

Interest Income and Expense

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Interest Expense	(1,207)	(1,169)	(38)	(3)%
Interest Income	3	9	(6)	(67)%

Interest income was €3 thousand during the fiscal year ended December 31, 2016, compared with €9 thousand during the fiscal year ended December 31, 2015.

The interest expense in the fiscal years ended December 31, 2016 and December 31, 2015 was €1.2 million and €1.2 million, respectively. Interest expense consists primarily of interest payable for our 2009/2017 warrant bonds issued in 2009, or Warrant Bond I (€0.5 million in the fiscal year ended December 31, 2016, and €0.4 million in fiscal year ended December 31, 2015) and for our 2011/2016 warrant bonds issued in 2011, or Warrant Bond II (€0.7 million in the fiscal year ended December 31, 2016, and €0.7 million in the fiscal year ended December 31, 2015), calculated using the effective interest method. The interest payments for the 2014 calendar year for Warrant Bond I and Warrant Bond II were made in January 2015. The payment of interest on Warrant Bond I for the 2015 calendar year was made in the end of December 2015, and the payment of interest on Warrant Bond II for the 2015 calendar year was made in the beginning of January 2016.

Other income and (expense), net

Other Income and (Expense), Net

	Year ended December 31,		Increase (decrease)	
	2016	2015	Amount	Percentage
	€ thousands (except percentages)			
Other income and (expense), net	(2,404)	(187)	(2,217)	Not meaningful

Other income (expense), net was €(2.4) million for the fiscal year ended December 31, 2016, compared with €(0.2) million for the fiscal year ended December 31, 2015. A significant portion of this increase was attributable to the reimbursement of the PDUFA fee as discussed under "Research and development expenses".

Liquidity and Capital Resources

We devote a substantial portion of our cash resources to research and development and sales, general and administrative activities primarily related to the commercialization of our products, Ameluz® and BF-RhodoLED®. We have financed our operations primarily with the proceeds of the issuance and sale of equity securities, warrant bonds and convertible bonds

and, since May 2017, with proceeds from the EIB credit facility, and supply revenue and licensing income from some of our distribution partners. To date, we have generated supply revenue from direct sales in Germany, Spain and the UK as well as from sales to distribution partners in some European countries.

We have incurred losses and generated negative cash flows from operations since inception. As of June 30, 2017, we had an accumulated deficit of €129.1 million. As of June 30, 2017, we had cash and cash equivalents of €11.5 million. In May 2017, we entered into the EIB credit facility under which EIB agreed to provide us with loans of up to €20 million in the aggregate. After June 30, 2017, we borrowed €10 million under the EIB credit facility, all of which remains outstanding as of the date of this prospectus. We cannot borrow more than €10 million in the aggregate under the EIB credit facility until we achieve revenues of €15 million on a 12-month rolling basis, and we must meet other conditions in order to borrow the full amount. See "Description of Our Principal Financing Documents — European Investment Bank Loan Commitment and Security Agreements" below.

The following table summarizes our cash flows from operating, investing and financing activities for the periods presented:

	Six months ended June 30,		Year ended December 31,	
	2017	2016	2016	2015
	€ thousands			
Consolidated Statement of Cash Flows Data:				
Net cash provided by (used in):				
Operating activities	(8,087)	(2,511)	(10,259)	(9,655)
Investing activities	(192)	(143)	(455)	17
Financing activities	4,605	8,867	21,881	5,088
Net increase (decrease) in cash and cash equivalents	(3,674)	6,213	11,167	(4,550)

Operating Activities

For the fiscal years ended December 31, 2016 and December 31, 2015, our net cash used in operating activities was €10.3 million and €9.7 million, respectively. The increase in net cash used in operating activities in the fiscal year ended December 31, 2016 resulted primarily from an increase in operating loss for the year.

For the six months ended June 30, 2017, our net cash used in operating activities was €8.1 million, compared with €2.5 million in the six months ended June 30, 2016. This increase in net cash used in operating activities for the six months ended June 30, 2017 resulted primarily from the €2.1 million in cash received from the FDA during the six months ended June 30, 2016 for the reimbursement of the PDUFA fee that did not recur during the six months ended June 30, 2017. In addition, trade payables decreased by €1.7 million as of June 30, 2017.

Investing Activities

For the fiscal year ended December 31, 2016, our net cash used in investing activities was €0.5 million, compared to cash provided by investing activities of €17 thousand for the fiscal year ended December 31, 2015. The net cash used in investing activities in the fiscal years ended December 31, 2016 and December 31, 2015 was primarily for the purchases of tangible and intangible assets.

For the six months ended June 30, 2017 and the six months ended June 30, 2016, our cash used in investing activities was €0.2 million and €0.1 million, respectively. This increase was primarily driven by capital expenditures.

Financing Activities

Our net cash provided by financing activities was €21.9 million for the fiscal year ended December 31, 2016 compared to €5.1 million for the fiscal year ended December 31, 2015. The cash provided by financing activities for the fiscal year ended December 31, 2016 was primarily the result of the issuance of shares in our rights offering as well as the issuance of convertible bonds, providing net proceeds of €29.0 million. In the fiscal year ended December 31, 2015, we generated net proceeds of €6.3 million from the issuance of our ordinary shares.

For the six months ended June 30, 2017 and the six months ended June 30, 2016, our cash flow from financing activities was €4.6 million and €8.9 million, respectively. This decrease was primarily driven by capital increases in the six months ended

June 30, 2016. The proceeds of the convertible bond issuance of €5.0 million in January 2017 were lower than the aggregate proceeds from our issuances of shares (€9.3 million) in the same period of 2016.

Future Capital Requirements

We believe that our existing cash and cash equivalents, the credit facilities available to us under the EIB credit facility, the anticipated net proceeds from this offering, and revenue from product sales and future milestone or license payments will be sufficient to enable us to fund our operating expenses and to advance our commercialization strategy in the U.S. for the next 12 months. After such period, however, we will require additional public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives to meet our working capital requirements and to fund the continuing commercialization of our existing products and the launch of any new products in the U.S., the EU or other jurisdictions. Our existing financing arrangements place important restrictions on our ability to raise additional debt. See "Description of Our Principal Financing Documents" below.

Our need for additional sources of liquidity and capital will depend significantly on the level and timing of regulatory approval and product sales, as well as the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our products and product candidates. Moreover, changing circumstances may cause us to spend cash significantly faster than we currently anticipate, and we may need to spend more cash than currently expected because of circumstances beyond our control.

We expect to continue to incur substantial additional operating losses from significant sales, marketing and manufacturing expenses in the U.S as we seek to expand the commercialization of Ameluz® in the U.S. and undertake further clinical trials and other activities related to extending the approved indications for Ameluz®. In addition, we expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. We also expect to incur significant costs to continue to comply with corporate governance, internal controls and similar requirements applicable to us as a public company in the U.S and in Germany.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the costs of our commercialization activities for Ameluz®, most importantly in the U.S.;
- the scope, progress, results and costs of development for extending indications for Ameluz®;
- the costs of maintaining and extending our regulatory approvals;
- the extent to which we acquire or invest in products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our products; and
- the costs of preparing, submitting and prosecuting patent applications and maintaining, enforcing and defending intellectual property claims.

We may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under our existing debt obligations, in particular the minimum €13 million payment that we must make on July 6, 2022. To the extent that our capital resources are insufficient to meet our future operating and capital requirements, we will need to finance our cash needs through public or private equity offerings, debt financings, corporate collaboration and licensing arrangements or other financing alternatives. We have no committed external sources of funds, other than the EIB credit facility, under which future borrowings are subject to draw conditions, including, the achievement of specified milestones. Additional equity or debt financing or corporate collaboration and licensing arrangements may not be available on acceptable terms, if at all. In addition, the covenants under our existing debt obligations could limit our ability to obtain additional debt financing. For example, under the EIB credit facility, we are not permitted to incur additional third-party debt in excess of €1 million without the prior consent of EIB (subject to certain exceptions).

If we raise additional funds by issuing equity securities, our shareholders will experience dilution. Any additional debt financing or additional equity that we raise may contain terms that are not favorable to us or our shareholders. If we raise additional funds through collaboration and licensing arrangements with third parties, it may be necessary to relinquish valuable rights to our technologies, future revenue streams or product candidates or to grant licenses on terms that may not be favorable to us.

Contractual Obligations

Set forth below is a description of our contractual obligations as of December 31, 2016:

	Payments due by period				
Contractual Obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
			€ thousands		
Operating leases	4,719	817	1,326	956	1,620
Warrant bond 2009/2017[(1)]	5,226	—	5,226	—	—
Interest	394	394	—	—	—
Convertible bond 2016/2021	190	—	—	190	—
Interest	55	11	22	22	—
Total[(2)(3)]	**10,584**	**1,222**	**6,574**	**1,168**	**1,620**

(1) This warrant bond was repaid in full on August 3, 2017.

(2) In January 2017, we issued convertible bonds maturing on January 1, 2022 in the aggregate initial principal amount of €5 million of which €2.3 million has already been converted into shares as of the date of this prospectus. We are obligated to pay interest on the outstanding principal amount of these bonds at a rate of 6.0% per annum.

(3) We have borrowed €10 million under our EIB credit facility. These borrowings mature on July 6, 2022. We pay interest on these borrowings quarterly at a rate per annum equal to EURIBOR *plus* 4%. In addition, these borrowings accrue deferred interest, which is payable in its entirety at maturity, at a rate of 6.0% per annum. At maturity, we also must pay a performance participation interest amount. Thus, on July 6, 2022, we will be required to repay €10 million in principal, plus €3 million in deferred interest and an additional amount of performance participation interest under the EIB credit facility. See "Description of Our Principal Financing Documents—European Investment Bank Loan Commitment and Security Agreements" for more information.

Our long-term commitments under operating leases shown above consist of payments relating to our facility leases in Leverkusen, Germany, which all expire by 2025 and our facility lease in Wakefield, Massachusetts. Operating leases also include contracts for the lease of certain office equipment as well as our obligations under lease contracts for company cars.

Description of Principal Financing Documents

European Investment Bank Loan Commitment and Security Agreements

On May 19, 2017, we entered into a Finance Contract with EIB, whereby EIB has committed to lend to us up to €20 million. The loan terms specify that the amounts drawn will be used to finance up to approximately 50% of specified research and development expenses forecast to be made by us between 2017 and 2020. The key terms of the EIB credit facility are as follows:

- *Term and Availability*. The EIB credit facility can be drawn in up to four tranches each in a minimum amount of €5 million, each of which matures 5 years from the scheduled date of disbursement for the relevant tranche. The final availability date for the EIB credit facility is May 19, 2019.

- *Conditions to disbursement.* We have already drawn the first €10 million of the loan commitment in the form of two €5 million tranches. We may draw up to an additional €5 million (for a total aggregate draw of up to €15 million) if we provide evidence satisfactory to EIB that we have reached consolidated revenues of €15 million on a 12-month rolling basis, and we may draw up to a further €5 million (for a total aggregate draw of up to €20 million) if we provide evidence satisfactory to EIB that we have reached consolidated revenues of €35 million on a 12-month rolling basis and that we have raised at least an additional €5 million in equity financing.

- *Use of Proceeds and Co-Funding Requirement*. We are required to use proceeds from the EIB credit facility in order to fund post-marketing level clinical trials to produce data for obtaining regulatory clearance in the EU and U.S. for Ameluz® in different indications and treatment modalities, referred to as the "Project". In addition, we are required to ensure that we have available, and to expend, our own funds to finance approximately 50% of the Project budget (which is approximately €40 million in total). This means that, for any given year we may use the EIB credit facility to finance only approximately 50% of costs related to the Project.

- *Interest*. There are three components to the interest we pay under the EIB credit facility: quarterly floating interest payments, a deferred interest payment, and a performance participation interest payment. We make floating interest payments each quarter based on a rate per annum equal to EURIBOR *plus* 4.00%. The deferred interest and the performance participation interest payments are payable in full when the relevant tranche matures (or on any earlier prepayment date). Deferred interest accrues daily on each €5 million tranche at a rate of 6.0% per annum. For each €5 million tranche, the performance participation interest amount is equal to the *product of* EIB's disbursement date notional equity proportion in respect of such tranche *multiplied by* our market capitalization on the maturity date of such tranche. The disbursement date notional equity proportion in relation to the outstanding €10 million loan is 0.64%.

- *Restriction on Debt.* We are not permitted to incur additional third-party debt in excess of €1 million without the prior consent of EIB. This restriction is subject to certain exceptions, such as for ordinary course deferred purchase arrangements and, subject to maximum amounts, various types of leases.

- *Events of Default*. The EIB credit facility contains a number of provisions allowing EIB to accelerate the payment of all or part of amounts outstanding under the EIB credit facility, including customary acceleration provisions for failure to make payments, inaccuracy of representations and warranties, default on other loan obligations (cross-default), illegality or change of law, and events relating to bankruptcy, insolvency and administration. In addition, EIB may accelerate upon any event or change in condition which in the opinion of EIB has a material adverse effect on our business, operations, property, condition (financial or otherwise) or prospects, or on the business, operations, property, condition (financial or otherwise) or prospects of Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH or Biofrontera Inc.

- *Other Covenants.* Subject in each case to certain exceptions, the EIB credit facility contains negative covenants and restrictions, including among others: restrictions on the granting of security, on the provision of loans and guarantees, on the disposal of assets and on a change of business. Furthermore, we must retain 100% ownership of Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH and Biofrontera Inc. and 51% ownership of any other subsidiary whose gross revenues, total assets or EBITDA represent 5% or more of our consolidated gross revenues, total assets or EBITDA. The EIB credit facility also contains affirmative covenants, such as the execution of the Project as described in the EIB credit facility agreement, mandatory periodic reporting of financial and other information and the notification upon the occurrence of any event of default.

- *Cancellation Upon Project Cost Reduction.* If it is determined that the total principal amount of the loan drawn by us exceeds 50% of the total cost of the Project, EIB may cancel the undisbursed portion of the loan and demand prepayment of the loan up to the amount by which the loan, excluding accrued interest, exceeds 50% of the total cost of the Project.

Convertible Bond II

In January 2017, we issued a convertible bond with an aggregate principal amount of €4.999 million, which is divided into 49,990 non-registered pari passu ranking bonds, each with a principal amount of €100. These bonds bear interest at a rate of 6% per annum on their principal amount from and including February 1, 2017. We must pay interest on these bonds semi-annually in arrears on January 1 and July 1 of each year. We must redeem these bonds in full on January 1, 2022, by paying the outstanding principal amount, together with accrued interest on the principal amount until (but excluding) the maturity date, unless they have previously been redeemed or converted or purchased and cancelled. The bonds were offered on a preemptive basis to all existing shareholders and were fully subscribed.

The terms and conditions of these bonds provide that each bondholder is entitled to declare due and payable the entire principal amount and any other claims arising from the bonds if we fail to pay within 30 days after the relevant payment date any amounts due and payable on the bonds or we exceed the "permissible indebtedness" under the terms and conditions by incurring additional debt. We will be deemed to exceed the "permissible indebtedness" if, as a result of our incurrence of any debt, both (1) our "net financial indebtedness" exceeds €25 million, and (2) our "net indebtedness quota" exceeds 4.0. "Net financial indebtedness" is defined as (i) the sum of long-term financial liabilities and short-term financial debt, less (ii) cash and cash equivalents, and "net indebtedness quota" is defined as the quotient of (i) our "net financial indebtedness" divided by (ii) our EBITDA (as defined in the terms and conditions of the bonds). For purposes of these calculations, all relevant figures are determined based on our most recent published annual or interim quarterly financial reports at the time we incur additional debt.

We will not be deemed to exceed the "permissible indebtedness" if the "net indebtedness quota" exceeds 4.0 due to a reduction of our EBITDA.

We granted each bondholder the right to convert its bonds, at any time, in whole but not in part, into our ordinary shares, at a conversion price per share equal to: €3.50 per share from the date of issuance until March 31, 2017; €4.00 per share from April 1, 2017 until December 31, 2018; and €5.00 per share from January 1, 2018 until maturity. As of the date of this prospectus, a principal amount of €2.3 million of these convertible bonds has been converted into shares.

Convertible Bond I

In December 2016, we issued a convertible bond with a maturity date of January 1, 2021 ("Convertible Bond I"). The Convertible Bond I has an aggregate principal amount of €4.999 million, which is divided into 49,990 non-registered pari passu ranking bonds, each with a principal amount of €100. These bonds bear interest at a rate of 6% per annum on their principal amount from and including January 1, 2017. The bonds were offered on a preemptive basis to all existing shareholders and were fully subscribed. As of the date of this prospectus, a principal amount of €4,916,000 of these convertible bonds have been converted into our ordinary shares.

The terms and conditions of the Convertible Bond I do not contain any financial or other covenants that would have a material impact on our ability to incur additional indebtedness. For more information on Convertible Bond I and Convertible Bond II, see Note 10 (Financial Liabilities) to our audited consolidated financial statements for the years ended December 31, 2016 and 2015.

Off-Balance Sheet Transactions

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements that have or are reasonably likely to have a current or future effect on the company's financial condition, changes in financial condition, revenues or expenses, results of operations, liquidity, capital expenditures or capital resources.

CRITICAL ACCOUNTING POLICIES AND USE OF ESTIMATES

The consolidated financial statements of Biofrontera for the fiscal year ending December 31, 2016 have been prepared in accordance with the International Financial Reporting Standards, or IFRS, of the International Accounting Standards Board, or IASB, and the interpretations of the International Financial Reporting Standards Interpretations Committee, or IFRS IC, which are endorsed by the EU and applicable on the balance sheet date. In addition, statutory provisions pursuant to Section 315a (1) of the German Commercial Code have been complied with.

The assets and liabilities are recognized and measured in accordance with the IFRS that were required on December 31, 2016.

The preparation of the consolidated financial statements for the fiscal year ended December 31, 2016 in accordance with IFRS required the use of estimates and assumptions by the management that affect the value of assets and liabilities — as well as contingent assets and liabilities — as reported on the balance sheet date, and revenues and expenses arising during the fiscal year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lives of non-current assets and the formation of provisions, as well as income taxes. 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.

While our significant accounting policies are more fully discussed in Note 1 to our consolidated financial statements included in this prospectus, we believe that the following accounting policies are critical to the process of making significant judgments and estimates in the preparation of our consolidated financial statements. We have reviewed these critical accounting policies and estimates with the audit committee of our supervisory board.

Revenue Recognition

Our company recognizes revenue in accordance with IAS 18 if the risks and opportunities connected with ownership have transferred to the customer. The company realizes its revenue primarily through the sale of its products. Income from milestone and licensing agreements with third parties are recognized once the underlying contractual conditions come into effect. The receipt of revenue can always be fully and immediately recognized as revenue if the conditions of IAS 18 IE 20 are met in the form of a one-off contract start payment.

Revenue and other income are recognized if the amount can be measured reliably and payment is sufficiently probable as well as other conditions mentioned below are met. All income in connection with the sale of products and license income is recognized as revenue. Revenue is deemed to be realized when the deliveries and services owed have been provided and substantial risk and chances have been passed to the acquirer.

Most of our revenue is generated by product sales. The sale of Ameluz® almost exclusively occurs in Europe through pharmaceutical wholesalers or, to a lesser extent, directly to pharmacies or hospitals. Sales in the U.S. are primarily directly to physicians, hospitals or other qualified healthcare providers. Above and beyond this, in the fiscal year ended December 31, 2016, a considerable portion of sales revenue was achieved through passing costs on to Maruho as part of the collaboration and partnership agreement we have entered into with Maruho.

In the case of direct sales of our BF-RhodoLED® lamps, the delivered products and services on which amounts are owed are settled only after complete installation, since the installation services require specialized knowledge, are not just an ancillary service and, for legal reasons, the lamp may only be used by the customer after successful installation. In the case of lamps on loan, that is, lamps already installed for testing by buyers before a purchase, the preconditions are met through the origination of a valid purchase agreement and the generation of an outgoing invoice.

Belixos® is predominantly sold through local Amazon websites in the EU. Revenue is recognized after delivery and payment by the customer. Based on experience, return rights granted with the sale through Amazon are exercised by customers in very few cases.

Revenue is recognized, less revenue based trade taxes and sales deductions. Expected sales deductions, such as rebates, discounts or returns, are recognized based on estimated values at revenue recognition. Payment terms for Ameluz® include short-term payment terms with a possibility for sales rebates. Instalment payments over 48 months, which include a financing component, are sometimes agreed upon with the sale of our BF-RhodoLED® lamp.

License income as well as milestone-based payments are recognized when the contractual obligation has been fulfilled.

Share-Based Payments

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 we have 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 market value of share options are estimated using the Monte Carlo Simulation valuation model and we use the following methods to determine its underlying assumptions: expected volatilities are based on our calculation of annualized volatilities (based on daily prices and assuming 250 trading days per year) of around 49.00%; the expected term of options granted is based on the assumption that the option holders will exercise their options evenly within the exercise window (years 5 and 6 after the grant date) and have imputed a standardized five-year holding period; the risk-free interest rate of-0.49% is based on the valuation date for a five-year term (spot rate) from the yield curve; and the expected returns are based on applying the capital asset pricing model (CAPM) using the yield curve to first calculate the standard risk-free rate for a perpetual term as applicable on the valuation date. Forfeitures are estimated at the time of grant and adjusted, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

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 capitalising development costs as assets are only fulfilled by us 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 Ameluz®, which has been approved in Europe, and to our company's other research and development projects are expensed in the period in which they are incurred, based on industry standards. Almost all research and development expenses for a drug product are incurred before clinical phase III trials are completed. Whether or not a product may receive approval or could be commercialized and generate cash flows at all can only be determined once data from such phase III trials are available, and consequently development costs cannot be capitalized.

QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are exposed to various risks in relation to financial instruments including credit risk, liquidity risk and currency risk. Our risk management is coordinated by our management board. We do not engage in the trading of financial assets for speculative purposes. The most significant financial risks to which we are exposed include the following discussed below. Please see Note 14 (Reporting on Financial Instruments) to our Consolidated Financial Statements for additional information.

Liquidity risk

We have been dependent on our shareholders and bondholders for the funding of our operations. As described in Note 1 of our consolidated financial statements, our ability to continue as a going concern is dependent on our ability to raise additional funds by way of debt and/or equity offerings to enable us to fund our clinical trial programs and commercialization plans. We believe that our existing cash and cash equivalents, the credit facilities available to us under the EIB credit facility, the anticipated net proceeds from this offering, and revenue from product sales and future milestone or license payments will be sufficient to enable us to fund our operating expenses and to advance our commercialization strategy in the U.S. for the next 12 months. However, changing circumstances may cause us to consume capital significantly faster than we currently anticipate, and we may need to spend more money than currently expected because of circumstances beyond our control. We will require additional capital for the further development and commercialization of our products and product candidates. We may need substantial additional funds to fully develop, manufacture, market and sell our other potential products. See “Risk Factors”.

Currency risk

We are subject to currency risk, as our income and expenditures are denominated in Euro, Swiss Francs and the U.S. dollar. As such we are exposed to exchange rate fluctuations between such foreign currencies and the Euro. We aim to match foreign currency cash inflows with foreign cash outflows where possible. We do not hedge this exposure. If we increase sales of our products in the U.S., we would expect to have significant increases in cash balances, revenues and sales and marketing costs denominated in U.S. dollars and in Swiss Francs, while we would expect the majority of our development and operating costs to remain denominated in Euro. Between January 2014 and July 2017, the exchange rate between the U.S. dollar and the euro ranged between 1.03903 dollars per euro and 1.39305 dollars per euro, and the exchange rate between the Swiss franc and the euro ranged between 0.98665 Swiss franc per euro and 1.23805 Swiss franc per euro.

Overview

We are an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Our approved products focus on the treatment in the U.S. and Europe of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of basal cell carcinoma in the EU. We conduct our own research and development and, in several regions, including the U.S., market and sell our own products.

Our principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy (when used together, "Ameluz® PDT") in all of the countries of the EU (including the UK), in Switzerland, in Israel and in the U.S. for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. We are currently selling Ameluz® for this indication in the U.S., in 11 countries in Europe and in Israel.

In addition, in the EU, Ameluz® is currently approved by the European Commission for the photodynamic therapy treatment of field cancerization (entire skin areas infiltrated by tumor cells and entailing several actinic keratoses), as well as superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. We are also seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy (*i.e.*, using natural daylight to activate the drug), which we applied for in the second quarter of 2017. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. As further described below, we plan to seek further extensions of the approved indications for Ameluz® photodynamic therapy in both the EU and the U.S.

The following table summarizes the indications for which we are currently approved to market Ameluz® or for which we are in the process of seeking approval to market Ameluz®, as well as products currently in development, organized by territory*:

Product	Indication / comments	Territory	Preclinical	Clinical	Submitted	Status
Ameluz®	Actinic keratosis (AK), Field Cancerization	EU, CH, IL				On market
Ameluz®	AK, lesion- and field-directed	US				On market
Ameluz®	Basal Cell Carcinoma	EU				On market
Ameluz®	AK: Daylight PDT	EU				EMA review
Ameluz®	AK: trunk & extremities	EU/US				Phase III ongoing
Ameluz®	Basal Cell Carcinoma	US				IND for Phase III submitted
Ameluz®	Squamous Cell Carcinoma *in situ*	EU/US				Phase III in preparation†
Ameluz®	AK: larger treatment areas	EU/US				Phase III in preparation†
Ameluz®	Acne	EU/US				Phase III in consideration†
BF-MA-11	Collaboration with Maruho Co. Ltd.	EU/US				Preclinical
BF-MA-12	Collaboration with Maruho Co. Ltd.	EU/US				Preclinical
BF-MA-13	Collaboration with Maruho Co. Ltd.	EU/US				Preclinical
BF-MA-14	Collaboration with Maruho Co. Ltd.	EU/US				Preclinical

* "CH" = Switzerland; "IL" = Israel

† Timeline for pursuing phase III trial to be determined

Recent Achievements

In 2016, we reached several milestones for our business by executing our strategies of expanding worldwide sales of our products and extending the approved indications of Ameluz® PDT.

In the six months ended June 30, 2017, our sales revenue increased 193% to €5.0 million compared to €1.7 million in the same period the year before, reflecting mainly our entry into the U.S. market. During the year ended December 31, 2016, our sales increased 48% to €6.1 million compared to €4.1 million for the year ended December 31, 2015.

In May 2016, we received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016.

In 2016, we also received approvals by the European Commission of label extensions for Ameluz® to include the treatment of field cancerization and superficial and/or nodular basal cell carcinoma unsuited for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. In addition, during that year we reported positive Phase III results for Ameluz® in combination with daylight photodynamic therapy. We submitted to the EMA our application (which included the Phase III data) for label extension during the second quarter of 2017. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks.

In 2016, we began to hire employees in the U.S., including a sales force. As of the date of this prospectus, we have a sales force consisting of 34 employees who cover most of the continental U.S.

In July 2016, we entered into a collaboration and partnership agreement with Maruho, a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of our company. This agreement provides for the joint development of up to four branded generic pharmaceutical product candidates using our proprietary formulation technology. Our planned indications for all four development projects with Maruho are atopic dermatitis and psoriasis.

In August 2017, we agreed with the FDA on the requirements necessary to obtain approval for our application of Ameluz® PDT for the treatment of superficial basal cell carcinoma in the U.S. Under the agreed plan with the FDA, our application could be based on a single additional phase III placebo-controlled pivotal trial to be conducted in the U.S., in which Ameluz® PDT will be compared to placebo PDT, which can be conducted with relatively few patients minimizing both time and expense. We will be required to present a combined read-out of clinical and histological clearance. We believe our agreement with the FDA on the requirements for the potential approval of our application to extend Ameluz® for the treatment of superficial basal cell carcinoma in the U.S. represents a significant milestone that should allow us to reduce cost and to achieve approval more quickly than if we had been required to undertake additional or more complex clinical trials. In December 2017, we filed an investigational new drug application with the FDA for our proposed phase III study protocol to evaluate Ameluz® PDT for the treatment of superficial basal cell carcinoma. This investigational new drug application enables us to initiate our phase III trial to be conducted in the U.S. to compare Ameluz® PDT to placebo PDT.

In November 2017, we achieved a significant milestone in our marketing efforts in the U.S. when the U.S. Center for Medicare and Medicaid Services (CMS) assigned us a unique, product-specific billing code for Ameluz®. The J-code for Ameluz® became effective and available for use by doctors on January 2, 2018. A permanent J-code is generally required for a drug to be eligible for reimbursement by Medicare. Before a permanent J-code is obtained, doctors making reimbursement claims must apply for reimbursement by use of a "miscellaneous" code, which can create additional administrative hurdles and delay for the doctors to receive reimbursement, especially shortly after a drug has launched when payors are not yet familiar with claims for the new drug. Since the permanent J-code for Ameluz® became effective on January 2, 2018, we expect that the process of claiming reimbursement for Ameluz® will become easier for doctors in the U.S., which we expect to have a positive effect on our sales and revenue.

Key Strengths

We believe we are well positioned for growth due to multiple drivers, including: our recent commercial launch of Ameluz® in the U.S. for treatment of minimally to moderately thick actinic keratosis of the face and scalp, our recent label extension in the EU of Ameluz® for treatment of field cancerization (larger areas of skin on the face and scalp with multiple actinic keratoses) and superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome, our pending application for Ameluz® to be used in daylight PDT in the EU and proposed reimbursement changes for cryotherapy in U.S. In addition, we believe that there is a trend toward field therapy as opposed to single lesion therapy, which would make Ameluz® PDT more competitive versus treatments (such as cryotherapy) that are more suited to single lesion therapy.

Key Strengths include:

- Minimal clinical risk. Our principal product — Ameluz® — is now approved and commercialized in the U.S. to treat minimally to moderately thick actinic keratosis of the face and scalp (which can develop into squamous cell carcinoma) using our BF-RhodoLED® lamp and in the EU to treat actinic keratosis, field cancerization (i.e., larger areas of skin on the face and scalp with multiple actinic keratoses) and, in certain circumstances, basal cell carcinoma, among other approvals.

- Ease of treatment. Ameluz® is an easy to use, non-invasive treatment that a physician applies directly to the skin, requires simple light activation and has shown no serious side effects.

- Expanding presence in U.S. and EU with an experienced in-house sales force. Sales of Ameluz®, which was recently launched commercially in the U.S., are increasing significantly, with recent quarterly revenue growth over 160%. We are leveraging our own experienced sales force to drive this growth.

- Strong pipeline. We recently submitted an application for approval of Ameluz® for use in daylight PDT in the EU. In addition, we are planning and/or have begun preparation for Phase III trials that will form the basis of applications we plan to submit to regulators for the treatment of basal cell carcinoma in the U.S. and squamous cell carcinoma *in situ*, actinic keratosis on the trunk and extremities and larger treatment areas for actinic keratosis, in each case in both the U.S. and the EU. In August 2017, we agreed with the FDA on the requirements for the potential approval of our application to extend Ameluz® PDT for the treatment of superficial basal cell carcinoma in the U.S., and in December 2017 we filed an investigational new drug application with the FDA for our proposed phase III study protocol to evaluate Ameluz® PDT for the treatment of superficial basal cell carcinoma. See "— Overview" and "— Recent Achievements" above for more information. In addition, we are pursuing research and development of up to four branded generic dermatology drugs under a collaboration and partnership agreement with Maruho, a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of our company. See "Business — Our Research and Development Plans — Our Development Collaboration with Maruho" for more information.

Our strategy

Our principal objectives are to obtain regulatory approvals for the marketing of Ameluz® PDT for additional indications and in additional countries, and to increase the sales of our approved products. The key elements of our strategy include the following:

- geographic expansion of Ameluz® sales worldwide, including by:

  - expanding our sales in the U.S. of Ameluz® in combination with our BF-RhodoLED® lamp for the treatment of minimally to moderately thick actinic keratosis of the face and scalp and positioning Ameluz® to be a leading photodynamic therapy product in the U.S., by growing our dedicated sales and marketing infrastructure in the U.S.;

  - expanding our sales in the EU of Ameluz® by marketing it for the treatment not only of minimally to moderately thick actinic keratosis of the face and scalp, but also for the treatment of field cancerization (larger skin areas containing potentially pre-cancerous cells and multiple actinic keratosis lesions) and basal cell carcinoma, indications for which we recently obtained approval; and

  - expanding our sales of Ameluz® in other countries where it is an approved product by entering into arrangements with distribution partners;

- extension of the approved indications for Ameluz® photodynamic therapy, including by:

  - seeking to extend the approved label for actinic keratosis to include actinic keratosis lesions located other than on the head or scalp and increase the maximal size of the treatment field;

  - seeking to extend the approved indications in the U.S. for Ameluz® in combination with our BF-RhodoLED® lamp for the treatment of basal cell carcinoma;

  - seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy, or exposure to sunlight, an indication for which we have recently applied in the EU and which we believe may increase the market potential of Ameluz® in such region (since Ameluz® could be used without doctor's office procedures, which procedures can render photodynamic therapy treatment in European markets commercially unattractive due to lack of reimbursement); and

  - seeking to extend the approved indications in the EU and U.S. for Ameluz® to additional indications, such as squamous cell carcinoma *in situ*, actinic cheilitis, acne, warts, wound healing, and/or cutaneous leichmania; all of which would require further clinical trials, and other research and development activities.

We also plan to develop additional drug candidates and seek partnerships or other opportunities for drug development collaborations, such as our collaboration and partnership agreement with Maruho and to continue to develop and expand marketing and sales of our cosmetic skin care products.

Our Products

Ameluz®

Our principal marketed product is Ameluz®. Ameluz® is used in photodynamic therapy to selectively remove tumor cells. We are currently selling Ameluz® in the U.S., in 11 countries in Europe and in Israel. We outsource the production of Ameluz® to a third party contract manufacturer in Switzerland.

In general, photodynamic therapy is a two-step process:

- the first step is the application of a drug known as a "photosensitizer," or a pre-cursor of this type of drug, which tends to collect in cancerous cells; and
- the second step is activation of the photosensitizer by controlled exposure to a selective light source in the presence of oxygen.

During this process, energy from the light activates the photosensitizer. In photodynamic therapy, the activated photosensitizer transfers energy to oxygen molecules found in cells, converting the oxygen into a highly energized form known as "singlet oxygen," which destroys or alters the sensitized cells.

The longer the wavelength of visible light, the deeper into tissue it penetrates. Different wavelengths, or colors of light, including red and blue light, may be used to activate photosensitizers. The selection of the appropriate color of light for a given indication is primarily based on two criteria:

- the desired depth of penetration of the light into the target tissue; and
- the efficiency of the light in activating the photosensitizer.

In the U.S., our approved treatment method involves applying Ameluz® gel to individual or entire fields of actinic keratosis lesions, followed three hours later with exposure to our red light BF-RhodoLED® lamp for approximately ten minutes. In the EU, Ameluz® is also indicated for field cancerization and for superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome. See *"— History of Approved Indications and Active Applications*" below.

Photodynamic therapy can be a highly selective treatment that targets specific tissues while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. The most common side effect of photosensitizers that are applied topically or taken systemically is temporary skin sensitivity to bright light. Treatment is generally well tolerated but tingling discomfort or pain is common during PDT. In our Phase III trials, the resulting redness and/or inflammation resolved within 1 to 4 days in most cases; in some cases, however, it persisted for 1 to 2 weeks or even longer. Patients undergoing photodynamic therapy treatments are usually advised to avoid direct sunlight and/or to wear protective clothing and sunscreen for some days after the treatment. Patients' indoor activities are generally unrestricted except that they are told to avoid bright lights. The degree of selectivity and period of skin photosensitivity varies among different photosensitizers and is also related to the drug dose given. Unless activated by light, photosensitizers have no direct photodynamic therapy effects.

History of Approved Indications and Active Applications

In December 2011, Ameluz® ("love the light") 78 mg/g Gel (development name BF-200 ALA) received a centralized European regulatory approval by the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. In the EU, Ameluz® is to be used in combination with exposure to a red light source (although the approved labelling does not specify the light source). We launched the commercialization of Ameluz® for the treatment of actinic keratosis in Germany for this indication in February 2012 followed by other EU countries during the following two years.

In November 2015, our license partner Louis Widmer SA obtained approval to market Ameluz® in Switzerland for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. In April 2016, our licensee Perrigo Israel Agencies Ltd.

obtained approval to market Ameluz® in Israel for the same indication. We launched the commercialization of Ameluz® in Switzerland in April 2016 and in Israel in August 2017.

In May 2016, we received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Thus, in the U.S., Ameluz® is to be used in combination with exposure to light using our BF-RhodoLED® lamp. We launched the commercialization of Ameluz® and BF-RhodoLED® for the treatment actinic keratosis in the U.S. in October 2016.

In September 2016, the European Commission approved Ameluz® for the photodynamic therapy treatment of field cancerization following a prior recommendation of the EMA. This decision was based on a field-directed Phase III trial during which the skin rejuvenating effects of Ameluz® were also studied. The skin rejuvenation results of this trial are included in the authorized EU product information and are summarized in the table entitled "Table 3: Skin quality parameters in the treated area during 12-month follow-up" in the section "Research and Development and Regulatory Affairs — Ameluz® — Trial 3" below. We launched the commercialization of Ameluz® for the photodynamic therapy treatment of field cancerization in the EU shortly after approval.

We initiated our efforts to extend indications for Ameluz® to include basal cell carcinoma in 2014. We conducted Phase III clinical testing in direct comparison with the European competitor product Metvix®. We completed patient recruitment in May 2015 and the last patient concluded the clinical part of the trial in November 2015. We will have a 5-year follow-up period for all patients, of which 6-month and 12-month data are currently available. We published the results of the trial in January 2016, which demonstrated clinical benefits of Ameluz® for non-aggressive forms of basal cell carcinoma. In comparison with the competitor product Metvix®, in the clinical trials Ameluz® demonstrated generally higher clearance rates, especially for thicker and nodular carcinomas and significant non-inferiority of the clinical endpoint, which was total patient clearance of all basal cell carcinomas.[2] These trial results demonstrated to the EMA that Ameluz® is a viable treatment option for superficial and nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome, which resulted in approval of this indication in the EU in January 2017.

We are also seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy (*i.e.*, using natural daylight to activate the drug), which we applied for in the second quarter of 2017. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. We believe that if we obtain this approval, we may increase the market potential of Ameluz® in the EU since Ameluz® could be used without doctor's office procedures, which procedures can render photodynamic therapy treatment in European markets commercially unattractive due to lack of reimbursement.

Actinic keratoses

Actinic keratoses are superficial potentially pre-cancerous skin lesions caused by chronic sun exposure that may, if left untreated, develop into a form of potentially life-threatening skin cancer called squamous cell carcinoma. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots.

According to The Skin Cancer Foundation, actinic keratosis is becoming a widespread disease, with more than 58 million people affected in the U.S. According to The Skin Cancer Foundation, if left untreated, up to 1 percent of actinic keratosis lesions develop into squamous cell carcinomas every year. On average, this transformation into squamous cell carcinoma occurs within two years of formation of the initial actinic keratosis lesion.

Squamous cell carcinoma is an uncontrolled growth of abnormal cells arising in the squamous cells, which compose most of the skin's upper layers (the epidermis). Squamous cell carcinomas often appear as scaly red patches, open sores, elevated growths with a central depression, or warts; and they may crust or bleed. They can become disfiguring and sometimes deadly if allowed to grow. According to The Skin Cancer Foundation, squamous cell carcinoma has been the second most common form of skin

2 We demonstrated this outcome through one controlled study. Generally, two controlled studies are necessary to support comparative claims in the marketing of drugs. Therefore, the results of this clinical trial comparing Ameluz® and Metvix® are presented for informational purposes only.

cancer, but its incidence has been rapidly increasing. According to The Skin Cancer Foundation, more than one million cases of squamous cell carcinoma are diagnosed each year in the U.S., and it has been estimated that as many as 8,800 people die from the disease each year in the U.S. Incidence of the disease has increased by 200 percent in the past three decades in the U.S. and it has recently matched the incidence of basal cell carcinoma in the Medicare fee-for-service population, which had been the most common form of human cancers.

Because actinic keratosis can develop into squamous cell carcinomas, actinic keratosis is classified by The European Academy of Dermatology and Venereology and other international treatment guidelines as a tumor that requires treatment, 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.

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

Market Overview for Treatment of Actinic Keratosis

Actinic keratosis is a disease that is most frequent in the Caucasian, light-skinned population. It has been estimated that actinic keratosis affects up to 10% of the entire Caucasian population worldwide. Only a fraction of these patients is currently being treated. Actinic keratoses are treated using a wide range of methods. The traditional methods of treating actinic keratoses are:

- cryotherapy, or the deep freezing of skin;
- simple curettage;
- self-applied topical prescription products; and
- combination of medication with photodynamic therapy.

Although any of these methods can be effective, each has limitations and can result in significant side effects.

Cryotherapy is non-selective (meaning it cannot target specific tissues but affects all tissues in the area of application), can be painful at the site of freezing, and can cause blistering and loss of skin pigmentation, leaving temporary or permanent white spots. In addition, because there is no standardized treatment protocol, results are not uniform and can depend on the skill or technique of the doctor treating the patient.

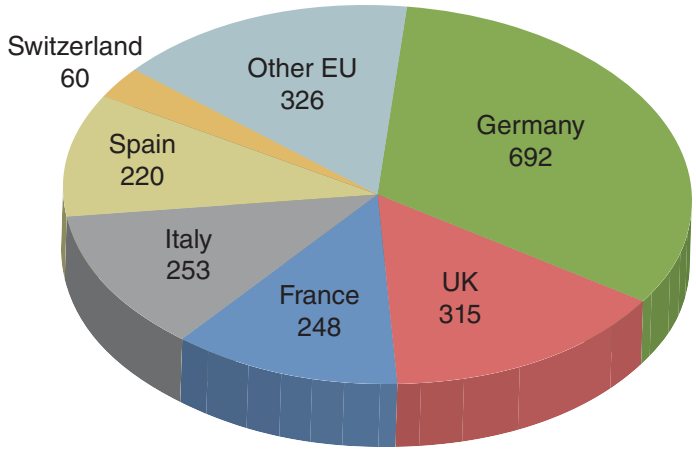
Topical prescription products, such as 5-fluorouracil cream, or 5-FU, can be irritating and require twice-a-day application by the patient for approximately 2 to 4 weeks, resulting in inflammation, redness and erosion or rawness of the skin. Following the treatment, up to several weeks of healing may be required. Imiquimod or diclofenac, other topical prescription products, require extended applications of cream, lasting up to 3 or 4 months, during which the skin is often very red and inflamed. Treatment with ingenol mebutate is faster, requiring application for only a few days, but side effects can be long-lasting and this drug has been labeled with a black-box warning by the FDA.

Simple curettage is generally most useful for one or a few individual lesions, but not for a large number of lesions, and it leaves permanent scars.

<u>European Markets</u>

In Europe, most actinic keratosis patients are treated with various available medications, which can be assessed through the number of prescriptions. Throughout Europe, there are more than 2 million prescriptions written per year for actinic keratosis drugs, and the number of prescriptions has been growing by about 10% annually over the past four years. In 2016 in Europe, total sales of prescription drugs to treat actinic keratosis were approximately €120 million, with PDT drugs accounting for approximately €22 million of sales. In Europe, although the total number of cryotherapy or simple curettage treatments for actinic keratosis is not available, we believe that only a small number of patients with actinic keratosis is treated by cryotherapy or simple curettage treatments. We therefore disregard treatment by cryotherapy or simple curettage treatments in the following estimates of European market share. We estimate that approximately 33% of all prescriptions for actinic keratosis drugs in

Europe are written in Germany, followed by the UK (15%), France (12%), Italy (12%), Spain (10%) and Switzerland (3%), and the remaining European countries account for approximately 15% of such prescriptions.



Prescription numbers of actinic keratosis drugs in Europe (in 1000 units; year 2016).
Sources: Insight Health; IMS; Biofrontera market research

In Europe, only a small portion of prescriptions written for drugs to treat actinic keratosis are for PDT drugs: approximately 120,000 prescriptions in 2016, representing sales of €22 million. Thus, in Europe, PDT drugs are prescribed for a relatively low percentage of treatments for actinic keratosis, notwithstanding the fact that clinical trials have demonstrated that photodynamic therapy achieves higher clearance rates compared to other drugs used to treat actinic keratosis. We believe that, in Europe, the extra time and effort required from patients and medical practitioners have historically prevented significant market penetration in the statutory health insurance sector in Europe — a photodynamic therapy treatment requires a patient to visit a medical office for the procedure and requires time from doctors or other medical practitioners to administer it. In Europe, topical prescription product creams are reimbursed by government authorities (or other third party payors) and do not require a medical office based procedure, whereas photodynamic therapy requires a procedure that, to date, is not reimbursed in all markets in Europe. We are also seeking to extend the approved indications in the EU for Ameluz® to include treatment for actinic keratosis with Ameluz® in combination with daylight photodynamic therapy (*i.e.*, using natural daylight to activate the drug), which we applied for in the second quarter of 2017. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. Daylight PDT eliminates the need for a medical office based procedure and should allow easier reimbursement in Germany, where PDT procedures performed by physicians have not been reviewed or approved for reimbursement by the relevant governmental authorities. As a result, we see the potential for daylight PDT to significantly grow its share of the actinic keratosis treatment market in Europe.

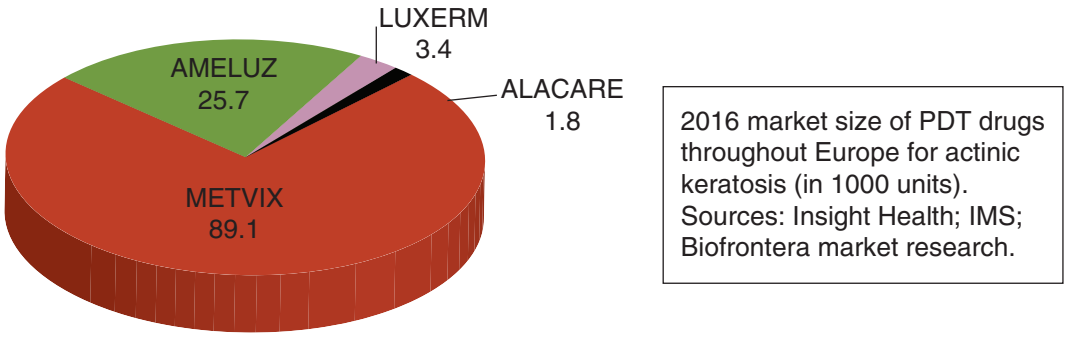
In Europe, sales of PDT drugs generally have been growing slightly faster, by about 15% per year, than sales of PDT drugs in the actinic keratosis market, but sales of PDT drugs in Europe still represent less than 6% of all prescriptions for actinic keratosis. This market size may, however, be an underestimation since in many countries in Europe PDT drugs may be sold directly to hospitals and, therefore, are not tracked by market research sources. Since PDT drugs generally have a higher price than the self-applied topical drugs, their percentage of revenues is higher than that of prescription numbers (18.3% vs. 5.7%, respectively).

Available PDT drugs for treatment of actinic keratosis in Europe include Ameluz® gel, Metvix® cream, Alacare® adhesive plaster and Luxerm® cream. Metvix® has been on the market in the EU since 2002, and is the most frequently used PDT drug for treatment of actinic keratosis throughout the EU. Metvix® is approved for treatment with a red light source and contains methylesther, which is metabolized to 5-ALA in the tissue, as its active ingredient. As with Ameluz®, in the treatment of actinic keratosis, Metvix is used in a PDT treatment once, and the PDT treatment is repeated after several weeks if residual lesions remain. In our phase III trial, we compared the efficacy of Ameluz® with that of Metvix® and demonstrated the non-inferiority of Ameluz® in the treatment of actinic keratosis.[3] Alacare® is a 2x2 cm plaster that has low market share because of its limited size of treatment area. Metvix® has also recently been approved in the EU for use in daylight photodynamic therapy for which it is sold by Galderma under the brand name Luxerm® in Germany and Luxera® in other European countries.

3 We demonstrated this outcome through one controlled study. Generally, two controlled studies are necessary to support comparative claims in the marketing of drugs. Therefore, the results of this clinical trial comparing Ameluz® and Metvix® are presented for informational purposes only.

Throughout Europe, Metvix® has 74% market share among PDT treatments of actinic keratosis, followed by Ameluz® with 21%, Luxerm® with 3% and Alacare® with 2%. Since commercial launch in Germany (where our sales force has been most active), the market share of Ameluz® in the segment of photodynamic therapy drugs for treatment of actinic keratosis dispensed by German public pharmacies had been over 75%. In recent months, however, our market share has fallen to approximately 60%. We believe this decline resulted primarily from the introduction to the market of the medication Luxerm® in 2016. Using our Phase III trial, we filed for label extension in the EU for the treatment of actinic keratosis using Ameluz® and daylight PDT. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. If the approved indications for Ameluz® are extended to include daylight PDT, an office-based procedure would not longer be required in the EU for PDT treatment using Ameluz® (since the medication can be administered by the patient). We believe that we may obtain approval as early as the first half of 2018, although there is no guarantee that we will receive approval for this label extension. We believe that daylight photodynamic therapy products will play an increasingly important role in Europe in the future and will begin to be prescribed as an alternative to less effective, self-applied, topical prescription product creams (which have historically been market leaders in the EU in treating actinic keratosis).

In Spain, the market share of Ameluz® for photodynamic therapy treatment of actinic keratosis has been growing from less than 5% in 2014 to 12% in 2015 and 23% in 2016.



Most of the prescriptions in Europe for treatment of actinic keratosis are for self-applied topical drugs, for which the driver seems to be the minimal amount of time required by doctors and other medical practitioners (since no office based procedure is required). Almost half of all drug prescriptions in Europe for the treatment of actinic keratosis are for Solaraze® (45%), which according to a meta-analysis of clinical trials by Vector and Tolley (2014)[4] has a rather low efficacy. We believe that this supports our belief that another driver, such as time required to be spent in consultation as compared to time required for a medical office based procedure, may be more determinative of treatment selection than efficacy. In Europe, Solaraze® prescriptions for actinic keratosis are followed by prescriptions for Aldara® (18%), Picato® (16%) and Actikerall® (7%).

U.S. Market

The market for the treatment of actinic keratosis in the U.S. differs significantly from the European market. We believe this is because the U.S. reimbursement system generally has favored procedures, for which doctors in Europe may not get paid or reimbursed. In the U.S., the most common treatment for actinic keratosis is cryotherapy. In 2013, Medicare alone paid for 5.977 million actinic keratosis patients to be treated with cryotherapy. This number of patients so treated had been growing by 2-3% per year since 2008. We estimate that, if the number of patients so treated is extrapolated to 2016 with an assumed 2% growth rate, approximately 6.4 million Medicare patients with actinic keratosis were treated with cryotherapy in 2016. An analysis of "National Ambulatory Medical Care Survey" and "Medicare Current Beneficiary Survey" data with respect to the frequency and cost of actinic keratosis treatment concluded that about 60% of actinic keratosis patients were covered by Medicare, and 40% of treatments were reimbursed by private payors during the period from 1998 through 2000 (Dermatology Surgery 2006;32(8):1045-9). Thus, we assume that the above number of cryotherapies for Medicare patients represents only 60% of all cryotherapy treatments performed in the U.S. in the relevant year, so the number of cryotherapies for medicare

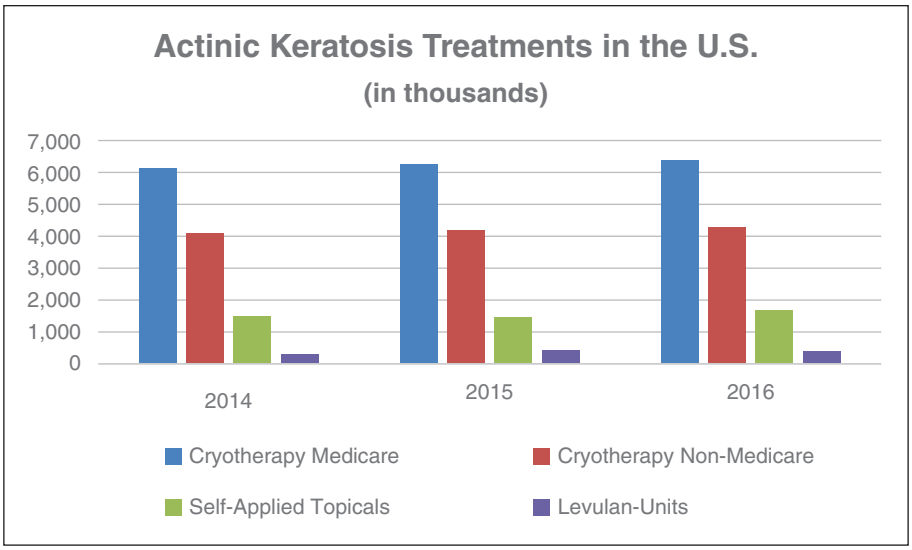
4 This research was funded by Biofrontera AG. Our personnel commented on the draft manuscript but did not have control of the methodology, conduct, results, or conclusion of this study. Additionally, this paper was not dependent on our approval for submission to the PLoS One journal.

patients should be divided by 0.6 in order to estimate the total number of cryotherapy treatments in the U.S. in that year. Simple curettage is generally not used to treat actinic keratosis in the U.S.

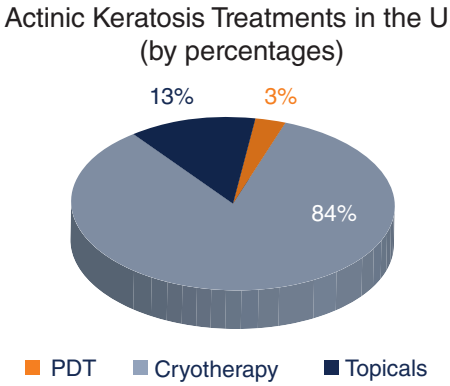
In the U.S., Levulan® is approved for the treatment of minimally to moderately thick actinic keratosis of the face or scalp in combination with PDT with a blue light source. Levulan® contains 5-aminolevulinic acid (5-ALA) as its active ingredient. As with Ameluz®, in the treatment of actinic keratosis, Levulan® is used in a PDT treatment once, and the PDT treatment is repeated after several weeks if residual lesions remain. Sun Pharma has reported annual revenue of $136 million from its sales of Levulan® in 2016. Assuming an approximate annual average sales price of $309 per Levulan® Kerastick, we estimate such sales represents approximately 343,000 prescriptions.

We estimate that there were an additional 1.65 million prescriptions for self-applied topical drugs in the U.S. for the treatment of actinic keratosis in 2016. These prescriptions are for various topical products, with the most frequently prescribed ones being drugs with the active ingredient 5-fluorouracil (44% generic plus 4% branded), followed by imiquimod drugs (31%), diclofenac drugs (16%) and ingenol mebutate drugs (5.5%).

In 2016, the cryotherapy treatments and the topical products (including PDT drugs) in the aggregate constituted an estimated 12.6 million treatments for actinic keratosis in the U.S. According to these numbers, PDT was only applied in about 3% of all actinic keratosis treatments in the U.S., and, therefore, we believe there is substantial market potential and room for growth in the U.S. Some of our estimates and judgments are based on various sources which we have not independently verified and which potentially include outdated information, or information that may not be precise or correct, potentially rendering our estimates of the U.S. market size for treatment of actinic keratosis with Ameluz® smaller, which may reduce our potential and ability to increase sales of Ameluz® and revenue in the U.S. Although we have not independently verified the data obtained from these sources, we believe that this data provides the best information available to us relating to the present market for actinic keratosis treatments in the U.S., and we often use these data for our business and planning purposes. We are responsible for the inclusion of these data in this prospectus.



The chart above displays the number of drug prescriptions and treatments for actinic keratosis in the U.S during 2014-2016 by: (i) cryotherapy, reimbursed by Medicare (Source: Resource-Based Relative Value Scale (RBRVS) of the American Medical Association); (ii) cryotherapy, not reimbursed by Medicare (the remaining 40% of cryotherapies) (Source: Dermatology Surgery 2006; 32(8):1045-9); (iii) self-applied topical drugs (Source: Biofrontera's internal market research); and (iv) Levulan® (Source: Sun Pharma's annual reports). The chart below shows the relative percentages of these actinic keratosis treatments in 2016 in the U.S.



We believe our opportunities in the U.S. market for Ameluz® sales growth for treatment of actinic keratosis are to supersede Levulan® Kerastick as the leading PDT product in the current PDT market sector for actinic keratosis treatment and to expand the PDT market as a first-option therapy to treat actinic keratosis as compared to cryotherapy and self-applied topical products.

Basal Cell Carcinoma

Basal cell carcinomas are abnormal, uncontrolled growths or lesions that arise in the skin's basal cells, which line the deepest layer of the epidermis (the outermost layer of the skin). Basal cell carcinomas often appear as open sores, red patches, pink growths, shiny bumps or scars and are typically caused by accumulated sun exposure.

Basal cell carcinomas are the most common invasive tumors affecting humans, accounting for approximately 80 percent of all non-melanoma skin cancers worldwide. Studies of populations in the U.S. and Switzerland have shown that approximately 20 to 30 percent of Caucasians will develop at least one basal cell carcinoma in their lifetime, and cases are increasing worldwide, which is believed to be caused by increased exposure to ultraviolet light. More than 4 million cases of basal cell carcinoma are diagnosed in the U.S. each year. Although basal cell carcinoma rarely spreads to other parts of the body and becomes life-threatening, it can be disfiguring if not treated promptly.

Market Overview for Treatment of Basal Cell Carcinoma

The most common treatment for basal cell carcinoma in the EU and U.S. is surgical removal. In many European countries, dermatology specialists are hospital-based and, as a result, basal cell carcinoma is most commonly treated by hospital surgery in such European countries, which is rarely the case for actinic keratosis. The treatment of basal cell carcinoma by a surgical procedure can result in high costs and clearly visible scarring. But thin, non-aggressive basal cell carcinomas can also be treated with photodynamic therapy. The advantage of treating basal cell carcinoma with photodynamic therapy is that it is a non-invasive alternative that can have better cosmetic results, *i.e.*, removal of tumors without leaving clearly visible scarring.

According to a market study published in 2014 by Technavio, the international market for actinic keratosis medication is expected to grow by approximately 8% annually, from approximately $546 million in 2013 to approximately $942 million in 2020. During this same period, the global market for basal cell carcinoma medication is expected to grow from approximately $236 million in 2013 to nearly $5 billion in 2020, because of the availability of new drugs (such as Ameluz®), which would likely mean that fewer patients will undergo surgery for treatment of basal cell carcinoma.

BF-RhodoLED® Lamp

Our BF-RhodoLED® is a red light lamp specifically designed for photodynamic therapy, and uses LEDs emitting red light at a wavelength of approximately 635 nm to activate the photosensitizer. We believe light emitted at this wavelength is effective for photodynamic therapy illumination with Ameluz® or other medications containing ALA or methyl ALA. The red light emitted by our BF-RhodoLED® lamp is outside the infrared range, reducing the likelihood for discomfort from warming. Other light wavelengths, including the blue range, can also activate the photosensitizer, but penetrate less deeply into tissues as compared to red light. We manufacture our BF-RhodoLED® lamp at our corporate headquarters in Leverkusen, Germany.

We believe our BF-RhodoLED® lamp combines a controlled and consistent emission of light at the required wavelength with simplicity of design, user-friendliness and energy efficiency. Our BF-RhodoLED® lamp contains a fan used to blow air over

the treated skin surface and power settings for the fan. In the model used in the EU, our lamp also allows adjustment of the light intensity during photodynamic therapy in order to reduce any discomfort experienced during the treatment. Our BF-RhodoLED® lamp has been CE-certified since November 2012 and is currently distributed throughout the EU. Our lamp is approved in the U.S. by the FDA as a combination product for use in treatment with Ameluz®.

We have been performing the final assembly of our BF-RhodoLED® lamp at our facilities in Leverkusen, Germany since July 2016 and, thus, we are considered the responsible manufacturer by the FDA.

History of Clinical Trials for Ameluz® and BF-RhodoLED® Lamp

Clinical trials relating to treatment of actinic keratosis with Ameluz® photodynamic therapy

The initial two Phase III trials we conducted in connection with obtaining approval for Ameluz® in the EU included a variety of CE marked photodynamic therapy light sources, and best results were achieved with LED lamps. The efficacy of Ameluz® was tested in comparison with Metvix®, the approved standard medication already available in the EU, that is a topical cream used in connection with photodynamic therapy. The results of the trial demonstrated that Ameluz® was significantly non-inferior to Metvix® for the treatment of actinic keratoses with photodynamic therapy. The complete clearance rates of patients from all keratoses at the average of all lamp types were 78 percent for Ameluz® and 64 percent for Metvix®. With LED lamps only, the clearance rates increased to 85 percent for Ameluz® and 68 percent for Metvix®. The side-effect profiles were comparable for both products. In another trial, using Ameluz® with LED lamps completely removed all keratoses in 87 percent of the patients. For the individual lesions, 96 percent and 94 percent were completely eradicated in the two trials using LED lamps (all values cited are from the intent to treat, or ITT, population). See *"Research and Development and Regulatory Affairs-Ameluz® Actinic Keratosis-Trial 1 and —Trial 2"*.

Prior to obtaining approval in the U.S. for treatment of actinic keratoses using Ameluz® photodynamic therapy, the FDA requested two Phase I clinical trials for Ameluz®, one to determine the plasma concentration of the drug after application of an entire tube of Ameluz® to maximally damaged skin, the other to investigate a sensitizing effect of the product. These Phase I trials were performed with approximately 240 subjects and were completed in 2015.

A maximal use pharmacokinetics study was conducted in 12 patients bearing at least 10 mild to moderate actinic keratoses on the face or forehead. An entire tube of vehicle and Ameluz® followed by photodynamic therapy was applied in a fixed sequence design with a washout period of 7 days to evaluate baseline and Ameluz® dependent plasma concentrations of aminolevulinic acid, or ALA, and protoporphyrine IX, or PpIX. An up to 2.5-fold increase of basic ALA plasma concentrations was observed during the first three hours after Ameluz® application, still remaining within the normal range of previously reported and published endogenous ALA concentrations. The plasma concentrations of metabolite PpIX were generally low in all patients, and in none of the patients, was an obvious increase of PpIX plasma concentrations observed after Ameluz® application.

In a clinical trial designed to investigate the sensitization potential of ALA with 216 healthy subjects, 13 subjects (6 percent) developed allergic contact dermatitis after continuous exposure for 21 days with doses of ALA that were higher than doses normally used in the treatment of actinic keratosis. Allergic contact dermatitis was not observed under regular treatment conditions.

Approval of photodynamic therapy treatment of actinic keratoses in the U.S. required us to obtain a combination approval of both Ameluz® and the light source. As a result, we developed our own photodynamic therapy lamp, the BF-RhodoLED®. Our photodynamic therapy lamp is CE-certified in the EU, which required the company to be certified pursuant to the ISO 9001 and ISO 13485 standards.

In preparation for seeking FDA approval in the U.S., we conducted a Phase III trial using the combination of Ameluz® and our BF-RhodoLED® lamp. In this Phase III trial, completed in 2015, with this combination treatment, all keratoses of a patient were completely eradicated in 91 percent of patients, and 94 percent of all lesions were completely removed (99.1 percent of mild lesions and 91.7 percent of moderate lesions). Further, 63.3 percent of the patients who were initially completely asymptomatic were still asymptomatic one year later. In this Phase III trial, the drug was applied over large skin areas (field therapy) for the first time in a Phase III trial of photodynamic therapy. Field directed treatment is advisable if a patient has several actinic keratosis lesions in close proximity since multiple actinic keratoses are believed to arise from "cancerized fields," *i.e.*, skin areas in which neoplastic cells are spread over a larger area, and additional subclinical (not yet visible) lesions may exist in the same field. Based on this study, the EU granted Ameluz® the approval for the indication "field cancerization", and the prescribing

information in the U.S. specifically approves the field directed approach. See *"Research and Development and Regulatory Affairs-Actinic Keratosis-Ameluz®-Trial 3"*.

By testing larger skin areas, we could also investigate the effect of photodynamic therapy on photo-damaged skin. Thus, in this field directed Phase III trial for Ameluz®, we measured the improvement of previously existing skin impairment. Based on the parameters we tested for skin impairment, the patients with the treatment showed improvements as a result of the treatment. The proportion of patients with impaired skin surface, including rough, dry and scaly skin, decreased from 85 percent to 28 percent within 12 months after treatment with Ameluz®. Patients with skin hyperpigmentation or hypopigmentation decreased from 59 percent to 24 percent and from 46 percent to 11 percent, respectively. The proportion of patients with mottled pigmentation, mixed hyperpigmentation and hypopigmentation, decreased from 48 percent to 18 percent. Before treatment, 26 percent of the patients had mild to moderate/severe scarring, this decreased to 7 percent of patients after treatment. Atrophic skin was diagnosed in 31 percent before but only in 4 percent of patients 12 months after treatment. See table 3 under See *"Research and Development and Regulatory Affairs-Ameluz®-Actinic Keratosis-Trial 3"*. These skin improvement results are now included in our official EU product information for Ameluz®.

Clinical trials relating to treatment of basal cell carcinoma with Ameluz® photodynamic therapy

To extend the EU approval for Ameluz® to the treatment of basal cell carcinoma, we conducted another Phase III trial. A total of 281 patients with 1 to 3 non-aggressive basal cell carcinomas enrolled in this Phase III trial, of which 138 were treated with Ameluz® PDT. We conducted the trial under the clinical supervision of Prof. Colin Morton (UK) and Prof. Markus Szeimies (Germany) at 27 clinical trial centers in the UK and Germany. The comparative trial tested Ameluz® side by side with its major European competitor Metvix®, which was already approved in the EU for the treatment of basal cell carcinoma. Patient recruitment lasted until May 2015, the last patient completed the trial in November 2015, and we obtained results of the trial in January 2016. Non-aggressive basal cell carcinomas with a thickness of up to 2 mm were included in the trial.

Photodynamic therapy treatment with Ameluz® completely eliminated all of a patient's non-aggressive (superficial and nodular) basal cell carcinomas in 93.4 percent of cases, compared to 91.8 percent from photodynamic therapy treatment with Metvix®. Of the individual lesions, 94.6 percent were completely eliminated after Ameluz® treatment, 92.9 percent were completely eliminated after Metvix® treatment. Greater differences were observed in the case of thicker basal cell carcinomas. In photodynamic therapy treatment with Ameluz®, 89.3 percent of the nodular carcinomas were completely removed, compared to only 78.6 percent with Metvix®. Superficial basal cell carcinoma lesions were completely eradicated by photodynamic therapy treatment with Ameluz® in 95.8 percent of patients, compared to photodynamic therapy treatment with Metvix®, in which superficial basal cell carcinoma lesions were completely eradicated in 96.9 percent of the cases. After 12 months, recurrence rates were slightly higher for patients treated with Metvix® as compared to patients treated with Ameluz®. In the Ameluz® group, 6.7 percent of the lesions were recurrent after 12 months, and in the Metvix® group 8.2 percent of the lesions were recurrent after 12 months. See table 4 under *"Research and Development and Regulatory Affairs-Ameluz®-Basal Cell Carcinoma"*.

In July 2016, Biofrontera applied to the EMA for approval for the photodynamic therapy treatment of basal cell carcinoma with Ameluz® based on the results of this Phase III trial. The approval was granted by the European Commission in January 2017.

Clinical trials relating to treatment of actinic keratosis with daylight photodynamic therapy

Between June and September 2016, we conducted a Phase III trial to evaluate the safety and efficacy of Ameluz® in combination with daylight photodynamic therapy, or daylight PDT, for the treatment of mild to moderate actinic keratosis. In the trial, Ameluz® was compared to Metvix®, which had previously obtained approval for daylight photodynamic therapy in some European countries. The intra-individual, randomized, observer-blinded, multi-center study took place at 7 sites in Spain and Germany, and evaluated a total of 52 patients, each with 3 to 9 mild to moderate actinic keratosis lesions in each of two comparable treatment areas on the face and/or scalp. For an intra-patient comparison of the treatments, each patient received daylight photodynamic therapy with Ameluz®, on one side, and Metvix®, on the other side, of the face or scalp.

The Phase III trial met its primary endpoint, exhibiting after a single treatment with daylight photodynamic therapy a total lesion clearance rate (percentage of completely cleared individual lesions per patient's side) of 79.8 percent for the areas treated with Ameluz®, which demonstrated non-inferiority to treatment with Metvix®, in which 76.5 percent of lesions were fully cleared after one daylight photodynamic therapy ($p<0.0001$). Histological evaluation of lesion clearance resulted in a similar outcome, with 72.5 percent versus 66.7 percent of lesions fully cleared after treatment with Ameluz® and Metvix®, respectively, in combination with daylight photodynamic therapy.

In the Phase III trial, the secondary endpoints for treatment with Ameluz® in combination with daylight photodynamic therapy compared favorably with Metvix® and showed equivalent or better clearance rates. After a single daylight photodynamic therapy with Ameluz®, 85 percent of lesions on the face were fully cleared, and 72 percent of the more difficult to treat lesions on the scalp were fully cleared. After a single daylight photodynamic therapy with Metvix®, 84 percent of the lesions on the face were fully cleared and 65 percent of the lesions on the scalp were fully cleared. The treatment of moderate actinic keratosis lesions resulted in full clearance of 76 percent of the lesions treated with Ameluz® in combination with daylight photodynamic therapy, compared to 73 percent cleared by treatment with Metvix® in combination with daylight photodynamic therapy. Mild actinic keratosis lesions had a clearance rate of 94 percent after treatment with Ameluz® in combination with daylight photodynamic therapy compared to 91 percent after treatment with Metvix® in combination with daylight photodynamic therapy. Lesions in patients with five or fewer actinic keratoses were fully cleared in 83 percent of cases after treatment with Ameluz® in combination with daylight photodynamic therapy and in 81 percent of cases after treatment with Metvix® in combination with daylight photodynamic therapy. In patients with more than 5 actinic keratoses, 75.2 percent of lesions were fully cleared after treatment with Ameluz® in combination with daylight photodynamic therapy, while 77.6 percent of lesions were fully cleared after treatment with Metvix® in combination with daylight photodynamic therapy.

In this Phase III trial, the most notable differences between Ameluz® and Metvix® clearance rates depended on the patient's age and the weather conditions. In patients younger than 65 years of age, the lesion clearance rate was 83 percent after treatment with Ameluz® in combination with daylight photodynamic therapy compared to a lesion clearance rate of 74 percent after treatment with Metvix® in combination with daylight photodynamic therapy. For patients treated with daylight photodynamic therapy during cloudy weather, the lesion clearance rate was 75 percent after treatment with Ameluz® compared to a lesion clearance rate of 66 percent after treatment with Metvix®. For patients treated with daylight photodynamic therapy during sunny weather, lesion clearance rates improved to 85 percent after treatment with Ameluz® and 83 percent after treatment with Metvix®. See *"Research and Development and Regulatory Affairs-Ameluz®-Actinic Keratosis with daylight photodynamic therapy"*.

There were no notable differences between Ameluz® and Metvix® in side effects in this Phase III trial. Furthermore, pain during the daylight photodynamic therapy illumination was rated by the patients on a scale of 0 (no pain) to 10 (very severe pain). The mean pain scale for Ameluz® was 1.2 and for Metvix® was 1.1.

We used these results to file, in the second quarter of 2017, for label extension in the EU for the treatment of actinic keratosis using Ameluz® in combination with daylight photodynamic therapy.

On January 23, 2018, we announced the twelve month follow up results from our Phase III trial of daylight PDT. The study evaluated the daylight PDT treatment of actinic keratosis with Ameluz® in direct comparison to Metvix®.

At the primary clinical endpoint, the paired comparison of complete removal of actinic keratosis lesions indicates that an average of 79.8% of lesions were no longer clinically visible three months following daylight PDT treatment with Ameluz®, as compared to 76.5% following Metvix® daylight PDT treatment. After twelve months, 19.9% of the lesions that had previously been completely removed with Ameluz® reappeared as compared to 31.6% of lesions with Metvix®.

The total removal of lesions on the face after 3 months was 85.2% with Ameluz® as compared to 84.2% with Metvix®. After 12 months, however, 25.0% of these lesions were again visible after daylight PDT treatment with Metvix® as compared to 20.1% after daylight PDT treatment with Ameluz®. Following actinic keratosis daylight PDT treatment with Ameluz®, a clinical clearing rate of 74.2% for lesions on the scalp was observed after 3 months, of which 23.4% recurred within 12 months. With daylight PDT treatment with Metvix®, this clearing rate was 67.5%, of which 43.7% recurred within twelve months.

In patients with mild actinic keratosis, 93.7% of all lesions were initially not visible following daylight PDT treatment with Ameluz®, and in patients with moderate actinic keratosis, 77.5% of actinic keratoses could no longer be diagnosed three months after treatment. After twelve months, these patients were diagnosed with 16.7% and 20.5%, respectively, of actinic keratoses not previously visible. With daylight PDT treatment with Metvix®, 91.2% of lesions in patients with mild actinic keratosis and 74.1% of lesions in patients with moderate actinic keratoses were not clinically detectable three months after treatment, while 17.5% and 34.3%, respectively, of these actinic keratoses, however, recurred after twelve months.

Weather conditions also affect the efficacy of Ameluz® in combination with daylight PDT. At temperatures up to 20°C and above 20°C, the healing rates for daylight PDT treatment with Ameluz® after three months were 80.1% and 79.5%, respectively, while recurrence rates were 21.5% at temperatures below 20°C and 18.6% at temperatures above 20°C. A significant difference was observed with daylight PDT treatment with Metvix®, for which clearing rates of 78.4% and 74.6% and recurrence rates of 26.8% and 36.1%, respectively, were observed.

Our Research and Development Programs

In addition to our approved products, we also have several research and development programs.

Current Clinical Trials for Ameluz®

Basal Cell Carcinoma

In August 2017, we agreed with the FDA on the requirements necessary to obtain approval for our application of Ameluz® PDT for the treatment of superficial basal cell carcinoma in the U.S. Under the agreed plan with the FDA, our application could be based on a single additional phase III placebo-controlled pivotal trial to be conducted in the U.S., in which Ameluz® PDT will be compared to placebo PDT, which can be conducted with relatively few patients minimizing both time and expense. We will be required to present a combined read-out of clinical and histological clearance. In December 2017, we filed an investigational new drug application with the FDA for our proposed phase III study protocol to evaluate Ameluz® PDT for the treatment of superficial basal cell carcinoma. This investigational new drug application enables us to initiate our phase III trial to be conducted in the U.S. to compare Ameluz® PDT to placebo PDT.

In connection with this application, we are planning a study with the following design. The primary objective will be to compare the efficacy of Ameluz® PDT with PDT using just the vehicle that is used to deliver the active ingredient in Ameluz®, in combination with BF-RhodoLED® illumination, in the treatment of superficial basal cell carcinoma. A randomized, double blind, vehicle-controlled multicenter phase III study will be performed to evaluate the safety and efficacy of Ameluz® in combination with BF-RhodoLED®. We plan to work with 10 to 11 clinical centers in the U.S., and enroll 120 patients in order to achieve an alpha level of $p<0.001$. Ameluz® and placebo will be applied at a 3:1 ratio. The primary efficacy variable is the composite clinical and histological complete clearance rate of the patient's main target lesion, assessed at the end of the clinical observation period, 12 weeks after the start of the first or second PDT cycle. Each PDT cycle will consist of two PDTs one to two weeks apart. Secondary objectives will include the evaluation of the safety and secondary efficacy parameters (including stratification according to lesion size, location, patient age and sex) related to Ameluz® and BF-RhodoLED®, also including clinical clearance of additional treated lesions on the same patients. The double blind clinical observation period for each patient will be up to 6.5 months (up to two weeks screening and pre-randomization period, and three or six months double blind part of the study) followed by a 2-year follow-up period after the start of the last PDT cycle. The recruitment phase is expected to start in the second quarter of 2018 and last for six to nine months. We may revise the design of this study based on our further discussions with the FDA.

Field-Directed Treatment of Actinic Keratosis on the Extremities and the Trunk

We have initiated a double blind, placebo controlled, intra-individual phase III trial at 4 clinical centers in Germany investigating the field-directed treatment of actinic keratosis on the extremities and the trunk with Ameluz®. The primary clinical endpoint of this trial is total patient clearance of all actinic keratosis. Secondary endpoints include total lesion clearance, other efficacy variables and safety endpoints. All endpoints will be stratified by lesion and patient subgroups, including lesion severity, lesion location and patient sex and age. The trial will seek to enroll 52 patients. As of November 2017, 6 potential patients had been screened, and 3 had been randomized. We originally planned to complete recruitment within 6 months, but initial randomization speed is lower than we expected. As a result, recruitment may not be complete until the third quarter of 2018. We are currently considering the addition of more clinical centers to accelerate recruitment. The clinical portion of the study is scheduled to end approximately 9 months after recruitment of the last patient. The clinical part of the study will be followed by a 1-year follow up, which will be reported separately.

Preparation of Additional Clinical Trials for Ameluz®

We have started preparation for the following phase III trials:

(i) Squamous cell carcinoma: We are planning a randomized, double-blind, multi-center phase III study to evaluate the safety and efficacy of Ameluz® versus placebo in the treatment of Bowen's disease (squamous cell carcinoma in situ) with photodynamic therapy when using the BF-RhodoLED® lamp. The study is expected to have an inter-individual design similar in treatment regime and patient number to our planned trial for the treatment of superficial basal cell carcinoma in the U.S., as described above under "— Current Clinical Trials for Ameluz — Basal Cell Carcinoma." The primary clinical endpoint will be total clearance of all of a patient's lesions. A 2-year follow-up is planned for this trial.

(ii) Larger treatment area: We are planning a randomized, double-blind, intra-individual, multi-center phase III study to evaluate the safety and efficacy of Ameluz® at an application thickness of 1 mm versus application of a thin layer of Ameluz® in the treatment of mild to severe actinic keratosis on the face and/or scalp with photodynamic therapy when using the BF-RhodoLED® lamp. The primary clinical endpoint will be the pairwise comparison of the percentage of cleared lesions on both sides of patients. The trial is expected to enroll 52 patients and will include a 1-year follow-up.

(iii) Acne: This phase III trial is in the early planning stages. No trial design has been defined, and we are currently collecting information of investigators with off-label experience in this indication.

These studies have been discussed with clinical centers in Germany, and study synopses have been written and agreed upon with investigators. We delayed these trials after our discussion with the FDA regarding our phase III trial to be conducted in conjunction with our application for approval of Ameluz® PDT to treat superficial basal cell carcinoma in the U.S. and during preparation of that trial. Once we have received the FDA's responses to our proposed basal cell carcinoma study protocol (which we expect to receive in the first quarter of 2018), we will determine the timeline and manner for continuing the phase III trials listed above, which will also depend on availability of sufficient funds.

BF-derm1

BF-derm1 is a drug candidate we have been developing in the form of a tablet for the treatment of severe, chronic, antihistamine-resistant urticaria, or hives. In its most severe and chronic form, this illness cannot be treated adequately using currently available drugs. The BF-derm1 tablet contains an active ingredient that covalently binds to histidine decarboxylase that we believe to be a novel mechanism of action to soothe chronic urticarial (hives). The project is currently not being actively developed. Since we expect to focus on further commercializing Ameluz® PDT in the next several years, we intend to seek a partner for the further development and funding of the Phase III costs and regulatory approval expenses relating to developing BF-derm1.

BF-1

Our BF-1 candidate involves a patented active ingredient that is intended to be used for the prophylactic treatment of patients who frequently suffer from migraines. We have conducted preclinical investigations concerning the tissue distribution, metabolism and toxicology of the substance. We have further conducted a Phase 0 trial involving humans in which the substance was orally administered to healthy subjects, demonstrating favorable bioavailability and pharmacokinetics of the active agent. Since these trials did not yield any critical findings, we believe further tests on humans should be conducted. Because this product candidate no longer fits our dermatological product focus, we are not actively developing it, but we intend to explore licensing opportunities.

Our Development Collaboration with Maruho

In July 2016, we entered into a collaboration and partnership agreement with Maruho, a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of our company. This agreement provides for the joint development of up to four branded generic pharmaceutical product candidates for the European market using our proprietary formulation technology. The current agreement covers the initial part of the collaboration, in which the feasibility of the product development is tested, which we expect to be completed by the end of the first quarter of 2018. Under this agreement, Maruho will bear all the costs connected with the development of these pharmaceutical product candidates (subject to a cap of €2.3 million).

If these product candidates progress to clinical development, the collaboration and partnership agreement provides that we will negotiate in good faith a new agreement with Maruho, without any obligation to enter into it. Maruho has not been granted any rights to our formulation technology in the first phase of the project. The collaboration and partnership agreement provides that, if the parties ultimately determine to enter into a new agreement, Biofrontera would be granted an exclusive sublicensable right to market the product in Europe. As the agreement is related to Europe only, there are currently no firm understandings with respect to other geographical regions. The collaboration and partnership agreement further specifies that all results, information and data developed during the term of such agreement will be the property of Maruho. Any intellectual property (such as trade secrets, copyrights, patents and other patent rights, trademarks and moral rights) developed during the term of such agreement will be the joint property of us and Maruho. We do not currently expect any such intellectual property to be developed during the term of the agreement. The collaboration and partnership agreement prohibits us from manufacturing, selling or otherwise

dealing in any products similar to and competitive with the product candidates developed under the agreement without Maruho's consent. Maruho has the right to terminate the collaboration and partnership agreement for any or no reason. We believe that these development projects will not yield any products for commercial launch before 2020.

Our Cosmetic Skin Care Products — Belixos®

Our Belixos® line is our over-the-counter line of skin care cosmetics products developed by us to help moisturize and soothe dry, itchy and irritated or sun-damaged skin. Our Belixos® cosmetic products are available for sale in Germany and certain other European countries at selected pharmacies, dermatological institutes, and through local Amazon websites. These cosmetic products are not currently available for sale in the U.S.

Sales, marketing and distribution

We are currently selling Ameluz® in the U.S., in 11 countries in Europe and in Israel.

Sales, marketing and distribution in Europe and Israel

With its central European approval, Ameluz® for the photodynamic therapy treatment of actinic keratosis and basal cell carcinoma, can be sold and distributed in all EU countries as well as in Norway, Iceland, and Liechtenstein. We have marketed and sold Ameluz® to dermatologists in Germany and, since March 2015, also in Spain through our own field sales force. We sell Ameluz® in other countries within the European Union, in Switzerland and in Israel through license partners.

In many European countries, the price and the medical reimbursement status have to be defined prior to market launch, which can be a lengthy process. To date, in Europe our company or our license partners have commenced sales in Germany, Spain, Austria, the Netherlands, Luxembourg, Belgium, Denmark, Sweden, Norway, the UK and Switzerland. The medication is available in these countries at a pharmacy retail price of between approximately €150 – €270 per 2 gram tube.

In the EU, distribution to public pharmacies generally takes place via pharmaceutical wholesalers, whereas hospital pharmacies may also be supplied directly. In addition to regular visits by our field sales force to dermatologists, we have since launch presented Ameluz® at major dermatological conferences both in Germany and in other European countries.

We have a license and supply agreement with Desitin Arzneimittel GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Denmark, Sweden, and Norway; and we have a license and supply agreement with Pelpharma Handels GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Austria.

We terminated a marketing collaboration agreement with Spirit Healthcare Limited to market Ameluz® in the UK and Ireland in July 2015.

On September 13, 2017, we terminated our license and supply agreement with BiPharma B.V., effective as of October 31, 2017.

We initially marketed and sold Ameluz® in Spain pursuant to an agreement with Allergan SA. After termination of this agreement, since March 2015 we have marketed and sold our products in Spain through our branch, Biofrontera Pharma GmbH sucursal en España.

We have a license and supply agreement with Louis Widmer SA in which we have granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Switzerland and Liechtenstein. We have a license and supply agreement with Perrigo Israel Agencies Ltd. in which we have granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Israel, the West Bank and the Gaza Strip. In these regions, the licensees were required to obtain independent regulatory approvals in collaboration with Biofrontera. In Switzerland, the regulatory approvals for Ameluz® and reimbursement were issued in December 2015 and commercial launch commenced in the beginning of 2016. In Israel, regulatory approval for Ameluz® was granted by the Israeli health agency in April 2016, reimbursement for treatment with Ameluz® of immunosuppressed patients was subsequently granted. We commenced sales in Israel in August 2017.

In these agreements with our sales partners the sales partners purchase Ameluz® from us at a price that is linked to their own anticipated sales price. Our share of the sales price varies, depending on any up front payment as well as market conditions within each country or region, ranging from 35% to 60% of net revenue.

Sales, marketing and distribution in the U.S.

We decided to market and sell Ameluz® in combination with our BF-RhodoLED® lamp for the treatment of actinic keratosis in the U.S. with our own sales force, and launched the commercialization of Ameluz® and our BF-RhodoLED® lamp for actinic keratosis in October 2016. Prior to launch, and with the help of a consulting firm specializing in market access, we analyzed the reimbursement mechanisms for photodynamic therapy in the U.S. healthcare system. Ameluz® is distributed as a "buy-and-bill" drug that is purchased by the dermatologist, rather than distribution through pharmacies.

Sales in the U.S. are made through our wholly-owned subsidiary, Biofrontera Inc., a Delaware corporation, which we established in March 2015. Based on our experience, we concluded that we could most effectively market our products in the U.S. by using our own sales force, which we can train to sell our drug Ameluz® in combination with the BF-RhodoLED® lamp and related procedure. During 2016, we hired 26 employees for our U.S. marketing and sales efforts, and we launched the commercialization of Ameluz® and BF-RhodoLED® lamp for actinic keratosis in the U.S. in October 2016. We have filled the key positions for our U.S. operations with qualified and experienced employees, and we expect to continue to fill positions and build our field sales force for the market. Several of our employees have joined us from competitors and, as a result, have specific experience with the photodynamic therapy market sector, including experience in selling medication as a "buy-and-bill" combination product. This is particularly helpful to us because, in the U.S., we sell Ameluz® in combination with our BF-RhodoLED® photodynamic therapy lamp.

Group structure

The Biofrontera group consists of a parent company, Biofrontera AG, and five wholly-owned subsidiaries, Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH and Biofrontera Inc. All companies are based at Hemmelrather Weg 201, 51377 Leverkusen, Germany, except Biofrontera Inc., which is based at 201 Edgewater Dr., Wakefield, Massachusetts 01880, U.S.

Biofrontera AG is a holding company that leads financing activities for the group. Its subsidiary Biofrontera Bioscience GmbH has responsibility for research and development activities for the group and holds our patents and approvals for Ameluz®. Pursuant to a license agreement with Biofrontera Bioscience GmbH, our subsidiary Biofrontera Pharma GmbH is responsible for the manufacturing and further licensing and marketing of our approved products.

We established Biofrontera Development GmbH and Biofrontera Neuroscience GmbH in December 2012 as additional wholly-owned subsidiaries of Biofrontera AG. The purpose of these subsidiaries is to pursue the further development of pipeline products that are not part of our core business. To this end, in December 2012, Biofrontera AG purchased two projects, BF-derm1 and BF-1, from Biofrontera Bioscience GmbH pursuant to purchase and transfer agreements, and then transferred the projects to the two new subsidiaries, with the contribution agreement being effective from December 31, 2012. The product candidate BF-derm1, which we intend to develop as a treatment for severe chronic urticarial (hives), is the responsibility of Biofrontera Development GmbH, while the product candidate BF-1, which we intend to develop as a prophylactic treatment for migraines, is the responsibility of Biofrontera Neuroscience GmbH. Although we are not developing these two product candidates at this time, if we choose to develop them in the future we believe this corporate structure will better allow us to finance such development.

We established Biofrontera Inc., a Delaware corporation, as a wholly-owned subsidiary, with a headquarters in Wakefield, Massachusetts to pursue our business and commercialization efforts in the U.S. under a license from our wholly-owned subsidiary Biofrontera Pharma GmbH.

Research and Development and Regulatory Affairs

Ameluz®

To date, we have focused our research and development efforts on Ameluz® in order to try to optimize its market potential. We have advanced our Ameluz® development program through additional clinical trials with the goal of extending approved indications and achieving better market positioning.

We have conducted three Phase III trials for Ameluz®. Two of them, trials CT002 and CT003, including 12-month follow-up studies, were used to apply for the centralized European marketing approval with the EMA. The third Phase III trial, CT007, was conducted to test Ameluz® for use in combination with our own light source, the BF-RhodoLED® lamp, as well as testing

for field cancerization therapy. In September 2010, we submitted the dossier for Ameluz® for the treatment of actinic keratosis to the EMA for centralized EU approval, and obtained marketing approval in December 2011. In July 2015, we filed an NDA with the FDA for Ameluz® and our BF-RhodoLED® lamp. In May 2016, we received approval from the FDA to market in the U.S. Ameluz® in combination with photodynamic therapy using our BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp.

The summary of clinical trials below discusses confidence intervals in relation to those trials. For clinical endpoints that are binary (i.e., the specified endpoint either is observed or not observed with respect to a patient), the result of a trial is a single number describing the percentage of patients reaching the endpoint. An example of this type of endpoint is total patient clearance, where patients are observed either to reach total clearance or not to do so. Total patient clearance is the primary endpoint in most of our trials. When the clinical endpoint is binary, there is no specific numerical result associated with individual patients, which does not give rise to a confidence interval for the results of the trial. In order to establish a confidence interval for such a trial, statisticians assume a binominal distribution, which forms the basis for the confidence interval. For a trial design where observation of the primary endpoint yields a quantifiable value for each patient, a confidence interval naturally arises from the results of the trial. For example, the primary clinical endpoint for our trial studying the safety and efficacy of Ameluz® in combination with daylight photodynamic therapy for the treatment of mild to moderate actinic keratosis was the pairwise comparison of the percentage of fully cleared lesions on each side of a patient's body. See "— Actinic Keratosis with photodynamic therapy" below for more information. In such a trial, a confidence interval can be defined based on the distribution of values among all patients. The p-value is then calculated based on the difference between the average results of the two clinical groups and the size of the confidence intervals. A p-value of <0.05 is considered a significant result; however, at this level the FDA requires two independent trials to verify the result. The FDA may waive the requirement of a second trial if the first trial was excellent in all respects, including a higher p-value.

Actinic Keratosis

We evaluated the efficacy and safety of Ameluz® in combination with photodynamic therapy to treat mild and moderate actinic keratosis lesions on the face/forehead and/or bald scalp, using a narrow spectrum (red light lamp) light source in three pivotal, randomized, multicenter clinical Phase 3 trials (Trials 1, 2, and 3). Trial 1 was double-blind with respect to vehicle and observer-blind regarding the active comparator arm. Trials 2 and 3 were vehicle-controlled and double-blind. Each of these clinical trials included a follow-up assessment after 6 and 12 months.

In these trials, 212 patients with 4 to 8 mild to moderate actinic keratosis lesions on the face/forehead and/or bald scalp were treated with Ameluz® and a narrow spectrum red light source. Patients ranged from 49 to 87 years of age (with a mean of 71 years), and 92% had Fitzpatrick skin type I (always burns, never tans), Fitzpatrick skin type II (usually burns, tans minimally), or Fitzpatrick skin type III (sometimes mild burn, tans uniformly). No patients had Fitzpatrick skin type V (very rarely burns, tans very easily) or VI (never burns, always tans). Approximately 86% of the patients were male, and all of the patients were Caucasian.

All sessions were comprised of lesion preparation to roughen the surface and remove crusts, application of Ameluz® with occlusion for 3 hours, and removal of the residual gel. Subsequently, the entire treatment area was given photodynamic therapy; it was illuminated with a narrow spectrum red light source, a lamp of either 630 nm or 633 nm, and a light dose of approximately 37 J/cm^2. In Trial 3, illumination of the treatment area was performed with our BF-RhodoLED® lamp, a narrow spectrum red light source, around 635 nm, and a light dose of approximately 37 J/cm^2.

In all trials, the lesions that were not completely cleared 12 weeks after the initial treatment were treated a second time with an identical regimen. In the trials, 42% (88/212) of the patients treated with Ameluz® needed a second photodynamic therapy.

The primary endpoint for all trials was complete clearance of all of a patient's lesions 12 weeks after the last photodynamic therapy.

Trial 1 was performed in Germany, Austria and Switzerland. Trials 2 and 3 were performed in Germany. The results of Trials 1, 2 and 3 as shown in the U.S. package inserts, or USPI, are presented in Table 2.

Table 2: Complete clearance 12 weeks after the last narrow spectrum photodynamic therapy in patients with actinic keratoses

	Narrow Spectrum photodynamic therapy	
	Ameluz®	Vehicle
Trial 1	106/125 (85%)	5/39 (13%)
Trial 2	27/32 (84%)*	2/16 (13%)*
Trial 3	50/55 (91%)	7/32 (22%)

* In the EU product information, the EMA reviewers considered one less patient as part of the ITT population, such that in the European product information the clearance rate of Trial 2 is shown as 87%. The FDA reviewers' position was that the ITT population includes all subjects randomized to treatment, whether or not they have had any post-baseline assessments, and included one more patient in the Ameluz® and the vehicle groups.

Patients who achieved complete clearance at 12 weeks after the last photodynamic therapy entered a 12-month follow-up period. In the three trials, patients who received Ameluz® with the narrow spectrum photodynamic therapy and achieved complete clearance 12 weeks after the last photodynamic therapy, had recurrence rates of 14%, 11%, and 25% in Trials 1, 2 and 3, respectively, at 6 months, and recurrence rates of 40%, 22%, and 37% in Trials 1, 2 and 3, respectively, at 12 months. Recurrence was defined as the percentage of patients with at least one recurrent lesion during the 6-month or 12-month follow up period in patients with completely cleared lesions 12 weeks after the last photodynamic therapy.

Trial 1

In Trial 1, a randomized, observer blinded clinical trial with 571 patients and a follow-up duration of 6 months and 12 months, photodynamic therapy with Ameluz® was tested for non-inferiority to Metvix and superiority over placebo. The red light sources were either narrow spectrum lamps (Aktilite CL 128 or Omnilux photodynamic therapy) or lamps with a broader and continuous light spectrum (Waldmann photodynamic therapy 1200 L, or Hydrosun Photodyn 505 or 750). The primary endpoint was complete patient clearance 12 weeks after the last photodynamic therapy on average with all lamp types. Ameluz® (78.2%) was significantly more effective than MAL (64.2%, [97.5%- confidence interval: 5.9; ∞], P<0.05) and placebo (17.1%, [95%-confidence interval: 51.2; 71.0], P<0.05). Total lesion clearance rates were higher for Ameluz® (90.4%) compared to MAL (83.2%) and placebo (37.1%). Clearance rates and tolerability were dependent on the illumination source. The following table presents the efficacy and the adverse reactions transient pain and erythema occurring at the application site during photodynamic therapy with different light sources.

Table 2a: Efficacy and adverse reactions (transient pain and erythema) occurring at the application site during photodynamic therapy with different light sources for the treatment of actinic keratosis

Light source	Medicinal product	Total patient clearance (%)	Application site erythema (%)			Application site pain (%)		
			mild	moderate	severe	mild	moderate	severe
Narrow	Ameluz®	85	13	43	35	12	33	46
Spectrum	MAL	68	18	43	29	12	33	48
Broad	Ameluz®	72	32	29	6	17	25	5
Spectrum	MAL	61	31	33	3	20	23	8

Clinical efficacy was re-assessed at follow-up visits 6 months and 12 months after the last photodynamic therapy. Recurrence rates after 12 months were slightly better for Ameluz® (41.6%, [95%-confidence interval: 34.4; 49.1]) as compared to MAL (44.8%, [95%-confidence interval: 36.8; 53.0]) and dependent on the light spectrum used for illumination, in favor of narrow spectrum lamps. The probability of a patient to be completely cleared 12 months after the last treatment was 53.1% or 47.2% for treatment with Ameluz® with narrow spectrum lamps or all lamp types, respectively, and 40.8% or 36.3% for treatment with MAL with narrow spectrum lamps or all lamp types, respectively. The probability of patients in the Ameluz® group to require only one treatment and remain completely cleared 12 months after the photodynamic therapy treatment was 32.3% that of patients in the MAL group and 22.4% on average with all lamps.

Trial 2

In Trial 2, Ameluz® was compared with placebo treatment in a randomized, double-blind clinical trial enrolling 122 patients. The red light source used was either a narrow spectrum, around 630 nm at a light dose of 37 J/cm2 (Aktilite CL 128), or a broader and continuous spectrum, in a range between 570 and 670 nm, at a light dose of 170 J/cm2 (Photodyn 750). The primary endpoint was complete patient clearance 12 weeks after the last photodynamic therapy. Photodynamic therapy with Ameluz® (66.3%) was significantly more effective than with placebo (12.5%, $p < 0.0001$). Total lesion clearance was higher for Ameluz® (81.1%) compared to placebo (20.9%). Clearance rates and tolerability were dependent on the illumination source, with the narrow spectrum light source being more effective. Clinical efficacy was maintained during the follow-up periods of 6 months and 12 months after the last photodynamic therapy. The probability of a patient being completely cleared 12 months after the last photodynamic therapy was 67.5% or 46.8% for treatment with Ameluz® with narrow spectrum lamps or all lamp types, respectively.

Table 2b: Efficacy and adverse reactions (transient pain and erythema) occurring at the application site during photodynamic therapy with different light sources for the treatment of actinic keratosis

Light source	Medicinal product	Total patient clearance (%)	Application site erythema (%)			Application site pain (%)		
			mild	moderate	severe	mild	moderate	severe
Narrow Spectrum	Ameluz®	84 (87 in EU product information)*	26	67	7	30	35	16
Broad Spectrum	Ameluz®	53	47	19	0	35	14	0

* See footnote to Table 2 above.

Trial 3

In Trial 3, one entire tube of Ameluz® was used for each photodynamic therapy session on skin areas with field cancerization containing several actinic keratosis lesions. A total of 87 patients were treated with one PDT using Ameluz® or vehicle, which was repeated if residual lesions remained. Illumination was performed with our BF-RhodoLED® lamp. Complete patient clearance 12 weeks after the last photodynamic therapy was 91% in the Ameluz® group and 22% in the vehicle group, respectively ($p < 0.0001$). The clearance rate for patients with lesions on the face was 97% while the clearance rate for patients with lesions on the scalp was 82%. Lesion clearance rates were 94% 12 weeks after the last photodynamic therapy, of which 6% were recurrent at 6 months after the last photodynamic therapy, and an additional 3% (a total of 9%) were recurrent at 12 months after the last photodynamic therapy. The clearance rate for patients with mild lesions only was 99%, while the clearance rate for patients with moderate lesions was 92%.

In this Trial, by testing larger skin areas, we could also investigate the effect of photodynamic therapy on skin impairment. The proportion of patients with impaired skin surface, including rough, dry and scaly skin, decreased from 85% to 28% within 12 months after treatment with Ameluz®. Patients with skin hyperpigmentation or hypopigmentation decreased from 59% to 24% and from 46% to 11%, respectively. The proportion of patients with mottled pigmentation, mixed hyperpigmentation and hypopigmentation, decreased from 48% to 18%. Before treatment, 26% of the patients had mild scarring, this decreased to 7% of patients after treatment. Atrophic skin was diagnosed in 31% of patients before treatment, but only in 4% of patients 12 months after treatment.

Table 3: Skin quality parameters in the treated area during 12- month follow-up

		Ameluz®		Vehicle	
Type of skin impairment	**Severity**	**Before photodynamic therapy**	**12 months after photodynamic therapy**	**Before photodynamic therapy**	**12 months after photodynamic therapy**
Roughness/ dryness/ scaliness	None	15%	72%	11%	58%
	Mild	50%	26%	56%	35%
	Moderate/severe	35%	2%	33%	8%
Hyper-pigmentation	None	41%	76%	30%	62%
	Mild	52%	24%	59%	35%
	Moderate/severe	7%	0%	11%	4%
Hypo-pigmentation	None	54%	89%	52%	69%
	Mild	43%	11%	44%	27%
	Moderate/severe	4%	0%	4%	4%
Mottled or irregular pigmentation	None	52%	82%	48%	73%
	Mild	44%	17%	41%	15%
	Moderate/severe	4%	2%	11%	12%
Scarring	None	74%	93%	74%	89%
	Mild	22%	7%	22%	12%
	Moderate/severe	4%	0%	4%	0%
Atrophy	None	69%	96%	70%	92%
	Mild	30%	4%	30%	8%
	Moderate/severe	2%	0%	0%	0%

Basal Cell Carcinoma

We performed an additional Phase III clinical trial in Germany and the UK for Ameluz® to test the efficacy of treating basal cell carcinoma with Ameluz® and photodynamic therapy. After completion of the trial, patients entered a 5-year follow-up phase.

In this Phase III trial, efficacy and safety of Ameluz® for the treatment of non-aggressive basal cell carcinoma with a thickness of up to 2mm was evaluated in 281 patients. A total of 138 patients were treated with Ameluz® in combination with photodynamic therapy. After excluding drop-outs and patients with major protocol violations, the per-protocol set comprised 121 patients with 148 lesions. All patients had 1 to 3 basal cell carcinoma lesions on the face/forehead, bald scalp, extremities and/or neck/trunk. In this trial, photodynamic therapy with Ameluz® was tested for non-inferiority as compared to photodynamic therapy with a cream (Metvix®) containing 16% methyl-aminolevulinate (MAL, methyl-[5-amino-4-oxopentanoate]). Our BF-RhodoLED® lamp was used as the red light source, which provided a narrow spectrum around 635 nm at a light dose of 37 J/cm^2. The primary endpoint was complete patient clearance 12 weeks after the last photodynamic therapy.

The complete patient clearance rate for photodynamic therapy with Ameluz® was 93.4%, compared to 91.8% for the photodynamic therapy with MAL (Metvix®). The trial demonstrated the non-inferiority of Ameluz® compared to MAL (Metvix®) cream [97.5% -confidence interval -6.5]. Of the basal cell carcinoma lesions, 94.6% were cleared by treating with photodynamic therapy and Ameluz®, whereas 92.9% were cleared by treating with photodynamic therapy and MAL (Metvix®). For nodular basal cell carcinoma, 89.3% of the lesions were cleared with photodynamic therapy and Ameluz®, whereas 78.6% of the lesions were cleared with photodynamic therapy and MAL. Adverse events and tolerability were comparable for both treatments.

Clinical efficacy was re-assessed at follow-up visits 6 months and 12 months after the last photodynamic therapy. Lesion recurrence rates 6 months and 12 months after the last photodynamic therapy were 2.9% and 6.7%, respectively, for Ameluz®, and 4.3% and 8.2%, respectively, for MAL (Metvix®). For this Trial, patients will be assessed up to five years after the last photodynamic therapy.

Table 4: Efficacy of photodynamic therapy for the treatment of basal cell carcinoma for all patients and selected subgroups

	Ameluz® Patient number number (%)	Ameluz® Full patient clearance number (%)	Ameluz® Full lesion clearance number (%)	MAL Patient number number (%)	MAL Full patient clearance number (%)	MAL Full lesion clearance number (%)
Total	121	113 (93.4)	140 (94.6)	110	101 (91.8)	118 (92.9)
Subgroups:						
Patients with more than 1 basal cell carcinoma	23 (19.0)	23/23 (100.0)	n.a.	16 (14.5)	14/16 (87.5)	n.a.
Superficial (only)	95 (78.5)	90/95 (94.7)	114/119 (95.8)	83 (75.5)	80/83 (96.4)	95/98 (96.9)
Nodular (only)	21 (17.4)	18/21 (85.7)	25/28 (89.3)	21 (19.1)	16/21 (76.2)	22/28 (78.6)
Others (including mixed [s/n] basal cell carcinomas)	5 (4.1)	5/5 (100.0)	1/1 (100.0)	6 (5.5)	5/6 (83.3)	1/1 (100.0)
Thickness >1mm	n.a.	n.a.	8/11 (72.7)	n.a.	n.a.	8/12 (66.7)
basal cell carcinoma on the head (only)	13 (10.7)	10/13 (76.9)	14/17 (82.4)	14 (12.7)	10/14 (71.4)	12/17 (70.6)
basal cell carcinoma on the trunk (only)	77 (63.6)	75/77 (97.4)	95/97 (97.9)	73 (66.4)	70/73 (95.9)	84/87 (96.6)

Patient distribution in the subgroups was similar for both products and represents the distribution in the general population, where more than 70% of basal cell carcinomas are located in the head/trunk region. Basal cell carcinomas located in this region mainly belong to the superficial subtype. In conclusion, even though subgroup sizes are too small to draw significant conclusions on individual groups, the distribution of the two products to the relevant subgroups is very similar. Thus, it seems not plausible that an imbalance in subgroups could negatively impact the non-inferiority claim of the primary study endpoint or the general trends observed across all subgroups.

Actinic Keratosis with daylight photodynamic therapy

Between June and September 2016, we conducted a Phase III trial in Germany and Spain to evaluate the safety and efficacy of Ameluz® in combination with daylight photodynamic therapy for the treatment of mild to moderate actinic keratosis. In the trial, Ameluz® was compared to Metvix®, which has marketing approval for daylight photodynamic therapy treatment of actinic keratosis in some European countries. The intra-individual, randomized, observer-blinded, multi-center study took place at 7 sites in Spain and Germany, and evaluated a total of 52 patients, each with 3 to 9 mild to moderate actinic keratosis lesions in each of two comparable treatment areas on the face and/or scalp. For an intra-patient comparison of the treatments, each patient received daylight photodynamic therapy treatment with Ameluz®, on one side, and Metvix®, on the other side, of the face or scalp.

After a single daylight photodynamic therapy with Ameluz®, 79% of the actinic keratosis lesions were cleared, compared to 75% with Metvix® (intent-to-treat population), demonstrating the non-inferiority of Ameluz® ($p < 0.0001$). Subgroup analyses shown in the table below generally showed higher clearance rates for Ameluz® versus Metvix®.

Table 5: Total lesion clearance 12 weeks after a single photodynamic therapy with Ameluz® or Metvix®

	Ameluz® (%)	Metvix® (%)
All lesions	79	75
Age < 65	83	74
Age >65 to < 84	78	75
Face	85	84
Scalp	72	65
Mild	94	91
Moderate	76	73
≤ 5 lesions per side	83	81
> 5 lesions per side	77	72
Histologically controlled clearance	73	67
Expression of the tumor marker p53	34	41

This Phase III trial will be followed by assessments of lesion recurrence 6 months and 12 months after the treatment with daylight photodynamic therapy.

Intellectual Property

In the ordinary course of our business, we seek to protect commercially important products, product candidates and technology through a combination of patents, trademarks, processes, proprietary know-how and information, regulatory exclusivity and contractual restrictions on disclosure in the U.S., EU and/or other foreign markets, including filing of applications for German utility models. In addition, we rely upon trade secrets and contractual arrangements to protect proprietary information that may be important to the development and operation of our business and intend to file for, prosecute, maintain or license the intellectual property that we believe is relevant to the strategic needs of our business.

Trademarks

We have filed for and received trademark protection for Biofrontera® (as word marks), several Biofrontera® figurative marks, the figurative mark Natural heritage with herbal biocolloids® in two embodiments as well as for the Ameluz®, Belixos®, BF-RhodoLED® and Rhodoled® word marks in the EU, the U.S. and/or certain other jurisdictions. The word marks BF-200 ALA® and Nanoxosan® are registered in Austria, Germany, and Switzerland. The word marks Lumixeen® and Dynala® are registered in Germany and the word mark Gefühlt mir® is registered in the EU and in Switzerland.

A Biofrontera® word mark is registered in Armenia, Australia, China, the EU, Iran, Japan, Norway, Russia, Singapore, South Korea, Switzerland, Syria, and the U.S. with an International Registration. Two national Biofrontera® word marks are registered in Chile, for the classes 1 and 5, respectively.

A Biofrontera® figurative mark is registered in Armenia, Australia, China, the EU, Germany, Iran, Japan, Norway, Russia, South Korea, Singapore, Switzerland, Syria and the U.S. with an International Registration. Another Biofrontera® combined mark is registered in Switzerland and a third Biofrontera® figurative mark is registered in the EU.

An Ameluz® word mark is registered in Armenia, Australia, China, the EU, Iran, Liechtenstein, Norway, Russia, Singapore, South Korea, Switzerland, Syria, and the U.S. with an International Registration. Other national Ameluz® word marks are registered in Germany and Israel. Another national Ameluz® word mark is pending in Canada.

A Belixos® word mark is registered in Class 3 in Algerian, Armenia, Australia, Bahrain, China, the EU, Iran, Japan, Morocco, Norway, Russia, Singapore, South Korea, Sudan, Sultan Oman, Switzerland, Syria, and the U.S. with an International Registration. Other national Belixos® word marks are registered in Brazil, Germany, Kuwait, Lebanon, Qatar, Saudi Arabia, Tunisia, the United Arab Emirates, and Yemen. Other Belixos® word marks are pending in Iraq and Libya. A Belixos® word mark is registered in Class 5 in Armenia, Australia, China, the EU, Iran, Japan, Norway, Russia, Singapore, South Korea, Switzerland, Syria and the U.S. with an International Registration. Other national Belixos® word marks are registered in Canada, Germany, and Israel.

A BF-Rhodoled® word mark is registered in Armenia, Australia, China, the EU, Iran, Japan, Norway, Liechtenstein, Russia, Singapore, South Korea, Switzerland, Syria and the U.S. with an International Registration. Other national BF-Rhodoled® word marks are registered in Canada, Germany, and Israel.

A Rhodoled® word mark is registered in Armenia, Australia, China, the EU, Iran, Japan, Norway, Russia, Singapore, South Korea, Switzerland, Syria, and the U.S. with an International Registration. Other national Rhodoled® word marks are registered in Canada, Germany, and Israel.

Patents

We have filed for and received issued patents in various jurisdictions for our technologies relating to our nanoemulsion, nanoemulsions with 5-aminolevulinic acid, and derivatives of 4-(Thio- or Seleno-xanthene-9-ylidine)-Piperidine or Acridine and its use as a selective 5-HT2B receptor.

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 Argentina, Brazil, Paraguay, the United Arab Emirates, Uruguay, and the U.S.

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.

We have been issued composition of matter patents for our technology relating to derivatives of 4-(Thio- or Sele no-xanthene-9-ylidine)-Piperidine or Acridine and its use as a selective 5-HT2B 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.

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. Two U.S. patents have been granted, expiring in January, 2022 and January, 2034.

We have additionally filed a German utility model for our technology relating to pharmaceutical and/or cosmetic compositions for treating skin, which provides a type of intellectual property protection for a period of eight years after filing of the application, so that it will expire on April 9, 2018.

The composition of matter patent family that protects the combination of nanoemulsions with aminolevulinic acid hydrochloride, an active ingredient in Ameluz®, against copying by competitors will expire on November 12, 2019. This patent family includes U.S. Patent No. 6,559,183, which is listed in the U.S. Food and Drug Administration Orange Book and identified as covering nanoemulsions combined with aminolevulinic acid hydrochloride, the active ingredient in Ameluz®. 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, that may deter potential generic competitors. Nonetheless, if we are unable to prevent manufacture and sales of the active ingredient in Ameluz® in combination with our specific nanoemulsion, we may not be able to maintain a competitive advantage in our market, which could materially adversely affect our business, results of operations and financial condition.

To our knowledge, there are no contested proceedings or third party claims relating to any of our patent applications. We are not aware of any impediments to the granting of patent or other intellectual property protection for the various technologies for which we have made filings or otherwise applied for protection. However, these applications may never issue as patents, and our issued patents, and any others that may issue in the future, may be challenged, invalidated, rendered unenforceable, or circumvented by third parties.

Trade Secrets and Proprietary Information

Trade secrets play an important role in protecting our products, product candidates and technology and provide protection beyond patents, trademarks, processes, proprietary know-how and information, regulatory exclusivity and contractual restrictions on disclosure in the U.S., EU and/or other foreign markets. The scale-up and commercial manufacture of our products involve processes and in-process and release analytical techniques that we believe are unique to us. Accordingly, we seek to protect our proprietary information by requiring our employees, consultants and other advisors to execute proprietary information and confidentiality agreements upon the commencement of their employment or engagement. These agreements generally provide that all confidential information developed or made known during the course of the relationship with us be kept confidential and not be disclosed to third parties except in specific circumstances. In the case of our employees, the agreements also typically provide that all inventions resulting from work performed for us, utilizing our property or relating to our business and conceived or completed during employment shall be our exclusive property to the extent permitted by law. Where appropriate, agreements we obtain with our consultants also typically contain similar assignment of invention obligations. Further, we require confidentiality agreements from entities that receive our confidential data or materials.

Competition

There are many pharmaceutical companies that compete with us in the field of dermatology, including in the photodynamic therapy market. The pharmaceutical and biotechnology industry is characterized by intense competition and rapid and significant innovation and change. Our competitors may be able to develop other drugs or products that are able to achieve similar or better results than our product candidates or marketed products. Several of these companies have significantly greater experience than we do in developing products, conducting preclinical and clinical testing, and obtaining regulatory approvals to commercialize products for health care. Our competitors include organizations such as major multinational pharmaceutical companies, established biotechnology companies, specialty pharmaceutical companies and generic drug companies. Many of our competitors have greater financial and other resources than we have, such as more commercial resources, larger research and development staffs, and more extensive marketing and manufacturing facilities and organizations. Our competitors may succeed in developing, acquiring or licensing on an exclusive basis technologies and products that are more effective or less costly than Ameluz® or any other products that we sell or are developing or that we may develop, which could render our products obsolete and noncompetitive. Our competitiveness may also be affected by our ability to manufacture and commercialize our products and by the level of reimbursement for the cost of our drug and treatment by third party payors, such as insurance companies, health maintenance organizations and government agencies.

Competition in the EU

There are a few other companies that are selling photodynamic therapy agents other than Ameluz® for the treatment of actinic keratoses and certain other skin conditions. Our major competitor in the EU is methyl aminolaevulinate (160mg/g) (MAL) Metvix®/Metvixia®, a drug owned and distributed by Galderma S.A., which is used in photodynamic therapy with red light. Its approved indications include: the treatment of thin or non-hyperkeratotic and non-pigmented actinic keratoses on the face and scalp when other therapies are considered less appropriate; the treatment of superficial and/or nodular basal cell carcinoma unsuitable for other available therapies due to possible treatment related morbidity and poor cosmetic outcome, such as lesions on the mid-face or ears, lesions on severely sun damaged skin, large lesions, or recurrent lesions; and the treatment of squamous cell carcinoma *in situ* (Bowen´s disease) when surgical excision is considered less appropriate. Metvix is indicated in adults above 18 years of age. We believe that, historically, we lost sales of Ameluz® in the EU to Metvix because Metvix was approved in the EU to treat both actinic keratosis and basal cell carcinoma. Since obtaining our indication extension to treat basal cell carcinoma in the EU in 2016, we expect improved sales of Ameluz® in the EU because of our product's generally higher clearance rates, especially for thicker and nodular carcinomas, as demonstrated in our clinical trials.

Metvix® has also recently been approved in the EU for use in daylight photodynamic therapy for which it is sold by Galderma under the brand name Luxerm® in Germany and Luxera® in other European countries. This gives that drug a competitive advantage compared to Ameluz®, as Ameluz® is not yet approved to be used in daylight photodynamic therapy to treat actinic keratosis. We have applied to extend our indication for Ameluz® to daylight photodynamic therapy in the EU. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. If this extension is approved, we believe we should better compete with Metvix® and Luxerm®, but there can be no assurance that we will do so.

A patch containing 5-ALA (Alacare®), which is owned and sold by Galderma, is approved for the treatment of mild actinic keratosis in a single treatment session in combination with red light without pretreatment of the lesion.

In addition, we also compete with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions, including: Efudex® (5-fluorouracil), sold by Valeant; Solaraze® (diclofenac sodium), sold by Almirall; ALDARA® and Zyclara® (imiquimod), sold by Meda Pharma; Picato® (Ingenolmebutat), sold by LEO Pharma; and Actikerall® (5-fluorouracil and salicylic acid) sold by Almirall.

The relative benefits of different treatment options for mild to moderate actinic keratosis has been analyzed in a European meta-analysis (Vegter & Tolley 2014). The objective of this study was to compare different treatments for mild to moderate actinic keratosis on the face and scalp available in clinical practice in Europe. A network meta-analysis was performed to compare different treatment modalities by combining a network of both head to head and indirect comparative evidence. Study selection was based on the Cochrane systematic search and review for actinic keratosis treatments available in Europe. In total, 25 randomized, controlled studies (5,562 patients) with the primary outcome measure "complete patient clearance" were considered and included. For PDT, only studies with LED lamps were included. Although this study was a meta-analysis of placebo-controlled trials, rather than a head-to-head comparison of treatments, we believe this data shows significant support for Ameluz PDT as the best available treatment option for mild to moderate actinic keratosis of the face and scalp.

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

In addition, we expect to extend our indications in the EU for Ameluz® to include daylight photodynamic therapy in the first half of 2018 to better compete with Metvix® and Luxerm®. In January 2018, the Committee for Medicinal Products for Human Use of the EMA issued a positive opinion regarding our submission for label extension for the use of Ameluz® in combination with daylight photodynamic therapy. Based on this positive opinion, we anticipate formal approval by the European Commission in the coming weeks. Approval for daylight photodynamic therapy would also allow us to more effectively compete with other topical prescription drugs, which are widely used in Europe. If the indication is not so extended, then it will be difficult for Ameluz® to effectively compete with Metvix® and other drugs in the EU.

Competition in the U.S.

In the U.S., we believe dermatologists have favored cryotherapy to treat actinic keratosis because of a favorable reimbursement regime, which may be under review by the CMS. Although the photodynamic therapy market in the U.S. for actinic keratosis treatment only represented an estimated three percent of the actinic keratosis treatments during 2016, the market has grown rapidly in recent years (as evidenced by the sales of Levulan through 2012 reported by Dusa Pharmaceuticals and Sun Pharma in their annual reports) and represented sales of over $136 million in 2016. In addition, we believe that there is treatment guideline pressure towards field-directed therapy (as opposed to single lesion therapy), which may also help support sales of photodynamic therapy treatments.

In the U.S., our treatment of actinic keratosis with Ameluz® in combination with our BF-RhodoLED® red light device competes with Levulan®, an approved photodynamic therapy drug for actinic keratosis used in combination with a blue light lamp. The Ameluz® approval covers both lesion-directed and field-directed treatment, while the Levulan® approval is restricted to lesion-directed treatment. In addition, we also compete with a number of non-photodynamic therapy products for the treatment of actinic keratoses and certain other skin conditions similar to those listed above under "*—Competition in the EU*", as well as cryotherapy with liquid nitrogen.

Because our approval for Ameluz® in the U.S. covers not only lesion-directed treatment, but also field-directed therapy, we believe our approval provides us with the ability to provide broader treatment possibilities compared to certain competitor products.

In addition, in August 2017, we agreed with the FDA on the requirements for the potential approval of our application to extend Ameluz® PDT for the treatment of superficial basal cell carcinoma in the U.S. Under the agreed plan with FDA, our application could be based on a single additional phase III placebo-controlled pivotal trial to be conducted in the U.S., in which Ameluz® PDT will be compared to placebo PDT, which can be conducted with relatively few patients minimizing both time and cost. We will be required to present a combined read-out of clinical and histological clearance. We believe this agreed plan represents a significant milestone that should allow us to reduce cost and to achieve approval more quickly than if we had been required to undertake additional or more complex clinical trials. If the FDA approves this application, we believe this will further enhance our competitive advantage in the U.S.

Competitive Outlook

We expect that comparisons of the properties of various photosensitizing photodynamic therapy drugs will also highlight important competitive issues. We expect that our ability to compete with other photodynamic therapy companies will be based upon such factors as:

- the efficacy from treatment with Ameluz® photodynamic therapy as compared to other treatment options;
- the lower recurrence rates from treatment with Ameluz® photodynamic therapy as compared to other treatment options;
- the ease of administration of our photodynamic therapy, including with respect to the ease of application of our formulation and the duration of illumination time;
- the ability of our drug to provide both lesion- and field-directed treatment;
- the ability of our drug to treat different indications;
- the cost of our drug and the type and cost of our photodynamic therapy light device;
- the number of required doses; and
- the cosmetic outcome and improvement of skin impairment.

We expect any products that we develop and commercialize to compete on the basis of, among other things, efficacy, safety, cosmetic outcome, convenience of administration and delivery, price and the availability of reimbursement from government and other third party payor. We also expect to face competition in our efforts to identify appropriate collaborators or partners to help commercialize our product candidates in our target commercial markets. New drugs or future developments in photodynamic therapy, laser products or other drug technologies may provide therapeutic or cost advantages for competitive products. No assurance can be given that developments by other parties will not render our existing products or product candidates uncompetitive or obsolete.

Commercial Partners and Agreements

In July 2016, we entered into a collaboration and partnership agreement with Maruho, a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of our company. See "Business — Our Research and Development Plans — Our Development Collaboration with Maruho" for more information.

We have a license and supply agreement with Desitin Arzneimittel GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Denmark, Sweden, and Norway; and we have a license and supply agreement with Pelpharma Handels GmbH to market and sell Ameluz® and the BF-RhodoLED lamp in Austria.

We terminated a marketing collaboration agreement with Spirit Healthcare Limited to market and sell Ameluz® in the UK and Ireland in July 2015, and we are currently preparing to commence our own sales activities in the UK.

On September 13, 2017, we terminated our license and supply agreement with BiPharma B.V., effective as of October 31, 2017.

We initially marketed and sold Ameluz® in Spain pursuant to an agreement with Allergan SA. After termination of this agreement, since March 2015 we have marketed and sold our products in Spain through our branch, Biofrontera Pharma GmbH sucursal en España.

We have a license and supply agreement with Louis Widmer SA in which we have granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Switzerland and Liechtenstein. We have a license and supply agreement with Perrigo Israel Agencies Ltd. in which we have granted a distribution license for Ameluz® and the BF-RhodoLED lamp in Israel, the West Bank and the Gaza Strip. In these regions, the licensees were required to obtain independent regulatory approvals in collaboration with Biofrontera. In Switzerland, the regulatory approvals for Ameluz® and reimbursement were issued in December 2015 and commercial launch commenced in the beginning of 2016. In Israel, regulatory approval for Ameluz® was granted by the Israeli health agency in April 2016, reimbursement for treatment with Ameluz® of immunosuppressed patients was subsequently granted. We commenced sales in Israel in August 2017.

In these agreements with our sales partners, we often (but not always) receive an initial up-front payment. The sales partners purchase Ameluz® from us at a price that is linked to their own anticipated sales price. Our share of the sales price varies, depending on the up-front payment as well as market conditions within each country or region, ranging from 35% to 60% of net revenue.

We depend on a single unaffiliated contract manufacturer, Frike Group, located in Switzerland to manufacture Ameluz® for us. Pursuant to this contract, Frike Group produces, upon request by us, the volumes of Ameluz® that we require according to pre-agreed specifications. Our contract with Frike Group has an initial term through October 2022 and thereafter may be terminated by either party at any time upon 12 months' prior notice.

We rely on two suppliers to obtain 5-aminolevulinic acid (5-ALA), the active pharmaceutical ingredient contained in Ameluz®. Hapila GmbH ("Hapila"), located in Germany, manufactures 5-ALA directly for us. Midas Pharma GmbH ("Midas"), located in Germany, relies on two sub-contractors, located in India and Italy, to manufacture the 5-ALA that it supplies to us. 5-ALA provided by Hapila is approved for use in Ameluz® in the EU, Switzerland and Israel. 5-ALA provided by Midas is approved for use in the U.S. and the EU. Pursuant to our contracts with Hapila and Midas, those entities supply, upon request by us, the volumes of 5-ALA that we require according to pre-agreed specifications. Our contract with Hapila has an initial term through May 2020. Thereafter, the contract with Hapila automatically renews for one-year periods, unless it is terminated by us upon 6 months' prior notice. Our contract with Midas has an initial term through December 2021. Thereafter, the contract with Midas automatically renews for one-year periods, unless it is terminated by either party by notice to the other party given 6 months prior to the end of the initial contract term or renewal period, as applicable.

Legal Proceedings

In June 2017, one of our major shareholders, Deutsche Balaton AG, brought a lawsuit against our company in the Cologne District Court for rescission and nullity against certain resolutions passed by our shareholders at our company's annual general meeting of shareholders on May 24, 2017 relating to our authorized capital and to the discharge of our supervisory board members under German law (a corporate formality without significant legal effect). We believe this lawsuit is without merit and we are vigorously defending our interests. On December 1, 2017, the Cologne District Court ruled that the lawsuit was dismissed; however, this decision is not yet legally binding, as German law allows for a claimant to file an appeal within one month after it has been formally served with the decision. On December 21, 2017, Deutsche Balaton AG appealed this ruling. Based on the proceedings as of the date of this prospectus and our analysis of applicable German law, we expect that this lawsuit will be resolved favorably for our company; however, even if this lawsuit proceeds and if the court ultimately issues an adverse judgment against us, we do not expect such an outcome to have a material adverse effect on our company or on our ability to complete this offering or the German preemptive rights offering.

On January 23, 2018, we were informed by the Cologne District Court that Deutsche Balaton AG has initiated a proceeding pursuant to article 142 para 2 AktG (German Stock Corporation Act) to appoint a special auditor. Under German law, the subject of a special audit can only be specific business management measures and determinations if the management has committed a breach of duty in this regard. The subject of this special audit would be the collaboration and partnership agreement between us and Maruho entered into in July 2016. Our annual shareholders meeting held in May 2017 had already rejected a similar action for a special audit brought forward at that meeting. The court may only appoint the special auditor if, according to the court's assessment, facts exist that justify the suspicion that dishonesty or gross violations of the law or of our articles of association have occurred. If any conclusions are reached by a special auditor, they primarily may be the legal basis for a liability of management with respect to our company. Under certain circumstances the special auditor may also inquire into the liability of the company with respect to third parties. Regarding the present request for a special auditor, we have no indication of any breach of duty by the management board and, therefore, although there can be no assurance, we expect no material impact on our business or financial position in connection with such request, whether or not it is granted by the court.

Facilities

Our global corporate headquarters is located in Leverkusen, Germany. We lease approximately 37,000 square feet at this facility, in which we house our corporate offices and a manufacturing facility under an operating lease expiring on June 15, 2019. This lease extends automatically on December 31 of each year thereafter for one additional year unless terminated by either party upon twelve months' prior notice. Our U.S. headquarters is located in Wakefield, Massachusetts. We lease approximately 5,300 square feet at this facility, in which we house our U.S. corporate offices under a sub-lease agreement expiring on June 15, 2019. We have the option to extend this sublease for one additional five-year term. We believe our existing facilities are sufficient to meet our needs for the foreseeable future and that, if needed, additional space will be available to us in the near term at a reasonable cost.

Employees

As of September 30, 2017, we had 125 employees worldwide, 114 of whom were full-time, 22 of whom hold Ph.D. or M.D. degrees, 14 of whom were engaged directly or indirectly in production, two of whom were engaged in research and development activities, ten of whom were engaged in clinical and regulatory activities, 53 of whom were engaged in marketing and sales activities, and 49 of whom were engaged in management, business development or marketing, finance, human resources or administrative support. Of our 125 total employees, 70 work in Germany, 49 work in the U.S., and 6 work in Spain, as compared to 94 total employees as of December 31, 2016, 58 total employees as of December 31, 2015 and 46 total employees as of December 31, 2014. None of our employees is subject to a collective bargaining agreement. We consider our relationship with our employees to be good.

Government Regulation

Regulation by governmental authorities in the U.S. and other countries is a significant factor in the development, manufacture and marketing of pharmaceutical products and in ongoing research and development activities. All of our products will require regulatory approval by governmental agencies prior to commercialization. In particular, pharmaceuticals are subject to rigorous preclinical testing and clinical trials and other pre-marketing approval requirements by the FDA and regulatory authorities in other countries.

Government authorities in the U.S. (at the federal, state and local level) and in other countries extensively regulate, among other things, the research, development, testing, manufacturing, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of drug and medical device products such as those we are developing. Ameluz® and our medical device products are only marketed in certain countries and our products and product candidates must be approved or cleared by the FDA before they may be legally marketed in the U.S. and by the appropriate foreign regulatory agency before they may be legally marketed in foreign countries.

U.S. Drug Development and Review

Drug Development Process

Post-Approval Requirements for Approved Drugs

Any drug products for which we receive FDA approvals are subject to continuing regulation by the FDA, including, among other things, record-keeping requirements, reporting of adverse experiences with the product, providing the FDA with updated safety and efficacy information, product sampling and distribution requirements, and complying with FDA promotion and advertising requirements, which include, among other requirements, standards for direct-to-consumer advertising, restrictions on promoting drugs for uses or in patient populations that are not described in the drug's approved labeling (known as "off-label use"), limitations on industry sponsored scientific and educational activities, and requirements for promotional activities involving the internet. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, quality control and manufacturing procedures must continue to conform to applicable manufacturing requirements after approval. We are relying exclusively on our manufacturing partner's facilities for the production of clinical and commercial

quantities of our products in accordance with cGMP regulations. cGMP regulations require among other things, quality control and quality assurance as well as the corresponding maintenance of records and documentation and the obligation to investigate and correct any deviations from cGMP. Drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and certain state agencies, and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain cGMP compliance. Discovery of problems with a product after approval may result in restrictions on a product, manufacturer or holder of an approved NDA, including, among other things, recall or withdrawal of the product from the market. In addition, changes to the manufacturing process are strictly regulated, and depending on the significance of the change, may require prior FDA approval before being implemented and development of and submission of data to support the change. Other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval, as well as, possibly, the development and submission of data to support the change.

The FDA also may require post-approval, sometimes referred to as Phase 4, trials and surveillance to monitor the effects of an approved product or place conditions on an approval that could restrict the distribution or use of the product. Discovery of previously unknown problems with a product or the failure to comply with applicable FDA requirements can have negative consequences, including adverse publicity, judicial or administrative enforcement, warning letters from the FDA, mandated corrective advertising or communications with doctors, and civil or criminal penalties, among others. Newly discovered or developed safety or effectiveness data may require changes to a product's approved labeling, including the addition of new warnings and contraindications, and also may require the implementation of other risk management measures, such as a risk evaluation and mitigation strategy. Also, new government requirements, including those resulting from new legislation, may be established, or the FDA's policies may change, which could delay or prevent regulatory approval of our product label extensions or products under development.

Pervasive and Continuing FDA Regulation for Medical Devices

After a device is placed on the market, regardless of its classification or premarket pathway, numerous regulatory requirements apply. These include, but are not limited to:

- establishing establishment registration and device listings with the FDA;
- Quality System Regulation, or QSR, which requires manufacturers, including third party manufacturers and certain other parties, to follow stringent design, testing, process control, documentation, corrective action/preventive action, complaint handling and other quality assurance procedures, as applicable;
- labeling statutes and regulations, which prohibit the promotion of products for uncleared or unapproved, or off-label, uses and impose other restrictions on labeling;
- clearance or approval of product modifications that could affect (or for 510(k) devices, significantly affect) safety or effectiveness or that would constitute a change (or for 510(k) devices, a major change) in intended use;
- medical device reporting regulations, which require that manufacturers report to the FDA if an event reasonably suggests that their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if the malfunction of the same or a similar device of the manufacturer were to recur;
- corrections and removals reporting regulations, which require that manufacturers report to the FDA field corrections and product removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA, that may present a risk to health. In addition, the FDA may order a mandatory recall if there is a reasonable probability that the device would cause serious adverse health consequences or death; and
- post-approval restrictions or conditions, including requirements to conduct post-market surveillance studies to establish additional safety or efficacy data.

The FDA has broad post-market and regulatory enforcement powers. The agency may conduct announced and unannounced inspections to determine compliance with the QSR and other regulations, and these inspections may include the manufacturing facilities of subcontractors. Failure by us or our suppliers to comply with applicable regulatory requirements can result in enforcement action by the FDA or other regulatory authorities, which may result in sanctions and related consequences including, but not limited to:

- untitled letters or warning letters;
- fines, injunctions, consent decrees and civil penalties;
- recall, detention or seizure of our products;
- operating restrictions, partial suspension or total shutdown of production;
- refusal of or delay in granting our requests for 510(k) clearance or premarket approval of new products or modified products;
- withdrawing 510(k) clearance or premarket approvals that are already granted;
- refusal to grant export approval for our products;
- criminal prosecution; and
- unanticipated expenditures to address or defend such actions.

We are subject to announced and unannounced device inspections by FDA and other regulatory agencies overseeing the implementation and adherence of applicable local, state and federal statutes and regulations.

Affordable Care Act

In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the Affordable Care Act, was enacted, which includes measures that have or will significantly change the way health care is financed by both governmental and private insurers. Among the provisions of the Affordable Care Act of greatest importance to the pharmaceutical industry are the following:

- The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Effective in 2010, the Affordable Care Act made several changes to the Medicaid Drug Rebate Program, including increasing pharmaceutical manufacturers' rebate liability by raising the minimum basic Medicaid rebate on most branded prescription drugs and biologic agents from 15.1% of average manufacturer price (AMP) to 23.1% of AMP and adding a new rebate calculation for "line extensions" (i.e., new formulations, such as extended release formulations) of solid oral dosage forms of branded products, as well as potentially impacting their rebate liability by modifying the statutory definition of AMP. The Affordable Care Act also expanded the universe of Medicaid utilization subject to drug rebates by requiring pharmaceutical manufacturers to pay rebates on Medicaid managed care utilization as of 2010. Per a ruling by the U.S. Supreme Court in 2012, states have the option to expand their Medicaid programs which in turn expands the population eligible for Medicaid drug benefits. CMS has proposed to expand Medicaid rebate liability to the territories of the U.S. as well. In addition, the Affordable Care Act provides for the public availability of retail survey prices and certain weighted average AMPs under the Medicaid program. The implementation of this requirement by the CMS may also provide for the public availability of pharmacy acquisition of cost data, which could negatively impact our sales.
- In order for a pharmaceutical product to receive federal reimbursement under the Medicare Part B and Medicaid programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the AMP and Medicaid rebate amounts reported by the manufacturer. Effective in 2010, the Affordable Care Act expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs when used for the orphan indication. In July 2013, the Health Resources and Services

Administration (HRSA) issued a final rule allowing the newly eligible entities to access discounted orphan drugs if used for non-orphan indications. While the final rule was vacated by a federal court ruling, HRSA has stated it will continue to allow discounts for orphan drugs when used for any indication other than for orphan indications. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

- Effective in 2011, the Affordable Care Act imposed a requirement on manufacturers of branded drugs and biologic agents to provide a 50% discount off the negotiated price of branded drugs dispensed to Medicare Part D patients in the coverage gap (i.e., "donut hole").

- Effective in 2011, the Affordable Care Act imposed an annual, nondeductible fee on any entity that manufactures or imports certain branded prescription drugs and biologic agents, apportioned among these entities according to their market share in certain government healthcare programs, although this fee would not apply to sales of certain products approved exclusively for orphan indications.

- The Affordable Care Act required pharmaceutical manufacturers to track certain financial arrangements with physicians and teaching hospitals, including any "transfer of value" made or distributed to such entities, as well as any ownership or investment interests held by physicians and their immediate family members. Manufacturers were required to begin tracking this information in 2013 and to report this information to CMS by March 2014.

- As of 2010, a new Patient-Centered Outcomes Research Institute was established pursuant to the Affordable Care Act to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research. The research conducted by the Patient-Centered Outcomes Research Institute may affect the market for certain pharmaceutical products.

- The Affordable Care Act created the Independent Payment Advisory Board, IPAB, which, beginning in 2014, will have authority to recommend certain changes to the Medicare program to reduce expenditures by the program that could result in reduced payments for prescription drugs. Under certain circumstances, these recommendations will become law unless Congress enacts legislation that will achieve the same or greater Medicare cost savings. IPAB recommendations are only required when Medicare spending exceeds a target growth rate established by the Affordable Care Act. Members of the IPAB have still not been appointed and Medicare cost growth is below the threshold that would require IPAB recommendations.

- The Affordable Care Act established the Center for Medicare and Medicaid Innovation within CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending, potentially including prescription drug spending. Funding has been allocated to support the mission of the Center for Medicare and Medicaid Innovation from 2011 to 2019.

Non-U.S. Government Regulation

In addition to regulations in the U.S., we will be subject to a variety of regulations in other jurisdictions governing, among other things, clinical trials and any commercial sales, promotion and distribution of our products. Whether or not we obtain FDA approval for a product, we must obtain the requisite approvals from regulatory authorities in foreign countries prior to the commencement of clinical trials or marketing of the product in those countries. We, or our local partners, have filed marketing authorization applications for Ameluz® and BF-RhodoLED® in Israel and Switzerland and have obtained centralized European approval from the EMA in the EU.

Non-U.S. Government Regulation Applicable to Drugs

Certain countries outside of the U.S. have a similar process that requires the submission of a clinical trial application much like an Investigational New Drug, or IND, application prior to the commencement of human clinical trials. If we fail to comply with applicable foreign regulatory requirements, we may be subject in those countries to, among other things, fines, suspension or withdrawal of regulatory approvals, product recalls, seizure of products, operating restrictions and criminal prosecution.

In the European Economic Area, or EEA (which is comprised of the 27 Member States of the European Union plus Iceland, Liechtenstein and Norway), for example, medicinal products can only be commercialized after obtaining a Marketing Authorization, or MA. There are two types of marketing authorizations:

- The Community MA, which is issued by the European Commission through the Centralized Procedure, based on the opinion of the EMA Committee for Medicinal Products for Human Use (CHMP), and which is valid throughout the entire territory of the EEA. The Centralized Procedure is mandatory for certain types of products, such as biotechnology medicinal products, orphan medicinal products, and medicinal products containing a new active substance indicated for the treatment of AIDS, cancer, neurodegenerative disorders, diabetes, auto-immune and viral diseases. The Centralized Procedure is optional for products containing a new active substance not yet authorized in the EEA, or for products that constitute a significant therapeutic, scientific or technical innovation or which are in the interest of public health in the European Union. We received Community MA for Ameluz® in November 2011.

- National MAs, which are issued by the competent authorities of the Member States of the EEA and only cover their respective territory, are available for products not falling within the mandatory scope of the Centralized Procedure. Where a product has already been authorized for marketing in a Member State of the EEA (the Reference Member State, or RMS), this National MA can be recognized in other Member States (the Concerned Member States, or CMS) through the Mutual Recognition Procedure. If the product has not received a National MA in any Member State at the time of application, it can be approved simultaneously in various Member States through the Decentralized Procedure. Under the Decentralized Procedure, an identical dossier is submitted to the competent authorities of each of the Member States in which the MA is sought, one of which is selected by the applicant as the RMS. The competent authority of the RMS prepares a draft assessment report, a draft summary of the product characteristics, or SPC, and a draft of the labeling and package leaflet, which are sent to the CMS for their approval. If the CMS raise no objections, based on a potential serious risk to public health, to the assessment, SPC, labeling, or packaging proposed by the RMS, the product is subsequently granted a national MA in all the Member States (i.e., in the RMS and the CMS). If one or more CMS raise objections based on a potential serious risk to public health, the application is referred to the Coordination group for mutual recognition and decentralized procedure for human medicinal products (the CMDh), which is composed of representatives of the EEA Member States. If a consensus cannot be reached within the CMDh the matter is referred for arbitration to the CHMP, which can reach a final decision binding on all EEA Member States. A similar process applies to disputes between the RMS and the CMS in the Mutual Recognition Procedure.

As with FDA approval, we may not be able to secure regulatory approvals in Europe in a timely manner, if at all. Additionally, as in the U.S., post-approval regulatory requirements, such as those regarding product manufacture, marketing, or distribution, would apply to any product that is approved in Europe, and failure to comply with such obligations could have a material adverse effect on our ability to successfully commercialize any product.

With respect to the conduct of clinical trials in the European Union a clinical trial application, or CTA, must be submitted to each country's national health authority and an independent ethics committee, much like the FDA and Institutional Review Board requirements in the U.S., respectively. Once the CTA is approved in accordance with a country's requirements, clinical trials may proceed.

In addition to regulations in Europe and the U.S., we will be subject to a variety of foreign regulations governing clinical trials and commercial distribution of any existing or future products. For other countries outside of the European Union, such as countries in Eastern Europe, Latin America or Asia, the requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary from country to country. In all cases, again, the clinical trials are conducted in accordance with cGCP and the applicable regulatory requirements and the ethical principles that have their origin in the Declaration of Helsinki.

Non-U.S. Government Regulation Applicable to Medical Devices

The advertising and promotion of our products in the EEA is subject to the provisions of the Medical Devices Directive, Directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation in the EEA countries governing the advertising and promotion of medical devices. The European Commission has submitted a Proposal for a Regulation of the European Parliament and the Council on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009, to replace, *inter alia*, Directive 93/42/EEC and to amend regulations regarding medical devices in the European Union, which could result in changes in the regulatory requirements for medical devices in Europe. In Germany, the advertising and promotion of our products can also be subject to restrictions provided by the German Act Against Unfair Competition *(Gesetz gegen den unlauteren Wettbewerb)* and the law on the advertising of medicines *(Heilmittelwerbegesetz)*, criminal law, and some codices of conduct with regard to medical products and medical devices among others. These laws may limit or restrict the advertising and promotion of our products to the general public and may impose limitations on our promotional activities with healthcare professionals.

Sales of medical devices are subject to foreign government regulations, which vary substantially from country to country. In order to market our products outside the U.S., we must obtain regulatory approvals or CE Certificates of Conformity and comply with extensive safety and quality regulations. The time required to obtain approval by a foreign country or to obtain a CE Certificate of Conformity may be longer or shorter than that required for FDA clearance or approval, and the requirements may differ. In the EEA, we are required to obtain Certificates of Conformity before drawing up an EC Declaration of Conformity and affixing the CE Mark of conformity to our medical devices. Many other countries, such as Australia, India, New Zealand, Pakistan and Sri Lanka, accept CE Certificates of Conformity or FDA clearance or approval although others, such as Brazil, Canada and Japan require separate regulatory filings.

Reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third party payors, such as government health care programs, statutory health insurances, and commercial insurance and managed healthcare organizations. These third party payors are increasingly reducing reimbursements for medical products and services and there is no guarantee that we will be able to obtain reimbursement at all for any future products. In addition, the U.S. government, state legislatures and foreign governments have continued implementing cost-containment programs, including price controls, competitive bidding program, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit our net revenue and results. Decreases in third party reimbursement for our product or product candidates or a decision by a third party payor to not cover our product or product candidates could reduce physician usage of our products once approved and have a material adverse effect on our sales, results of operations and financial condition.

In the U.S., treatment of actinic keratosis with Ameluz® in combination with our BF-RhodoLED® photodynamic therapy lamp is eligible to be reimbursed by the U.S. federal government's Medicare Program through Part B, which means that dermatologists purchase the drug to treat a patient in combination with our BF-RhodoLED® photodynamic therapy lamp and the doctors can be reimbursed for the cost of the drug after its use to treat a patient. This differentiates Ameluz® from drugs that are reimbursed through the U.S. federal government's Medicare Program through Part D and distributed through pharmacies. As a result, "Part B" drugs tend to have lower prices than "Part D" drugs, since doctors must have the financial wherewithal to purchase the drugs before treating the patients. Problems with reimbursement can become a serious issue for doctors since they are personally liable for the cost of the drugs if they are not reimbursed.

Fraud and Abuse Laws

We will also be subject to several healthcare regulation and enforcement by the federal government and the states and foreign governments in which we will conduct our business for our existing and future products. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual for, or the purchase, order or recommendation of, any good or service for which payment may be made under federal healthcare programs such as the Medicare and Medicaid programs;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third party payors that are false or fraudulent;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- federal Civil Monetary Penalties Law that prohibits various forms of fraud and abuse involving the Medicare and Medicaid programs;
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third party payor, including commercial insurers;
- for Europe, directive 2006/114/EC concerning misleading and comparative advertising, and Directive 2005/29/EC on unfair commercial practices, as well as other national legislation in the European Union governing the advertising and promotion of medical devices; and
- in Germany the advertising and promotion of our products can be subject to restrictions provided by the German Act Against Unfair Competition protecting against commercial practices which unacceptably harass a market participants.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA's privacy and security standards directly applicable to "business associates," independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

In Europe and Germany, we may be subject to strict data protection regulations, in particular with regard to health data of individuals, which are categorized as "special categories of personal data" pursuant to Section 3 subsection 9 German Federal Data Protection Act (*Bundesdatenschutzgesetz*). "Personal data" refers to any information relating to an identified or identifiable natural person (data subject); an identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his physical, physiological, mental, economic, cultural or social identity. The special categories of data such as health data may only be processed if the data subject consented to such processing or if (i) this is necessary in order to protect vital interests of the data subject or of a third party, in so far as the data subject is unable to provide consent for physical or legal reasons; (ii) the data concerned have evidently been made public by the data subject; (iii) this is necessary in order to assert, exercise or defend legal claims and there is no reason to assume that the data subject has an overriding legitimate interest in excluding such collection, processing or use; or (iv) this is necessary for the purposes of scientific research, where the scientific interest in carrying out the research project substantially outweighs the data subject's interest in excluding collection, processing and use and the purpose of the research cannot be achieved in any other way or would otherwise necessitate disproportionate effort. Therefore, we may be subject to and our marketing activities may be limited by the regulations regarding the data protection of individuals (e.g., according to the Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data as well as to the German Federal Data Protection Act). These regulations could also restrict the transfer of data from Germany/Europe to the U.S. The general transfer of personal data outside of Europe is prohibited according to Section 4b subsection 2 sentence 2 German Federal Data Protection Act (implementing Art. 25 subsection 1 of the Directive 95/46/EC) if the data importer cannot guarantee an appropriate standard of data protection. A

transfer of personal data to a non-EU member state (third country) is allowed only if the third country guarantees a reasonable standard of protection. Currently the U.S. is not regarded to be a country with an appropriate level of data protection meaning that further contractual arrangements have to be adopted to permit the international transfer of personal data to the U.S. European data protection law is currently under review. A newly proposed European Data Protection Regulation is currently being negotiated by the European institutions. On March 12, 2014, the European Parliament voted for a new Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) which is expected to further strengthen the European data protection law.

MANAGEMENT

Overview

We are a German stock corporation (*Aktiengesellschaft* or *AG*) and, in accordance with the German Stock Corporation Act (*Aktiengesetz*), we have two separate boards of directors, the supervisory board (*Aufsichtsrat*) and the management board (*Vorstand*). The two boards are separate, and no individual may simultaneously be a member of both boards.

The management board is responsible for the management of our business in accordance with applicable law, our articles of association (*Satzung*) and the internal rules of procedure (*Geschäftsordnung*) adopted by our supervisory board. The management board represents us in our transactions with third parties and in other proceedings with third parties.

The principal responsibility of the supervisory board is to supervise the management board. The supervisory board is also responsible for appointing and removing members of the management board and representing the company in connection with transactions between a member of the management board and our company. The supervisory board is not itself permitted to make management decisions, but in addition to its statutory responsibilities, our supervisory board has determined in the rules of procedure for the management board, that certain transactions and decisions require its prior consent. The supervisory board has organized its internal affairs and structure by adopting rules of procedure.

The members of both the supervisory board and the management board are solely responsible for and manage the duties of the relevant board (as described above); therefore, neither board may make decisions that are the responsibility of the other board under applicable law, our articles of association or the internal rules of procedure. Members of both boards owe a duty of loyalty and care to the company. In exercising their duties, the applicable standard of care is that of a diligent and prudent businessperson. Members of both boards must take into account a broad range of considerations when making decisions, including the interests of the company and its shareholders.

As a general rule under German law, a shareholder has no direct recourse against the members of the supervisory board or the management board in the event that they are believed to have breached their duty of loyalty and care. Apart from insolvency or other special circumstances, only the company has the right to claim damages from members of either board. We may waive these damages or settle these claims only if at least three years have passed and the shareholders approve the waiver or settlement at the shareholders' meeting with a simple majority of the votes cast, provided that a minority holding, in the aggregate, ten percent or more of our share capital does not have their opposition formally noted in the minutes maintained by a German notary.

Our supervisory board has comprehensive monitoring functions. To ensure that these functions are carried out properly, our management board must, among other things, regularly report to the supervisory board with regard to current business operations and future business planning (including financial, investment and personnel planning). The supervisory board may, at any time, request special reports regarding our affairs, legal or business relations and our subsidiaries and the affairs of any of our subsidiaries to the extent that the affairs of such subsidiary may have a significant impact on us.

The following description, as far as it relates to our articles of association, is based on the articles of association which were registered in the commercial register on June 29, 2017.

Supervisory Board

Our articles of association establish that our supervisory board shall have six members and our supervisory board currently consists of six members. We had a vacancy on our supervisory board that was recently filled when, upon request of the management board, a court of competent jurisdiction appointed Reinhard Eyring to serve on our supervisory board until our next general meeting of shareholders. Except for the foregoing, all of the members of our supervisory board are elected at the shareholders' meeting in accordance with the provisions of the German Stock Corporation Act. Under German law, the members of a supervisory board may be elected for a term until the adjournment of the shareholders' meeting resolving on ratification of the acts of management for the fourth fiscal year following the commencement of their respective term of office, where the fiscal year in which such term of office commences shall not be taken into account (i.e., approximately five years, depending on the dates of the annual general meeting at which the members of the supervisory board are elected), which is a standard term of office. Pursuant to our supervisory board's rules of procedure, only persons who have not yet reached the statutory retirement age (currently: the age of 67) should be proposed as members of our supervisory board. Members of our supervisory board do not have service contracts that provide for benefits upon termination of employment.

Any member so elected by our shareholders may be removed by the shareholders in a general meeting. In addition, any member of the supervisory board may, at any time, resign by giving one month's prior written notice to the end of a month to the management board, or for important cause without notice. According to our articles of association and the internal rules of procedure of the supervisory board, the supervisory board has a quorum when all members were invited or requested to participate in a decision and no less than three of the members of the supervisory board participated. Unless otherwise provided by our articles of association, resolutions of the supervisory board are passed by simple majority of the votes cast. In the case of a deadlock, the chairman of the supervisory board has the deciding vote. The supervisory board meets at least twice each half-year.

The shareholders' meeting may, at the same time as it elects the members of the supervisory board, elect one or more substitute members. The substitute members replace members who cease to be members of our supervisory board and take their place for the remainder of their respective terms of office. We have not elected any substitute members.

Our supervisory board elects a chairman and a vice chairman from its members. The vice chairman exercises the chairman's rights and obligations whenever the chairman is unable to do so. The members of our supervisory board have elected Ulrich Granzer as chairman and Jürgen Baumann as vice chairman, each for the term of their respective membership on our supervisory board, but may at any time remove them as chairman and vice chairman, respectively, by supervisory board resolution.

The following table sets forth the names and functions of the current members of our supervisory board and their ages. The terms of all current members of the supervisory board, with the exception of Reinhard Eyring, commenced May 31, 2016 and will end on the date of the annual shareholders' meeting relating to the accounts of the fiscal year ending December 31, 2020. The term of Mr. Eyring commenced on February 7, 2018, and will end on the date of our next annual shareholders' meeting.

The business address of the members of our supervisory board is our principal executive office at Hemmelrather Weg 201, D-51377 Leverkusen Germany.

Name	Age	Position
Ulrich Granzer[1][3][4]	57	Chairman
Jürgen Baumann[1][2]	63	Vice chairman
John Borer[1][2]	60	Supervisory board member
Hansjörg Plaggemars[2][4]	47	Supervisory board member
Kevin Weber[3]	59	Supervisory board member
Reinhard Eyring	59	Supervisory board member

(1) Member of the personnel committee.
(2) Member of the audit committee.
(3) Member of the research and development and market access committee.
(4) Member of the nomination committee.

The following is a brief summary of the business experience of the members of our supervisory board:

Ulrich Granzer, Ph.D. Dr. Granzer has been the chairman of our supervisory board since 2016. He is Managing Director of Granzer Regulatory Consulting & Services and was formerly director of regulatory affairs at GlaxoSmithKline plc, Knoll AG and Bayer AG. Dr. Granzer is a pharmacist and has been a member of the supervisory board of Biofrontera since 2006.

Jürgen Baumann. Mr. Baumann has been the vice chairman of our supervisory board since 2016 and has been a member of our supervisory board since 2007. As an economics graduate, Mr. Baumann was formerly a member of the Management Board of Schwarz Pharma AG responsible for European operations with eight national subsidiaries and four production sites. Mr. Baumann was chairman of the Supervisory Board of Biofrontera from 2007 through 2016. Up until October 2012, Mr. Jürgen Baumann was a member of the Supervisory Board of Riemser AG, Greifswald.

John Borer III, J.D. Mr. Borer has been a member of our supervisory board since 2016. He is the Senior Managing Director and Head of Investment Banking at The Benchmark Company, LLC, the lead underwriter in this offering. He was formerly the Chief Executive Officer and Head of Investment Banking at Rodman & Renshaw, and has held senior positions at Pacific Business Credit and Barclays American Business Credit. He holds a Doctor of Law degree (J.D.) from Loyola Law School in Los Angeles, California.

Hansjörg *Plaggemars*. Mr. Plaggemars has been a member of our supervisory board since 2016. He is a member of the Management Board of Delphi Unternehmensberatung AG and formerly a member of the Management Board of Deutsche Balaton AG, one of our major shareholders, and was appointed at Deutsche Balaton AG's recommendation. See "Principal Shareholders" below. He was formerly the Managing Director and Chief Financial Officer at CoCreate Software GmbH, KAMPA AG, Unister Holdings and Müller Holdings. Mr. Plaggemars is also a board member of Bolanta AG, Carus AG, Eurohaus Frankfurt AG, and Fidelitas Deutsche Industrie Holding AG, among others. He holds a degree in Business Administration from the University of Bamberg.

Kevin Weber. Mr. Weber has been a member of our supervisory board since 2016. He is a Principal at Skysis, LLC, a firm that provides commercial strategy consulting services to pharmaceutical, biotech and medical device companies. Prior to Skysis, LLC, Mr. Weber was Chief Executive Officer of Paraffin International Inc. Before Paraffin International, Mr. Weber was the Vice President of Marketing for Depomed, a specialty pharmaceutical company focused on pain medicine and neurology products. Mr. Weber is also a board member of the American Chronic Pain Association and holds a B.S. in Management and Marketing from Western Michigan University.

Reinhard Eyring. Mr. Eyring has been a member of our supervisory board since February 2018. He is head of Ashurst Germany and a partner in the corporate department at that firm in Frankfurt. Prior to joining Ashurst Germany, Mr. Eyring was partner and managing partner with another major law firm. Mr. Eyring graduated from the University of Freiburg/Breisgau in 1988. Mr. Eyring has also served as Chairman of the Advisory Committee of Stiftung Leben mit Krebs, Wiesbaden since September 2009.

Supervisory Board Committees and Independence

Decisions are generally made by our supervisory board as a whole; however, decisions on certain matters may be delegated to committees of our supervisory board to the extent permitted by law. The chairman, or if he or she is prevented from doing so, the vice chairman, chairs the meetings of the supervisory board and determines the order in which the agenda items are discussed, the method and order of the voting, any adjournment of the discussion and passing of resolutions on individual agenda items after a due assessment of the circumstances.

Pursuant to Section 107(3) of the German Stock Corporation Act, the supervisory board may form committees from among its members and charge them with the performance of specific tasks. The committees' tasks, authorizations and processes are determined by our supervisory board. Where permissible by law, important powers of the supervisory board may also be transferred to committees. The internal rules of procedure of the supervisory board explicitly provide for a personnel committee, an audit committee, and a nomination committee. Furthermore, the supervisory board has set up and appointed a research & development and market access committee.

German law does not require the majority of our supervisory board members to be independent. However, the rules of procedure for our supervisory board require that the supervisory board be composed of a sufficient number of independent members, as determined by our supervisory board. The supervisory board passed a resolution, as recommended by the German Corporate Governance Code, regarding targets for the composition of the supervisory board, and determined that at least half of the supervisory board members should be independent within the meaning of the German Corporate Governance Code. Under rule 5.4.2 of the German Corporate Governance Code, as adopted by our supervisory board's rules of procedure, a board member is deemed to be independent if such member has no business or personal relationships with us, the management board, a controlling shareholder or an affiliate, that could constitute a material and not only temporary conflict of interest. Our supervisory board has determined that a majority of our supervisory board members are independent directors in accordance with the listing requirements of The NASDAQ Capital Market. The NASDAQ independence definition includes a series of objective tests, including that the board member is not, and has not been for at least three years, one of our employees and that neither the board member nor any of his family members has engaged in various types of business dealings with us. In addition, as required by NASDAQ rules, our supervisory board has made a subjective determination as to each independent director that no relationships exist, which, in the opinion of our supervisory board, would interfere with the exercise of independent judgment in carrying out the responsibilities of a board member. In making these determinations, our supervisory board reviewed and discussed information provided by the members of the supervisory board and us with regard to each board member's business and personal activities and relationships as they may relate to us and our management. The wife of our chief executive officer, Prof. Hermann Lübbert, serves as a senior employee of our company responsible for regulatory affairs and manufacturing ("*Prokurist*"); however, there are no family relationships among any of the members of our supervisory board, the members of our management board or our executive officers.

Personnel Committee

The personnel committee consists of three members: the committee chairman and two other supervisory board members, who are elected by our supervisory board from among its members. The personnel committee prepares the decisions of our supervisory board on the appointment and dismissal of management board members. The personnel committee prepares the conclusion, amendment and termination of the service contracts of the management board members, the determination of an annual bonus and other flexible remuneration elements for the decision of our supervisory board. Only persons who have not yet reached the statutory retirement age (currently: the age of 67) should be proposed as members of our management board.

The personnel committee also decides on: legal transactions with our management board members within the meaning of section 112 of the German Stock Corporation Act, consent concerning work by our management board members outside the company according to section 88 of the German Stock Corporation Act and on ancillary activities (including the assumption of supervisory board offices outside companies that are affiliated with our company within the meaning of sections 15 ff of the German Stock Corporation Act), consent concerning the granting of loans to the categories of persons referred to in sections 89, 115 of the German Stock Corporation Act, the approval of contracts with our supervisory board members pursuant to section 114 of the German Stock Corporation Act, and personnel matters for which our management board requires the approval of our supervisory board in accordance with the rules of procedure. The personnel committee is comprised of the following individuals: Dr. Ulrich Granzer, Jürgen Baumann and John Borer. Mr Baumann is the current chairman.

Audit Committee

The audit committee consists of three members, who elect one committee chairperson. Pursuant to the German Corporate Governance Code, the chairperson should not be a former member of our management board, whose appointment has ended less than two years prior, and should have special knowledge and experience in the application of accounting standards and internal control systems within the meaning of sec. 100(5) of the German Stock Corporation Act. Furthermore, pursuant to the German Corporate Governance Code and our supervisory board's rules, the chairperson of the supervisory board should not be elected as the chairperson of the audit committee. The audit committee's main function is to oversee our accounting and financial reporting processes and the audits of our financial statements and, insofar as legally permitted, pass resolutions with respect to these topics. The audit committee's responsibilities explicitly include (but are not limited to) questions of:

- accounting and risk management;
- the necessary independence of our independent registered public accounting firm elected by our annual general meeting, and giving the audit mandate;
- entering into the remuneration agreement with the auditor, and determining any focus of the audit; and
- financial matters, for which the management board requires the approval of the supervisory board pursuant to the rules of procedure of the management board.

The members of our audit committee are Hansjörg Plaggemars, Jürgen Baumann and John Borer. Hansjörg Plaggemars and Jürgen Baumann whom qualify as an "independent director" as such term is defined in Rule 10A-3 under the Exchange Act; however, because John Borer is the Senior Managing Director and Head of Investment Banking of The Benchmark Company, LLC, one of the underwriters that will be compensated in connection with this offering, he does not qualify as an "independent director" under Rule 10A-3. Jürgen Baumann serves as chairman of the audit committee. Our supervisory board has determined that Hansjörg Plaggemars is a financial expert as contemplated by the rules of the SEC implementing Section 407 of the Sarbanes Oxley Act. Our audit committee focuses in particular on issues relating to accounting and risk management, the auditor's mandatory independence and the issuing of the audit mandate to the auditor, as well as the overseeing of the audit of the company's annual financial statement. In companies as defined in Section 264d of the German Commercial Code, which includes Biofrontera, the supervisory board's nomination for the election of the auditor must be based on the audit committee's recommendation. Furthermore, in companies as defined in Section 264d of the German Commercial Code, at least one member of the supervisory board must have expertise in the fields of accounting or auditing and be a member of the audit committee.

Research & Development and Market Access Committee

The Research & Development and Market Access Committee deals with key issues related to product development as well as with any aspects related to the commercialization of our products. After discussions within this committee, it makes appropriate recommendations to our management board and supervisory board. The Research & Development and Market Access Committee does not have an explicit written charter, but was established pursuant to a supervisory board resolution. Our Research & Development and Market Access Committee is comprised of the following individuals: Dr. Ulrich Granzer, Hansjörg Plaggemars and Kevin Weber. Dr. Granzer is the current chairman.

Nomination Committee

In addition to the supervisory board chairman, the nomination committee includes two other supervisory board members, who are elected to the committee. Our nomination committee currently is comprised of Dr. Ulrich Granzer (chairman), John Borer and Hansjörg Plaggemars. Our nomination committee proposes suitable candidates for the future staffing of our supervisory board for its nominations at our annual general meeting. In so doing, our nomination committee considers the balance and variation of knowledge, skills and experience of all our supervisory board members, and creates candidate profiles. Insofar as possible, the nomination committee takes into account the targets adopted by our supervisory board for its composition, including the target for equal gender participation. In addition, our nomination committee makes recommendations to or informs our supervisory board of results from regular evaluations of the knowledge, skills and experience of individual board members and our supervisory board in its entirety. In the course of performing its duties, pursuant to the supervisory board's rules of procedure, our nomination committee can draw on company resources deemed appropriate and also on external consultants within the necessary framework.

Management Board

Under German law and our articles of association, our management board must consist of one or more persons, and the supervisory board determines the exact number of members of the management board. Our supervisory board also appoints the chairman and the vice chairman of the management board, if any.

Currently, our management board consists of three members: Professor Hermann Lübbert, Ph.D., is appointed as chief executive officer (i.e., chairman of the management board); Thomas Schaffer is appointed as chief financial officer; and Christoph Dünwald is appointed as chief commercial officer. Members of our management board conduct the daily business of our company in accordance with applicable laws, our articles of association and the rules of procedure for the management board. The management board is generally responsible for the management of our company and for handling our daily business relations with third parties, the internal organization of our business and communications with our shareholders. In addition, the management board has the responsibility for:

- the preparation of our annual financial statements;
- the making of a proposal to our shareholders' meeting on how our profits (if any) should be allocated (such proposal to be submitted simultaneously by our supervisory board); and
- regular reporting to the supervisory board on our current operating and financial performance, our budgeting and planning processes and our performance under them and on future business planning (including strategic, financial, investment and personnel planning).

Our supervisory board appoints the members of the management board for a maximum term of five years. Reappointment or extension of the term for up to five years is permissible. Our supervisory board may revoke the appointment of a management board member prior to the expiration of his or her term for good cause only, such as for gross breach of fiduciary duties or if the shareholders' meeting passes a vote of no-confidence with respect to such member, unless the supervisory board deems the no-confidence vote to be clearly unreasonable. Our supervisory board is also responsible for entering into, amending and terminating service agreements with the management board members and, in general, for representing us in disputes with the management board, both in and out of court. Our supervisory board may assign these duties to a committee of our supervisory board, except in certain cases in which the approval of the entire supervisory board is required, such as the approval of the compensation of members of our management board and the reduction of the compensation of members of our management board upon a deterioration of our financial condition, which includes, among other things, a bankruptcy or the layoff of a significant number of employees.

According to our articles of association, either (i) two management board members or (ii) one management board member acting jointly with an authorized representative have the authority to act on our behalf. The supervisory board may grant any management board member the right to represent us alone and may release any member of the management board from the restrictions on multiple representations under Section 181, 2nd Case of the German Civil Code.

Prof. Hermann Lübbert has been granted authority to represent us alone. He and Thomas Schaffer were furthermore released from the restrictions imposed by Section 181, 2nd Case of the German Civil Code with respect to transactions conducted with some of our subsidiaries.

Our management board has the authority to determine our business areas and operating segments and resolve upon the internal allocation of responsibility for certain business areas and operating segments among the various members of the management board by setting up a business responsibility plan. Since we currently have only three members of our management board, we do not have a formal business responsibility plan in place at this time.

The following table sets forth the names and function of the current members of our management board and their ages:

Name	Age	Position
Professor Hermann Lübbert, Ph.D.	61	Chairman of the management board and chief executive officer
Thomas Schaffer	55	Member of the management board and chief financial officer
Christoph Dünwald	50	Member of the management board and chief commercial officer

The business address of the members of our management board is our principal executive office at Hemmelrather Weg 201, D-51377 Leverkusen Germany.

The following is a brief summary of the business experience of the members of our management board:

Prof. Hermann Lübbert, Ph.D. Prof. Lübbert has served as our chief executive officer since 1997. He is chairman of the management board of Biofrontera AG and a managing director of all subsidiaries of Biofrontera AG. He studied biology in his home town of Cologne and received his doctorate there in 1984. Following 3.5 years in academic research at the University of Cologne and the California Institute of Technology, he gained experience in managing a global research organization during 10 years at Sandoz, where he served as Head of Genome Research, and Novartis Pharma AG, where he served as a member of the global Neuroscience Research Management Team. Prof. Lübbert founded Biofrontera in 1997 and has been managing the company ever since. He qualified as a university lecturer at the Swiss Federal Institute of Technology (ETH) Zurich and in addition to his engagement as Executive Director, holds a professorship for animal physiology at the Ruhr-University Bochum.

Thomas Schaffer. Mr. Schaffer has served as our chief financial officer since 2013. He began his professional career with various positions in the finance and controlling division at Siemens Semiconductor. He held the position of Vice President and Chief Financial Officer in the Security & Chipcard IC business area of Siemens and the subsequently formed Infineon Technologies AG. Following this, he spent four years as Managing Director and Chief Financial Officer of Infineon Ventures GmbH and continued his career as Vice President and Chief Financial Officer of the Specialty DRAM Division of Qimonda AG, where he also took over management of Qimonda Solar GmbH, Dresden. With positions as Chief Financial Officer at Heptagon Oy, Finland/Switzerland, and Ubidyne Inc., Delaware, U.S., he expanded his extensive international experience. Mr. Schaffer has broad expertise in finance and accounting and has made significant contributions to the strategic development of the companies for which he has previously worked. Since June 2013, Mr. Schaffer has held the position of chief financial officer at Biofrontera AG and is a managing director of all subsidiaries of Biofrontera AG.

Christoph Dünwald. Mr. Dünwald has served as our chief commercial officer since 2015. He began his professional career at Bayer, where he worked for 15 years in positions of increasing responsibility in marketing in both Spain and the U.S., as well as in strategic management positions in Germany and Asia Pacific. He then oversaw Bayer's Healthcare Diagnostics Division in Belgium and Luxembourg as the General Manager. Following two years as International Sales and Marketing Director for Corporacion Dermoestetica SA in Spain and the UK, he became Senior Commercial Director to Allergan, the global pharmaceutical company. From 2009 until 2015, he was assigned the responsibility for Allergan's Medical Business Unit in

Spain and Portugal. Mr. Dünwald holds a significant track record of increasing sales and profit in all of his leadership roles. We believe that Mr. Dünwald's management and marketing and sales experience qualify him to serve on our management board.

Code of Business Conduct and Ethics

We have adopted a written Code of Conduct that applies to members of our management board, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions.

No waivers have been granted to the code of business conduct and ethics since its adoption.

German Corporate Governance Code

The German Corporate Governance Code, or Corporate Governance Code, was originally published by the German Ministry of Justice in 2002 and was most recently amended on February 7, 2017 and published in the German Federal Gazette on April 24, 2017. The Corporate Governance Code contains recommendations and suggestions relating to the management and supervision of German companies that are listed on a stock exchange. It follows internationally and nationally recognized standards for good and responsible corporate governance. The purpose of the Corporate Governance Code is to make the German system of corporate governance transparent for investors. The Corporate Governance Code includes corporate governance recommendations and suggestions with respect to shareholders and shareholders' meetings, the supervisory and management boards, transparency, accounting policies, and auditing.

There is no obligation to comply with the recommendations or suggestions of the Corporate Governance Code. The German Stock Corporation Act requires only that the supervisory board and management board of a German listed company issue an annual declaration that either (i) states that the company has complied with the recommendations of the Corporate Governance Code (*einverständniserklärung*), (ii) lists the recommendations that the company has not complied with and explains its reasons for deviating from the recommendations of the Corporate Governance Code (*qualifizierte Abweichungserklärung*) ("Comply or Explain"), or (iii) states that the company has not complied with the recommendations of the Corporate Governance Code (*Abweichungserklärung*). In addition, a listed company is also required to state in this annual declaration whether it intends to comply with the recommendations or list the recommendations it does not plan to comply with in the future. These declarations must be published permanently on our website. If we change our policy on certain recommendations between such annual declarations, we must disclose this fact and explain our reasons for deviating from the recommendations. As opposed to such noncompliance with recommendations, noncompliance with mere suggestions contained in the Corporate Governance Code need not be disclosed.

As a result of the listing of our shares on the regulated market of the Frankfurt Stock Exchange, the Corporate Governance Code applies to us and we are required to issue the annual declarations described above. According to their respective rules of procedure, our supervisory board and management board are obliged to comply with the Corporate Governance Code except for such provisions which they have explicitly listed in their annual declaration and for which they have stated that they do not comply with.

In particular, we adhere to the following significant recommendations of the Corporate Governance Code: (i) the supervisory board will establish audit and nominating committees; (ii) the management board must keep the supervisory board closely informed, in particular with respect to measures which can fundamentally affect our condition; and (iii) significant management measures are subject to supervisory board approval.

Differences between Our Corporate Governance Practices and the Rules of The NASDAQ Capital Market

The NASDAQ listing rules allow for a foreign private issuer, such as us, to follow the laws, rules, and regulations, or home country practice, of its home country in lieu of certain of NASDAQ's corporate governance standards. Specifically, NASDAQ Listing Rule 5615(a)(3)(A) permits a foreign private issuer to follow its home country practice instead of following the requirements of the NASDAQ Listing Rule 5600 series, the requirement to disclose third party director and nominee compensation set forth in NASDAQ Listing Rule 5250(b)(3), and the requirement to distribute annual and interim reports set forth in NASDAQ Listing Rule 5250(d).

In accordance with the requirements of the German Stock Corporation Act, and unlike many publicly traded companies in the U.S., we utilize a two-tier board structure, consisting of a supervisory board and a management board. This two-tier governance system provides a strict separation of supervisory and management functions, with the roles and responsibilities of each of the two boards clearly defined by German law.

Differences between the corporate governance practices that we follow and those set forth in the NASDAQ stock market rules are described below:

- *Distribution of Annual and Interim Reports.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5250(d) that an annual report, containing our audited financial statements and those of our subsidiaries, be distributed to shareholders a reasonable period of time following the filing of the annual report with the SEC. Consistent with the German Stock Corporation Act, we do not distribute annual and interim reports automatically to shareholders. Instead, our annual reports are available to shareholders at our offices or on our website. Under the deposit agreement relating to our ADSs, we have agreed to provide annual reports to the depositary bank so that the depositary bank may arrange for distribution of such information to holders of our ADSs.

- *Independent Directors.* NASDAQ Stock Market Rule 5605(b)(1) requires listed companies to have a majority of independent directors. There is no requirement under German law that the majority of members of a supervisory board be independent. The rules of procedure of our supervisory board provide that the supervisory board should have a sufficient number of independent members within the meaning of the German Corporate Governance Code, and the supervisory board has resolved that a number of at least one-half of the board members should be sufficient, though this is not a mandatory requirement. The supervisory board has determined that a majority of the current members of our supervisory board are independent.

  In addition, under our two-tier board system, our methods for determining and ensuring the independence of our supervisory board generally differ from those set forth in NASDAQ rule 5605, which contemplates a U.S.-style, one-tier system. For instance, while NASDAQ rules require the board to affirmatively determine the independence of individual directors via specific tests of independence, German law does not require the supervisory board to make such affirmative findings on an individual basis. At the same time, the rules of procedure of our supervisory board contain provisions to help ensure the independence of the supervisory board's advice and supervision. Furthermore, the members of our supervisory and management boards are independent from one another. A member of one board is legally prohibited from being concurrently active on the other. Supervisory board members have independent decision making authority and are legally prohibited from following the direction or instruction of any affiliated party. Moreover, supervisory board members may not enter into advisory, service or certain other contracts with us, unless approved by our supervisory board.

- *Executive Sessions.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5605(b)(2) that independent directors have regularly scheduled meetings during which only independent directors are present. German law does not require executive sessions of independent directors. However, German law provides that the supervisory board holds meetings at least twice in each half-year period. Additionally, where supervisory board members are subject to conflicts of interest, they generally have to refrain from taking part in deliberations and voting.

- *Audit Committee Charter.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5605(c)(1) that we adopt a formal written audit committee charter specifying certain audit committee responsibilities. German law does not require a separate charter for an audit committee. Instead, the responsibilities and authority of our audit committee are set forth in the rules of procedure of our supervisory board and in the applicable German laws. Pursuant to the German Stock Corporation Act, independent auditors are elected at the shareholders' meeting, instead of being appointed by the audit committee. Also pursuant to the German Stock Corporation Act and applicable German law, our entire supervisory board, together with our management board, and in some cases, our shareholders, are responsible for the final approval of the audited financial statements and our supervisory board as a whole is responsible for many of the same functions that Nasdaq requires of an audit committee under its rules.

- *Compensation Committee Charter.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5605(d)(1) that we certify we have adopted a formal written compensation committee charter and that the compensation committee will review and reassess the adequacy of the formal written charter on an annual basis. German law does not require a separate charter for a compensation committee. Instead, the responsibilities and

authority of our personnel committee (which is responsible for nominating members of the management board and questions of compensation of the management board) are set forth in the rules of procedure of our supervisory board and in applicable German law. Pursuant to the German Stock Corporation Act and applicable German law, our entire supervisory board is responsible for the appointment and final approval of remuneration of the management board.

- *Compensation Committee Responsibilities and Authority.* We expect to rely on an exemption from the requirements under NASDAQ Listing Rule 5605(d)(3) identifying specific compensation committee responsibilities and authority. The responsibilities and authority of our personnel committee are set forth in the rules of procedure of our supervisory board and in applicable German law. The personnel committee does not have independent authority to retain legal and professional advice; rather, the supervisory board as a whole can generally retain such advice.

- *Nominations Committee Charter.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5605(e)(2) that we certify we have adopted a formal written charter or board resolution, as applicable, addressing the nominations process and related matters as required under federal securities laws. German law does not require a separate charter or board resolution addressing nominations. Instead, the responsibilities and authority of our personnel committee (responsible for nominating members of the management board) and the nomination committee (responsible for nominating members of the supervisory board) are set forth in the rules of procedure of our supervisory board and in applicable German law.

- *Solicitation of Proxies.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5620(b) that we solicit proxies and provide proxy statements for all meetings of shareholders and provide copies of such proxy solicitation to NASDAQ. Consistent with German law, we offer to our shareholders the right to exercise their voting rights in the general meeting through proxies appointed by our company and keep the declarations of such proxies available for inspection for a period of three years. The proxies appointed by us are obligated to vote only in accordance with the instructions of the represented shareholder. Under the deposit agreement pertaining to our ADSs, our depositary bank mails to holders of ADSs a notice stating, among other things, that each holder of ADSs is entitled to instruct the depositary bank as to the exercise of the voting rights. Each holder of ADSs who desires to exercise or to give instructions for the exercise of voting rights must execute and return a document provided by the depositary bank that instructs the depositary bank as to how the number of the shares represented by such holders' ADSs are to be voted. See "Description of American Depositary Shares — Voting Rights" for more information.

- *Quorum.* We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5620(c) that our by-laws provide for a quorum that is not less than 33 1/3% of the outstanding shares of our ordinary voting shares. Consistent with German law, our articles of association do not provide for a quorum for shareholders' meetings.

- *Shareholder Approval*. We expect to rely on an exemption from the requirement under NASDAQ Listing Rule 5635(c) requiring companies to obtain shareholder approval of all equity compensation plans (including share option plans) and any material revisions to them. Consistent with the German Stock Corporation Act, the adoption of our stock option plans and any material revisions thereto must be approved by our shareholders insofar as the issuance of shares and/or share options under authorized or contingent capital authorizations requires shareholder approval. For the avoidance of doubt, this only applies insofar as actual shares are to be delivered under the plan. Phantom stock or other remuneration programs linked to share value, but not requiring delivery of physical shares, do not require shareholder approval.

Compensation of Management Board and Supervisory Board Members

Compensation of Supervisory Board Members

2016 Supervisory Board Member Compensation Table

The following table sets forth information for the fiscal year ended December 31, 2016 regarding the compensation awarded to, earned by or paid to our supervisory board members who served on our supervisory board during 2016.

Name	Fees Earned or Paid in Cash (€)	Option or other Equity Awards (€)	All Other Compensation (€)	Total (€)
Jürgen Baumann*	25,625	**	—	25,625
Prof. Bernd Wetzel, Ph.D.	9,375	**	—	9,375
Andreas Fritsch	6,250	**	—	6,250
Ulrich Granzer, Ph.D.*	23,750	**	—	23,750
Ulrike Kluge	6,250	**	—	6,250
Alfred Neimke	6,250	**	—	6,250
John Borer*	8,750	**	—	8,750
Hansjörg Plaggemars*	8,750	**	—	8,750
Mark Reeth†	8,750	**	—	8,750
Kevin Weber*	8,750	**	—	8,750

* Current member of our supervisory board.

** No option or other equity awards were made to any of our supervisory board members as compensation in 2016.

† Member of our supervisory board until October 31, 2017.

Under German law, the compensation of the supervisory board of a German stock corporation can only be determined by the shareholders' meeting.

The following remuneration system for our supervisory board has been approved by our shareholders.

Each member of our supervisory board receives a fixed annual fee of €15,000 (fixed fee component). If our consolidated results per share in the fiscal year for which the fixed fee is paid (salary year), and in the salary year of the previous fiscal year, improve by 25% or more compared with each respective previous fiscal year, each member of our supervisory board will be awarded an annual performance-related fee of €10,000 over and above the fixed fee component for the salary year (performance-related pay). If our consolidated results per share improve by 50% or more, the performance-related pay will increase to €20,000. The basis for calculating whether or not the required improvement is achieved in the relevant successive fiscal years (period under consideration) is the consolidated results per share in the fiscal year 2006 and in subsequent years; for example, if the required improvement in terms of consolidated results per share is achieved in 2007 compared with 2006, and subsequently in 2008 compared with 2007, the performance-related pay for the fiscal year 2008 will have been earned.

Our chairman receives twice and our vice chairman receives one-and-a-half times the fee.

Our company has obtained an indemnity insurance policy, for the benefit of the members of our supervisory board, which covers statutory liability arising from the activities of our supervisory board.

We do not pay fees for attendance at supervisory board meetings.

The members of our supervisory board are entitled to reimbursement of their reasonable, documented expenses (including, but not limited to, travel, board and lodging and telecommunication expenses).

Compensation of Management Board Members

2016 Management Board Member Compensation Table

The following table sets forth information concerning the compensation of our named executive officers during the fiscal year ended December 31, 2016.

Name and Principal Position	Salary	Bonus	Option Awards	All Other Compensation	Total
Prof. Hermann Lübbert, Ph.D. *Chief Executive Officer*	€363,387	€72,000	€199,200	—	€634,587
Thomas Schaffer *Chief Financial Officer*	€213,139	€63,000	€124,500	—	€400,639
Christoph Dünwald *Chief Commercial Officer*	€237,000	€5,625	€124,500	—	€367,125

In the fiscal year ended December 31, 2016, Prof. Lübbert received total compensation of €634,587, which included base salary, bonus, option awards and other benefits, Mr. Schaffer received total compensation of €400,639, which included base salary, bonus, option awards and other benefits, and Mr. Dünwald received total compensation of €367,125, which included base salary, bonus, option awards and other benefits.

Employment Agreement with Prof. Hermann Lübbert

We entered into an employment agreement with Prof. Hermann Lübbert that provides that Prof. Lübbert will serve as our chief executive officer and as the chairman of our management board and under which he is entitled to receive an initial annual base salary of €350,000. Prof. Lübbert is further eligible to receive an annual target performance bonus of €80,000, based on certain annual corporate goals and individual performance goals established annually by our supervisory board. Prof. Lübbert's total annual target bonus increases proportionately to up to 150% of the annual target performance bonus if the corporate and individual goals are exceeded, as determined by our supervisory board. No bonus will be paid if our supervisory board determines that the target achievement of the respective year was below 70%. Prof. Lübbert's annual base salary shall be increased to €400,000 upon the achievement of profitability.

The employment agreement further provides that Prof. Lübbert shall be granted options to purchase ordinary shares from our employee stock option plan. Prof. Lübbert must hold personally at least one ordinary share of Biofrontera for each option he has been granted.

The employment agreement also provides that if we terminate Prof. Lübbert's employment for reasons other than cause, he is entitled to continue to receive his base salary and annual bonus for a period of two years after the termination in consideration for a non-compete obligations agreed by Prof. Lübbert. These obligations include a non-solicitation covenant and a covenant not-to-compete with us worldwide during his employment with us and for a period of two years thereafter.

Further, the employment agreement includes a "change of control" provision pursuant to which Prof. Lübbert may terminate his employment agreement in the event that one party or a group of parties acting in concert acquires 50% or more of the voting rights of our company. Upon termination of his employment in the event of a "change of control," Prof. Lübbert shall be entitled to a payment of 300% of his annual salary, including the base salary and 100% of his annual bonus.

The term of the employment agreement with Prof. Lübbert is until October 31, 2020.

Employment Agreement with Thomas Schaffer

We entered into an employment agreement with Thomas Schaffer that provides that Mr. Schaffer will serve as our chief financial officer and a member of our management board and under which he is entitled to receive an initial annual base salary of €230,000. Mr. Schaffer is further eligible to receive an annual target performance bonus of €70,000, based on certain annual corporate goals and individual performance goals established annually by our supervisory board. Mr. Schaffer's total annual target bonus increases proportionately to up to 150% of the annual target performance bonus if the corporate and individual goals are exceeded, as determined by our supervisory board. No bonus will be paid if our supervisory board determines that the target achievement of the respective year was below 70%. Mr. Schaffer's annual base salary shall be increased to €250,000 upon the achievement of profitability.

The employment agreement further provides that Mr. Schaffer shall be granted options to purchase ordinary shares from our employee stock option plan. Mr. Schaffer must hold personally at least one ordinary share of Biofrontera for each option he has been granted, up to an aggregate amount of €15,000 per annum.

Further, the employment agreement includes a "change of control" provision pursuant to which Mr. Schaffer may terminate his employment agreement in the event that one party or a group of parties acting in concert acquires 50% or more of the voting rights of Biofrontera AG. Upon termination of his employment in the event of a "change of control," Mr. Schaffer shall be entitled to a payment of 300% of his annual salary, including the base salary and 100% of his annual bonus.

The term of the employment agreement with Mr. Schaffer is until November 30, 2020.

Employment Agreement with Christoph Dünwald

We entered into an employment agreement with Christoph Dünwald that provides that Mr. Dünwald will serve as our chief commercial officer and a member of our management board and under which he is entitled to receive an initial annual base salary of €225,000. Mr. Dünwald is further eligible to receive an annual target performance bonus of €50,000, based on certain annual corporate goals and individual performance goals established annually by our supervisory board. Mr. Dünwald's total annual target bonus increases proportionately to up to 200% of the annual target performance bonus if the corporate and individual goals are exceeded, as determined by our supervisory board. No bonus will be paid if our supervisory board determines that the target achievement of the respective year was below 70%. Mr. Dünwald's annual base salary shall be increased to €300,000 upon the achievement of profitability.

The employment agreement further provides that Mr. Dünwald shall be granted options to purchase ordinary shares from our employee stock option plan. Mr. Dünwald must hold personally at least one ordinary share of Biofrontera for each option he has been granted, up to an aggregate amount of €15,000 per annum.

Further, the employment agreement includes a "change of control" provision pursuant to which Mr. Dünwald may terminate his employment agreement in the event that one party or a group of parties acting in concert acquires 50% or more of the voting rights of our company. Upon termination of his employment in the event of a "change of control," Mr. Dünwald shall be entitled to a payment of 300% of his annual salary, including the base salary and 100% of his annual bonus.

The term of the employment agreement with Mr. Dünwald is until November 30, 2020.

Equity Incentive Plans

2010 Employee Stock Option Plan

At our annual general meeting of shareholders held on July 2, 2010, our management board and supervisory board proposed a share option program for employees to the annual general meeting, which approved the initiative. In accordance with this plan, our management board, or the supervisory board if the beneficiaries are management board members, is entitled to issue up to 839,500 share options, the exercise of which is linked to specific targets.

The plan has a total nominal value of €839,500 and a term ending upon the expiration of the option rights issued pursuant to the plan. The plan provides that option rights may be exercised until six years following the date of issuance of the options in question and only after the expiration of the vesting period of the options, which is four years after the date of issuance. To this end, contingent capital of €839,500 was enacted as a result of the issuing of up to 839,500 registered ordinary shares without par value, with a stake in the share capital of €1.00 per share pursuant to Section 192 paragraph 1 No. 3 of the German Stock Corporation Act. The contingent capital was registered on July 30, 2010 in the commercial register of Cologne District Court as HRB 49717. Eligibility for the 2010 share option plan was granted to members of our management board and employees of our company as well as to executive officers and employees of affiliates of Biofrontera AG.

The date of issue of the options was November 24, 2010 and the option grants were made without any payment being provided in return. On November 24, 2010, 106,400 options (first tranche) were issued, with an exercise price per share of €1.91. On September 30, 2011 and on October 7, 2011 (second tranche), an additional 96,400 options were issued, with an exercise price per share of €2.48. On March 23, 2012 and May 11, 2012 (third tranche), 65,000 options were issued, with an exercise price

per share of €3.30 and 51,500 options were issued with an exercise price per share of €4.09. On September 2, 2013, 179,500 options were issued (fourth tranche), with an exercise price per share of €3.373. On April 2, 2014, 159,350 options were issued, with an exercise price per share of €3.43. A total of 137,250 options have been forfeited by employees who have terminated employment with our company and an additional total of 106,400 options (from the first tranche) expired because the exercise conditions were not met. The authorization to issue options under our 2010 stock option plan ended on July 1, 2015. By resolution of our annual general meeting on August 28, 2015, the contingent capital authorized to service options under this plan was reduced to €542,400.

In accordance with the associated conditions, each subscription right that is granted under the plan entitles the beneficiary to acquire one new registered ordinary share, without par value, of our company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange via floor and XETRA trading for our shares on the ten trading days prior to the issuance of the share. However, the minimum exercise price amounts to the proportionate share of our company's share capital allocated to each individual no-par value share, pursuant to Section 9, paragraph 1 of the German Stock Corporation Act.

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

Exercise of 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 of Biofrontera exceeds the exercise price by at least 20%, and a minimum reference price of at least €5.00 is achieved (hereinafter referred to as the "minimum reference price"). The reference price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange via floor and XETRA trading for our shares between the 15th and the 5th trading day (inclusive in each case) prior to the respective exercise window.

The minimum reference price is adjusted in the following cases in order to bring the stated performance target into line with changed circumstances:

- In the event of a capital increase from company funds as a result of the issuance of shares, the minimum reference price is reduced by the same proportion as new shares issued compared to existing shares. If the capital increase is carried out from company funds without the issuing of new shares (Section 207 paragraph 2 clause 2 of the German Stock Corporation Act), the minimum reference price remains unchanged.

- In the event of a capital reduction taking place, no adjustment is made to the minimum reference price, provided that the total number of shares is not affected by the reduction of capital, or if the capital reduction is associated with a return of capital or an acquisition of our own shares in return for payment. In the event of a capital reduction achieved by consolidation of shares without repayment of capital or in the event of an increase in the number of shares without a change in capital (a share split), then the minimum reference price is increased in proportion to the reduction of capital or to the share split.

There are no other cases in which adjustments are made to the minimum reference price.

The exercise of options under this plan is limited to the following time periods, or exercise windows:

- the period commencing on the 6th and continuing over the following 14 banking days after the date of the annual general meeting (exclusive);

- the period commencing on the 6th and continuing over the following 14 banking days after the date of issue of a half-yearly or quarterly report or an interim announcement by our company (exclusive); and

- the period between the 15th and 5th banking day before the expiration of the option rights of the expiry date in question.

Any options not exercised before the date of expiration of the options are forfeited without compensation. We assume an average holding period of five years in assessing the employee options.

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

employment contract with our company or another company affiliated with our company or if the holder is a member of our management board or the management team of another company affiliated with our company.

In the event of the exercise of a subscription right, our 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 obligation 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.

2015 Employee Stock Option Plan

At our annual general meeting of shareholders held on August 28, 2015, our management board and supervisory board proposed a share option program for employees to the annual general meeting, which approved the initiative. In accordance with this plan, our management board, or the supervisory board if the beneficiaries are management board members, is entitled to issue up to 1,814,984 share options, the exercising of which is linked to specific targets.

The program has a total nominal value of €1,814,984 and the right to exercise options issued pursuant to this plan ends six years following the issue date of the respective option. To this end, contingent capital of €1,814,984 was enacted as a result of the issuing of up to 1,814,984 registered ordinary shares, without par value, and with a stake in the share capital of €1.00 per share pursuant to Section 192 paragraph 1 No. 3 of the German Stock Corporation Act. The contingent capital was registered on September 18, 2015 in the commercial register of Cologne District Court as HRB 49717. Eligibility for the 2015 share option plan was granted to members of the management board and employees of our company as well as to members of management bodies and employees of affiliates of Biofrontera AG.

The date of issue of the options was April 7, 2016 and the options grants were made without any payment being provided in return. On April 18, 2016, 425,500 options (first tranche) were issued, with an exercise price per share of €2.49. On December 1, 2016, 130,500 options (second tranche) were issued, with an exercise price per share of €3.28. On April 28, 2017, 329,000 options (third tranche) were issued, with an exercise price per share of €4.02. A total of 38,500 options have been forfeited by employees who have terminated employment with our company.

In accordance with the associated conditions, each subscription right that is granted entitles the beneficiary to acquire one new registered share, without par value, in our company. The exercise price is equal to the arithmetical average (unweighted) of the closing prices ascertained on the Frankfurt Stock Exchange via floor and XETRA trading for our shares on the ten trading days prior to the issuing of the share. However, the minimum exercise price amounts to the proportionate share of our company's share capital allocated to each individual no-par value share, pursuant to Section 9, paragraph 1 of the German Stock Corporation Act.

The options granted may 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 exercise of the options is that the following performance targets are achieved.

Options under this plan may only be exercised if the following performance targets are met:

- Exercise of the options from a tranche is possible if, at the beginning of the respective exercise window, the price of a share of our company exceeds the exercise price by at least 20% (the reference price); and

- if in comparison with the exercise price of the option, the reference price has performed as well as or better in percentage terms than the MSCI World Health Care Index TR or a comparable successor index (the reference index), during the period from the last trading day before the issue date until the 5th trading day before the beginning of the respective exercise window (the reference period). As the reference index is a total return index, the gross amount of dividends distributed by our company during the reference period and other distributions to shareholders are taken into account as a value-enhancing factor when determining the performance of our company's shares.

The reference price corresponds to the non-weighted average price of our company's shares in the Xetra closing auction on the Frankfurt Stock Exchange or in an equivalent successor system between the 15th and 5th trading days (inclusive in each case) before the beginning of the respective exercise window.

The plan provides the following option right adjustments and anti-dilution provisions:

- If during the term of the options, our company grants a direct or an indirect subscription right to our shareholders, our company increases its share capital by issuing new shares or debt instruments or profit participation rights with conversion or option rights, and the conversion or option price per share determined in this process is lower than the exercise price of the options, our management board and, in the event that members of our management board are affected, our supervisory board, is authorized to put the beneficiary of the options on an equal financial footing as far as is necessary to ensure that the value of the options to which an eligible person is entitled remains unchanged before and after implementation of a capital measure using recognized methods in financial mathematics. At the option of our company this adjustment can be made by reducing the exercise price or adjusting the number of options or a combination of both. If no subscription rights trade takes place, in the event of an adjustment by our company, the value of the subscription right will be calculated as follows with binding effect:

  $$SR = (Po - Pn) / (SRa + 1)$$

  where:

  SR = subscription right
  Po = market price of the old shares
  Pn = issue price of the new shares
  SRa = subscription ratio

The market price of the old shares, "Po", is determined as follows: arithmetic average (non-weighted) of the closing price of our shares determined in trading on the XETRA electronic trading platform of the Frankfurt Stock Exchange during the subscription period.

- In the event of a capital increase from company funds through the issuing of shares, the contingent capital pursuant to Section 218 of the German Stock Corporation Act will be increased by the same ratio as the share capital. The beneficiary's right to subscribe to new shares through exercise of the subscription right will increase by the same ratio; the exercise price per share will be reduced by the same ratio. In the event of a capital increase from company funds without the issue of new shares (Section 207 (2) second sentence of the German Stock Corporation Act), the subscription right under the options and the exercise price will remain unchanged.

- In the event of a capital reduction, the exercise price and option ratio will not be adjusted, provided that the capital reduction does not change the total number of shares or the capital reduction is linked to a capital repayment or an acquisition of treasury shares against payment. In the event of a capital reduction through the consolidation of shares without a capital repayment and in the event of an increase in the number of shares without a change in capital (share split), the number of shares that can be acquired for each option at the exercise price will be reduced or increased in proportion to the capital reduction or share split; the exercise price per share will be changed by the same ratio.

If an adjustment is made in accordance with the foregoing paragraphs, fractions of shares will not be issued when the subscription right is exercised. There will be no cash settlement.

- In the event that our company merges with another company, changes its legal form or undertakes similar transactions that impair the rights of the beneficiary due to the loss of or changes to our shares, the option rights will be replaced by the right to acquire, at the exercise price, a number of shares, shares in a business or other rights replacing our shares to invest in our company or our legal successor that corresponds in value to the market value of one of our shares at the time such transaction occurs (full entry of its execution in the commercial register).

- In the event of an integration, the conclusion of profit transfer or domination agreements, a squeeze-out of minority shareholders or an asset transfer within the meaning of Section 174 et seq. of the German Act Regulating Transformation of Companies, our company will, as far as is legally and practicably possible, place the eligible person in the position when exercising his options in which he would have been had he already exercised his option rights at the time of the contract coming into effect or such transaction being implemented. If trading in our company's shares is suspended as a result of such a transaction and for this reason it is no longer possible to determine if performance targets have been met, the extent to which targets have been met will be determined by means of an assessment by a public auditor/public audit firm commissioned by our company at its expense calculating the capitalized earnings value of our shares on December 31 of each year in each case.

In the event of other measures having an effect comparable to that of an adjustment as described in the foregoing cases, our company may adjust the exercise price in accordance with Section 315 of the German Commercial Code.

The exercise of options under this plan is limited to the following time periods (hereinafter "exercise windows"), *i.e.*, only declarations of the exercise of rights submitted to our company within an exercise window will be considered:

- the period commencing on the 6th banking day and continuing over the following 20 banking days after our annual general meeting;
- the period commencing on the 6th banking day and continuing over the following 20 banking days after presentation of the half-yearly or quarterly report or of an interim announcement or interim financial report of our company; and
- the period between the 20th and 5th banking days before the option rights lapse.

The right to exercise the options expires no later than six years after the first day of issue. Any options not exercised by that date are forfeited without compensation. We assume an average holding period of five years in assessing the employee options.

Any claim by the beneficiary to receive a cash settlement in the event of non-exercise of the options is invalid, notwithstanding the existence of the above exercise prerequisites. An option right may only be exercised if the holder has a current service or employment contract with our company or another company affiliated with our company or if the holder is a member of the management board or the management team of another company affiliated with our company.

In the event of the exercise of a subscription right, our 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 obligation 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.

Share Ownership by Members of our Supervisory Board and Management Board

Supervisory Board

The following table provides information with respect to ownership of our ordinary shares, options and convertible bonds for each of the members of our supervisory board as of February 12, 2018, based on an aggregate of 38,416,828 shares outstanding as of such date.

Name	Shares	% of Outstanding Shares	Convertible Bonds
Jürgen Baumann	30,000	*	—
John Borer	—	—	—
Ulrich Granzer	—	—	—
Hansjörg Plaggemars	—	—	—
Mark Reeth†	—	—	—
Kevin Weber	—	—	—
Reinhard Eyring	—	—	—
Total	30,000	*	—

* Less than one percent of class.

† Member of our supervisory board until October 31, 2017.

Management Board

The following table provides information with respect to ownership of our ordinary shares and options for each of the members of our management board as of January 23, 2018, based on an aggregate of 38,416,828 shares outstanding as of such date.

Name	Shares	% of Outstanding Shares	Options	Exercise Price (€)	Expiration Date
Prof. Hermann Lübbert, Ph.D.	724,678	1.89%	40,000 options	3.30	03/30/2018
			30,000 options	3.373	09/01/2019
			16,850 options	3.43	04/01/2020
			80,000 options	2.49	04/17/2022
			70,000 options	4.02	04/27/2023
Thomas Schaffer	44,265	*	15,000 options	3.373	09/01/2019
			20,000 options	3.43	04/01/2020
			50,000 options	2.49	04/17/2022
			40,000 options	4.02	04/27/2023
Christoph Dünwald	107,500	*	50,000 options	2.49	04/17/2022
			40,000 options	4.02	04/27/2023
Total	**876,443**	**2.28%**	**451,850 options**		

* Less than one percent of class.

As of February 12, 2018, the members of our management board held an aggregate of 876,433 of our ordinary shares, while the members of our supervisory board held an aggregate of 30,000 of our ordinary shares. As of February 12, 2018, the aggregate number of our shares owned by current management board and supervisory board members amounts to approximately 2.36% of our outstanding shares as of such date.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

Employment Agreements and Options Grants

We have entered into employment agreements with, and granted options to, the members of our management board. See "Management — Compensation of Management Board and Supervisory Board Members — Compensation of Management Board Members" for more information.

Arrangements with The Benchmark Company, LLC

The Benchmark Company, LLC is acting as representative for the underwriters in connection with this offering. John Borer is the Senior Managing Director and Head of Investment Banking of the representative. Mr. Borer is also a supervisory board member of our company for which he is compensated by our company pursuant to our company's supervisory board member compensation policies and practices described above under "Management — Compensation of Management Board and Supervisory Board Members". Therefore, Mr. Borer may be deemed a related person of our company, and the representative may be deemed to be a related person of our company as well by virtue of Mr. Borer's positions at our company and the representative. In addition, the representative may be deemed to have a conflict of interest under applicable FINRA rules as a result of Mr. Borer's relationships with our company and the representative. Refer to "Underwriting — Conflict of Interest" for additional disclosures relating this matter, including the amount of compensation to be paid to The Benchmark Company, LLC.

Development Agreement with Maruho

In July 2016, we entered into a collaboration and partnership agreement with Maruho Co. Ltd., an affiliate of Maruho Deutschland GmbH, one of our major shareholders. See "Business — Our Research and Development Plans — Our Development Collaboration with Maruho" for more information.

Consulting Arrangement with Dr. Ulrich Granzer

During 2016, 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, 2016, advisory services amounting to €10 thousand (previous year: €62 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to €7 thousand on December 31, 2016 (December 31, 2015: €0). For the nine months ended September 30, 2017, we paid €34 thousand to Granzer Regulatory Consulting & Services for advisory services. The amounts stated here do not include statutory value added tax at the current rate of 19%.

Share Loan Agreement

To facilitate the orderly closing of this offering of ADSs and because of timing considerations related to the technical issuance and registration of new ordinary shares under German law, under the terms of a Share Loan Agreement dated January 26, 2018, by and between Lang & Schwarz Broker GmbH (acting as service provider for Biofrontera AG pursuant to a separate mandate agreement) and Maruho Deutschland GmbH, Maruho Deutschland GmbH agreed to temporarily lend to Lang & Schwarz Broker GmbH (acting as our service provider) 6,000,000 ordinary shares (the "Borrowed Shares") in connection with the initial deposit of ordinary shares into our ADS program immediately prior to and concurrent with the consummation of this offering.

Lang & Schwarz Broker GmbH (acting as our service provider) has agreed to cause to be conveyed (pursuant to the Share Loan Agreement) to the custodian, whose role is more fully described in the section entitled "Description of American Depositary Shares", and the custodian has agreed to deposit into the ADS program, ordinary shares, concurrently with or immediately after the consummation of this offering sufficient to cover the number of ADSs to be sold in this offering (including any ADSs that may be issued if the underwriters exercise their over-allotment option in full). In connection with the consummation of this offering, we will initially receive proceeds equal to one-quarter of the nominal value of the ordinary shares underlying the ADSs sold in this offering (i.e., €0.25 per ordinary share), and Lang & Schwarz Broker GmbH will provide a subscription certificate to us. Upon receipt of the partial proceeds of the offering and the subscription certificate, we will initiate the registration of a capital increase for the number of shares underlying the ADSs sold in this offering with the commercial register of the local court of Cologne. Although we expect to complete the registration process within approximately one week, it is possible that registration

of the capital increase may take as long as three weeks. The time required to complete registration of the capital increase is determined by the schedule of the local court. Once the capital increase has been registered, newly issued ordinary shares of our company equal to the number of shares underlying the ADSs sold in this offering will be delivered to Lang & Schwarz Broker GmbH, which will return the shares to Maruho Deutschland GmbH in repayment and satisfaction in full of the Share Loan. We will receive the full net proceeds of this offering only upon registration of the capital increase with the commercial register. If for any reason we fail to complete registration of the capital increase, then we will not retain any proceeds from this offering, which would have a material adverse effect on our financial position, liquidity and results of operations.

If the underwriters exercise their over-allotment option then the over-allotment option will be settled with shares conveyed to the custodian pursuant to the Share Loan Agreement.

Transactions with Family Members

Montserrat Foguet Roca, the wife of our chief executive officer, Prof. Hermann Lübbert, serves as a senior employee of our company responsible for regulatory affairs and manufacturing ("*Prokurist*").

Dr. Matthias Lübbert, the son of our chief executive officer, Prof. Hermann Lübbert, serves as an employee of our Company, with the title "Clinical Trial Manager USA."

PRINCIPAL SHAREHOLDERS

The following table sets forth information relating to the beneficial ownership of our shares as of January 15, 2018 by:

- each person, or group of affiliated persons, known by us to beneficially own more than 5% of our outstanding shares;
- each of the members of our supervisory board; and
- each of the members of our management board.

The number of shares beneficially owned by each entity, person, member of our supervisory board, member of our management board is determined in accordance with the rules of the SEC, and the information is not necessarily indicative of beneficial ownership for any other purpose. Under such rules, beneficial ownership includes any shares over which the individual has sole or shared voting power or investment power as well as any shares that the individual has the right to subscribe for within 60 days of January 15, 2018 through the exercise of any warrants or other rights. Except as otherwise indicated, and subject to applicable community property laws, the persons named in the table have sole voting and investment power with respect to all shares owned by that person.

The percentage of shares beneficially owned is computed on the basis of 38,416,828 shares outstanding as of January 15, 2018. Shares for which a person has the right to subscribe within 60 days of January 15, 2018 are deemed outstanding for purposes of computing the percentage ownership of the person holding such rights, but are not deemed outstanding for purposes of computing the percentage ownership of any other person. There were 548,960 shares for which a person has the right to subscribe within 60 days of January 15, 2018. Additionally, a person is considered to have the right to subscribe for shares which are subject to outstanding options and vested within 60 days of January 15, 2018, although such options may only be exercised in 4 annual exercise periods. See also "Description of Share Capital — Notification and Disclosure Obligations".

	Beneficial ownership prior to this offering				Beneficial ownership after this offering[1]	
Name and address of beneficial owner	Number of shares beneficially owned	Number of options exercisable within 60 days	Fully diluted number of shares beneficially owned	Fully diluted percentage of beneficial ownership	Number of shares beneficially owned	Percentage of beneficial ownership
5% and greater shareholders						
Maruho Deutschland Co. Ltd., Osaka Japan[2]	7,631,586	—	7,631,586	19.9	7,631,586	19.9
Universal Investment Gesellschaft mbH Frankfurt, Germany[3]	799,463	—	799,463	2.1	799,463	2.1
Wilhelm Konrad Thomas Zours[4]	3,400,907	—	3,400,907	8.9	3,400,907	8.9
Includes the following shares held directly by Deutsche Balaton AG[5]	2,512,799	—	2,512,799	6.5	2,512,799	6.5
Supervisory board members and management board members[6]						
Ulrich Granzer	—	—	—	—	—	—
Jürgen Baumann	30,000	—	30,000	*	30,000	*
John Borer	—	—	—	—	—	—
Hansjörg Plaggemars	—	—	—	—	—	—
Kevin Weber	—	—	—	—	—	—
Reinhard Eyring	—	—	—	—	—	—
Prof. Hermann Lübbert, Ph.D.	724,678	40,000[7]	764,678	2.0	764,678	2.0
Thomas Schaffer	44,265	—	44,265	*	44,265	*
Christoph Dünwald	107,500	—	107,500	*	107,500	*
All supervisory board members and management board members as a group (9 persons)	**906,443**	**40,000**	**946,443**	**2.5**	**946,443**	**2.5**

* Indicates beneficial ownership of less than 1% of the total shares outstanding.

(1) Assuming that the underwriters exercise their option to purchase 85,483 additional ADSs (170,966 ordinary shares) in full for the purpose of covering over-allotments. See "Underwriting (Conflicts of Interest)".
(2) Based on public filings by Maruho Co., Ltd, Osaka which is deemed to be the owner of shares held by its controlled subsidiary, Maruho Deutschland GmbH, Düsseldorf. Maruho Deutschland GmbH's address is c/o Biofrontera AG, Hemmelrather Weg 201, 51377 Leverkusen, Germany.
(3) Based on public filings by Universal-Investment GmbH, which is deemed to be the owner of shares held through its controlled subsidiary through the company FEHO Vemögensverwaltungsgesellschaft. Universal-Investment-GmbH's address is Theodor-Heuss-Allee 70, 60486 Frankfurt am Main, Germany.
(4) Based on public filings in Germany on May 27, 2016 by Mr. Wilhelm Konrad Thomas Zours, who is deemed to be the owner of shares held by the following entities he controls: DELPHI Unternehmensberatung AG, VV Beteiligungen AG, Deutsche Balaton AG (which directly held 2,512,799, or approximately 8.28%, of our shares as of that date), ABC Beteiligungen AG and Heidelberger Beteiligungsholding AG.
(5) Based on public filings in Germany on May 27, 2016 by Deutsche Balaton AG. Based on public filings in Germany, Deutsche Balaton AG is controlled by Mr. Wilhelm Konrad Thomas Zours, who is deemed to be the owner of shares held by Deutsche Balaton AG.
(6) The address of the members of our supervisory board and management board is c/o Biofrontera AG at Hemmelrather Weg 201, D-51377 Leverkusen, Germany.
(7) Includes 40,000 ordinary shares issuable upon exercise of stock options exercisable on or before March 30, 2018.

As of January 23, 2018, there were 5,252 holders of record entered in our share register, of which three were U.S. residents, holding less than 0.1% of our outstanding shares. The number of individual holders of record is based exclusively upon our share register and does not address whether a share or shares may be held by the holder of record on behalf of more than one person or institution who may be deemed to be the beneficial owner of a share or shares in our company.

To our knowledge, no other shareholder beneficially owns more than 5% of our shares. Under German law, shareholders of a public company are required to notify the company and the German Federal Financial Supervisory Authority of the number of shares they own when their percentage ownership reaches, exceeds or falls below certain threshold levels. German law does not require a shareholder to update this information unless it again reaches, exceeds or falls below a notification threshold. As a result, we cannot be certain whether the number of shares owned by the shareholders (other than the shareholders who are members of our supervisory board and management board) listed above is accurate. See "Description of Share Capital — Notification and Disclosure Obligations."

Our company is not owned or controlled directly or indirectly by any government or by any corporation or by any other natural or legal person severally or jointly. Our major shareholders do not have any special voting rights.

DESCRIPTION OF SHARE CAPITAL

The following description is a summary of certain information relating to our share capital, as well as certain provisions of our articles of association and the German Stock Corporation Act. Unless stated otherwise, the description insofar as it relates to our articles of association is based on the amended version of our articles of association which was registered with the commercial register in Köln, Germany, on June 29, 2017. This summary does not purport to be complete and speaks as of the date of this prospectus. Copies of our articles of association are publicly available from the commercial register of the local court in Köln, Germany, electronically at *www.unternehmensregister.de* and as an exhibit to the Registration Statement of which this prospectus forms a part.

Incorporation of the company

Our company was formed in 1997 as a limited liability company (*Gesellschaft mit beschränkter Haftung* or *GmbH*) under German law and under the name "BioFrontera Laboratories GmbH" to provide services to the pharmaceutical industry. In September 1997, the company was renamed "BioFrontera Pharmaceuticals GmbH" and commenced its current operations, which include the development, marketing, sales, manufacturing and distribution of drugs and medical devices, cosmetics, and other dermatology-related products. On August 24, 2000, our company was converted into a German stock corporation (*Aktiengesellschaft or AG*), and on November 27, 2003, our company was renamed "Biofrontera AG".

Share Capital

As of the date of this prospectus, our registered share capital amounts to €38,416,828, divided into 38,416,828 no par-value ordinary registered shares with a notional value of €1.00 per share. The shares were created according to German law.

Form, Certification and Transferability of the Shares

Our shares are in registered form (*Namensaktien*). The form and contents of our share certificates, any dividend certificates, renewal certificates and interest coupons are determined by our management board with the approval of our supervisory board. A shareholder's right to certificated shares is excluded, to the extent permitted by law and to the extent certification is not required by the stock exchange on which the shares are admitted to trading. We are permitted to issue share certificates that represent one or more shares.

Our share capital is represented by one or more global share certificates deposited with Clearstream Banking AG. All our outstanding shares are no par-value ordinary registered shares. Under German law, if a resolution regarding a capital increase does not specify whether such increase will be in bearer or registered form, the new shares resulting from such capital increase will be no par-value ordinary registered shares by default. Any resolution regarding a capital increase may determine the profit participation of the new shares resulting from such capital increase.

Our shares are freely transferable under German law, with the transfer of ownership governed by applicable laws and the rules of the relevant clearing system.

General Information on Capital Measures

Pursuant to our articles of association, an increase of our share capital generally requires a resolution passed at our shareholders' meeting with both a simple majority of the share capital represented at the relevant shareholders' meeting and a simple majority of the votes cast. See also "— Subscription Rights" below.

The shareholders at such meeting may authorize our management board to increase our share capital with the consent of our supervisory board within a period of five years by issuing shares for a certain total amount as "authorized capital" (*genehmigtes Kapital*), which is a concept under German law that enables us to issue shares without going through the process of obtaining a shareholders' resolution.

Furthermore, our shareholders may resolve to amend or create "contingent capital" (*bedingtes Kapital*); however, they may do so only to issue conversion or subscription rights to holders of convertible bonds, in preparation for a merger with another company or to issue subscription rights to employees and members of the management of our company or of an affiliated company by way of a consent or authorization resolution.

According to German law, any resolution pertaining to the creation of authorized or contingent capital requires the vote of at least three-quarters of the share capital represented at the relevant shareholders' meeting and a simple majority of the votes cast. The shareholders may also resolve to increase the share capital from company resources by converting capital reserve and profit reserves into share capital.

Pursuant to our articles of association, any resolution pertaining to an increase in share capital from company resources ("*Kapitalerhöhung aus Gesellschaftsmitteln*") requires the vote of a simple majority of the share capital represented at the relevant shareholders' meeting and a simple majority of the votes cast.

According to German law, the aggregate nominal amount of the authorized capital created by the shareholders may not exceed 50% of the share capital existing at the time of registration of the authorized capital with the commercial register.

According to German law, the aggregate nominal amount of the contingent capital created at any shareholders' meeting may not exceed one-half of the share capital existing at the time of the shareholders' meeting adopting such resolution. The aggregate nominal amount of the contingent capital created for the purpose of granting subscription rights to employees and members of the management of our company or of an affiliated company may not exceed 10% of the share capital existing at the time of the shareholders' meeting adopting such resolution.

Any resolution relating to a reduction of our share capital ("*Kapitalherabsetzung*") requires the vote of at least three-quarters of the share capital represented at the relevant shareholders' meeting as well as a simple majority of the votes cast according to German law.

Changes in Our Share Capital during the Last Three Fiscal Years

On January 28, 2014, our share capital was increased from authorized capital by €4,438,292 to €22,191,460 pursuant a capital increase against cash contribution by issuing 4,438,292 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00. All existing shareholders were offered the right to subscribe for shares in the issuance and make offers for additional subscriptions. The price per share was €3.50 each, and we received net proceeds from this share issuance of approximately €15.3 million.

On March 13, 2014, an increase of our share capital by €5,110 to €22,196,570 was registered, pursuant to the exercise of option rights from our warrant bond issued in 2009, resulting in a subscription of 5,110 new shares. The shares were created from contingent capital. On May 28, 2015, our share capital was increased from authorized capital by €1,377,272 to €23,573,842 pursuant to a capital increase against cash contribution by issuing 1,377,272 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00. All existing shareholders were offered the right to subscribe for shares in the issuance and make offers for additional subscriptions. The subscription price per share was €2.30 each, and we received net proceeds from this share issuance of approximately €3.1 million.

On September 18, 2015, based on the resolution of our general meeting dated August 28, 2015, we restructured our share capital, creating an Authorized Capital I in an amount of €11,786,921, a Contingent Capital I in an amount of €6,434,646, a Contingent Capital III in an amount of €542,400, and a Contingent Capital V in an amount of €1,814,984.

On November 25, 2015, our share capital was increased from Authorized Capital I by €1,916,588 to €25,490,430 pursuant to a capital increase against cash contribution by issuing 1,916,588 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00, reducing the Authorized Capital I proportionally. All existing shareholders were offered the right to subscribe for shares in the issuance and make offers for additional subscriptions. The subscription price per share was €1.90 each, and we received net proceeds from this share issuance of approximately €3.5 million.

On February 18, 2016, our share capital was increased from Authorized Capital I by €2,357,384 to €27,847,814 pursuant to a capital increase against cash contribution by issuing 2,357,384 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00, reducing the Authorized Capital I proportionally. The shareholders' subscription right was excluded in this issuance and the shares were offered to selected institutional investors. The subscription price per share was €1.90 each, and we received net proceeds from this share issuance of approximately €4.4 million.

On April 20, 2016, our share capital was increased from Authorized Capital I by €2,499,999 to €30,347,813 pursuant to a capital increase against cash contribution by issuing 2,499,999 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00, reducing the Authorized Capital I proportionally. Our shareholders were granted the statutory subscription right to participate in the issuance. The subscription price per share was €2.00, and we received net proceeds from this share issuance of approximately €4.9 million.

On November 17, 2016, our share capital was increased from Authorized Capital I by €5,012,950 to €35,360,763 pursuant to a capital increase against cash contribution by issuing 5,012,950 new registered no-par ordinary shares, with an amount of the share capital attributable to each share of €1.00, using up the Authorized Capital I completely. Our shareholders were granted the statutory subscription right to participate in the issuance. The subscription price per share was €3.00, and we received net proceeds from this share issuance of approximately €14.7 million.

In December 2016 and January 2017, we issued convertible bonds which could be converted into shares. Insofar as shares are to be delivered as a consequence of conversion of the bonds, we can issue these shares from Contingent Capital I.

In January 2017, an increase of our share capital by €2,354,510 to €37,715,273 was registered pursuant to the conversion of our warrant bonds into 1,603,050 of our ordinary shares, and the exercise of options from our convertible bond issued in 2009 (which was fully repaid upon maturity on December 31, 2016) into 751,460 shares. The 1,603,050 shares from the conversion of convertible bonds were issued from Contingent Capital I, reducing the available Contingent Capital I proportionally. The 751,460 shares from the exercise of option rights were issued from Contingent Capital IV, reducing the available Contingent Capital IV proportionally.

In February 2017, an increase of our share capital by €7,160 to €37,722,433 was registered pursuant to the exercise of options from the warrant bond issued in 2009 into 7,160 of our ordinary shares. The 7,160 shares from the exercise of option rights were issued from Contingent Capital IV, reducing the available Contingent Capital IV proportionally.

On June 29, 2017, our share capital was increased by €693,995 to €38,416,428 pursuant to the conversion of our convertible bonds into 693,995 of our ordinary shares. The 693,995 shares from the conversion of convertible bonds were issued from Contingent Capital I, reducing the available Contingent Capital I proportionally.

In August 2017, our share capital was increased by €75 to €38,416,503 pursuant to the conversion of convertible bonds into 75 of our ordinary shares. The 75 shares resulting from the conversion of convertible bonds were issued from our Contingent Capital I, reducing the available Contingent Capital I proportionately.

In December 2017, our share capital was increased by €325 to €38,416,828 pursuant to the conversion of convertible bonds into 325 of our shares. The 325 shares resulting from the conversion of convertible bonds were issued from our Contingent Capital I, reducing the available Contingent Capital I proportionately.

Authorized Capital (*genehmigtes Kapital*)

At our annual general meeting on May 24, 2017, our shareholders resolved to create two sets of authorized capital. The authorized capital was entered into our articles of association on May 25, 2017. However, one shareholder, Deutsche Balaton AG, has contested one of the resolutions of the annual general meeting creating authorized capital by filing a lawsuit in the Cologne District Court in June 2017. Due to the pending lawsuit, only one set of authorized capital approved by our shareholders at such meeting has been entered into the commercial register, which entry is a requirement for the authorized capital to become effective. See "Management's Discussion and Analysis of Financial Condition and Results of Operations — Legal Proceedings".

As a result of such meeting, pursuant to the first set of authorized capital, our management board is authorized to increase our share capital until May 23, 2022, with the approval of our supervisory board, by up to a nominal amount of €6,000,000 by issuing up to 6,000,000 new ordinary registered shares (which amount includes any shares that may be issued pursuant to the underwriters' over-allotment option), against contribution in cash (which we sometimes refer to in this prospectus as "Authorized Capital I"). Our management board is authorized, with the approval of our supervisory board, to determine the rights associated with the shares as well as their terms of issuance. If any such new shares were to be issued therefrom, they must be first offered to our shareholders for subscription (as we will do pursuant to the German preemptive rights offering). Our management board is authorized, with the approval of our supervisory board, to exclude subscription rights of our shareholders in cases of fractional shares.

Pursuant to the second set of authorized capital approved by the shareholders at such meeting (but which has not been entered into the commercial register and is therefore currently not effective), our management board would be authorized to increase our share capital until May 23, 2022, with the approval of our supervisory board, by up to €4,000,000 by issuing up to 4,000,000 new ordinary registered shares, against contribution in cash (which we sometimes refer to in this prospectus as "Authorized Capital II"). Our management board would be authorized, with the approval of our supervisory board, to determine the rights associated with the shares as well as their terms of issuance. If this set of authorized capital is registered, if any such new shares were to be issued therefrom, they must be first offered to our shareholders for subscription; however, our management board would be authorized, with the approval of our supervisory board, to exclude subscription rights of our shareholders in the following cases:

- cases of fractional shares;
- in cases of cash contributions up to an amount not exceeding 10% of the share capital at the time of this authorization becoming effective or – if this amount should be lower – when this authorization is utilized, if the issue price of the shares is not significantly lower than the exchange price of shares already being traded on the stock market at the time of the final determination of the issue price. (Shares that are sold or issued during the term of this authorization on the basis of other authorizations, by direct or analogous application of sec. 186(3)(4) of the German Stock Corporation Act under exclusion of subscription rights, are taken into account in the above-mentioned 10% limit. The issue of purchase or conversion rights or obligations arising from bonds and/or profit participation rights regarding shares is treated as the issue of shares for this purpose, if these were issued by analogous application of sec. 186(3)(4) of the German Stock Corporation Act under exclusion of subscription rights).

The authorization to exclude the subscription rights may not be exercised (with the exception of the subscription right exclusion for fractional shares) if and insofar during the term of this authorization, together with other authorizations to exclude subscription rights, subscription rights have been excluded for a total of more than 20% of the share capital existing at the time of the use of such exclusion. This does not include subscription rights exclusions for fractional shares and for shares issued in the context of certain employee participation programs. However, the limit includes purchase or conversion rights or obligations arising from bonds and/or profit participation rights regarding shares, if these were issued under exclusion of subscription rights.

Upon resolution of the shareholder lawsuit contesting this second set of authorized capital, we may be able to enter it into the commercial register, at which time it would become effective.

Contingent Capital (*bedingtes Kapital*)

According to our articles of association we have established four sets of contingent capital as follows:

- Our company's share capital is conditionally increased by up to €4,137,201 (reduced from original amount of €4,831,596 as a result of warrants we have issued), through the issue of 4,137,201 new registered ordinary shares, which constitute a proportion of the share capital of €1.00 each (Contingent Capital I). At this time, €548,960 of the Contingent Capital I is required to secure conversion rights from our convertible bonds issued in December 2016 and January 2017.
- The contingent capital increase serves (i) to secure granting of option rights and agreeing on option obligations pursuant to the terms of a respective bond, or (ii) to secure fulfillment of conversion rights and fulfillment of conversion obligations pursuant to the terms of a respective bond, each issued, agreed upon or guaranteed based on the authorization of the general meeting of August 28, 2015, by us or our affiliates.

  The contingent capital increase will be implemented only if and insofar as (i) financial instruments based on the authorization of the general meeting of August 28, 2015, are issued, and (ii) the holders or creditors of financial instruments, exercise their option or conversion rights, or fulfill an option or conversion obligation, as the case may be. The new shares issued on the basis of the previous sentence entitle their holders to dividends of company profits from the beginning of the fiscal year in which they are issued.

  Our management board is authorized (subject to the approval of our supervisory board) to make further stipulations regarding the implementation of the contingent capital increase.

- Our company's share capital is conditionally increased by up to €500,000, through the issue of up to 500,000 new registered ordinary shares, which constitute a proportion of the share capital of €1.00 each (Contingent Capital II).

  The contingent capital increase serves to redeem option rights, according to the option terms, to the benefit of the holders of share options from warrant bonds issued pursuant to the authorization resolution by our general meeting of shareholders held on March 17, 2009. The new shares are issued at the option price to be set in accordance with such authorization resolutions (issue price in the sense of Section 193 Para. 2 No. 3 of the German Stock Corporation Act).

  The contingent capital increase must be carried out only in the event of the issuance of warrant bonds, and only if the holders of share options from warrant bonds exercise their option rights, and if our company does not draw the necessary shares from other sources or replace them with cash payments. The new shares issued on the basis of the exercise of option rights entitle their holders to dividends from company profits from the beginning of the fiscal year in which they are issued.

  Our management board is authorized (subject to the approval of our supervisory board) to make further stipulations regarding the implementation of the contingent capital increase.

- Our company's share capital is conditionally increased by €542,400, through the issuance of up to 542,400 no-par-value registered ordinary shares (Contingent Capital III). The contingent capital increase serves exclusively to fulfill options granted until July 1, 2015 pursuant to the authorization by resolution of our general meeting of shareholders held on July 2, 2010. The contingent capital increase will be implemented only if the holders of the options issued exercise their right to purchase shares of our company, and if our company does not grant our own shares or pay a cash settlement in order to fulfill the options. The new shares entitle their holders to dividends from company profits from the beginning of the fiscal year in which they are issued.

- Our company's share capital is conditionally increased by up to €1,814,984, through the issue of up to 1,814,984 new no-par-value registered ordinary shares (Contingent Capital V). The contingent capital increase serves to ensure that option rights are fulfilled which were granted on the basis of the authorization of our general meeting of shareholders held on August 28, 2015, in the period up to August 27, 2020. The capital increase must be implemented only insofar as the holders of the share options exercise their options and we do not fulfill the option rights by delivering our own shares or paying a cash compensation. The new shares entitle their holders to dividends of company profits from the beginning of the fiscal year in which they are issued.

Subscription Rights

According to the German Stock Corporation Act, every shareholder is generally entitled to subscription rights (commonly known as preemptive rights) to any new shares issued in connection with a capital increase, including convertible bonds, bonds with warrants, profit-sharing rights or income bonds, in proportion to the number of shares such shareholder holds in the corporation's existing share capital. Under German law, these rights do not apply to shares issued out of contingent capital. A minimum subscription period of two weeks must be provided for the exercise of such subscription rights. Subscription rights are freely transferable and may be traded on German Stock exchanges within a specified period prior to the expiration date of the subscription period. In the past, we have refrained from arranging tradability of subscription rights on stock markets, since the issue price of our new shares had generally been close to market price, meaning that the subscription rights did not have inherent value.

Under German law, the shareholders' meeting may pass a resolution excluding subscription rights if at least a simple majority of votes and three-quarters of the share capital represented adopts the resolution. In addition to approval by the general shareholders' meeting, the exclusion of subscription rights requires a justification. The justification must be based on the principle that our interest in excluding subscription rights outweighs the shareholders' interest in their subscription rights and may be subject to judicial review. Under German law, the exclusion of subscription rights upon the issuance of new shares is permitted, however, if we increase the share capital against cash contributions and the amount of the capital increase does not exceed 10% of our existing share capital and the issue price of the new shares is not significantly lower than the market price of our shares. The management board must also make a report available to the shareholders justifying the exclusion and demonstrating that the company's interest in excluding the subscription rights outweighs the shareholders' interest in having them. If subscription rights to authorized capital are excluded, such report must be presented at the general meeting resolving on the creation of the authorized capital.

Shareholders' Meetings and Voting Rights

Pursuant to our articles of association, the annual general shareholders' meeting takes place at the discretion of the corporate body convening such meeting at the corporate seat of the company, the seat of a German stock exchange, or in a German city with more than 100,000 inhabitants. Each share entitles its holder to one vote at the general shareholders' meeting. Shareholders can vote their shares by proxy. Unless otherwise stipulated by the German Stock Corporation Act or our articles of association, resolutions of the general shareholders' meeting are adopted by a simple majority of the votes cast or, if a capital majority is required, by a simple majority of the registered share capital represented at the meeting.

Pursuant to the German Stock Corporation Act, resolutions of fundamental importance require both a majority of votes cast and a mandatory majority of at least 75% of the registered share capital represented at the vote on the resolution. Resolutions of fundamental importance generally include:

- changes to the articles of association regarding our business purpose;
- capital increases if shareholders' subscription rights are excluded;
- capital decreases;
- the creation of authorized or contingent capital;
- reorganizations pursuant to the German Reorganization Act (*Umwandlungsgesetz*), including mergers (*Verschmelzungen*), spin-offs ("*Abspaltungen*"), transfers of assets ("*Ausgliederungen*") and changes in legal form ("*Formwechsel*");
- an agreement to transfer all of the company's assets pursuant to Section 179a of the German Stock Corporation Act;
- the conclusion of enterprise agreements ("*Unternehmensverträge*"), such as domination and profit and loss transfer agreements ("*Beherrschungs-und Gewinnabführungsvertrag*"); and
- the dissolution of the company.

Our management board and our supervisory board may call a shareholders' meeting. Shareholders holding an aggregate of 5% or more of our registered share capital may request the management board to call a general meeting, and, if the management board refrains from doing so, may be authorized by a court to call the meeting themselves. Our supervisory board must call a shareholders' meeting whenever the interests of our company so require. Our company must hold our annual general shareholders' meeting during the first eight months of each fiscal year. The current version of our articles of association requires us to publish notices of shareholders' meetings in the Federal Gazette at least 36 days before such meeting. The registration deadline for attending the meeting is published concurrently with the notice of meeting. Neither German law nor our articles of association restrict the right of foreign shareholders or shareholders not domiciled in Germany to hold or vote our shares.

Other than as set forth above, neither German law nor our articles of association provide for a minimum participation for a quorum for our shareholders' meetings.

For a description of the voting rights for ADS holders, please see "Description of American Depositary Shares — Voting Rights."

Dividend Rights

Under the German Stock Corporation Act, distributions of dividends on shares for a given fiscal year are generally determined by a process in which our supervisory board and management board submit a proposal to our annual general shareholders' meeting held in the subsequent fiscal year and such annual general shareholders' meeting adopts a resolution. The German Stock Corporation Act provides that a resolution concerning dividends and distribution thereof may be adopted only if the company's unconsolidated financial statements under the applicable law show net retained profits ("*Bilanzgewinn*"). In determining the profit available for distribution, the result for the relevant fiscal year must be adjusted for profits and losses brought forward from the previous year and for withdrawals from or transfers to reserves. Certain reserves are required by law and must be deducted when calculating the profits available for distribution.

Shareholders participate in profit distributions in proportion to the number of shares they hold. Dividends on shares approved by the general shareholders' meeting are paid annually, shortly after the general shareholders' meeting, in compliance with the rules of the respective clearing system. Dividend payment claims are subject to a three-year statute of limitation in the company's favor.

We do not anticipate declaring or paying dividends for the foreseeable future. For information about the tax considerations relating to dividend payments, please see "Taxation — German Taxation of ADSs."

Liquidation Rights

Apart from a liquidation as a result of insolvency proceedings, our company may be liquidated only with a simple majority of votes and a majority of 75% or more of our share capital represented at the general shareholders' meeting at which such vote is taken. Pursuant to the German Stock Corporation Act, in the event of our company's liquidation, any assets remaining after all of our company's liabilities have been settled will be distributed pro rata among our shareholders. The German Stock Corporation Act provides certain protections for creditors which must be observed in the event of liquidation.

Merger and Division

Any merger into or with another company, split-off and split-ups, or the transfer of all or substantially all of our assets requires a resolution of the shareholder's meeting and a majority of at least 75% of our share capital present or represented at the time of adoption of the resolution.

Repurchase of our Own Shares

Our articles of association do not allow us to repurchase our own shares. German law, however, permits the purchase of a company's own shares in certain limited cases. In particular, the general meeting may authorize the purchase of shares of up to ten percent of the registered capital, if the company has sufficient free reserves. We do not have such an authorization in place at this time.

Squeeze-Out of Minority Shareholders

Under German law, the shareholders' meeting of a stock corporation may resolve upon request of a shareholder that holds at least 95% of the share capital that the shares held by any remaining minority shareholders be transferred to this shareholder against payment of "adequate cash compensation". This amount must take into account the full value of the company at the time of the resolution, which is generally determined using the future earnings value method.

A squeeze-out in the context of a merger ("*umwandlungsrechtlicher Squeeze-Out*") only requires a majority shareholder to hold at least 90% of the share capital. A squeeze-out in the context of a public take-over ("*übernahmerechtlicher Squeeze-Out*") requires a majority shareholder to hold at least 95% of the share capital, but has a simplified process.

Objects and Purposes of our Company

Our business purpose, as described in paragraph 3 of our articles of association, is to research, develop and sell pharmaceuticals, and to assume the status of a holding company, *i.e.*, to acquire and manage companies or stakes in companies. We may engage in all business activities which serve, directly or indirectly, our business purpose. Furthermore, we may establish branch offices and may acquire participations in enterprises of the same or similar kind.

Registration of our Company with Commercial Register

We are a German stock corporation that is organized under the laws of Germany. Our company is registered in the commercial register of Köln, Germany under the number HRB 49717.

Listing

Our ordinary shares are listed on the Frankfurt Stock Exchange under the symbol "B8F". Prior to this offering, no public market existed in the U.S. for our ordinary shares or the ADSs. We have been approved for listing of the ADSs on The NASDAQ Capital Market under the symbol "BFRA".

Notification and Disclosure Obligations

The German Securities Trading Act requires every shareholder whose equity participation in a company with a registered seat in Germany, and that is listed for trading on an organized market in a member state of the European Union or a country that is a party to the Treaty on the European Economic Area, reaches, exceeds, or falls below thresholds of 3%, 5%, 10%, 15%, 20%, 25%, 30%, 50%, or 75% of the voting rights of such company to inform the company and the German Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht* or BaFin) without undue delay and, in any case, no later than four trading days after reaching, exceeding or falling below these thresholds, using a standardized form. In the context of this requirement, the German Securities Trading Act and other regulations contains various rules that are meant to ensure that share ownership is attributed to the person that actually controls the voting rights pertaining to such shares. As long as the shareholder fails to make such notification, he may generally not exercise any rights pertaining to these shares (including voting rights and dividend rights). Upon receipt of any such shareholder notification, the German company is required to immediately publish the notification by a so-called European media bundle.

In addition, the European Market Abuse Regulation requires, *inter alia*, the members of the management board and the supervisory board, their spouses and close relatives, who purchase or sell shares, or other types of securities representing the right to acquire shares, including convertible bonds and bonds with warrants attached, issued by a company whose shares have been admitted to trading on a German stock exchange in excess of a *de minimis* number, to immediately notify the issuer and the BaFin of such purchases or sales. Upon receipt of such notice, the issuer is required to publish this notification by, among other things, posting it on its website.

DESCRIPTION OF AMERICAN DEPOSITARY SHARES

The Bank of New York Mellon, as depositary, will register and deliver ADSs. Each ADS will represent two shares (or a right to receive two shares) deposited with The Bank of New York Mellon SA/NV, as custodian for the depositary in Frankfurt (but see "Certain Relationships and Related Party Transactions — Share Loan Agreement" for a description of the mechanics of closing and the timing of share issuances). Each ADS will also represent any other securities, cash or other property which may be held by the depositary. The depositary's office at which the ADSs will be administered is located at 101 Barclay Street, New York, New York 10286. The Bank of New York Mellon's principal executive office is located at 225 Liberty Street, New York, New York 10286.

You may hold ADSs either (A) directly (i) by having an American Depositary Receipt, also referred to as an ADR, which is a certificate evidencing a specific number of ADSs, registered in your name, or (ii) by having uncertificated ADSs registered in your name, or (B) indirectly by holding a security entitlement in ADSs through your broker or other financial institution that is a direct or indirect participant in The Depository Trust Company, also called DTC. If you hold ADSs directly, you are a registered ADS holder, also referred to as an ADS holder. This description assumes you are an ADS holder. If you hold the ADSs indirectly, you must rely on the procedures of your broker or other financial institution to assert the rights of ADS holders described in this section. You should consult with your broker or financial institution to find out what those procedures are.

Registered holders of uncertificated ADSs will receive statements from the depositary confirming their holdings.

As an ADS holder, we will not treat you as one of our shareholders and you will not have shareholder rights. German law governs shareholder rights. The depositary will be the holder of the shares underlying your ADSs. As a registered holder of ADSs, you will have ADS holder rights. A deposit agreement among us, the depositary, ADS holders and all other persons indirectly or beneficially holding ADSs sets out ADS holder rights as well as the rights and obligations of the depositary. New York law governs the deposit agreement and the ADSs.

The following is a summary of the material provisions of the deposit agreement. For more complete information, you should read the entire deposit agreement and the form of ADR. Directions on how to obtain copies of those documents are provided on page 167.

Dividends and Other Distributions

How will you receive dividends and other distributions on the shares?

The depositary has agreed to pay or distribute to ADS holders the cash dividends or other distributions it or the custodian receives on shares or other deposited securities, upon payment or deduction of its fees and expenses. You will receive these distributions in proportion to the number of shares your ADSs represent.

Cash

The depositary will convert any cash dividend or other cash distribution we pay on the shares into U.S. dollars, if it can do so on a reasonable basis and can transfer the U.S. dollars to the U.S. If that is not possible or if any government approval is needed and cannot be obtained, the deposit agreement allows the depositary to distribute the foreign currency only to those ADS holders to whom it is possible to do so. It will hold the foreign currency it cannot convert for the account of the ADS holders who have not been paid. It will not invest the foreign currency and it will not be liable for any interest.

Before making a distribution, any withholding taxes or other governmental charges that must be paid will be deducted. See "Certain Material U.S. Federal Income and German Tax Considerations". It will distribute only whole U.S. dollars and cents and will round fractional cents to the nearest whole cent. *If the exchange rates fluctuate during a time when the depositary cannot convert the foreign currency, you may lose some of the value of the distribution.*

Shares

The depositary may distribute additional ADSs representing any shares we distribute as a dividend or free distribution. The depositary will only distribute whole ADSs. It will sell shares which would require it to deliver a fraction of an ADS (or ADSs representing those shares) and distribute the net proceeds in the same way as it does with cash. If the depositary does not distribute additional ADSs, the outstanding ADSs will also represent the new shares. The depositary may sell a portion of the distributed shares (or ADSs representing those shares) sufficient to pay its fees and expenses in connection with that distribution.

Rights to purchase additional shares

If we offer holders of our securities any rights to subscribe for additional shares or any other rights, the depositary may (i) exercise those rights on behalf of ADS holders, (ii) distribute those rights to ADS holders or (iii) sell those rights and distribute the net proceeds to ADS holders, in each case after deduction or upon payment of its fees and expenses. To the extent the depositary does not do any of those things, it will allow the rights to lapse. *In that case, you will receive no value for them.* The depositary will exercise or distribute rights only if we ask it to and provide satisfactory assurances to the depositary that it is legal to do so. If the depositary will exercise rights, it will purchase the securities to which the rights relate and distribute those securities or, in the case of shares, new ADSs representing the new shares, to subscribing ADS holders, but only if ADS holders have paid the exercise price to the depositary. U.S. securities laws may restrict the ability of the depositary to distribute rights or ADSs or other securities issued on exercise of rights to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

Other Distributions

The depositary will send to ADS holders anything we distribute on deposited securities by any means it thinks is legal, fair and practical. If it cannot make the distribution in that way, the depositary has a choice. It may decide to sell what we distributed and distribute the net proceeds, in the same way as it does with cash. Or, it may decide to hold what we distributed, in which case ADSs will also represent the newly distributed property. However, the depositary is not required to distribute any securities (other than ADSs) to ADS holders unless it receives satisfactory evidence from us that it is legal to make that distribution. The depositary may sell a portion of the distributed securities or property sufficient to pay its fees and expenses in connection with that distribution. U.S. securities laws may restrict the ability of the depositary to distribute securities to all or certain ADS holders, and the securities distributed may be subject to restrictions on transfer.

The depositary is not responsible if it decides that it is unlawful or impractical to make a distribution available to any ADS holders. We have no obligation to register ADSs, shares, rights or other securities under the Securities Act. We also have no obligation to take any other action to permit the distribution of ADSs, shares, rights or anything else to ADS holders. *This means that you may not receive the distributions we make on our shares or any value for them if it is illegal or impractical for us to make them available to you*.

Deposit, Withdrawal and Cancellation

How are ADSs issued?

The depositary will deliver ADSs if you or your broker deposits shares or evidence of rights to receive shares with the custodian. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will register the appropriate number of ADSs in the names you request and will deliver the ADSs to or upon the order of the person or persons that made the deposit.

How can ADS holders withdraw the deposited securities?

You may surrender your ADSs for the purpose of withdrawal at the depositary's office. Upon payment of its fees and expenses and of any taxes or charges, such as stamp taxes or stock transfer taxes or fees, the depositary will deliver the shares and any other deposited securities underlying the ADSs to the ADS holder or a person the ADS holder designates at the office of the custodian. Or, at your request, risk and expense, the depositary will deliver the deposited securities at its office, if feasible. The depositary may charge you a fee and its expenses for instructing the custodian regarding delivery of deposited securities.

How do ADS holders interchange between certificated ADSs and uncertificated ADSs?

You may surrender your ADR to the depositary for the purpose of exchanging your ADR for uncertificated ADSs. The depositary will cancel that ADR and will send to the ADS holder a statement confirming that the ADS holder is the registered holder of uncertificated ADSs. Upon receipt by the depositary of a proper instruction from a registered holder of uncertificated ADSs requesting the exchange of uncertificated ADSs for certificated ADSs, the depositary will execute and deliver to the ADS holder an ADR evidencing those ADSs.

Voting Rights

How do you vote?

ADS holders may instruct the depositary how to vote the number of deposited shares their ADSs represent. If we request the depositary to solicit your voting instructions (and we are not required to do so), the depositary will notify you of a shareholders' meeting and send or make voting materials available to you. Those materials will describe the matters to be voted on and explain how ADS holders may instruct the depositary how to vote. For instructions to be valid, they much reach the depositary by a date set by the depositary. The depositary will try, as far as practicable, subject to the laws of Germany and the provisions of our articles of association or similar documents, to vote or to have its agents vote the shares or other deposited securities as instructed by ADS holders. If we do not request the depositary to solicit your voting instructions, you can still send voting instructions and, in that case, the depositary may try to vote as you instruct, but it is not required to do so.

Except by instructing the depositary as described above, you won't be able to exercise voting rights unless you surrender your ADSs and withdraw the shares. However, you may not know about the meeting enough in advance to withdraw the shares. In any event, the depositary will not exercise any discretion in voting deposited securities and it will only vote or attempt to vote as instructed.

We cannot assure you that you will receive the voting materials in time to ensure that you can instruct the depositary to vote your shares. In addition, the depositary and its agents are not responsible for failing to carry out voting instructions or for the manner of carrying out voting instructions. *This means that you may not be able to exercise voting rights and there may be nothing you can do if your shares are not voted as you requested.*

In order to give you a reasonable opportunity to instruct the depositary as to the exercise of voting rights relating to deposited securities, if we request the depositary to act, we agree to give the depositary notice of any such meeting and details concerning the matters to be voted upon at least 45 days in advance of the meeting date.

Fees and Expenses

***Persons depositing or withdrawing shares or ADS holders must pay*:**	***For*:**
$5.00 (or less) per 100 ADSs (or portion of 100 ADSs)	Issuance of ADSs, including issuances resulting from a distribution of shares or rights or other property
	Cancellation of ADSs for the purpose of withdrawal, including if the deposit agreement terminates
$.05 (or less) per ADS	Any cash distribution to ADS holders
A fee equivalent to the fee that would be payable if securities distributed to you had been shares and the shares had been deposited for issuance of ADSs	Distribution of securities distributed to holders of deposited securities (including rights) that are distributed by the depositary to ADS holders
$.05 (or less) per ADS per calendar year	Depositary services
Registration or transfer fees	Transfer and registration of shares on our share register to or from the name of the depositary or its agent when you deposit or withdraw shares
Expenses of the depositary	Cable, telex and facsimile transmissions (when expressly provided in the deposit agreement) Converting foreign currency to U.S. dollars
Taxes and other governmental charges the depositary or the custodian has to pay on any ADSs or shares underlying ADSs, such as stock transfer taxes, stamp duty or withholding taxes	As necessary
Any charges incurred by the depositary or its agents for servicing the deposited securities	As necessary

The depositary collects its fees for delivery and surrender of ADSs directly from investors depositing shares or surrendering ADSs for the purpose of withdrawal or from intermediaries acting for them. The depositary collects fees for making distributions to investors by deducting those fees from the amounts distributed or by selling a portion of distributable property to pay the fees. The depositary may collect its annual fee for depositary services by deduction from cash distributions or by directly billing investors or by charging the book-entry system accounts of participants acting for them. The depositary may collect any of its fees by deduction from any cash distribution payable (or by selling a portion of securities or other property distributable) to ADS holders that are obligated to pay those fees. The depositary may generally refuse to provide fee-attracting services until its fees for those services are paid.

From time to time, the depositary may make payments to us to reimburse us for costs and expenses generally arising out of establishment and maintenance of the ADS program, waive fees and expenses for services provided to us by the depositary, or share revenue from the fees collected from ADS holders. In performing its duties under the deposit agreement, the depositary may use brokers, dealers, foreign currency dealers or other service providers that are owned by or affiliated with the depositary and that may earn or share fees, spreads or commissions.

The depositary may convert currency itself or through any of its affiliates and, in those cases, acts as principal for its own account and not as agent, advisor, broker or fiduciary on behalf of any other person and earns revenue, including, without limitation, transaction spreads, that it will retain for its own account. The revenue is based on, among other things, the difference between the exchange rate assigned to the currency conversion made under the deposit agreement and the rate that the depositary or its affiliate receives when buying or selling foreign currency for its own account. The depositary makes no representation that the exchange rate used or obtained in any currency conversion under the deposit agreement will be the most favorable rate that could be obtained at the time or that the method by which that rate will be determined will be the most favorable to ADS holders, subject to the depositary's obligations under the deposit agreement. The methodology used to determine exchange rates used in currency conversions is available upon request.

Payment of Taxes

You will be responsible for any taxes or other governmental charges payable on your ADSs or on the deposited securities represented by any of your ADSs. The depositary may refuse to register any transfer of your ADSs or allow you to withdraw the deposited securities represented by your ADSs until those taxes or other charges are paid. It may apply payments owed to you or sell deposited securities represented by your ADSs to pay any taxes owed and you will remain liable for any deficiency. If the depositary sells deposited securities, it will, if appropriate, reduce the number of ADSs to reflect the sale and pay to ADS holders any proceeds, or send to ADS holders any property, remaining after it has paid the taxes.

Tender and Exchange Offers; Redemption, Replacement or Cancellation of Deposited Securities

The depositary will not tender deposited securities in any voluntary tender or exchange offer unless instructed to do by an ADS holder surrendering ADSs and subject to any conditions or procedures the depositary may establish.

If deposited securities are redeemed for cash in a transaction that is mandatory for the depositary as a holder of deposited securities, the depositary will call for surrender of a corresponding number of ADSs and distribute the net redemption money to the holders of called ADSs upon surrender of those ADSs.

If there is any change in the deposited securities such as a sub-division, combination or other reclassification, or any merger, consolidation, recapitalization or reorganization affecting the issuer of deposited securities in which the depositary receives new securities in exchange for or in lieu of the old deposited securities, the depositary will hold those replacement securities as deposited securities under the deposit agreement. However, if the depositary decides it would not be lawful to hold the replacement securities because those securities could not be distributed to ADS holders or for any other reason, the depositary may instead sell the replacement securities and distribute the net proceeds upon surrender of the ADSs.

If there is a replacement of the deposited securities and the depositary will continue to hold the replacement securities, the depositary may distribute new ADSs representing the new deposited securities or ask you to surrender your outstanding ADRs in exchange for new ADRs identifying the new deposited securities.

If there are no deposited securities underlying ADSs, including if the deposited securities are cancelled, or if the deposited securities underlying ADSs have become apparently worthless, the depositary may call for surrender or of those ADSs or cancel those ADSs upon notice to the ADS holders.

Amendment and Termination

How may the deposit agreement be amended?

We may agree with the depositary to amend the deposit agreement and the ADRs without your consent for any reason. If an amendment adds or increases fees or charges, except for taxes and other governmental charges or expenses of the depositary for registration fees, facsimile costs, delivery charges or similar items, or prejudices a substantial right of ADS holders, it will not become effective for outstanding ADSs until 30 days after the depositary notifies ADS holders of the amendment. *At the time an amendment becomes effective, you are considered, by continuing to hold your ADSs, to agree to the amendment and to be bound by the ADRs and the deposit agreement as amended*.

How may the deposit agreement be terminated?

The depositary will initiate termination of the deposit agreement if we instruct it to do so. The depositary may initiate termination of the deposit agreement if:

- 60 days have passed since the depositary told us it wants to resign, but a successor depositary has not been appointed and accepted its appointment;
- we delist our shares from an exchange on which they were listed and do not list the shares on another exchange;
- we appear to be insolvent or enter insolvency proceedings;
- all or substantially all the value of the deposited securities has been distributed either in cash or in the form of securities;
- there are no deposited securities underlying the ADSs or the underlying deposited securities have become apparently worthless; or
- there has been a replacement of deposited securities.

If the deposit agreement will terminate, the depositary will notify ADS holders at least 90 days before the termination date. At any time after the termination date, the depositary may sell the deposited securities. After that, the depositary will hold the money it received on the sale, as well as any other cash it is holding under the deposit agreement, unsegregated and without liability for interest, for the *pro rata* benefit of the ADS holders that have not surrendered their ADSs. Normally, the depositary will sell as soon as practicable after the termination date.

After the termination date and before the depositary sells, ADS holders can still surrender their ADSs and receive delivery of deposited securities, except that the depositary may refuse to accept a surrender for the purpose of withdrawing deposited securities if it would interfere with the selling process. The depositary may refuse to accept a surrender for the purpose of withdrawing sale proceeds until all the deposited securities have been sold. The depositary will continue to collect distributions on deposited securities, but, after the termination date, the depositary is not required to register any transfer of ADSs or distribute any dividends or other distributions on deposited securities to the ADSs holders (until they surrender their ADSs) or give any notices or perform any other duties under the deposit agreement except as described in this paragraph.

Limitations on Obligations and Liability

Limits on our Obligations and the Obligations of the Depositary; Limits on Liability to Holders of ADSs

The deposit agreement expressly limits our obligations and the obligations of the depositary. It also limits our liability and the liability of the depositary. We and the depositary:

- are only obligated to take the actions specifically set forth in the deposit agreement without negligence or bad faith;
- are not liable if we are or it is prevented or delayed by law or circumstances beyond our or its control from performing our or its obligations under the deposit agreement;
- are not liable if we or it exercises discretion permitted under the deposit agreement;

- are not liable for the inability of any holder of ADSs to benefit from any distribution on deposited securities that is not made available to holders of ADSs under the terms of the deposit agreement, or for any special, consequential or punitive damages for any breach of the terms of the deposit agreement;
- have no obligation to become involved in a lawsuit or other proceeding related to the ADSs or the deposit agreement on your behalf or on behalf of any other person;
- are not liable for the acts or omissions of any securities depository, clearing agency or settlement system; and
- may rely upon any documents we believe or it believes in good faith to be genuine and to have been signed or presented by the proper person.

In the deposit agreement, we and the depositary agree to indemnify each other under certain circumstances.

Requirements for Depositary Actions

Before the depositary will deliver ADSs or register a transfer of ADSs, make a distribution on ADSs, or permit withdrawal of shares, the depositary may require:

- payment of stock transfer or other taxes or other governmental charges and transfer or registration fees charged by third parties for the transfer of any shares or other deposited securities;
- satisfactory proof of the identity and genuineness of any signature or other information it deems necessary; and
- compliance with regulations it may establish, from time to time, consistent with the deposit agreement, including presentation of transfer documents.

The depositary may refuse to deliver ADSs or register transfers of ADSs when the transfer books of the depositary or our transfer books are closed or at any time if the depositary or we think it advisable to do so.

Your Right to Receive the Shares Underlying your ADSs

ADS holders have the right to cancel their ADSs and withdraw the underlying shares at any time except:

- when temporary delays arise because: (i) the depositary has closed its transfer books or we have closed our transfer books; (ii) the transfer of shares is blocked to permit voting at a shareholders' meeting; or (iii) we are paying a dividend on our shares;
- when you owe money to pay fees, taxes and similar charges; or
- when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to ADSs or to the withdrawal of shares or other deposited securities.

This right of withdrawal may not be limited by any other provision of the deposit agreement.

Pre-release of ADSs

The deposit agreement permits the depositary to deliver ADSs before deposit of the underlying shares. This is called a pre-release of the ADSs. The depositary may also deliver shares upon cancellation of pre-released ADSs (even if the ADSs are canceled before the pre-release transaction has been closed out). A pre-release is closed out as soon as the underlying shares are delivered to the depositary. The depositary may receive ADSs instead of shares to close out a pre-release. The depositary may pre-release ADSs only under the following conditions: (1) before or at the time of the pre-release, the person to whom the pre-release is being made represents to the depositary in writing that it or its customer owns the shares or ADSs to be deposited; (2) the pre-release is fully collateralized with cash or other collateral that the depositary considers appropriate; and (3) the depositary must be able to close out the pre-release on not more than five business days' notice. In addition, the depositary will limit the number of ADSs that may be outstanding at any time as a result of pre-release, although the depositary may disregard the limit from time to time if it thinks it is appropriate to do so.

Direct Registration System

In the deposit agreement, all parties to the deposit agreement acknowledge that the Direct Registration System, also referred to as DRS, and Profile Modification System, also referred to as Profile, will apply to the ADSs. DRS is a system administered by DTC that facilitates interchange between registered holding of uncertificated ADSs and holding of security entitlements in ADSs through DTC and a DTC participant. Profile is a feature of DRSs that allows a DTC participant, claiming to act on behalf of a registered holder of uncertificated ADSs, to direct the depositary to register a transfer of those ADSs to DTC or its nominee and to deliver those ADSs to the DTC account of that DTC participant without receipt by the depositary of prior authorization from the ADS holder to register that transfer.

In connection with and in accordance with the arrangements and procedures relating to DRS/Profile, the parties to the deposit agreement understand that the depositary will not determine whether the DTC participant that is claiming to be acting on behalf of an ADS holder in requesting registration of transfer and delivery as described in the paragraph above has the actual authority to act on behalf of the ADS holder (notwithstanding any requirements under the Uniform Commercial Code). In the deposit agreement, the parties agree that the depositary's reliance on and compliance with instructions received by the depositary through the DRS/Profile system and in accordance with the deposit agreement will not constitute negligence or bad faith on the part of the depositary.

Shareholder Communications; Inspection of Register of Holders of ADSs

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. The depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to. You have a right to inspect the register of holders of ADSs, but not for the purpose of contacting those holders about a matter unrelated to our business or the ADSs.

SHARES AND ADSs ELIGIBLE FOR FUTURE SALE

Our ordinary shares are listed and are currently traded on the Frankfurt Stock Exchange under the symbol "B8F". Prior to this offering, no public market existed in the U.S. for our ordinary shares or the ADSs. Future sales of ordinary shares or ADSs in the public market after this offering, and the availability of ordinary shares or ADSs for future sale, could adversely affect the market price of the ADSs prevailing from time to time. As described below, most of our currently outstanding ordinary shares will be available for sale immediately after this offering, and the remainder will be available for sale 180 days after the expiration of contractual restrictions on transfers of ordinary shares and ADSs. Accordingly, sales of substantial amounts of ordinary shares or ADSs, or the perception that these sales could occur, could adversely affect prevailing market prices for ordinary shares and the ADSs and could impair our future ability to raise equity capital.

Based on the number of shares outstanding as of February 8, 2018, and assuming (1) no exercise of the underwriters' over-allotment option to purchase additional ADSs and (2) no exercise or conversion of any of our outstanding convertible bonds or stock options, upon completion of this offering (see "Certain Relationships and Related Party Transactions — Share Loan Agreement") we will have outstanding an aggregate of 44,245,462 ordinary shares (including ordinary shares represented by the ADSs). All of the ADSs sold in this offering will be freely transferable without restriction or further registration under the Securities Act, except for any ADSs sold to our "affiliates" (subject to the terms of the lock-up agreements referred to below, as applicable). In addition, all of our ordinary shares outstanding before this offering will be freely transferable and may be resold without restriction or further registration under the Securities Act (subject to the terms of the lock-up agreements referred to below, as applicable). Under Rule 144 under the Securities Act, an "affiliate" of a company is a person that directly or indirectly controls, is controlled by or is under common control with that company. Affiliates may sell only the volume of shares described below and their sales are subject to additional restrictions described below.

Lock-Up Agreements

We and our chief executive officer has agreed that, without the prior consent of The Benchmark Company, LLC, we and he will not, subject to limited exceptions, during the period ending 180 days after the date of this prospectus, directly or indirectly, offer, pledge, sell, contract to sell, pledge or otherwise dispose of any ordinary shares or other shares of our capital stock or any securities convertible into, exercisable or exchangeable for, such capital stock (including our ADSs). See "Underwriting" for additional information.

The Benchmark Company, LLC, on behalf of the underwriters, will have discretion in determining if, and when, to release any ordinary shares or ADSs subject to any lock-up agreements.

Rule 144

Rule 144 provides an exemption from the registration requirements of the Securities Act for restricted securities and securities held by certain affiliates of an issuer being sold in the U.S., to U.S. persons or through U.S. securities markets. In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, a person (or persons whose securities are required to be aggregated) who is not deemed to have been one of our "affiliates" for purposes of Rule 144 at any time during the three months preceding a sale, and who has beneficially owned restricted securities within the meaning of Rule 144 for at least six months, including the holding period of any prior owner other than one of our "affiliates," is entitled to sell such securities in the U.S. public market (subject to any lock-up agreement referred to above, if applicable) without complying with the manner of sale, volume limitations or notice provisions of Rule 144, but subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the securities proposed to be sold for at least one year, including the holding period of any prior owner other than "affiliates," then such person is entitled to sell such securities in the public market without complying with any of the requirements of Rule 144 (subject to any lock-up agreement referred to above, if applicable).

In general, under Rule 144, as currently in effect, once we have been subject to the public company reporting requirements of the Exchange Act for at least 90 days, our "affiliates," as defined in Rule 144, who have beneficially owned the securities proposed to be sold for at least six months are entitled to sell in the public market, upon expiration of any applicable lock-up agreements and within any three-month period, a number of those securities that does not exceed the greater of:

- 1% of the number of ADSs then outstanding, which will equal approximately 13,022 ADSs immediately after this offering (assuming the underwriters exercise their option to purchase 85,483 additional ADSs for the purpose of covering over-allotments); or
- the average weekly trading volume of our ADSs on The NASDAQ Capital Market during the four calendar weeks preceding the filing of a notice on Form 144 with respect to such sale.

Such sales under Rule 144 by our "affiliates" or persons selling ADSs on behalf of our "affiliates" are also subject to certain manner of sale provisions, notice requirements and to the availability of current public information about us.

Regulation S

Regulation S under the Securities Act provides that shares owned by any person may be sold without registration in the U.S., provided that the sale is effected in an offshore transaction and no directed selling efforts are made in the U.S. (as these terms are defined in Regulation S), subject to certain other conditions. In general, this means that our shares may be sold in offshore transactions in compliance with Regulation S.

EXCHANGE CONTROLS AND LIMITATIONS AFFECTING SHAREHOLDERS

There are currently no legal restrictions in Germany on international capital movements and foreign-exchange transactions, except in limited embargo circumstances relating to certain areas, entities or persons as a result of applicable resolutions adopted by the United Nations and the European Union. Restrictions currently exist with respect to, among others, Afghanistan, Belarus, Burma/Myanmar, Central African Republic, Congo, Egypt, Eritrea, Guinea, Guinea-Bissau, Iran, Iraq, Ivory Coast, Lebanon, Liberia, Libya, North Korea, Russia, Somalia, South Sudan, Sudan, Syria, Tunisia, Ukraine, Yemen and Zimbabwe.

For statistical purposes, there are, however, limited notification requirements regarding transactions involving cross-border monetary transfers. With some exceptions, every corporation or individual residing in Germany must report to the German Central Bank (Deutsche Bundesbank) (i) any payment received from, or made to, a non-resident corporation or individual that exceeds €12,500 (or the equivalent in a foreign currency) and (ii) any claim against, or liability payable to, a non-resident or corporation in excess of €5 million (or the equivalent in a foreign currency) at the end of any calendar month. Payments include cash payments made by means of direct debit, checks and bills, remittances denominated in euros and other currencies made through financial institutions, as well as netting and clearing arrangements.

German Taxation of ADSs

Scope of Discussion

The following is a general summary of the material German tax consequences for U.S. holders (as defined below) of the ADSs. It does not purport to be a complete analysis of all German tax considerations relating to the ADSs. It is based upon the laws in force and their interpretation at the time of preparation of this prospectus and is subject to any change in law or interpretation after such date, potentially having retrospective or retroactive effect. It does not address the German tax consequences for holders of the ADSs who are not U.S. holders (as defined below). Furthermore, it does not address the German tax consequences resulting from the ADSs being attributable to (1) a permanent establishment outside of the U.S., or (2) a permanent representative outside of the U.S.

A U.S. holder in terms of this section on the German taxation of the ADSs is:

- a resident of the U.S. in terms of the Agreement between the United States of America and the Federal Republic of Germany for the Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income and Capital and to certain other Taxes as of June 4, 2008 (Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung und zur Verhinderung der Steuerverkürzung auf dem Gebiet der Steuern vom Einkommen und vom Vermögen und einiger anderer Steuern in der Fassung vom 4. Juni 2008, "Treaty");

- who is not subject to German unlimited tax liability by way of a German residence or habitual abode or, as the case may be, a German registered seat or place of management;

- who is the beneficial owner of the ADSs and any payments such as dividends under the ADSs; and

- who is not subject to the limitation of benefits clause of the Treaty.

In particular because it is not possible to take into account the personal circumstances of prospective U.S. holders, they should consult their tax advisors as to the consequences under the tax laws of Germany resulting from acquiring, holding and disposing of ADSs and receiving payments under the ADSs such as dividends.

German Taxation of Dividends and Capital Gains

At the time of preparation of this prospectus, no decisions of German tax courts have been published that comprehensively outline the treatment of ADRs or ADSs under German tax law. However, the German Federal Ministry of Finance has issued a circular dated May 24, 2013 (reference number BMF IV C 1 — S 2204/12/10003, "ADR Circular") on the treatment of ADRs under German tax law. According to the ADR Circular, holders of ADRs are in general treated like the beneficial owners of the respective shares for German tax purposes. It has to be noted, however, that the ADR Circular does not address ADSs and it is therefore not clear whether or not the ADSs fall within the scope of the ADR Circular. If the ADS fall within the scope of the ADR Circular, U.S. holders of the ADSs would be treated as if they held the respective amount of ordinary shares and if they received dividends under the ordinary shares for German tax purposes. Furthermore, U.S. holders of the ADSs should note that the ADR Circular is not binding on German tax courts and it is unclear whether a German tax court would follow the ADR Circular with respect to the German tax treatment of ADRs or ADSs. For the purposes of this section on the German taxation of the ADSs it is assumed that the ADSs fall within the scope of the ADR Circular.

German Taxation of Capital Gains of the U.S. Treaty Beneficiaries of the ADSs

The company maintains its registered seat in Germany. As a consequence, capital gains resulting from the disposition of ADSs realized by a U.S. holder are treated as German source income and are subject to German limited tax liability (*beschränkte Steuerpflicht*) if such U.S. holder at any time within five years prior to the disposition directly or indirectly held ADSs, shares and/or other rights representing together 1% or more of the company's shares. If such holder had acquired the ADSs without consideration, the previous owner's holding period and percentage of the holding would also be taken into account. However, U.S. holders may invoke the Treaty and, as a result, are not subject to German taxation on capital gains resulting from the disposition of ADSs.

Under German law, disbursing agents are required to levy withholding tax on capital gains from the sale of shares or other securities held in a custodial account. Disbursing agent in this context means a German bank, a financial services institution, a securities trading enterprise or a securities trading bank (each as defined in the German Banking Act (*Kreditwesengesetz*) and, in each case, including a German branch of a foreign enterprise, but excluding a foreign branch of a German enterprise) that holds the ADSs in custody or administers the ADSs for the U.S. holder or conducts sales or other dispositions and disburses or credits the income from the ADSs to the U.S. holder of the ADSs. Under German law, the obligation to withhold taxes on capital gains does not explicitly depend on the capital gains being subject to German limited or unlimited taxation or on an applicable double taxation treaty permitting Germany to tax such capital gains.

However, the German Federal Ministry of Finance has issued a circular dated October 9, 2012 (reference number BMF IVC1 — S 2252/10/10013, "Capital Income Circular") due to which taxes need not be withheld when the capital gains are not subject to German taxation. The Capital Income Circular further states that there is no obligation to withhold such tax on capital gains even if a U.S. holder owns 1% or more of the shares. While the Capital income Circular is only binding on the tax authorities but not on the tax courts, in practice, the disbursing agents nevertheless typically rely on the guidance contained in such circular. Therefore, a disbursing agent would only withhold tax at 26.375% on capital gains derived by a U.S. holder from the sale of ADSs held in a custodial account in Germany in the unlikely event that the disbursing agent did not follow this guidance. In this case, the U.S. holder should be entitled to claim a refund of the withholding tax from the German tax authorities under the Treaty.

Taxation of Dividends

Dividends distributed by the company to a U.S. holder under the ADS are subject to a German withholding tax of 25% plus 5.5% solidarity surcharge thereon, resulting in an overall withholding tax rate of 26.375%.

However, U.S. holders may invoke the Treaty. Therefore, the German withholding tax may in general not exceed 15% of the dividends received by U.S. holders. A further reduction of the permitted withholding tax rate under the Treaty may apply depending on further requirements. The excess of the total amount withheld over the maximum rate of withholding tax permitted under the Treaty is refunded to U.S. holders upon application (as described below under "Withholding Tax Refund for U.S. Treaty Beneficiaries").

Withholding Tax Refund for U.S. Treaty Beneficiaries

As described above, U.S. holders are entitled to claim a refund of the portion of the generally applicable 26.375% German withholding tax on dividends that exceeds the permitted withholding tax rate under the Treaty. However, U.S. holders should note that it is unclear how the German authorities will apply the refund process to dividends paid under ADSs and ADRs. In general, any potential refund claim becomes time-barred after four years following the calendar year in which the dividend is received.

Additionally, such refund is subject to the German anti treaty shopping provision. In general, this rule requires that the U.S. holder (in case it is corporation, "U.S. corporate holder") maintains its own administrative substance and conducts its own business activities. In particular, a U.S. corporate holder has no right to a full or partial refund to the extent persons holding ownership interests in the U.S. corporate holder would not be entitled to the refund had they received the income directly and the gross income realized by the U.S. corporate holder is not caused by the business activities of the U.S. corporate holder, and there are either no economic or other valid reasons for the interposition of the U.S. corporate holder, or the U.S. corporate holder does not participate in general commerce by means of a business organization with resources appropriate to its business purpose. However, this shall not apply if the U.S. corporate holder's principal class of stock is regularly traded in substantial volume on a recognized stock exchange, or if the U.S. corporate holder is subject to the provisions of the German Investment Tax Act (*Investmentsteuergesetz*).

U.S. holders claiming a refund of German withholding tax should in any case consult their tax advisors with respect to the refund procedure as there is only limited guidance of the German tax authorities on the practical application of the refund procedure with respect to the ADS.

German Inheritance and Gift Tax (Erbschaft-und Schenkungsteuer)

As the ADR Circular does not refer to the German Inheritance and Gift Tax Act, it is unclear whether or not the German inheritance or gift tax applies to the transfer of the ADSs. However, if German inheritance or gift tax is applicable to ADSs, under German domestic law, the transfer of the ordinary shares in the company and, as a consequence, the transfer of the ADSs would be subject to German gift or inheritance tax if:

- the decedent or donor or heir, beneficiary or other transferee (1) maintained his or her residence or a habitual abode in Germany or had its place of management or registered seat in Germany at the time of the transfer, or (2) is a German citizen who has spent no more than five consecutive years outside of Germany without maintaining a residence in Germany or (3) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person's household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of residence or habitual abode with respect to assets located in such country (special rules apply to certain former German citizens who neither maintain a residence nor have their habitual abode in Germany);

- at the time of the transfer, the ADSs are held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed; or

- the ADSs subject to such transfer form part of a portfolio that represents at the time of the transfer 10% or more of the registered share capital of the company and that has been held directly or indirectly by the decedent or donor, either alone or together with related persons.

Under the Agreement between the Federal Republic of Germany and the United States of America for the avoidance of double taxation with respect to taxes on inheritances and gifts (*Abkommen zwischen der Bundesrepublik Deutschland und den Vereinigten Staaten von Amerika zur Vermeidung der Doppelbesteuerung auf dem Gebiet der Nachlass-, Erbschaft-und Schenkungsteuern in der Fassung vom 21. December 2000*, "Inheritance and Gift Tax Treaty"), a transfer of ADSs by gift or upon death is not subject to German inheritance or gift tax if the donor or the transferor is domiciled in the U.S. in terms of the Inheritance and Gift Tax Treaty, and is neither a citizen of Germany nor a former citizen of Germany and, at the time of the transfer, the ADSs are not held by the decedent or donor as business assets forming part of a permanent establishment in Germany or for which a permanent representative in Germany has been appointed.

Notwithstanding the foregoing, in case the heir, transferee or other beneficiary (i) has, at the time of the transfer, his or her residence or habitual abode in Germany, or (ii) is a German citizen who has spent no more than five (or, in certain circumstances, ten) consecutive years outside Germany without maintaining a residence in Germany or (iii) is a German citizen who serves for a German entity established under public law and is remunerated for his or her service from German public funds (including family members who form part of such person's household, if they are German citizens) and is only subject to estate or inheritance tax in his or her country of residence or habitual abode with respect to assets located in such country (or special rules apply to certain former German citizens who neither maintain a residence nor have their habitual abode in Germany), the transferred ADSs are subject to German inheritance or gift tax.

If, in this case, Germany levies inheritance or gift tax on the ADSs with reference to the heir's, transferee's or other beneficiary's residence in Germany or his or her German citizenship, and the U.S. also levies federal estate tax or federal gift tax with reference to the decedent's or donor's residence (but not with reference to the decedent's or donor's citizenship), the amount of the U.S. federal estate tax or the U.S. federal gift tax, respectively, paid in the U.S. with respect to the transferred ADSs is credited against the German inheritance or gift tax liability, provided the U.S. federal estate tax or the U.S. federal gift tax, as the case may be, does not exceed the part of the German inheritance or gift tax, as computed before the credit is given, which is attributable to the transferred ADSs. A claim for credit of the U.S. federal estate tax or the U.S. federal gift tax, as the case may be, may be made within one year of the final determination and payment of the U.S. federal estate tax or the U.S. federal gift tax, as the case may be, provided that the determination and payment are made within ten years of the date of death of the decedent or of the date of the gift by the donor. Similarly, U.S. state-level estate or gift taxes are also creditable against the German inheritance or gift tax liability to the extent that U.S. federal estate or gift tax is creditable.

U.S. Taxation of ADSs and Ordinary Shares

The following discussion describes the material U.S. federal income tax consequences of the acquisition, ownership and disposition of the ADSs and ordinary shares by a U.S. holder (as defined below). The information provided below is based on the Internal Revenue Code of 1986, as amended ("Code"), Internal Revenue Service ("IRS") rulings and pronouncements, and judicial decisions all as now in effect and all of which are subject to change or differing interpretations, possibly with retroactive effect. This summary addresses only U.S. federal income tax considerations of U.S. holders that will hold ADSs or ordinary shares as capital assets. It does not provide a complete analysis of all potential tax considerations. In particular, this summary does not address all the tax considerations applicable to a particular holder of ADSs or ordinary shares in light of the holder's circumstances, for example:

- financial institutions;
- insurance companies;
- dealers or traders in securities;
- persons that will hold ADSs or ordinary shares as part of a hedging or conversion transaction or as a position in a straddle or other integrated transaction for U.S. federal income tax purposes;
- persons that have a functional currency other than the U.S. dollar;
- persons that own (or are deemed to own) ADSs or ordinary shares representing 10% or more of our voting shares;
- regulated investment companies, real estate investment trusts;
- tax-exempt entities;
- tax-deferred or other retirement accounts;
- persons who hold ADSs or ordinary shares through partnerships or other pass-through entities;
- certain former citizens or residents of the U.S.;
- persons deemed to sell ADSs or ordinary shares under constructive sale provisions of the Code; or
- persons holding ADSs or ordinary shares in connection with a trade or business conducted outside of the U.S.

Finally, the summary does not describe the effect of the U.S. federal alternative minimum, estate and gift tax laws on U.S. holders or the effects of any applicable state, local, or non-U.S. laws.

For purposes of this summary, a "U.S. holder" is a beneficial owner of ADSs or ordinary shares that for U.S. federal income tax purposes, is (1) an individual who is a citizen or resident of the U.S.; (2) a corporation, or other entity treated as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the U.S., any state thereof or the District of Columbia; (3) an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or (4) a trust, if it (i) is subject to the primary supervision of a U.S. court and the control of one or more U.S. persons or (ii) has a valid election in effect under applicable U.S. Treasury Regulations to be treated as a U.S. person. A "non-U.S. holder" is a beneficial owner of the ADSs or ordinary shares (other than an entity or arrangement treated as a partnership for U.S. federal income tax purposes) that is not a U.S. holder.

If a partnership (including an entity or arrangement, U.S. or non-U.S., treated as a partnership for U.S. federal income tax purposes) holds ADSs or ordinary shares, the tax treatment of a partner in the partnership will depend upon the status of the partner and the activities of the partnership. A holder of ADSs or ordinary shares that is a partnership, and partners in such partnership, should consult their own tax advisors about the U.S. federal income tax consequences of acquiring, owning and disposing of the ADSs or ordinary shares.

Each prospective holder of ADSs or ordinary shares should consult its own tax advisors regarding the U.S. federal, state and local or other tax consequences of acquiring, owning and disposing of our ADSs or ordinary shares in light of their particular circumstances. U.S. holders should also review the discussion under "— German Taxation of ADSs" for the German tax consequences to a U.S. holder of the ownership of the ADSs.

General

In general and taking into account the earlier assumptions, a U.S. holder of ADSs is treated as the owner of the ordinary shares represented by such ADSs. Exchanges of ordinary shares for ADSs, and ADSs for ordinary shares, respectively, generally will not be subject to U.S. federal income tax.

Distributions

Under the U.S. federal income tax laws, and subject to the passive foreign investment company ("PFIC") rules discussed below, the gross amount of any distribution that is actually or constructively received by a U.S. holder with respect to its ordinary shares (including shares deposited in respect of ADSs) will be a dividend includible in gross income of a U.S. holder as ordinary income to the extent the amount of such distribution is paid out of our current or accumulated earnings and profits, as determined for U.S. federal income tax purposes. To the extent that the amount of such distribution exceeds our current and accumulated earnings and profits as so computed, it will be treated first as a non-taxable return of capital to the extent of such U.S. holder's adjusted tax basis in its ADSs or ordinary shares, and to the extent the amount of such distribution exceeds such adjusted tax basis, will be treated as gain from the sale of the ADSs or ordinary shares. If you are a non-corporate U.S. holder, dividends paid to you that constitute qualified dividend income will be taxable to you at a reduced maximum U.S. federal income rate of taxation, the maximum of which is currently 20% (rather than the higher rates of tax generally applicable to items of ordinary income, the maximum of which is currently 37%) provided that you hold our ADSs or ordinary shares for more than 60 days during the 121-day period beginning 60 days before the ex-dividend date and meet other holding period requirements. If we are a PFIC (as discussed below under "Additional U.S. Federal Income Tax Consequences — PFIC Rules"), distributions paid by us with respect to ADSs or ordinary shares will not be eligible for the preferential income tax rate. Prospective investors should consult their own tax advisors regarding the taxation of distributions under these rules.

You must include any German tax withheld from the dividend payment in this gross amount even though you do not in fact receive it. The gross amount of the dividend is taxable to you when you receive the dividend, actually or constructively. Dividends paid on ADSs or ordinary shares generally will constitute income from sources outside the U.S. and will generally not be eligible for the dividends-received deduction generally available to corporate U.S. holders. The gross amount of any dividend paid in non-U.S. currency will be included in the gross income of a U.S. holder in an amount equal to the U.S. dollar value of the non-U.S. currency calculated by reference to the exchange rate in effect on the date the dividend distribution is includable in the U.S. holder's income, regardless of whether the payment is in fact converted into U.S. dollars. If the non-U.S. currency is converted into U.S. dollars on the date of receipt by the depositary, in the case of ADSs, or the U.S. holder in the case of ordinary shares, a U.S. holder generally should not be required to recognize non-U.S. currency gain or loss in respect of the dividend. If the non-U.S. currency received is not converted into U.S. dollars on the date of receipt, a U.S. holder will have a basis in the non-U.S. currency equal to its U.S. dollar value on the date of receipt. Any gain or loss on a subsequent conversion or other disposition of the non-U.S. currency will be treated as ordinary income or loss, and will generally be income or loss from sources within the U.S. for foreign tax credit limitation purposes. The amount of any distribution of property other than cash will be the fair market value of the property on the date of the distribution, less the sum of any encumbrance assumed by the U.S. holder.

Subject to applicable limitations that may vary depending upon a U.S. holder's circumstances, a U.S. holder will be entitled to a credit against its U.S. federal income tax liability for any German withholding taxes withheld in respect of our dividend distributions not in excess of the applicable rate under the treaty. The limitation on foreign taxes eligible for credit is calculated separately with respect to specific classes of income, such as "passive" or "general" income. In addition, the amount of the qualified dividend income, if any, paid to a U.S. holder that is subject to the reduced dividend income tax rate and that is taken into account for purposes of calculating the U.S. holder's U.S. foreign tax credit limitation must be reduced by the rate differential portion of the dividend. The rules governing foreign tax credits are complex. Prospective investors should consult their own tax advisors regarding the availability and implications of foreign tax credits in light of their particular situation. In lieu of claiming a foreign tax credit, U.S. holders may elect to deduct all non-U.S. taxes paid or accrued in a taxable year in computing their taxable income, subject to generally applicable limitations under U.S. federal income tax law. Prospective investors should consult their own tax advisors regarding the availability and deductibility of non-U.S. taxes in light of their particular situation.

U.S. Taxation of Sale or Other Disposition

Subject to the discussion below under "Additional U.S. Federal Income Tax Consequences — PFIC Rules," a U.S. holder will generally recognize gain or loss for U.S. federal income tax purposes upon the sale or other disposition of ADSs or ordinary shares in an amount equal to the difference between the U.S. dollar value of the amount realized from such sale or other disposition and the U.S. holder's tax basis in such ADSs or ordinary shares. Such gain or loss generally will be capital gain or loss. Capital gain of a non-corporate U.S. holder recognized on the sale or other disposition of ADSs or ordinary shares held for more than one year is generally eligible for a reduced maximum U.S. federal income tax rate of taxation, the maximum of which is currently 20%. The gain or loss will generally be income or loss from sources within the U.S. for foreign tax credit limitation purposes. The deductibility of capital losses is subject to limitations.

A U.S. holder that receives non-U.S. currency on the sale or other disposition of ADSs or ordinary shares will realize an amount equal to the U.S. dollar value of the non-U.S. currency on the date of sale (or, in the case of cash basis and electing accrual basis taxpayers, the U.S. dollar value of the non-U.S. currency on the settlement date) provided that the ADSs or ordinary shares, as the case may be, are treated as being "traded on an established securities market." If a U.S. holder receives non-U.S. currency upon a sale or exchange of ADSs or ordinary shares, gain or loss, if any, recognized on the subsequent sale, conversion or disposition of such non-U.S. currency will be ordinary income or loss, and will generally be income or loss from sources within the U.S. for foreign tax credit limitation purposes. However, if such non-U.S. currency is converted into U.S. dollars on the date received by the U.S. holder, a cash basis or electing accrual U.S. holder should not recognize any gain or loss on such conversion.

Redemption

Depending on the particular U.S. holder, a redemption of ADSs or ordinary shares by us will be treated as a sale of the redeemed ADSs or ordinary shares by the U.S. holder or as a distribution to the U.S. holder (which is taxable as described above under "— Distributions").

Additional U.S. Federal Income Tax Consequences

Controlled Foreign Corporation Rules. Generally, a non-U.S. corporation, such as us, will be classified as a controlled foreign corporation ("CFC") if more than 50% (by vote or value) of the shares of the corporation are held directly, indirectly, or constructively, by "U.S. Shareholders." For this purpose, a U.S. Shareholder is generally any U.S. holder that possess, directly, indirectly or constructively, 10% or more of the combined voting power or value of all classes of shares of the corporation. Based on our current and anticipated ownership structure, we do not expect to be classified as a CFC. However, we can offer no assurances in this regard.

If we were classified as a CFC, however, any of our U.S. Shareholders generally would be required to include in gross income (as ordinary income) such U.S. shareholder's global intangible low-taxed income and, at the end of each of our taxable years, and may be increased by certain deserved earnings an amount equal to the U.S. Shareholder's pro rata share of our "subpart F income." Subpart F income generally includes dividends, interest, rents and royalties, gains from the sale of securities, and income from certain transactions with related parties. If we are classified as both a CFC and a PFIC, we generally will not be treated as a PFIC with respect to those U.S. holders that meet the definition of a U.S. Shareholder.

PFIC Rules. Special adverse U.S. federal income tax rules apply to U.S. holders owning shares of a PFIC. In general, if you are a U.S. holder, we will be a PFIC with respect to you if for any taxable year in which you held our ADSs or ordinary shares: (i) at least 75% of our gross income for the taxable year is passive income or (ii) at least 50% of the value, determined on the basis of a quarterly average, of our assets is attributable to assets that produce or are held for the production of passive income. The determination of whether we are a PFIC will be made annually. Accordingly, it is possible that we may become a PFIC in the current or any future taxable year due to changes in our asset or income composition. Assuming we are a publicly traded corporation for purposes of the PFIC rules, the value of our assets would generally be determined by reference to the market price of our shares. Fluctuations in the market price of our shares may cause us to become a PFIC for the current taxable year or later taxable years. In addition, the composition of our income and assets will be affected by how, and how quickly, we use our liquid assets and the cash raised in this offering. If we were unable to deploy significant amounts of cash for active purposes, our risk of being classified as a PFIC would substantially increase. Because there are uncertainties in the application of the relevant rules and PFIC status is a factual determination made annually after the close of each taxable year, there can be no assurance that we will not be a PFIC for the current taxable year or any future taxable year.

Passive income generally includes dividends, interest, royalties, rents (other than certain rents and royalties derived in the active conduct of a trade or business), annuities and gains from the disposition of assets that produce passive income. Any cash we hold, including the cash raised in this offering, generally will be treated as held for the production of passive income for the purpose of the PFIC test, and any income generated from cash or other liquid assets generally will be treated as passive income for such purpose. If a non-U.S. corporation owns at least 25% by value of the shares of another corporation, the non-U.S. corporation is treated for purposes of the PFIC tests as owning its proportionate share of the assets of the other corporation, and as receiving directly its proportionate share of the other corporation's income. Although we do not believe that we are currently a PFIC, the determination of PFIC status is highly factual, determined annually, and based on technical rules that are difficult to apply. Accordingly, there can be no assurances that we will not be a PFIC for the current year or any future taxable year.

If we were to be treated as a PFIC, except as otherwise provided by election regimes described below, a U.S. holder would be subject to special adverse tax rules with respect to (i) "excess distributions" received on our ADSs or ordinary shares and (ii) any gain recognized upon a sale or other disposition (including a pledge) of our ADSs or ordinary shares. A U.S. holder would be treated as if it had realized such gain and certain "excess distributions" ratably over its holding period for our ADSs or ordinary shares. The amounts allocated to the then current taxable year and to any taxable year in the holding period prior to the first taxable year in which we were a PFIC would be taxed as ordinary income. The amounts allocated to any other taxable year would be taxed at the highest tax rate in effect for each such year to which the gain was allocated, together with an interest charge in respect of the tax attributable to each such year. Special rules apply for calculating the amount of the foreign tax credit with respect to "excess distributions" by a PFIC.

With certain exceptions, a U.S. holder's ADSs or ordinary shares will be treated as stock in a PFIC if we were a PFIC at any time during the U.S. holder's holding period for its ordinary shares or ADSs, even if we are not currently a PFIC.

Dividends that a U.S. holder receives from us will not be eligible for the special tax rates applicable to qualified dividend income if we are treated as a PFIC either in the taxable year of the distribution or the preceding taxable year, but instead will be taxable at rates applicable to ordinary income, or if an excess distribution treated as discussed above.

If a U.S. holder owns ordinary shares in a PFIC that are treated as "marketable stock," the U.S. holder may make a mark-to-market election. If a U.S. holder makes this election, the U.S. holder will not be subject to all of the PFIC rules described above. Instead, in general, the U.S. holder will include as ordinary income the excess, if any, of the fair market value of its ADSs or ordinary shares at the end of the taxable year over the U.S. holder's adjusted basis in its ADSs or ordinary shares. Similarly, any gain realized on the sale, exchange or other disposition of the ADSs or ordinary shares will be treated as ordinary income, and will not be eligible for the favorable tax rates applicable to qualified dividend income or long-term capital gains. The U.S. holder will also be allowed to take an ordinary loss in respect of the excess, if any, of the adjusted basis of its ADSs or ordinary shares over the fair market value at the end of the taxable year (but only to the extent of the net amount of previously included income as a result of the mark-to-market election). A U.S. holder's basis in the ADSs or ordinary shares will be adjusted to reflect any such income or loss amount.

A U.S. holder may in certain circumstances also mitigate adverse tax consequences of the PFIC rules by filing an election to treat the PFIC as a qualified electing fund ("QEF"), if the PFIC complies with certain reporting requirements. However, in the event that we are or become a PFIC, we do not intend to comply with such reporting requirements necessary to permit U.S. holders to elect to treat us as a QEF.

U.S. holders should consult their own tax advisors regarding the application of the PFIC rules to their investment in our ADSs or ordinary shares and the elections discussed above.

Tax on Net Investment Income. Certain U.S. holders who are individuals, estate and trusts will be required to pay an additional 3.8% tax on some or all of their "net investment income," which generally includes their dividend income (including qualified dividend income) and net gains from the disposition of our ADSs or ordinary shares. U.S. holders should consult their own tax advisors regarding the applicability of this additional tax on their particular situation.

Information with Respect to Foreign Financial Assets. Owners of "specified foreign financial assets" with an aggregate value in excess of $50,000 (and in some circumstances, a higher threshold) may be required to file an information report with respect to such assets on their tax returns. "Specified foreign financial assets" may include financial accounts maintained by foreign financial institutions, as well as the following, but only if they are not held in accounts maintained by financial institutions: (i) stocks and securities issued by non-U.S. persons; (ii) financial instruments and contracts held for investment that have

non-U.S. issuers or counterparties; and (iii) interests in foreign entities. U.S. holders are urged to consult their tax advisors regarding the application of this legislation to their ownership of the ADSs and ordinary shares.

Information with Respect to Interests in Passive Foreign Investment Companies (PFICs). If we were to be treated as a PFIC, owners of our ADSs or ordinary shares (including, potentially, indirect owners) would be required to file an information report with respect to such interest on their tax returns, subject to certain exceptions. U.S. holders are urged to consult their tax advisors regarding the application of these rules to their ownership of the ADSs and ordinary shares.

Backup Withholding and Information Reporting. Backup withholding and information reporting requirements will generally apply to certain payments to U.S. holders of dividends on ADSs or ordinary shares. We, our agent, a broker or any paying agent, may be required to withhold tax from any payment that is subject to backup withholding unless the U.S. holder (1) is an exempt payee, or (2) provides the U.S. holder's correct taxpayer identification number and complies with applicable certification requirements. Payments made to U.S. holders by a broker upon a sale of our ADSs or ordinary shares will generally be subject to backup withholding and information reporting. If the sale is made through a non-U.S. office of a non-U.S. broker, however, the sale will generally not be subject to either backup withholding or information reporting. This exception may not apply if the non-U.S. broker is owned or controlled by U.S. persons, or is engaged in a U.S. trade or business.

Backup withholding is not an additional tax. Any amounts withheld from a payment to a U.S. holder of ADSs or ordinary shares under the backup withholding rules can be credited against any U.S. federal income tax liability of the U.S. holder, provided the required information is timely furnished to the IRS. A U.S. holder generally may obtain a refund of any amounts withheld under the backup withholding rules that exceeds the U.S. holder's income tax liability by filing a refund claim with the IRS. Prospective investors should consult their own tax advisors as to their qualification and procedure for exemption from backup withholding.

THE COMBINED OFFERING

The shares being offered by this prospectus are part of a combined offering relating to up to 6,000,000 newly issued shares of our company. The combined offering consists of (i) a preemptive rights offering to our existing shareholders, pursuant to German law and (ii) this initial public offering of ADSs in the United States.

On May 24, 2017, our shareholders authorized our management board with the approval of our supervisory board to increase our company's capital by 6,000,000 shares, equivalent to 3,000,000 ADSs. In order to carry out the capital increase, we were required by German law and the terms of our authorized capital to make a preemptive rights offering to our existing shareholders. Based on subscriptions in the German preemptive rights offering, we will issue 3,399,034 newly issued shares.

The initial per share offering price to the public is the same for the ADSs sold in the U.S. offering and the shares sold in the German preemptive rights offering (adjusting for the euro/U.S. dollar exchange rate and the ratio of shares to ADSs). In determining the offer price, we considered, among other things, current market conditions, the trading price and volume of trading in our ordinary shares on the XETRA electronic trading platform of the Frankfurt Stock Exchange and the results of the bookbuilding process for the shares to be offered in this offering. See "Underwriting — Pricing of the Offering" for a discussion of factors considered in determining the price to the public of the ADSs.

UNDERWRITING

(CONFLICTS OF INTEREST)

Under the terms and subject to the conditions contained in an underwriting agreement dated the date of this prospectus, the underwriters named below, for whom The Benchmark Company, LLC is acting as representative, have severally agreed to purchase, and we have agreed to sell to them, severally, the number of ADSs indicated below:

Name	Number of ADSs
The Benchmark Company, LLC	384,785
Dawson James Securities, Inc.	364,500
Lake Street Capital Markets LLC	364,500
ViewTrade Securities	101,215
Total:	1,215,000

The underwriters and the representative are collectively referred to as the "underwriters" and the "representative," respectively. The underwriters are offering the ADSs subject to their acceptance of the ADSs from us and subject to prior sale. The underwriting agreement provides that the obligations of the several underwriters to pay for and accept delivery of the ADSs offered by this prospectus are subject to the approval of certain legal matters by their counsel and to certain other conditions, including the absence of any material adverse change in our business and the receipt of certain certificates, opinions and letters from us, our counsel and the independent registered public accounting firm. The underwriters are obligated, severally and not jointly, to take and pay for all of the ADSs offered by this prospectus if any such ADSs are taken. The underwriters are not required, however, to take or pay for the ADSs covered by the underwriters' over-allotment option to purchase additional ADSs described below. Any offers or sales of the ADSs in the U.S. will be conducted by registered broker-dealers in the U.S.

The underwriters have advised us that they propose to offer the ADSs to the public at $9.88 per ADS. The underwriters propose to offer the ADSs to certain dealers at the same price less a concession of not more than $0.3952 per ADS. The underwriters may allow and the dealers may reallow a concession of not more than $0.00 per ADS on sales to certain other brokers and dealers. After the offering, these figures may be changed by the underwriters.

Over-Allotment Option

Additionally, we have granted to the underwriters an option, exercisable for 45 days from the date of this prospectus, to purchase up to an aggregate of 85,483 additional ADSs at the public offering price listed on the cover page of this prospectus less underwriting discounts and commissions. The underwriters may exercise this option for the purpose of covering over-allotments, if any, made in connection with the offering of the ADSs offered by this prospectus. To the extent the option is exercised, each underwriter will become obligated, subject to certain conditions, to purchase about the same percentage of the additional ADSs as the number listed next to the underwriter's name in the preceding table bears to the total number of ADSs listed in the preceding table. If the underwriters' option is exercised in full, the total price to the public would be approximately $12.85 million, the total underwriters' discounts and commissions would be approximately $1.03 million and the total proceeds to us (before expenses) would be approximately $10.09 million.

Discounts, Commissions and Expenses

The table below shows the per ADS and total underwriting discounts and commissions that we will pay to the underwriters. The underwriting discounts and commissions are determined by negotiations among us and the underwriters and are a percentage of the offering price to the public. Among the factors considered in determining the discounts and commissions are the size of the offering, the nature of the security to be offered and the discounts and commissions charged in comparable transactions. These amounts are shown assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 85,483 ADSs.

Underwriting Discounts and Commissions	No Exercise	Full Exercise
Public offering price per ADS	$ 9.88[1]	$ 9.88[1]
Underwriting discounts	$ 960,336[1]	$ 1,027,902[1]
Proceeds to us, before expenses	$ 11,043,864[1]	$ 11,820,870[1]

(1) Assumes the maximum underwriting discount and commission of 8.0% per ADS.

We have agreed to pay a non-accountable expense allowance to The Benchmark Company, LLC equal to 1.0% of the gross proceeds received in this offering (excluding any amounts we receive from any sale of ADSs pursuant to the exercise of the underwriters' over-allotment option). In addition to the non-accountable expense allowance, we have also agreed to pay or reimburse the underwriters for certain of their out-of-pocket expenses in an amount not to exceed $125,000 (including reasonable "blue sky" fees and expenses of $25,000). Furthermore, pursuant to the underwriting agreement, the underwriters' obligations are subject to customary conditions, representations and warranties contained in the underwriting agreement, such as receipt by the underwriters of officers' certificates and legal opinions.

We estimate expenses payable by us in connection with this offering, other than the discounts and commissions referred to above, will be approximately $1.73 million. This estimate includes $125,000 of the fees and legal expenses of the representatives set forth in the above paragraph.

Future Financings

We also have agreed to pay to The Benchmark Company, LLC an underwriting commission (or equivalent fee or other compensation permitted in accordance with applicable law) of 8.0% and non-accountable expense allowance of 1.0% of the gross proceeds received by us from any public or private offering or other financing or capital-raising transaction, but only to the extent such financing is provided to us by U.S.-based investors that The Benchmark Company, LLC introduced to us during the 12-month engagement period contemplated under our engagement agreement with The Benchmark Company, LLC (including any U.S.-based investors that purchase ADSs in the offering contemplated by this prospectus), if any such financing is consummated during such engagement period or within 6 months following the earlier one to occur of (x) the expiration or termination of our engagement agreement with The Benchmark Company, LLC or (y) the completion of the offering contemplated by this prospectus.

Lock-Up Arrangements

Our chief executive officer has agreed or is otherwise contractually restricted for a period of 180 days after the date of this prospectus, without the prior written consent of the representative, not to directly or indirectly, sell, offer, contract or grant any option to sell, pledge, transfer, or otherwise dispose of or enter into any transaction which may result in the disposition of any ordinary shares or ADSs, or securities convertible into, exchangeable or exercisable for any ordinary shares or ADSs. There are no existing agreements between the representative and any person who will execute a lock-up agreement in connection with this offering providing consent to the sale of ordinary shares or ADSs prior to the expiration of the lock-up period. The lock up is subject to exceptions relating to open market transaction, estate planning transfer, transfers in satisfaction of the exercise price of or to pay taxes associated with options, transfers in the context of a *bona fide* third-party takeover, and similar limited exceptions, and does not apply to the exercise, exchange or conversion of any securities exercisable or exchangeable for or convertible into ordinary shares or ADSs upon the exercise of rights to acquire ordinary shares or ADSs pursuant to any existing option for ordinary shares or ADSs, so long as the shares or ADSs acquired on such exercise, exchange or conversion during the lock-up period are not transferred by the chief executive officer, unless otherwise permitted by the lock-up agreement and does not prohibit the chief executive officer from entering into or modifying any so-called "10b5-1" plan at any time (other than the entry into or modification of such a plan in such a manner as to cause the sale of securities within the lock-up period).

Indemnification and Contribution

The underwriting agreement provides for indemnification between us and the underwriters against specified liabilities, including liabilities under the Securities Act, advancement of costs and for contribution by us and the underwriters to payments that may be required to be made with respect to those liabilities. We have been advised that, in the opinion of the Securities and Exchange Commission, indemnification of liabilities under the Securities Act is against public policy as expressed in the Securities Act, and is therefore, unenforceable.

Stabilizing Transactions and Penalty Bids

To facilitate this offering of ADSs, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the ADSs. Specifically, the underwriters may sell more ADSs than they are obligated to purchase under the underwriting agreement, creating a short position. A short sale is covered if the short position is no greater than the number of ADSs available for purchase by the underwriters under their over-allotment option. The underwriters can close out a covered short sale by exercising their over-allotment option or purchasing ADSs in the open market. In determining the source of ADSs to close out a covered short sale, the underwriters will consider, among other things, the open market price of ADSs compared to the price available under the over-allotment option. The underwriters may also sell ADSs in excess of the over-allotment option, creating a naked short position. The underwriters must close out any naked short position by purchasing ADSs in the open market. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the ADSs in the open market after pricing that could adversely affect investors who purchase ADSs in this offering. In addition, to stabilize the price of the ADSs, the underwriters may bid for, and purchase, ADSs in the open market. Finally, the underwriting syndicate may reclaim selling concessions allowed to an underwriter or a dealer for distributing the ADSs in this offering, if the syndicate repurchases previously distributed ADSs to cover syndicate short positions or to stabilize the price of the ADSs. Any of these activities may raise or maintain the market price of the ADSs above independent market levels or prevent or retard a decline in the market price of the ADSs. The underwriters are not required to engage in these activities, and may end any of these activities at any time.

Electronic Offer, Sale and Distribution of ADSs

A prospectus in electronic format may be made available on websites maintained by one or more underwriters, or selling group members, if any, participating in this offering. The representatives may agree to allocate a number of ADSs to underwriters for sale to their online brokerage account holders. Internet distributions will be allocated by the representatives to underwriters that may make Internet distributions on the same basis as other allocations. In addition, ADSs may be sold by the underwriters to securities dealers who resell ADSs to online brokerage account holders. Other than the prospectus in electronic format, the information on any underwriter's or selling group member's website and any information contained in any other website maintained by any underwriter or selling group member is not part of the prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or any underwriter or selling group member in its capacity as underwriter or selling group member and should not be relied upon by investors.

Pricing of the Offering

Our ordinary shares are listed on the Frankfurt Stock Exchange under the symbol "B8F" (International Securities Identification Number (ISIN) DE0006046113; German securities code (WKN) 604611), and we have been approved for the listing of the ADSs on The NASDAQ Capital Market under the symbol "BFRA". On February 8, 2018, the closing price of our ordinary shares on the Frankfurt Stock Exchange was €5.15 ($6.39, based upon the noon buying rate of the Federal Reserve Bank of New York for the euro on January 31, 2018, which was €1.00 to $1.24) per share.

Prior to this offering, there has been no public market in the U.S. for our ordinary shares or ADSs. The initial public offering price is determined by negotiations between us and Dawson, as qualified independent underwriter. Among the factors considered in determining the initial public offering price are the trading price and volume of trading in the ordinary shares on the Frankfurt Stock Exchange, our future prospects and those of our industry in general, our sales, earnings, certain other financial and operating information in recent periods, the price-earnings ratios and market prices of our securities and securities of companies engaged in activities similar to ours, the general condition of the securities markets at the time of this offering, and other factors deemed relevant by the representative and us. Neither we nor the underwriters can assure investors that an active trading market will develop for the ADSs or our ordinary shares represented by the ADSs, or that the ADSs will trade in the public market at or above the initial public offering price.

Selling Restrictions

No action may be taken in any jurisdiction other than the U.S. that would permit a public offering of the ADSs or the possession, circulation or distribution of this prospectus in any jurisdiction where action for that purpose is required. Accordingly, the ADSs may not be offered or sold, directly or indirectly, and neither this prospectus nor any other offering material or advertisements in connection with the offering of ADSs, may be distributed or published in or from any country or jurisdiction except under circumstances that will result in compliance with any applicable laws, rules and regulations of any such country or jurisdiction.

Conflicts of Interest

The Benchmark Company, LLC is acting as representative for the underwriters in connection with this offering. An affiliate and a principal of The Benchmark Company, LLC holds a position as a member of the supervisory board of our company. Therefore, The Benchmark Company, LLC is deemed to have a "conflict of interest" under Rule 5121(f)(5) of FINRA. Accordingly, this offering will be conducted in accordance with the applicable provisions of Rule 5121, which requires, among other things, that a "qualified independent underwriter" participate in the preparation of, and exercise the usual standards of "due diligence" with respect to, the registration statement and this prospectus. Dawson has agreed to act as a "qualified independent underwriter" within the meaning of Rule 5121 in connection with this offering. We have agreed to indemnify Dawson against liabilities incurred in connection with acting as qualified independent underwriter, including liabilities under the Securities Act. Dawson will undertake the legal responsibilities and liabilities of an underwriter under the Securities Act, specifically including those inherent in Section 11 thereof. Dawson will not receive any additional fees for serving as a "qualified independent underwriter" in connection with this offering.

EXPENSES OF THIS OFFERING

Set forth below is an itemization of the total expenses, excluding underwriting discounts and commissions, which are expected to be incurred in connection with our sale of ADSs in this offering. With the exception of the registration fee payable to the SEC and the filing fee payable to FINRA, all amounts are estimates.

Itemized expenses*	**Amount ($)**
SEC registration fee	2,689
FINRA filing fee	3,740
NASDAQ listing fee	120,000
Printing expenses	30,000
Legal fees and expenses	1,200,000
Accounting fees and expenses	366,000
Miscellaneous fees and expenses	10,000
Total	1,732,429

* Estimated

LEGAL MATTERS

The validity of the shares underlying the ADSs offered in this prospectus and certain other matters of German law will be passed upon for us by LLR Legerlotz Laschet und Partner Rechtsanwälte Partnerschaft mbB, Köln, Germany. Certain matters of U.S. law will be passed upon for us by McGuireWoods LLP, New York, New York. Certain legal matters in connection with this offering will be passed upon for the underwriters by Schiff Hardin, LLP, Washington, DC, counsel for the underwriters with respect to U.S. law, and Luther Rechtsanwaltsgesellschaft mbH, Frankfurt, Germany, counsel for the underwriters with respect to German law. VRT Revisionsgesellschaft mbH, Bonn, Germany will pass on certain German tax matters for us.

EXPERTS

The audited consolidated financial statements included in this prospectus and elsewhere in this registration statement have been so included in reliance upon the report of Warth & Klein Grant Thornton AG Wirtschaftsprüfungsgesellschaft, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

SERVICE OF PROCESS AND ENFORCEMENT OF CIVIL LIABILITIES

Biofrontera AG is a German stock corporation and its registered offices and a substantial portion of its assets are located outside of the U.S. In addition, certain members of our management board, our supervisory board, our senior management and the experts named in the prospectus are residents of Germany and jurisdictions other than the U.S., and all or a substantial portion of the assets of such persons are located outside the U.S. As a result, it may not be possible, or may be very difficult, for you to effect service of process within the U.S. upon Biofrontera AG or these individuals or to enforce judgments obtained in U.S. courts based on the civil liability provisions of the U.S. securities laws against Biofrontera AG or these individuals in the U.S. Awards of punitive damages in actions brought in the U.S. or elsewhere may be unenforceable in Germany. In addition, actions brought in a German court against Biofrontera AG or the members of its supervisory board and management board, its senior management and the experts named herein to enforce liabilities based on U.S. federal securities laws may be subject to certain restrictions; in particular, German courts generally do not award punitive damages. An award for monetary damages under the U.S. securities laws would be considered punitive if it does not seek to compensate the claimant for loss or damage suffered and is intended to punish the defendant. The enforceability of any judgment in Germany will depend on the particular facts of the case as well as the laws and treaties in effect at the time.

Litigation in Germany is also subject to rules of procedure that differ from the U.S. rules, including with respect to the taking and admissibility of evidence, the conduct of the proceedings and the allocation of costs. Proceedings in Germany would have to be conducted in the German language, and all documents submitted to the court would, in principle, have to be translated into German. For these reasons, it may be difficult for a U.S. investor to bring an original action in a German court predicated upon the civil liability provisions of the U.S. federal securities laws against us, certain members of our management and supervisory boards and senior management and the experts named in this prospectus. The U.S. and Germany do not currently have a treaty providing for recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters, though recognition and enforcement of foreign judgments in Germany is possible in accordance with applicable German laws. Even if a judgment against our company, the non-U.S. members of our management board, supervisory board, senior management or the experts named in this prospectus based on the civil liability provisions of the U.S. federal securities laws is obtained, a U.S. investor may not be able to enforce it in U.S. or German courts.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form F-1 under the Securities Act, including amendments and relevant exhibits and schedules, covering the underlying ordinary shares represented by the ADSs to be sold in this offering. We have also filed with the SEC a related registration statement on Form F-6 to register our ADSs. This prospectus, which constitutes a part of the registration statement, summarizes material provisions of contracts and other documents that we refer to in the prospectus. Since this prospectus does not contain all of the information contained in the registration statement and the exhibits and schedules to the registration statement, you should read the registration statement and its exhibits and schedules for further information with respect to us and our shares and ADSs. If a document has been filed as an exhibit to the registration statement, we refer you to the copy of the document that has been filed. Each statement in this prospectus relating to a document filed as an exhibit is qualified in all respects by the filed exhibit.

You may review a copy the registration statement, including exhibits and any schedules filed therewith, and reports and other information we file, and obtain copies of such materials, at the SEC's public reference room at 100 F Street, N.E., Washington, D.C. 20549. You may also request copies of these documents upon payment of a duplicating fee by writing to the SEC. For further information on the public reference facility, please call the SEC at 1-800-SEC-0330. In addition, the SEC maintains an Internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

Upon completion of this offering, we will become subject to the informational requirements of the Exchange Act as applicable to foreign private issuers. Accordingly, we will be required to file reports and other information with the SEC, including annual reports on Form 20-F and reports on Form 6-K. Those reports may be inspected without charge at the locations described above.

As a foreign private issuer, we are exempt under the Exchange Act from, among other things, the rules prescribing the furnishing and content of proxy statements, and our executive officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we will not be required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as U.S. companies whose securities are registered under the Exchange Act, although we intend to report our results of operations voluntarily on a quarterly basis. In addition, as a foreign private issuer, we intend to avail ourselves of exemptions from certain corporate governance requirements under the NASDAQ Marketplace Rules, as discussed in detail above under "Management — Differences between Our Corporate Governance Practices and the Rules of The NASDAQ Capital Market". Our annual consolidated financial statements will be prepared in accordance with International Financial Reporting Standards, as issued by the International Accounting Standards Board, and certified by an independent public accounting firm.

As a foreign private issuer, we are also exempt from the requirements of Regulation FD (Fair Disclosure) which, generally, are meant to ensure that select groups of investors are not privy to specific information about an issuer before other investors. We are, however, still subject to the anti-fraud and anti-manipulation rules of the SEC, such as Rule 10b-5. Since many of the disclosure obligations required of us as a foreign private issuer are different than those required by other U.S. domestic reporting companies, our shareholders, potential shareholders and the investing public in general should not expect to receive information about us in the same amount and at the same time as information is received from, or provided by, other U.S. domestic reporting companies. We are liable for violations of the rules and regulations of the SEC which do apply to us as a foreign private issuer.

We maintain a corporate website at *www.biofrontera.com*. Information contained on, or that can be accessed through, our website does not constitute a part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

BIOFRONTERA AG

INDEX TO FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

Supervisory Board
Biofrontera AG

We have audited the accompanying consolidated balance sheets of Biofrontera AG and subsidiaries (the "Company") as of December 31, 2016 and 2015, and the related consolidated statements of comprehensive income, changes in equity, and cash flows for each of the years ended December 31, 2016 and 2015. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. We were not engaged to perform an audit of the Company's internal control over financial reporting. Our audits included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Biofrontera AG and subsidiaries as of December 31, 2016 and 2015, and the results of their operations and their cash flows for each of the years ended December 31, 2016 and 2015 in conformity with International Financial Reporting Standards as issued by the International Accounting Standards Board.

/s/ WARTH & KLEIN GRANT THORNTON AG

Düsseldorf, Germany
October 4, 2017

Biofrontera AG
Consolidated Balance Sheet as of
Assets

(in EUR thousands)

		31 December 2016	31 December 2015
Non-current assets			
Tangible assets	(1)	645	373
Intangible assets	(1)	1,252	1,902
Total Non-current assets		**1,897**	**2,275**
Current assets			
Current financial assets			
Trade receivables	(3)	1,624	895
Other financial assets	(4)	1,377	730
Cash and cash equivalents	(7)	15,126	3,959
Total Current financial assets		**18,127**	**5,584**
Other current assets			
Inventories	(2)		
Raw materials and supplies		1,350	590
Unfinished products		477	43
Finished products and goods		1,819	901
Income tax reimbursement claims	(5)	33	32
Other assets	(4)	176	73
Total Other current assets		3,855	1,639
Total Current assets		21,982	7,223
Total Assets		**23,879**	**9,498**

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

Biofrontera AG
Liabilities

(in EUR thousands)

		31 December 2016	31 December 2015
Equity	(9)		
Subscribed capital		37,722	25,490
Capital reserve		98,677	79,526
Capital reserve from foreign currency conversion adjustments		(154)	(1)
Loss carry forward		(109,824)	(98,621)
Net loss of the year		(10,579)	(11,203)
Total Equity		**15,842**	**(4,809)**
Long-term liabilities			
Long-term financial liabilities	(10)	3,597	11,230
Current liabilities			
Current financial liabilities			
Trade payables	(11)	2,093	1,043
Short-term financial debt	(9)	274	830
Other financial liabilities	(13)	59	38
Total Current financial liabilities		**2,426**	**1,911**
Other current liabilities			
Income tax provision	(8)	—	—
Other provisions	(12)	1,824	1,042
Other current liabilities	(13)	190	124
Total Other current liabilities		**2,014**	**1,166**
Total Current Liabilities		**4,440**	**3,077**
Total Equity and liabilities		**23,879**	**9,498**

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

Biofrontera AG
Consolidated Statement of Comprehensive Income

(in EUR thousands)

	Note	01.01.-31.12.2016	01.01.-31.12.2015
Sales revenue	(15)	6,130	4,138
Cost of sales	(16)	(1,652)	(1,236)
Gross profit from sales		4,478	2,902
Operating expenses			
Research and development costs	(17)	(4,640)	(6,204)
General administrative costs	(19)	(2,853)	(2,759)
thereof financing costs		(826)	(265)
Sales costs	(18)	(8,764)	(4,170)
Total Operating Expenses		(16,257)	(13,133)
Loss from operations		(11,779)	(10,231)
Interest expenses	(20)	(1,207)	(1,168)
Interest income	(20)	3	9
Other expenses	(21)	(47)	(32)
Other income	(21)	2,451	219
Total interest and other (expenses)/income		1,200	(972)
Profit/loss before income tax	(23)	(10,579)	(11,203)
Income tax		—	—
Profit or loss for the period	(23)	(10,579)	(11,203)
Expenses and income not included in profit/loss			
Items which may in future be regrouped into the profit and loss statement under certain conditions Translation differences resulting from the conversion of foreign business operations		(153)	(2)
Other income total		(153)	(2)
Total profit/loss for the period		(10,732)	(11,205)
Basic/diluted earnings per share	(22)	(0.36)	(0.48)

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

Biofrontera AG
Statement of Changes in Equity

(in EUR thousands except for share information)

	Ordinary shares number	Subscribed capital EUR	Capital reserve EUR	Capital reserve from foreign currency conversion adjustments EUR	Accumulated loss EUR	Total EUR
Balance as at 01 January 2015	22,196,570	22.196	76.403	1	(98.621)	(21)
Capital increase	3,293,860	3.294	3.515	—	—	6,809
Costs of equity procurement	—	—	(496)	—	—	(496)
Foreign currency conversion adjustment	—	—	—	(2)	—	(2)
Increase in capital reserve from the stock option programme	—	—	104	—	—	104
Net loss of the year	—	—	—	—	(11.203)	(11.203)
Balance as at 31 December 2015	25,490,430	25.490	79.526	(1)	(109.824)	(4.809)
Capital increase	9,870,333	9.870	14.648	—	—	24.518
Conversion from convertible bond 2016/2021	1,603,050	1.603	3.231	—	—	4.834
Exercise of detachable warrant rights from option bond 2011/2016	758,620	759	1.487	—	—	2.246
Foreign currency conversion adjustment	—	—	—	(153)	—	(153)
Costs of equity procurement	—	—	(321)	—	—	(321)
Changes in capital reserves pursuant to the issuance of the convertible bond 2016/2021	—	—	(4)	—	—	(4)
Increase in capital reserve from the stock option programme	—	—	110	—	—	110
Net loss of the year	—	—	—	—	(10.579)	(10.579)
Balance as at 31 December 2016	37,722,433	37.722	98.677	(154)	(120.403)	15.842

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

Biofrontera AG
Consolidated Cash Flow Statement

(in EUR thousands)

	01.01.-31.12.16	01.01.-31.12.15
Cash flows from operations		
Loss for the period	(10,579)	(11,203)
Adjustments to reconcile profit/loss for the period to cash flow into operations		
Financial result	1,204	1,159
Depreciation	831	812
Losses from disposal of assets	5	0
Non-cash expenses and income	(51)	40
Changes in operating assets and liabilities		
Trade receivables	(729)	(586)
Other assets and income tax assets	(750)	(11)
Inventories	(2,112)	(140)
Trade payables	1,050	76
Provisions	782	150
Other liabilities	90	48
Net cash flow from used in operating activities	(10,259)	(9,655)
Cash flows from investment activities		
Purchase of intangible and tangible assets	(484)	(180)
Interest received	3	184
Revenue from sale of intangible and tangible assets	26	13
Net cash flow (used in) provided by investment activities	(455)	17
Cash flows from financing activities		
Proceeds from the issue of shares	24,518	6,313
Costs of equity procurement	(321)	—
Proceeds from issuance of convertible bonds 2016/2021	4,995	—
The exercise of detachable warrant rights from the proceeds from issuance of option bond 2011/2016	2,246	—
Interest paid	(842)	(1,225)
Repayment of convertible bonds 2011/2016	(8,715)	—
Net cash flows provided by financing activities	21,881	5,088
Net increase (decrease) in cash and cash equivalents	11,167	(4,550)
Cash and cash equivalents at the beginning of the period	3,959	8,509
Cash and cash equivalents at the end of the period	15,126	3,959
Composition of financial resources at the end of the period		
Cash and cash equivalents	15,126	3,959

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

Biofrontera AG
As of and for the period ending December 31, 2016 and 2015

Information about the company

Biofrontera AG (*www.biofrontera.com*), registered in the commercial register of Cologne District Court, Department B under No. 49717, and 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, and Biofrontera Inc., based in Wakefield, Massachussetts and with its registered office in Wilmington, Delaware, U.S. research, develop and market dermatological products. Biofrontera AG is an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Its approved products focus on the treatment in the U.S. and Europe of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of basal cell carcinoma in the EU. Biofrontera AG (hereinafter also the "company" or "Biofrontera") pursues this goal along with its subsidiaries. All the companies together form the "Biofrontera Group".

The Biofrontera Group's principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy, or PDT, referred to as Ameluz® PDT. Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome.

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

In May 2016, Biofrontera received approval from the U.S. Food and Drug Administration, or the FDA, to market in the U.S. Ameluz® in combination with photodynamic therapy using its BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Inc. launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016.

The Biofrontera Group currently sells Ameluz® in the U.S., in 11 countries in Europe and in Israel.

The Biofrontera Group also sells Belixos®, an over-the-counter line of skin care cosmetics products. Belixos® cosmetic products are available for sale in Germany and certain other European countries at selected pharmacies, dermatological institutes, and through local Amazon websites.

In July 2016, the company agreed 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 are to be researched. This corresponds to the same strategy with which Ameluz® was also developed. The nanoemulsion technology stabilized the active substance and improved skin penetration, leading to greater clinical efficacy. This principle is also to be applied to other substances as part of the partnership with Maruho. According to the agreement, Maruho will bear all costs connected with the exploratory research for four new product candidates (subject to a cap of €2.3 million). It is planned that Biofrontera will receive an exclusive license to market the new products in Europe.

The BF-derm1 project was tested in a three-part Phase II trial for the treatment of chronic, antihistamine-resistant urticaria. The trial demonstrated the drug's efficacy, which reduced the intensity of urticaria rashes and itching and reduced the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is to develop a substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007. They show that the substance is almost completely absorbed in the intestine, and that it takes around two days for 50% of the substance to be broken down or excreted.

At present, the Biofrontera Group is not actively pursuing the BF-derm1 project or the BF-1 project.

Summary of significant accounting policies

Basis for preparation of the consolidated financial statements

The consolidated financial statements for Biofrontera AG 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) and applicable on the balance sheet date.

The assets and liabilities are recognized and measured in accordance with the IFRS that were mandatory on 31 December 2016.

Standards, amendments to standards and interpretations applied for the first time in the consolidated financial statements for 31 December 2016:

Standards and interpretations requiring first-time mandatory application

Standard/Interpretation	First-time mandatory application as per IASB
Amendments to IAS 19 "Employee benefits"	1 July 2014
Annual Improvements Project	1 July 2014
Amendments to IAS 1 "Presentation of financial statements"	1 January 2016
IFRS 14 "Regulatory Deferral Accounts"	1 January 2016
Amendments to IAS 16 "Property, Plant and Equipment"	1 January 2016
Amendments to IAS 16 "Property, Plant and Equipment"	1 January 2016
Amendments to IAS 27 "Separate Financial Statements"	1 January 2016
Amendments to IFRS 10 "Consolidated Financial Statements", IFRS 12 "Disclosure of Interests in Other Entities" and IAS 28 "Interests in Associates and Joint Ventures": Investment Entities: Applying the Consolidation Exception	1 January 2016
Amendments to IFRS 11 "Joint Arrangements": Acquisitions of Interests in Joint Operations	1 January 2016
Annual Improvements Project Cycle 2012 – 2014	1 January 2016

With the exception of minor changes due to IAS 1, no changes have arisen for the consolidated financial statements of Biofrontera AG.

Recent Standards and Interpretations not yet applied

Standard/Interpretation	First-time mandatory application as per IASB
IFRS 15 "Revenue from Contracts with Customers" (including supplements)	1 January 2018
IFRS 9 "Financial Instruments"	1 January 2018
Amendments to IAS 7 "Statements of Cash Flows": Disclosure Initiative	1 January 2017
Amendments to IAS 12 "Income Taxes": Recognition of Deferred Tax Assets for unrealized losses unrealized Losses	1 January 2017
Amendments to IAS 28 "Interest in Associates and Joint Ventures" and IFRS 10 "Consolidated Financial Statements": Sale or Contribution of Assets between an Investor and its Associate or Joint Venture	Postponed for an indefinite period
Amendments to IAS 40 "Investment Property": Transfers of Investment Property	1 January 2018
Amendments IFRS 2 "Share-based Payment": Classification and Measurement of share-based payment transactions	1 January 2018

Standard/Interpretation	First-time mandatory application as per IASB
Amendments to IFRS 4 "Insurance Contracts": Applying IFRS 9 Financial Instruments together with IFRS 4 Insurance Contracts	1 January 2018
IFRS 16 "Leases"	1 January 2019
IFRIC 22 "Foreign Currency Transactions and Advance Consideration"	1 January 2018
Annual Improvements Project Cycle 2014 – 2016	01.01.2017/ 01.01.2018
Clarification of IFRS 15 "Revenue from Contracts with Customers"	01 January 2018

It is expected that unless details of their effects are given below, the listed standards and interpretations that are not yet applied will have no effect on the Biofrontera Group, in the absence of relevant facts and circumstances.

As part of its disclosure initiative, the IASB has published amendments to IAS 7 — Statements of Cash Flows. The core changes are requirements for additional disclosures in the notes, which should enable the readers of financial statements to assess the changes in liabilities arising from the company's financing activities. The amendments are to be applied the first time in the first reporting period of a financial year beginning on or after 1 January 2017. Earlier application is also permitted. When first applied, there is no comparative information from the same period in the previous year to report. Apart from the requirement for additional notes, the Group expects no effects on its consolidated financial statements.

In May 2014, the IASB issued the new standard IFRS 15. The aim of this new standard concerning revenue recognition is to amalgamate the various rules previously contained in different standards and interpretations. At the same time, uniform principles are defined that are applicable for all sectors and for all types of revenue transactions. The questions regarding what amount, at what time and for which time period revenue is to be realized are to be answered with the help of the 5-stage model. In addition, the standard includes a number of other regulations covering detailed issues and an expansion of the disclosures required. The new standard is to be applied to annual periods beginning on or after 1 January 2018. The first application must in principle be carried out retrospectively, but various simplification options are available; earlier application is permitted.

The Group pursues instalment sales over several years which include a financing element. Furthermore, the adoption of the new standard IFRS 15 may lead in individual cases to a different approach in revenue recognition of licenses. The evaluation of individual license agreements is not yet completed. Requirements to make expanded disclosures will also arise.

In January 2016, the IASB issued the new standard IFRS 16 — Leases. IFRS 16 establishes principles for the recognition, measurement, presentation and disclosure of leases, and notes regarding leases, with the aim of ensuring that lessees and lessors provide relevant information regarding the impact of leases. At the same time, the previous accounting model applied in accordance with IAS 17, involving the classification into operating and finance leases, is abandoned in favour of a uniform accounting model for leasing agreements with a mandatory control concept. For the lessee, the standard provides a single accounting model. This model leads in the case of the lessee to all the assets and liabilities from leases being recognized on the balance sheet, provided that their term does not exceed 12 months or if they are minor assets (option). The lessor continues to differentiate, for accounting purposes, between finance and operating leases. The mandatory first-time application date of IFRS 16 — Leases is for financial years beginning on or after 1 January 2019. Early application is permitted, in principle, if IFRS 15 — Revenue from Contracts with Customers is already applied (early) in full. The lessee either has to fully apply IFRS 16 retrospectively, with the inclusion of prior reporting periods, or has to recognize the cumulative adjustment effect at the point in time of initial application as an entry in equity at the beginning of the financial year of initial application. The Group is currently evaluating the possible impact of the initial application of IFRS 16 on its consolidated financial statements, and will define an adoption date and transitional method.

In July 2014, the IASB approved the final version of IFRS 9 "Financial Instruments". The new standard includes revised regulations for the classification and measurement of financial assets, including impairment regulations, and supplements the new hedge accounting regulations published in 2013. Furthermore, more extensive disclosure obligations pursuant to IFRS 9 are to be complied with. The Group anticipates effects on the classification of financial instruments as well as expanded disclosures

in the notes to the financial statements. The company has evaluated the potential effects of IFRS 9, and has determined that it will not have a material impact on the financial statements.

The accounting policies applied are consistent with those applied on 31 December 2015, with the exception of the new and revised standards and interpretations described above that were applied from the 2016 financial year for the first time.

The consolidated financial statements are presented in euros (EUR) or thousands of euros.

The Biofrontera Group presents current and non-current assets and current and non-current liabilities as separate categories in the balance sheet, in accordance with IAS 1.60, with these categories also being subdivided to some extent according to their respective terms in the notes to the consolidated financial statement for 31 December 2016. The income statement is prepared applying the cost of sales method. In this reporting format, the net sales revenue is set against the expenses incurred in achieving it, subdivided into cost of sales, research and development costs, sales costs and general administration costs.

The consolidated financial statements for 31 December 2016 contain no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz®, including the supplementary products BF-RhodoLED® (PDT lamp) and Belixos®, and are internally monitored and managed accordingly.

On 4 October 2017 the Management Board approved the consolidated financial statements for the financial year ending 31 December 2016 for filing and forwarding to the Supervisory Board.

Basis of consolidation

The consolidated financial statements for the financial year ending 31 December 2016 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 or another means of exercising control. 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., Wilmington, Delaware, U.S. with a direct interest of 100% since March 2015.

The basis for the consolidation of the companies included in the consolidated financial statements are the financial information of these companies prepared for 31 December 2016 pursuant to uniform principles. The consolidated financial statements for 31 December 2016 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.

Immaterial Error Correction to Previously Issued Financial Statements

The company has made an immaterial error correction to the consolidated financial statements as of and for the years ended 31 December 2016 and 2015.

Management determined that it had incorrectly disclosed operating and financing cash flows related to non-cash components of its convertible warrant bonds. This resulted in a gross-up of operating and financing activities in the net amount of €481,000 and €62,000 as of 31 December 2016 and 2015, respectively. The error had no impact on revenues or the results of operations for either period presented.

Translation of amounts in foreign currencies

The consolidated financial statements for 31 December 2016 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 of the Group, 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 (2016: 1,052 USD/EUR, previous year: 1,091 USD/EUR). Income and expense items are translated applying the average exchange rates (2016: 1,107 USD/EUR, previous year: 1,102 USD/EUR) applicable to the relevant period. 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.

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 arising from such currency translations are recognized in income.

Application of estimates

The preparation of the consolidated financial statements in accordance with IFRS required the use of estimates and assumptions by management that affect the value of assets and liabilities — as well as contingent assets and liabilities — as reported on the balance sheet date, and revenues and expenses arising during the financial year. The main areas in which assumptions, estimates and the exercising of a degree of discretion are appropriate relate to the determination of the useful lives of non-current assets and the formation of provisions, as well as income taxes. 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 explanatory remarks concerning the items in the notes to the consolidated financial statements.

Transactions with related parties

With regard to transactions with shareholders, particularly in connection with capital increases and the issue of Biofrontera AG bonds, please see our comments in the appendix note "Equity".

With respect to the issue of share options to employees of the Biofrontera Group, please see our comments on the "Share Option Plan" in the appendix note "Equity".

With regard to the remuneration of Management Board members, please see our comments in the appendix note "Members of the Management Board".

With regard to the remuneration of Supervisory Board members, please see our comments in the appendix note "Members of the Supervisory Board".

Fixtures and equipment

Pursuant to IAS 16, the value of fixtures and equipment is recognized on the balance sheet at historical acquisition and production cost less scheduled depreciation.

Depreciation of fixtures and equipment 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 2008, low value assets with purchase costs of between EUR 150 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. Only intangible assets purchased from third parties are capitalized as assets, as the requirements for the recognition of internally generated intangible assets are not met. These intangible assets are capitalized as assets and generally amortized straight-line over an estimated useful life of between 4 and 20 years.

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 are incurred, because the Group has no qualifying assets in the meaning of IAS 23.5.

Impairment of assets

The company tests assets for impairment when indications exist that the carrying amount of an asset exceeds its recoverable amount. A possible impairment requirement of assets held for use is evaluated by comparing the carrying amount of an asset with the cash flows that the asset is expected to generate in the future. When such an asset is considered to be impaired, the impairment loss is measured at the amount by which the carrying amount of the asset exceeds its recoverable amount. Assets that are to be sold are reported at the lower of the carrying amount or fair value less costs to sell.

Financial instruments

The financial instruments held by the Biofrontera Group on the balance sheet date primarily consist of cash and cash equivalents, current (short-term) investments, trade payables and receivables as well as financial debt. Biofrontera does not currently deploy derivative financial instruments. Due to the short terms of the current financial investments, trade payables and trade receivables, the carrying amounts of these items correspond to their fair values. The current financial investments are assigned to the "financial investments held to maturity" category, and other receivables and liabilities are assigned to the "loans and receivables" category. The financial liabilities are measured applying the effective interest method.

The Biofrontera Group was not exposed to significant foreign currency risk on the balance sheet date. Financial investments have been transacted in euros. Trade payables denominated in foreign currency are of minor importance. Trade receivables are regularly reviewed with respect to potential default risk.

Various safeguarding criteria are applied when selecting of current capital investments (for example, ratings, capital guarantee, safeguarding by the deposit protection fund). Based on the selection criteria and the ongoing monitoring of capital investments, Biofrontera does not consider any default risks to exist in this area that have not been taken into account. The amounts reported in the balance sheet generally represent the maximum default risk.

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.

To date, Biofrontera has provided the necessary financing for its business operations through injections of equity and the issuance of warrant bonds and convertible bonds. See discussion of recent entry into a credit facility with European Investment Bank in Note 32.

As of 31 December 2016, Biofrontera held no financial positions that were exposed to interest rate risks.

Financial investments held to maturity

The company classifies the securities held as current financial investments as "financial investments held to maturity", in accordance with IAS 39.9. As of the 31 December 2016 reporting date, Biofrontera had in its portfolio holdings of its own Warrant Bond I 2009/2017 with a nominal value of EUR 1.5 million. In 2016, the company identified an error related to the financial instruments held to maturity made in 2014 and 2015. The warrant bonds were incorrectly impaired based on then existing market conditions in the amount of EUR 100,000 and EUR 167,000, respectively. Management concluded that an adjustment would be immaterial to the current and prior years both individually and in the aggregate. In order to correct the error, an out of period adjustment to reverse the cumulative impairment of EUR 267,000 was recorded in the period ended December 31, 2016. In accordance with IAS 32, the bonds are reported on a net basis with the corresponding bond debt.

Inventories

Raw materials and supplies, as well as finished and unfinished goods, are recognized at the lower of cost or net realisable 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, overdrafts

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 vesting 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, the award is recognized as equity over the vesting period in accordance with IFRS 2.41 and IFRS 2.43, with the cost being recognized as compensation expense. The fair value of both cash-settled and equity-settled share-based payment transactions is generally determined using a Monte Carlo valuation model.

Warrant bonds

In accordance with IAS 32, warrant bonds are classified as compound financial instruments that represent a debt security with an embedded conversion or subscription option. The issuer of such a financial instrument, which contains both a liability and an equity component, is required to present the liability component and the equity component separately from the financial instrument originally reported on the balance sheet. At the issue date, the fair value of the financial liability component is determined by discounting at the market interest rate for comparable financial instruments without conversion rights. The financial liability is subsequently measured at amortized cost until conversion or maturity of the instrument. In accordance with IAS 32, the difference between the contract value and the fair value of the financial liability is the equity component, which is reported within capital reserves with no subsequent adjustment.

If the warrant bonds are redeemed before maturity through early redemption or early repurchase, with the original conversion rights remaining unchanged, the fee paid and all transactions relating to the repurchase or redemption are allocated to the liability and equity components of the instrument at the time of the transaction. The method for the allocation of the fees and transaction costs to the two components is identical to that utilised in the original allocation applied to the proceeds received when issuing the bond.

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 utilise 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 no longer probable that sufficient taxable profit will be available against which the deferred tax claim can be at least partially utilised. 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 realise 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

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

Leasing

The leases that have been agreed are classified as either finance leases or operating leases. If the lessor has passed all significant opportunities and risks onto the Group as a lessee, the Group is assigned beneficial ownership. The companies included in the consolidated financial statements have usually concluded contracts that are classified as operating leases. In this case, ongoing lease payments are expensed as they are incurred. Agreed leases that are classified as finance leases are recognized as assets at the lower of the present value of the minimum lease payments or the fair value of the leased asset at the beginning of the lease, and depreciated over the shorter of the lease duration or useful life, if the transfer of ownership to the lessee at the end of the contract term is insufficiently certain.

Revenue recognition

The company recognizes revenue in accordance with IAS 18 if the risks and opportunities connected with ownership have transferred to the customer. The company realises its revenue primarily through the sale of its products. Income from milestone and licensing agreements with third parties are recognized once the underlying contractual conditions come into force. From time to time, the company may receive a cash payment at the inception of a distribution agreement. These payments are not

refundable and are recognized as revenue upon receipt in accordance with IAS 18 IE 20.These payments were immaterial for the years ended December 31, 2016 and 2015.

Revenue and other income are recognized if the amount can be measured reliably and payment is sufficiently probable as well as other conditions mentioned below are met. All income in connection with the sale of products and license income is recognized as revenue. Revenue is deemed to be realized when the deliveries and services owed have been provided and substantial risk and chances have been passed to the acquirer.

Most of the revenues are generated by product sales. The sale of Ameluz® almost exclusively occurs in Europe through pharmaceutical wholesalers or, to a lesser extent, directly to pharmacies, hospitals. Sales in the U.S. are primarily directly to physicians, hospitals or other qualified healthcare providers. Under a collaboration and partnership agreement entered into with Maruho, development work for certain product candidates is invoiced on a monthly basis after cost and/or time has been incurred. Revenue is recognized upon invoicing.

In the case of direct sales of the BF-RhodoLED® lamps, the delivered products and services on which amounts are owed are settled only after complete installation, since the installation services requires specialised knowledge, is not just an ancillary service and, for legal reasons, the lamp may only be used by the customer after successful installation. In the case of lamps on loan, in other words, in the case of lamps already installed for testing by buyers before a purchase, the preconditions are met through the origination of a valid purchase agreement and the generation of an outgoing invoice.

Belixos® is predominantly sold through Amazon in Germany. Revenue is recognized after delivery and payment by the customer. 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 instance rebates, discounts or returns, are recognized based on estimated values at revenue recognition. Payment terms for Ameluz® include short-term payment terms with a possibility for sales rebates. Instalment payments over 48 months, which include a financing component, are sometimes agreed upon with the sale of BF-RhodoLED®.

License income as well as milestone-based payments are recognized when the contractual obligation has been fulfilled.

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 capitalising 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.

1. Intangible assets and property, plant and equipment

Changes in non-current assets in the 2016 financial year, as well as accumulated depreciation, amortization and impairment losses, are presented in the statement of changes in non-current assets. Property, plant and equipment consist mainly of office and business equipment and laboratory and production facilities.

The additions to intangible assets and to property, plant and equipment in the reporting period arise mainly from the purchase of software to compare important documents (EUR 20 thousand; previous year: EUR 0), right-of-use assets connected with the prototype of the PDT lamp (EUR 36 thousand; previous year: EUR 26 thousand), as well as further laboratory devices (EUR 290 thousand; previous year: EUR 35 thousand) and other fixtures and equipment (EUR 117 thousand; previous year: EUR 42 thousand). The asset disposals with costs totalling EUR 66 thousand (previous year: EUR 20 thousand) resulted primarily from sales of the rental lamps in an amount of EUR 52 thousand (previous year: EUR 20 thousand).

The right-of-use assets reported with a net carrying amount totaling EUR 1.1 million relate mainly to rights to use technology developed by the company ASAT Applied Science and Technology AG, Zug, Switzerland, in terms of the active ingredient ALA (aminolevulinic acid), including all related patents and know how. The right-of-use assets that are acquired are amortized over their estimated remaining useful life, from their date of acquisition, due to their direct usability. This useful life is derived from the term of the patents issued and acquired by Biofrontera AG and is reviewed annually pursuant to IAS 38.104. The remaining amortization period amounts to 2 years (previous year: 3 years). No indications of impairment exist.

1. Intangible assets and property, plant and equipment (cont.)

Consolidated Statement of Changes in Non-Current Assets
(in EUR thousands)

	Cost					Accumulated depreciation, amortization and impairment losses					Carrying amounts	
	1 Jan. 16 EUR	Currency translation	Additions EUR	Disposals EUR	31 Dec. 16 EUR	1 Jan. 16 EUR	Currency translation	Additions EUR	Disposals EUR	31 Dec. 16 EUR	31 Dec. 16 EUR	31 Dec. 15 EUR
I. Property, plant and equipment												
Operating and business equipment	3,477	2	420	65	3,834	3,104	—	120	35	3,189	645	373
II. Intangible assets												
1. Software and license	419	—	25	—	444	295	—	9	—	304	140	124
2. Right-of-use assets	6,053	—	36	—	6,089	4,275	—	702	—	4,977	1,112	1,778
Total Intangible assets	6,472	—	61	—	6,533	4,570	—	711	—	5,281	1,252	1,902
Total Non-Current Assets	9,949	2	481	65	10,367	7,674	—	831	35	8,470	1,897	2,275

1. Intangible assets and property, plant and equipment (cont.)

Consolidated Statement of Changes in Non-Current Assets
(in EUR thousands)

	Cost					Accumulated depreciation, amortization and impairment losses					Carrying amounts	
	1 Jan. 15 EUR	Currency translation	Additions EUR	Disposals EUR	31 Dec. 15 EUR	1 Jan. 15 EUR	Currency translation	Additions EUR	Disposals EUR	31 Dec. 15 EUR	31 Dec. 15 EUR	31 Dec. 14 EUR
I. Property, plant and equipment												
Operating and business equipment	3,343	—	154	20	3,477	3,003	—	108	7	3,104	373	340
II. Intangible assets												
1. Software and license	419	—	—	—	419	282	—	13	—	295	124	137
2. Right-of-use assets	6,027	—	26	—	6,053	3,584	—	691	—	4,275	1,778	2,443
Total Intangible assets	6,446	—	26	—	6,472	3,866	—	704	—	4,570	1,902	2,580
Total Non-Current Assets	9,789	—	180	20	9,949	6,869	—	812	7	7,674	2,275	2,920

2. Inventories

Inventories comprise finished products, work in progress, and raw materials and supplies at the sales companies.

Inventories amount to EUR 3.6 million (previous year: EUR 1.5 million). In assessing the consumption of inventories, the sequence of consumption is assumed to be based on the first-in-first-out (FIFO) method.

3. Trade receivables

The trade receivables are mainly attributable to the sale of Ameluz®, the BF-RhodoLED® PDT lamp and the cosmetic product Belixos®, as well as receivables due from Maruho arising from revenues from development projects. 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 over due as of December 31, 2016. For December 31, 2015 a receivable allowance for EUR 20 thousand was recognized.

4. Other financial and other assets

The other assets comprise mainly prepayments (EUR 707 thousand; previous year: EUR 116 thousand), prepayments rendered for studies (EUR 570 thousand; previous year: EUR 585 thousand) and VAT reimbursement claims (EUR 174 thousand; previous year: EUR 57 thousand). No individual value adjustments were applied during the reporting year (previous year: EUR 0 thousand).

5. Income tax reimbursement claims

These consist of claims for tax refunds relating to withheld capital gains tax, plus the Solidarity Surcharge (EUR 33 thousand; previous year: EUR 32 thousand). These amounts were refunded as we were at a net loss position and no tax obligations existed for the periods presented.

6. Securities

The valuation of securities classified as financial investments held to maturity is based on amortized costs. On 31 December 2016, the company's holdings in its own Warrant Bond I 2009/2017 had a nominal value of EUR 1.5 million (previous year: EUR 1.5 million). The warrant bonds held by Biofrontera were written up in fiscal year 2016 by EUR 267 thousand (previous year: write-down of EUR 100 thousand), to EUR 1.5 million (previous year: EUR 1.2 million) due to an increase in the market price. In accordance with IAS 32, the bonds are offset against the bond debt.

7. Cash and cash equivalents

Cash and cash equivalents relate to cash in hand, cheques, bank deposits and money deposits with a term of up to three months at the time of acquisition amounting to EUR 15.1 million (previous year: EUR 4.0 million). 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

The Biofrontera Group reported a net loss before tax on 31 December 2016 and on 31 December 2015. Deferred tax assets are generally determined on the basis of the existing income tax rates in Germany. The corporate tax rate is 15% as a result of the 2008 German Corporation Tax Reform Act (UStRG 2008). Including the 5.5% Solidarity Surcharge, this results in a combined tax rate of 15.8% (previous year: 15.8%). Due to the basic federal rate of 3.5% on businesses and the fact that it is no longer possible to deduct business tax as an operating expense, the resulting tax rate, taking into account the local business tax rate, is 16.6% (previous year: 16.6%).

8. Deferred income tax (cont.)

The following table shows changes in the Group's existing deferred tax assets deriving, as a matter of principle, from tax loss carryforwards (the previous year's figures have been adjusted to the amounts determined for tax purposes):

	31 December 2016		31 December 2015	
	Loss carried forward	Deferred tax assets	Loss carryforward	Deferred tax assets
	€ thousands			
Corporation tax including Solidarity Surcharge	111,742	17,683	104,757	16,583
Business tax	100,716	16,744	94,915	15,784
Total		34,427		32,367

These loss carryforwards have an unlimited carryforward period under current German law.

Due to the lack of predictability regarding future taxable profits, the existing deferred tax claims deriving, as a matter of principle, from loss carryforwards (EUR 34.4 million; previous year: EUR 32.4 million) and tax deductible differences of EUR 3 thousand (previous year: EUR 33 thousand) were not recognized on the balance sheet, in accordance with IAS 12.34.

The following provides a reconciliation between expected and actual reported income tax expense, with the output value being based on the rounded income tax rate of 32.5% currently applicable to the Biofrontera Group:

	31.12.2016	31.12.2015
	€ thousands	
Consolidated earnings before tax	(10,579)	(11,203)
Expected income tax reimbursement at the tax rate of the parent company	3,433	3,635
Differences arising from different tax rates	(14)	0
Tax reductions due to changes in permanent differences	0	161
Tax increases due to non-deductible expenses	(222)	(187)
Changes in unrecognized deferred tax assets		
– from active temporary differences	3	33
– from loss carryforwards	(2,060)	(3,602)
Other effects	(1,140)	(40)
Income taxes as per statement of comprehensive income	0	0

9. Equity

The fully paid in share capital of the parent company, Biofrontera AG, amounted to EUR 37.7 million on 31 December 2016. It was divided into 37,722,433 registered shares with a nominal value of EUR 1.00 each. On 31 December 2015, the share capital amounted to EUR 25.5 million and was increased by a total of EUR 9.9 million, divided into 9,870,333 registered shares, during the course of the 2016 financial year as a result of three capital increases.

As part of the capital increase implemented in February 2016, the company's share capital was increased against cash capital contributions by EUR 2.4 million through issuing 2,357,384 new ordinary registered shares from approved capital. Shareholders' subscription rights were excluded for this capital increase. The new shares were offered to selected institutional investors at an issue price of EUR 1.90 per new share, consequently for a total issue amount of EUR 4.5 million. These shares were fully placed and the implementation of the capital increase was entered in the commercial register on 26 February 2016. The net proceeds amounted to EUR 4.4 million.

As part of the capital increase implemented in April 2016, the company's share capital was increased against cash capital contributions by EUR 2.5 million through issuing 2,499,999 new ordinary registered shares from approved capital. Statutory subscription rights were granted to the shareholders. An "additional subscription" was also offered. In other words, shareholders

9. Equity (cont.)

exercising subscription rights could apply to subscribe for unsubscribed shares at the subscription price. The subscription price per share amounted to EUR 2.00. The capital increase was fully placed. The implementation of the capital increase was entered in the commercial register on 26 April 2016. The net issue proceeds amounted to EUR 4.9 million.

As part of the capital increase implemented in November 2016, the company's share capital was increased against cash capital contributions by EUR 5.0 million through issuing 5,012,950 new ordinary registered shares from approved capital. The implementation of the capital increase was entered in the commercial register on 21 November 2016. Statutory subscription rights were granted to the shareholders in a 6:1 ratio. The subscription price per share amounted to EUR 3.00. The net issue proceeds amounted to EUR 14.7 million.

Also 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 bonds were offered at a subscription price of 100% of the nominal value per bond in a denomination of EUR 100.00 per bond, and were fully placed. Shareholders were granted indirect subscription rights to the bonds. 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. Shareholders were granted statutory subscription rights in a 607:1 ratio at an issue price of EUR 100.00 per bond. The total issue volume amounted to EUR 5.0 million.

The exercising of 751,460 warrant rights from the 2011/2016 warrant bond generated issue proceeds of EUR 2.2 million in the 2016 financial year.

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 admitted to the Prime Standard of the Frankfurt Stock Exchange and the AIM Market of the London Stock Exchange. The listing on the AIM Market was discontinued as of 18 February 2016.

The numbers of shares held by the shareholders on 31 December 2016, based on the most recent compulsory disclosures of the shareholders, are as follows:

	31.12.2016	31.12.2015
Maruho Deutschland Co., Ltd., Osaka Japan	7,631,586	4,467,143
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.		
Wilhelm Konrad Thomas Zours	3,400,907	1,053,154
The voting rights through the chain of subsidiaries listed below are attributed to Mr. Zours: • DELPHI Unternehmensberatung AG • VV Beteiligungen AG • Deutsche Balaton AG • ABC Beteiligungen AG • Heidelberger Beteiligungsholding AG		
Universal-Investment-Gesellschaft mbH, Frankfurt am Main, Germany	799,463	799,463
The share of voting rights is attributed to Universal-Investment GmbH through the company FEHO Vemögensverwaltungsgesellschaft.		
Free float	25,890,477	19,170,670
Total	37,722,433	25,490,430

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,

9. Equity (cont.)

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. Financing measures occurred in February 2016, April 2016 and November 2016.

The statement of changes in equity provides further information about the development of equity.

The following items are reported as of 31 December 2016 in connection with the 2009/2017 bond with warrants that was issued, the 2011/2016 bond with warrants that was issued in July 2011 (Tranche 1) and December 2011 (Tranche 2), and the 2016/2021 convertible bond:

€ thousands	31.12.2016 EUR	31.12.2015 EUR
Non-current financial liabilities (measured at amortized cost)	3,597	11,230
Current financial debt (accrued interest from nominal interest rate)	273	830
Capital reserve (equity component: 2009/2017 warrant bond)	1,485	1,485
Capital reserve (equity component: 2011/2016 warrant bond)	1,227	1,227
Capital reserve (equity component: 2016/2021 convertible bond)	323	—

The interest effects of the warrant bonds on the non-current borrowings were initially calculated applying an effective annual interest rate of 14.35% per annum for the 2009/2017 warrant bond, 9.8% per annum for the first tranche of the 2011/2016 warrant bond and 5.8% per annum for the second tranche of the 2011/2016 warrant bond as well as 7.9% per annum for the convertible bond 2016/2021.

In accordance with IAS 32.37, equity procurement costs less any related income tax benefits are to be deducted from equity. In the 2016 financial year, costs of raising equity totaling EUR 0.3 million (previous year: EUR 0.5 million) were recognized in connection with the capital increases that were implemented.

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' dividends are calculated based on the size of their holding of the share capital.

2010 share option program

At the Annual General Meeting on 2 July 2010, the Management and Supervisory boards proposed a share option program for employees to the Annual General Meeting, 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 0.8 million and a term of six years from the issue date, in other words, until 24 November 2016. For this, contingent capital amounting to EUR 0.8 million 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 contingent 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.

9. Equity (cont.)

The issue date was 24 November 2010. The granting of options is made without any consideration being rendered 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 3.373 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 amounts 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 at least 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 proportionally 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 the 5th banking day before expiration of the options for each respective expiry date (exclusive).

After expiry of the relevant vesting period, the options can be exercised up until the expiry of six years from the date of issue (exclusive).

9. Equity (cont.)

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 ended 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 program entails share-based payment transactions in which the terms of the arrangement provide the company with a choice of settlement, the company has determined, that the most likely form of settlement would be in the form of shares. Therefore, in accordance with IFRS 2.41 and IFRS 2.43, the transactions have been recognized 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. For the share options issued on 31 December 2010, this resulted in a total value of options of EUR 0.1 million. For the additional share options granted in 2011, a fair value of EUR 0.1 million was calculated. For the two tranches of options granted in 2012, fair values of EUR 0.1 million and EUR 0.1 million were calculated, respectively. For the share options granted in 2013, a fair value of EUR 0.2 million was calculated. For the share options granted in 2014, a fair value of EUR 0.1 million was determined. 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 30 November 2014, and the vesting period for the second tranche ran until 30 September 2015. The option rights from the first tranche expired on 24 November 2016, as the exercise conditions were not met. No options from the second tranche had been exercised as of the reporting date.

The vesting period for the third tranche ran until 30 March 2016, and the vesting period for the fourth tranche ended on 11 May 2016. No options had been exercised from these tranches up to the reporting date.

No options from the fifth tranche could be exercised due to the vesting period.

A total of 137,250 options were forfeited by employees leaving the company.

By resolution of the Annual General Meeting on 28 August 2015, the Contingent Capital III planned for the servicing of options under this program was reduced to EUR 0.5 million.

The cost expensed in the reporting period amounted to EUR 62 thousand (previous year: EUR 103 thousand).

2015 share option program

At the Annual General Meeting 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,

9. Equity (cont.)

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 1.8 million of the company's ordinary registered shares, whose exercise is tied to certain targets.

The program has a total nominal volume of EUR 1.8 million and a term of five years from the issue date, in other words, until 27 August 2020. For this, contingent capital amounting to EUR 1.8 million 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 contingent 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 each option of this share option program was calculated on the grant date 01 December 2016 based on a Monte Carlo risk simulation at a fair value of EUR 1.30/option. A volatility of the share price of approximately 50.6% was used to calculate the fair value of the options granted in the first tranche and a volatility of approximately 49.0% for the second tranche (based on daily rates, annualised assuming 250 trading days per annum), an earning yield of 2.31% for the first tranche (based on daily rates, annualised assuming 250 trading days per annum) and 7.00% for the second tranche respectively (based on a Capital Asset Pricing Model (CAPM)) and a total risk adjusted interest rate of 5.92% for the first tranche and 13.26% for the second tranche respectively as well as a standard annual beneficiary turnover rate of 12% for both tranches.

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 (second tranche) a further 130,500 options were issued with an exercise price of EUR 3.28 each.

A total of 7,500 options were forfeited by employees leaving the company.

The total option value for options issued as at 31 December 2016 was therefore EUR 1.5 million. 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. The expenditure recognized in the reporting period was EUR 49 thousand (previous year: EUR 0).

Share Option Program 2010	**December 31, 2015**	**December 31, 2016**	**June 30, 2017**
Outstanding at the beginning of the period	549,400	534,400	439,500
granted during the period	0	0	0
forfeited during the period	15,000	13,500	5,000
exercised during the period	0	0	0
expired during the period	0	81,400	0
outstanding at the end of the period	534,400	439,500	434,500
exercisable at the end of the period	0	0	0
range of exercise prices for options outstanding	€1.91 – €4.09	€2.44 – €4.05	€2.44 – €4.05
weighted average remaining contractual life	35 months	27 months	20 months

9. Equity (cont.)

Share Option Program 2015	December 31, 2015	December 31, 2016	June 30, 2017
Outstanding at the beginning of the period		0	548,000
granted during the period		555,500	329,000
forfeited during the period		7,500	31,000
exercised during the period		0	0
expired during the period		0	0
outstanding at the end of the period		548,000	846,000
exercisable at the end of the period		0	0
range of exercise prices for options outstanding		€2.49 – €3.28	€2.49 – €4.02
weighted average remaining contractual life		59 months	63 months

10. Financial liabilities

On 26 June 2009, Biofrontera announced the placement of a warrant bond with a term ending on 1 January 2018. As part of this financing measure on the part of the company, a warrant bond was placed in 2009 ("Warrant Bond I"). The warrant bond has a total nominal value of EUR 10,000,000.00, divided into up to 100,000 bonds with a nominal value of EUR 100.00. The redemption at the end of the term is at 106% of par. The warrant bonds bear interest on the following scale:

- from 01.09.2009 to 30.12.2010 at an annual rate of 4%;
- from 31.12.2010 to 30.12.2011 at an annual rate of 6%;
- from 31.12.2011 to 31.12.2017 at an annual rate of 8%.

The accrual of interest on each warrant bond ends on the day before it is due for redemption. The interest payment is made on the last business day of the calendar year, but not until 31 December 2010, in other words, the interest for 2009 does not become due until then. An ordinary call on the bond by the bondholders is not permitted. Biofrontera has the right, upon issuing of written notice to the bondholders of Warrant Bond I, to repay 106% of the nominal amount (plus any accrued interest) at any time. Each holder of a partial bond is, in accordance with the bond and option terms, entitled to five detachable option rights per bond, with each of these providing the irrevocable right to acquire a registered voting-entitled no par value ordinary share in Biofrontera AG with a notional proportion of the share capital of EUR 1.00, at a warrant price of EUR 5.00 each. The warrant right expires on 30 December 2017. The share resulting from the exercising of a warrant right is dividend-entitled from the beginning of the financial year in which it originated from the exercising of the option right and payment of the capital contribution. To provide financing for the warrant rights, contingent capital of the company amounting to up to EUR 0.5 million was approved at the Extraordinary General Meeting held on 17 March 2009.

Of these warrant bonds, partial bonds were issued with a total nominal value of EUR 4,930,300.

The liability from this warrant bond was measured at its present value of EUR 3.2 million on the issue date, and the carrying amount of the non-current financial liability amounts to a total of EUR 3.4 million applying the effective interest method as of 31 December 2016 (31 December 2015: EUR 2.8 million). The current (due within one year) portion of this financial liability amounts to EUR 0.3 million (31 December 2015: EUR 0.4 million).

On 7 June 2011, the Management Board resolved, with Supervisory Board approval and based on the authorization granted by the Annual General Meeting, to issue a warrant bond 2011/2016 (hereinafter "Warrant Bond II").

Warrant Bond II has a total nominal value of up to EUR 25 million and is divided into up to 250,000 individual warrant bonds with a nominal value of EUR 100.00 each. Each individual warrant bond is connected with ten detachable warrants issued by the company; each warrant entitles the holder to buy one registered voting-entitled no par value ordinary share in the company with an interest in the share capital of EUR 1.00 each at an option price of EUR 3.00. If all the warrant rights were to be issued and exercised, this would result in a calculated total exercise price of EUR 7.5 million. The issue price of each warrant bond is EUR 100.

10. Financial liabilities (cont.)

The term of the warrant bonds begins on 20 July 2011 and ends on 31 December 2016. To provide financing for the option rights, contingent capital of up to EUR 2.5 million was approved at the company's General Meeting on 10 May 2011 and entered in the commercial register on 18 May 2011. Warrant Bond II carries a coupon of 5% per annum. The accrual of interest on each warrant bond ended on 31 December 2016. Interest was paid annually on 1 January for the previous year, commencing on 1 January 2012 with a payment of EUR 0.2 million for the period 20 July 2011 until 31 December 2011. A nominal total of EUR 8.7 million of individual warrant bonds of Warrant Bond II was issued as a result of two transactions that exchanged the convertible bonds for Warrant Bond II in July and December 2011 and the direct subscription from the initial issue.

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 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 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.

The contractual interest and repayment obligations relating to warrant bonds are broken down on the balance sheet date as follows:

€ thousands	**31.12.2016**					
	2017	**2018**	**2019**	**2020**	**2021**	**Total**
Warrant bond 2009/2017:						
Principal repayment		5,226				5,226
Interest payment	394					394
Warrant bond 2011/2016:						
Principal repayment	0					0
Interest payment						0
Convertible bond 2016/2021:						
Principal repayment					190	190
Interest payment	11	11	11	11	11	55

The position was as follows in the previous year:

€ thousands	**31.12.2015**					
	2016	**2017**	**2018**	**2019**	**2020**	**Total**
Warrant bond 2009/2017:						
Principal repayment			5,226			5,226
Interest payment	394	394				788
Warrant bond 2011/2016:						
Principal repayment		8,715				8,715
Interest payment	436	436				872

11. Trade payables

The trade payables (EUR 2.1 million; previous year: EUR 1.0 million) increased by EUR 1.1 million from the previous year primarily due to the increase in inventory.

12. Other provisions

Other provisions report the following changes:

Biofrontera Group € thousands	01.01.2016	Utilised	Released	Added	31.12.2016
Bonuses for employees	143	143	—	506	506
Outstanding vacation	82	82	—	198	198
Outstanding invoices	660	399	6	681	936
Costs for financial statements and auditing	109	109	—	154	154
Miscellaneous other provisions	48	22	2	6	30
Total provisions	1,042	755	8	1,545	1,824

Other provisions concern various individually identifiable risks and contingent liabilities. Provisions classified as current are expected to be utilised prospectively within the subsequent financial year.

13. Other financial and other current liabilities

€ thousands	31 December 2016	31 December 2015
Payroll tax	114	97
Financial leasing	4	12
Credit card payments	28	16
Wages and salaries	57	10
Other	45	26
	248	161

14. Reporting on financial instruments

During the course 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. 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.

Credit risk: A credit risk arises for the Group if transaction partners cannot meet their obligations within 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 reporting year, no individual value adjustments were made for other financial assets (previous year: EUR 0 thousand); in addition, no individual value adjustments were applied to trade receivables in the reporting year (previous year: EUR 0).

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.

14. Reporting on financial instruments (cont.)

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 only has financial instruments at levels 1 and 2. No reclassifications between level 1 and level 2 were performed during the 2016 financial year. With regard to financial liabilities, the full amount of non-current and current financial liabilities (EUR 3.9 million; previous year: EUR 12.1 million) is allocated to Level 1. This involves financial debt arising from the two warrant bonds.

Biofrontera reports under other operating expenses value adjustments to trade receivables and miscellaneous financial obligations allocable to the "loans and receivables" category. The currency translation losses arise mainly from trade payables. The net gains and losses generally include specific value adjustments and currency conversion effects.

The financial assets and liabilities can be subdivided into measurement categories with the following carrying amounts, and net gains and losses:

		Carrying amounts				
Financial assets on 31.12.2016 € thousands	**Fair value**	**Loans and receivables**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**Financial assets available-for-sale**	**TOTAL CARRYING AMOUNTS**	**Net gains (+) or losses (-)**
Financial assets					0	0
Liquid assets	15,126	15,126			15,126	0
Trade receivables	1,624	1,624			1,624	0
Other current financial receivables and assets	1,377	1,377			1,377	0
TOTAL	18,127	18,127	0	0	18,127	0

		Carrying amounts			
Financial liabilities on 31.12.2016 € thousands	**Fair value**	**Other liabilities**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**TOTAL CARRYING AMOUNTS**	**Net gains (+) or losses (-)**
Financial liabilities current	274	274		274	0
Trade payables	2,093	2,093		2,093	(72)
Other financial liabilities current	59	58		58	0
Other financial liabilities non-current	3,660	3,597		3,597	0
TOTAL	6,086	6,022	0	6,022	(72)

14. Reporting on financial instruments (cont.)

		Carrying amounts				
Financial assets on 31.12.2015 € thousands	**Fair value**	**Loans and receivables**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**Financial assets available-for-sale**	**TOTAL CARRYING AMOUNTS**	**Net gains (+) or losses (-)**
Financial assets					0	0
Liquid assets	3,959	3,959			3,959	0
Trade accounts receivable	895	895			895	0
Miscellaneous current financial receivables and assets	730	730			730	0
TOTAL	5,584	5,584	0	0	5,584	0

		Carrying amounts			
Financial liabilities on 31.12.2015 € thousands	**Fair value**	**Other liabilities**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**TOTAL CARRYING AMOUNTS**	**Net gains (+) or losses (-)**
Financial liabilities current	830	830		830	0
Trade accounts payable	1,043	1,043		1,043	(22)
Other financial liabilities current	38	38		38	0
Other financial liabilities non-current	9,689	11,230		11,230	0
TOTAL	11,600	13,141	0	13,141	(22)

Liquidity risk: The refinancing of the Biofrontera Group companies is generally performed centrally by Biofrontera AG. A risk exists in this regard that the liquidity reserves may be insufficient to fulfil the financial obligations on the due date. In order to cover the liquidity requirements at 31 December 2016, cash and cash equivalents totalling EUR 15.1 million (31 December 2015: EUR 4.0 million) are available. See the relevant balance sheet notes on (undiscounted) payments from financial debt due in the next years.

Notes to the consolidated statement of comprehensive income as of 31 December 2016

15. Sales revenue

The Biofrontera Group recognized sales of EUR 6.1 million in the 2016 financial year (previous year: EUR 4.1 million), representing an increase of 48% compared with the previous year. This includes down payments of EUR 40 thousand (previous year: EUR 70 thousand). Revenues from selling products in Germany reduced by 17% to EUR 2.5 million (previous year: EUR 3.0 million), while revenues generated in European countries outside Germany grew by 20% to EUR 1.3 million (previous year: EUR 1.0 million). For the first time, revenues were also generated from the sale of products in the U.S. in an amount of EUR 1.2 million. Revenues in the U.S. were achieved using a title model with one wholesaler. Revenues of EUR 1.2 million were generated in the financial year from the development partnership with Maruho.

16. Cost of sales, gross profit

The gross profit on sales improved from EUR 2.9 million to EUR 4.5 million. The gross margin increased to 73%, compared to 70% in the same period in the previous year.

The cost of sales amounted to EUR 1.7 million, equivalent to 27% of sales revenue (previous year: EUR 1.2 million, or 30%).

17. Development costs

Research and development costs amounted to EUR 4.6 million in the 2016 financial year, a reduction of EUR 1.6 million, or 25%, year-on-year. The decrease mainly reflects the EUR 2.1 million submission fee (PDUFA fee) paid at submission of the application for approval to the FDA during the first half of 2015. The PDUFA fee is usually waived for small companies for their initial submission. Biofrontera lodged an application for a waiver of this fee, but this could not be processed on the filing date as the FDA did not have a process for handling such applications. This fee was refunded by the FDA in March 2016 and was recorded in other income in fiscal year 2016.

18. Sales and marketing costs

Sales and marketing costs of EUR 8.8 million reflect an approximately 110% increase compared with the previous year's period (EUR 4.2 million). The sales and marketing costs include the costs of our own field sales team in Germany, Spain and in the U.S., as well as marketing expenses. The increase is mainly attributable to expenses for the start-up of sales activities and to establish sales structures in the U.S..

19. Administrative costs

Administrative costs increased by EUR 94 thousand year-on-year to EUR 2.9 million in the 2016 financial year (previous year: EUR 2.8 million). Financing costs shown under administrative costs include primarily consultancy and placement fees in connection with support for the search of investors.

20. Financial result

The financial result consists primarily of the interest payable for the 2009/2017 warrant bond (EUR 0.5 million, previous year: EUR 0.4 million) and for the 2011/2016 warrant bond placed in 2011 (EUR 0.7 million, previous year: EUR 0.7 million), calculated using the effective interest method. The aforementioned interest expenses on the warrant bond 2009/2017 of EUR 0.5 million (previous year: EUR 0.4 million) include the opposite effect of EUR 0.2 million (previous year: EUR 0.2 million) from the repurchase of part of the warrant bond on 28 February 2014. The interest on Warrant Bond I for the 2015 financial year was paid at the end of December 2015, and the interest on Warrant Bond II was paid at the beginning of January 2016. The interest for the 2016 financial year for Warrant Bond I was paid at the start of January 2017. In December 2016, Warrant Bond II was repaid early with a principal repayment of EUR 8.7 million, plus accrued interest of EUR 0.4 million. See note 6 for details of the warrant bonds held by Biofrontera.

21. Other income (expenses), net

The submission fee paid to the FDA in 2015 (PDUFA fee) was reimbursed in an amount of EUR 2.0 million in March 2016 after a "small business waiver" was granted. This fee was reported under research and development costs in the income statement for 2015. The reimbursement is reported under other income. The difference to the amount originally paid results from currency translation differences.

22. 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.

	31.12.2016	31.12.2015
Number of weighted ordinary shares in circulation (on average)	29,742,634	23,156,343
Net loss for the year in EUR (in thousands)	(10,579)	(11,203)
Basic/Diluted earnings per share in EUR	(0.36)	(0.48)

When calculating diluted earnings per share for the 2015 and 2016 financial years, the warrant bond issued in 2009 (2009/2017), with a total nominal value of EUR 4.9 million and giving bondholders the right to acquire 246,515 shares at a price of EUR 5.00 each, as well as the warrant bond issued in 2011 (2011/2016), with a total nominal value of EUR 8.7 million and giving bondholders the right to acquire 871,500 shares at a price of EUR 3.00 each, have been taken into account as a matter of principle. As the Group achieved negative results for the year in the 2015 and 2016 financial years, no diluted earnings per share were reported, as the conversion or subscription rights for the periods shown counteracted any dilution.

23. 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.

Cost of materials

The cost of materials included in the cost of sales amounted to EUR 1.3 million for the 2016 financial year (previous year: EUR 1.0 million).

Depreciation, amortization and impairment losses

Depreciation and amortization on tangible and intangible assets of EUR 0.8 million in the 2016 financial year and of EUR 0.8 million in the previous year is included in the following items in the statement of comprehensive income:

€ thousands	31.12.2016	31.12.2015
Research and development costs	689	691
General administrative costs	127	113
Cost of sales	9	8
Sales	6	0
Depreciation, amortization and impairment losses	831	812

Personnel costs

€ thousands	31.12.2016	31.12.2015
Wages and salaries	5,753	3,557
Social security charges	908	482
Costs for pension schemes	33	34
Total	6,694	4,073

24. Staff

On average, the Biofrontera Group employed 64 people in the 2016 financial year (previous year: 46 employees).

25. Other information

Operating and finance 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:

	2016	2015	2016	2015	2016	2015
€ thousands	**≤ 1 year**		**1 year to 5 years**		**> 5 years**	
Operating leases						
Leases for business premises	520	424	1,870	2,156	1,620	1,620
Leases for cars	274	145	375	178	0	0
Operating and business equipment	23	18	37	35	0	0

Lease-related expenses for the reporting period amounted to EUR 0.2 million (previous year: EUR 0.2 million).

On the balance sheet date, a finance lease existed for a server leased by Biofrontera AG with a carrying amount of EUR 4 thousand (previous year: EUR 12 thousand). The contract has a minimum term of 60 months to 31 July 2017. Biofrontera AG is obliged to purchase the leased asset from the lessor for a fixed residual value of EUR 2 thousand if the lessor exercises its option to sell. In the reporting year, minimum lease payments of EUR 11 thousand were expensed (previous year: EUR 11 thousand).

On the balance sheet date of 31 December 2016, the present value of the sum of future minimum lease payments is reconciled to their present values as follows:

All amounts in € thousands	**Minimum lease payments**	**Discounting**	**Present value**
Up to 1 year:	7	2	4
Between 2 and 5 years:	0	0	0
More than 5 years:	0	0	0

26. 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, cheques, 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 0.8 million (previous year: EUR 1.2 million). The change resulted from the two interest payments for Warrant Bond I made in the 2015 financial year: firstly, on 1 January 2015 for the 2014 financial year, and, secondly, on 31 December 2015 interest for the 2015 financial year. Interest received amounted to EUR 3 thousand (previous year: EUR 0.2 million), consisting of interest received for deposits. In the previous year, the interest received from Warrant Bond I held by the company itself already accrued to the company as of 30 December 2015.

27. Members of the Management Board

Prof. Hermann Lübbert was the Management Board Chairman (Chief Executive Officer/CEO) in the reporting period. The CEO also holds a professorial chair at Bochum University in Germany. Prof. Lübbert was appointed to the Management Board from 27 March 2015 until 31 October 2020 by way of Supervisory Board resolution.

Mr. Thomas Schaffer is the Chief Financial Officer. Mr. Schaffer was appointed to the Management Board from 9 April 2015 until 30 November 2020 by way of Supervisory Board resolution.

Mr. Christoph Dünwald is the Management Board member responsible for the Sales and Marketing areas. With a Supervisory Board resolution of 9 July 2015, Mr. Dünwald was appointed to the Management Board until 15 November 2017.

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-based bonus exists for the Management board members, as well as a long-term remuneration component consisting of participation in the company's share option program. Company cars are also available to the directors for business and private use.

The remuneration for members of the Management Board in the 1 January until 31 December 2016 period consisted of a salary and a bonus as well as share options. The total remuneration for Management Board members in the reporting period, including the value of share options at the time they were granted, amounted to EUR 1.4 million (previous year: EUR 0.9 million). This was allocated as follows

Prof. Dr. Hermann Lübbert	Non-performance based salary component:	EUR 0.3 million (31 December 2015: EUR 0.4 million)
	Performance based salary component:	EUR 0.1 million (31 December 2015: EUR 35 thousand)
	stock options:	231,850 (fair value when granted: EUR 0.4 million) (previous year: 151,850, fair value when granted: EUR 0.2 million); of which granted in 2016: 80,000 (2015: 0)
Thomas Schaffer	Non-performance based salary component:	EUR 0.2 million (31 December 2015: EUR 0.2 million)
	Performance based salary component:	EUR 0.1 million (31 December 2015: EUR 28 thousand)
	stock options:	85,000 (fair value when granted: EUR 0.2 million) (previous year: 35,000, fair value when granted: EUR 32,650); of which granted in 2016: 50,000 (2015: 0).
Christoph Dünwald	Non-performance based salary component:	EUR 0.2 million (31 December 2015: EUR 29 thousand)
	Performance based salary component:	EUR 6 thousand (31 December 2015: EUR 0 thousand)
	stock options:	50,000 (fair value when granted: EUR 0.1 million) (previous year: 0, fair value when granted: EUR 0); of which granted in 2016: 50,000 (2015: 0).

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

28. Members of the Supervisory Board

As a result of the resolution passed by the Annual General Meeting held on 31 May 2016, the Supervisory Board has consisted of the following members since 31 May 2016:

Dr. Ulrich Granzer	Chairman of the Supervisory Board, Owner and Managing Director of Ulrich Granzer Regulatory Consulting & Services, resident in Munich, Germany
Jürgen Baumann	Deputy Chairman of the Supervisory Board, management consultant, resident in Monheim
John Borer	Head of Investment Banking at The Benchmark Company LLC, New York, U.S., resident in Jersey City, NJ, U.S.
Hansjörg Plaggemars	Management Board member of Deutsche Balaton Aktiengesellschaft, Heidelberg, resident in Stuttgart
Mark Reeth	Attorney, resident in Frederick, MD, U.S.
Kevin Weber	Principal of Skysis, LLC., Scottsdale, AZ, U.S., resident in Scottsdale, AZ, U.S.

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

Hansjörg Plaggemars	OOC CTV Verwaltungs GmbH, Managing Director
	Stellar Diamonds plc, Non-Executive Board Member
	Carus Grundstücksgesellschaft am Taubenfeld AG, Supervisory Board Chairman
	Eurohaus Frankfurt AG, Supervisory Board Chairman
	Youbisheng Greenpaper AG i.I., Supervisory Board Chairman
	Ming Le Sports AG, Supervisory Board Chairman
	Nordic SSW 1000 Verwaltungs AG, Supervisory Board Chairman
	Balaton Agro Invest AG, Deputy Supervisory Board Chairman
	Carus AG, Deputy Supervisory Board Chairman
	Deutsche Balaton Immobilien I AG, Supervisory Board member
	Ultrasonic AG i.I., Supervisory Board member

In the 2016 financial year, compensation paid to Supervisory Board members amounted to EUR 113 thousand (previous year: EUR 0.1 million). The compensation transactions are classified as short-term employee benefits as per IAS 24.17(a).

During the reporting period, the company availed itself of additional advisory services from Supervisory Board member Dr. Ulrich Granzer. These services went beyond the scope of normal Supervisory Board activities. Dr. Granzer assisted the 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 course of the 2016 financial year, advisory services amounting to EUR 10 thousand (previous year: EUR 0.1 million) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 7 thousand on 31 December 2016 (31 December 2015: EUR 0 thousand). The amounts stated here do not include statutory VAT at the current rate of 19%. The underlying consultancy contract was approved in consideration of the statutory provisions.

29. Related party disclosures

In July 2016, Biofrontera AG entered into a collaboration and partnership agreement with Maruho Co., Ltd., a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of Biofrontera AG. This agreement provides for the joint development of up to four branded generic pharmaceutical product candidates for the European market using Biofrontera AG's proprietary formulation technology. The current agreement covers the initial part of the collaboration, in which the feasibility of the product development is tested, which Biofrontera AG expects to be completed by the end of 2017. Under this agreement, Maruho will bear all the costs connected with the development of these pharmaceutical product candidates (subject to a cap of €2.3 million).

29. Related party disclosures (cont.)

If these product candidates progress to clinical development, the collaboration and partnership agreement provides that Biofrontera AG will negotiate in good faith a new agreement with Maruho, without any obligation to enter into it. Maruho has not been granted any rights to Biofrontera AG's formulation technology in the first phase of the project. The collaboration and partnership agreement provides that, if the parties ultimately determine to enter into a new agreement, Biofrontera AG would be granted an exclusive sublicensable right to market the product in Europe. As the agreement is related to Europe only, there are currently no firm understandings with respect to other geographical regions. The collaboration and partnership agreement further specifies that all results, information and data developed during the term of such agreement will be the property of Maruho. Any intellectual property (such as trade secrets, copyrights, patents and other patent rights, trademarks and moral rights) developed during the term of such agreement will be the joint property of Biofrontera AG and Maruho. We do not currently expect any such intellectual property to be developed during the term of the agreement. The collaboration and partnership agreement prohibits Biofrontera AG from manufacturing, selling or otherwise dealing in any products similar to and competitive with the product candidates developed under the agreement without Maruho's consent. Maruho has the right to terminate the collaboration and partnership agreement for any or no reason.

This development partnership generated revenue of EUR 1.2 million in the financial year under review (previous year: EUR 0 thousand). Receivables due from Maruho amounted to EUR 0.5 million as of 31 December 2016 (31 December 2015: 0).

In the 2016 financial year, no further reportable transactions or relationships with related parties existed beyond the aforementioned facts and circumstances stated in subsections 27 and 28. 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 access to the public capital market.

30. Auditor's fees and services

The total fee invoiced by the auditor Warth & Klein Grant Thornton AG for the 2016 financial year consists of the following:

€ thousands	**2016**	**2015**
Auditing services	184	122
[of which for the previous year]	[50]	[16]
Other certification services	55	43
	239	165

31. Events after the reporting date

On 24 January 2017, the company announced that the issue of up to 49,990 subordinated convertible bonds that had been approved in December 2016 had been placed in full in a total nominal amount of up to EUR 4,999,000 ("convertible bond").

On 30 January 2017, the European Commission followed the positive vote by the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) and issued the expansion of the approval of Ameluz® to treat basal cell carcinoma. The extended approval comprises the treatment of superficial and/or nodular basal cell carcinoma in adults where surgical removal is ruled out due to potential morbidity or due to an undesirable cosmetic result.

On 6 February 2017, the company announced positive preliminary results for the primary endpoint of the clinical Phase III trial to investigate the efficacy and safety of the prescription medication Ameluz® in combination with daylight photodynamic therapy (PDT). The trial reached its primary regulatory endpoint and proved the non-inferiority ($p<0.001$) of Ameluz® in daylight-PDT in relation to the comparator product Metvix® in treating mild or moderate actinic keratosis, a superficial skin cancer. After just one PDT, the trial reached its primary endpoint at 78.7% complete lesion clearance in a half side comparison per patient in treatment with Ameluz® and daylight-PDT, in comparison with 75.0% lesion clearance in treatment with Metvix®

31. Events after the reporting date (cont.)

and daylight-PDT. The company published detailed results of this trial on 13 March 2017. Ameluz® has also reported higher results in all relevant secondary endpoints than the competitor product, with the greatest differences between Ameluz® and the competitor product arising for patients under 65 years of age and for patients treated under cloudy weather.

On 9 March 2017, the lawsuit of a shareholder of June 30, 2016 was withdrawn by the plaintiff. The lawsuit brought charges for nullity, alternatively rescission, of some of the resolutions passed at the company's Ordinary Annual Shareholder Meeting on 31 May 2016. In particular, the election of Mr. John Borer, Mr. Jürgen Baumann and Mr. Kevin Weber to the company's Supervisory Board was contested.

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

Biofrontera AG
Condensed Consolidated Balance Sheet as at
Assets

(in EUR thousands)

	June 30, 2017	December 31, 2016
Non-current assets		
Tangible assets	662	645
Intangible assets	984	1,252
Total Non-current assets	**1,646**	**1,897**
Current assets		
Current financial assets		
Trade receivables	1,202	1,624
Other financial assets	1,136	1,377
Cash and cash equivalents	11,452	15,126
Total Current financial assets	**13,790**	**18,127**
Other current assets		
Inventories		
Raw materials and supplies	1,573	1,350
Unfinished products	428	477
Finished products and goods	1,834	1,819
Income tax reimbursement claims	33	33
Other assets	44	177
Total Other current assets	3,912	3,855
Total Current assets	**17,702**	**21,982**
Total Assets	**19,348**	**23,879**

Liabilities

(in EUR thousands)

	June 30, 2017	December 31, 2016
Equity		
Subscribed capital	38,417	37,722
Capital reserve	100,670	98,677
Capital reserve from foreign currency conversion adjustments	442	(154)
Loss carry forward	(120,403)	(109,824)
Net loss of the year	(8,737)	(10,579)
Total Equity	**10,389**	**15,842**
Long-term liabilities		
Long-term financial liabilities	2,654	3,597
Current liabilities		
Current financial liabilities		
Trade payables	448	2,093
Short-term financial debt	3,666	274
Other financial liabilities	47	59
Total Current financial liabilities	**4,161**	**2,426**
Other current liabilities		
Other provisions	1,880	1,824
Other Current liabilities	264	190
Total Other current liabilities	**2,144**	**2,014**
Total Current liabilities	**6,305**	**4,440**
Total Equity and liabilities	**19,348**	**23,879**

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

Biofrontera AG
Condensed Consolidated Statement of Comprehensive Income for the six months ended

(in EUR thousands)

	June 30, 2017	June 30, 2016
Sales revenue	5,006	1,709
Cost of sales	(635)	(764)
Gross profit from sales	4,371	945
Operating expenses		
Research and development costs	(2,185)	(1,852)
General administrative costs	(1,696)	(1,373)
thereof financing costs	(511)	(372)
Sales costs	(8,275)	(2,832)
Loss from operations	**(7,785)**	**(5,112)**
Interest expenses	(330)	(594)
Interest income	4	2
Other expenses	(741)	(14)
Other income	115	2,246
Profit/loss before income tax	**(8,737)**	**(3,472)**
Income tax	0.0	0.0
Profit or loss for the period	**(8,737)**	**(3,472)**
Expenses and income not included in profit/loss		
Items which may in future be regrouped into the profit and loss statement under certain conditions Translation differences resulting from the conversion of foreign business operations	596	0
Other income total	596	0
Total profit/loss for the period	**(8,141)**	**(3,472)**
Basic/diluted earnings per share	(0.23)	(0.12)

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

Biofrontera AG
Condensed Consolidated Cash Flow Statement for the six months ended

(in EUR thousands)

	June 30, 2017	June 30, 2016
Cash flows from operations		
Loss for the period	(8,737)	(3,472)
Adjustments to reconcile profit/loss for the period to cash flow into operations		
Financial result	326	593
Depreciation	444	404
Losses from disposal of assets	0.0	5
Non-cash expenses and income	789	46
Changes in operating assets and liabilities		
Trade receivables	422	382
Other assets and income tax assets	372	(339)
Inventories	(188)	(142)
Trade payables	(1,644)	(45)
Provisions	66	83
Other liabilities	63	(26)
Net cash flow into operational activities	**(8,087)**	**(2,511)**
Cash flows from investment activities		
Purchase of intangible and tangible assets	(204)	(155)
Interest received	2	2
Revenue from sale of intangible and tangible assets	10	10
Net cash flow into investment activities	**(192)**	**(143)**
Cash flows from financing activities		
Proceeds from the issue of shares	0.0	9,303
Proceeds from conversions of convertible bonds 2017/2022	4,999	0.0
Interest paid	(394)	(436)
Net cash flows from financing activities	**4,605**	**8,867**
Net (decrease)/increase in cash and cash equivalents	(3,674)	6,213
Cash and cash equivalents at the beginning of the period	15,126	3,959
Cash and cash equivalents at the end of the period	**11,452**	**10,172**
Composition of financial resources at the end of the period		
Cash and cash equivalents	11,452	10.172

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

Biofrontera AG
Condensed Statement of Changes in Equity
(in EUR thousands, except per share amounts)

	Ordinary shares number	Subscribed capital	Capital reserve	Capital reserve from foreign currency conversion adjustments	Accumulated loss	Total
Balance as at 01 January 2016	**25,490,430**	**25,490**	**79,526**	**(1)**	**(109,824)**	**(4,809)**
Capital increase	4,857,383	4,857	4,622	—	—	9,479
Costs of equity procurement	—	—	(176)	—	—	(176)
Foreign currency conversion adjustment	—	—	—	—	—	—
Increase in capital reserve from the stock option program	—	—	53	—	—	53
Net loss of the year	—	—	—	—	(3,472)	(3,472)
Balance as at June 30, 2016	**30,347,813**	**30,347**	**84,025**	**(1)**	**(113,296)**	**1,075**
Capital increase	5,012,950	5,013	10,026	—	—	15,039
Conversion from convertible bond 2016/2021	1,603,050	1,603	3,231	—	—	4,834
Exercise of detachable warrant rights from the option bond 2011/2016	758,620	759	1,487	—	—	2,246
Foreign currency conversion adjustment	—	—	—	(153)	—	(153)
Costs of equity procurement	—	—	(145)	—	—	(145)
Changes in capital reserves pursuant to the issuance of the convertible bond 2016/2021	—	—	(4)	—	—	(4)
Increase in capital reserve from the stock option programme	—	—	57	—	—	57
Net loss of the year	—	—	—	—	(7,107)	(7,107)
Balance as at 31 December 2016	**37,722,433**	**37,722**	**98,677**	**(154)**	**(120,403)**	**15,842**
Conversion from convertible bond 2016/2021	26,700	27	74	—	—	101
Conversion from convertible bond 2017/2022	667,295	668	1,836	—	—	2,504
Foreign currency conversion adjustment	—	—	—	596.0	—	596
Increase in capital reserve from the stock option programme	—	—	83	—	—	83
Net loss of the year	—	—	—	—	(8,737)	(8,737)
Balance as at June 30, 2017	**38,416,428**	**38,417**	**100,670**	**442**	**(129,140)**	**10,389**

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

Biofrontera AG
Notes to the Condensed Consolidated Financial Statements
As of and for the six months ending June 30, 2017

Information about the company

Biofrontera AG (*www.biofrontera.com*), registered in the commercial register of Cologne District Court, Department B under No. 49717, and 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, and Biofrontera AG, based in Wakefield, Massachusetts, U.S. and with its registered office in Wilmington, Delaware, U.S., research, develop and market dermatological products. Biofrontera AG is an international biopharmaceutical company specializing in the development and commercialization of a platform of pharmaceutical products for the treatment of dermatological conditions and diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Its approved products focus on the treatment in the U.S. and Europe of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer, as well as the treatment of basal cell carcinoma in the EU. Biofrontera Inc. (hereinafter also the "company" or "Biofrontera") pursues this goal along with its subsidiaries. All the companies together form the "Biofrontera Group".

The Biofrontera Group's principal product is Ameluz®, which is a prescription drug approved for use in combination with photodynamic therapy, or PDT, referred to as Ameluz® PDT. Ameluz® PDT received centralized European approval in 2011 from the European Commission for the treatment of actinic keratosis of mild to moderate severity on the face and scalp. Since the initial centralized European approval of Ameluz® PDT, the European Commission granted label extensions for the use of Ameluz® PDT for (i) the treatment of field cancerization, or larger areas of skin on the face and scalp with multiple actinic keratoses and (ii) the treatment of superficial and/or nodular basal cell carcinoma unsuitable for surgical treatment due to possible treatment-related morbidity and/or poor cosmetic outcome.

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

In May 2016, Biofrontera received approval from the U.S. Food and Drug Administration, or the FDA, to market in the U.S. Ameluz® in combination with photodynamic therapy using its BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Biofrontera Inc. launched the commercialization of Ameluz® and BF-RhodoLED® for actinic keratosis in the U.S. in October 2016.

The Biofrontera Group currently sells Ameluz® in the U.S., in 11 countries in Europe and in Israel.

The Biofrontera Group also sells Belixos®, an over-the-counter line of skin care cosmetics products. Belixos® cosmetic products are available for sale in Germany and certain other European countries at selected pharmacies, dermatological institutes, and through local Amazon websites.

In July 2016, the company agreed a research partnership with Maruho Co., Ltd. ("Maruho"), a Japanese company specializing in dermatology, in which possibilities to jointly develop pharmaceutical products for the European market based on Biofrontera's proprietary nanoemulsion technology are to be researched. This corresponds to the same strategy with which Ameluz® was also developed. The nanoemulsion technology stabilized the active substance and improved skin penetration, leading to greater clinical efficacy. This principle is also to be applied to other substances as part of the partnership with Maruho. According to the agreement, Maruho will bear all costs connected with the exploratory research for four new product candidates (subject to a cap of €2.3 million). It is planned that Maruho will be the owner of the results, but that all new inventions are to belong to both companies jointly. As part of the agreement, Biofrontera does not issue to Maruho any license for the utilisation of the nanoemulsion or other existing intellectual property. The license to market the new products in Europe shall be allocated to Biofrontera. The agreement does not cover other markets.

The BF-derm1 project was tested in a three-part Phase II trial for the treatment of chronic, antihistamine-resistant urticaria. The trial demonstrated the drug's efficacy, which reduced the intensity of urticaria rashes and itching and reduced the amount of drowsiness-inducing antihistamines required by patients.

The BF-1 project is to develop a substance that is intended to be used for migraine prophylaxis. The substance was administered to healthy subjects for the first time towards the end of 2006, by intravenous injection and in tablet form. The company received the results of this trial in early 2007. They show that the substance is almost completely absorbed in the intestine, and that it takes around two days for 50% of the substance to be broken down or excreted.

At present, the Biofrontera Group is not actively pursuing the BF-derm1 project or the BF-1 project.

Accounting policies

Pursuant to the regulations of Section 37y of the German Securities Trading Act (WpHG), in combination with Section 37w WpHG, this half-year financial report as of June 30, 2017 comprises condensed interim consolidated financial statements, an interim Group management report and a responsibility statement pursuant to the regulations of Section 297 (2) Clause 4, Section 315 (1) Clause 6 of the German Commercial Code (HGB).

The condensed interim consolidated financial statements of Biofrontera AG were prepared in accordance with the International Financial Reporting Standards (IFRS) of the International Accounting Standards Board (IASB) as well as the interpretations of the International Financial Reporting Standards Interpretations Committee (IFRS IC) for "Interim Financial Reporting" in accordance with IAS 34. As a consequence, they do not include all information and disclosures required for consolidated financial statements, and for this reason should be read in connection with the consolidated financial statements for the financial year ending 31 December 2016.

As part of preparing the interim consolidated financial statements, the Management Board must make assumptions that affect the application of accounting policies within the Group, and the reporting of assets and liabilities as well as income and expenses. Actual amounts can differ from such estimates. The results achieved during the first half of the 2017 financial year do not allow any predictions to be made about trends during the further course of business.

The accounting policies applied to prepare the consolidated financial statements as of 31 December 2016 continued to be applied on an unmodified basis for the preparation of the condensed interim consolidated financial statements. In this connection, please also refer to the notes to the consolidated financial statements as of 31 December 2016.

The consolidated financial statements for 31 December 2016 contain no separate segment-based reporting, as the activities of the Biofrontera Group are limited to a single business segment in terms of the definition in IFRS 8. All business operations focus on the product Ameluz®, including the supplementary products BF-RhodoLED® (PDT lamp) and Belixos®, and are internally monitored and managed accordingly.

This half-year financial report of Biofrontera AG was approved for publication by a Management Board resolution on October 4, 2017.

Rounding differences can arise in the tables due to commercial rounding.

Convertible bond 2017/2022

The company's Management Board passed a resolution to issue a further convertible bond on 23 December 2016. This EUR 5.0 million bond was fully placed in January 2017. The initial conversion price for the bond amounts to EUR 3.50, to EUR 4.00 from 1 April 2017 and to EUR 5.00 from 1 January 2018. The bonds carry 6 % annual interest on their par value from 1 February 2017. The bond will be redeemed in cash on 1 January 2022 unless it is converted previously. The conversion right was recorded upon issuance as the difference between the contract value and the fair value of the financial liability in the amount of €296,000 in accordance with IAS 32 and is included in the condensed statement of changes in equity in the "conversion from convertible bond 2017/2022" line item. As of 30 June 2017, bonds with a nominal amount of EUR 2.3 million had been converted into the company's shares.

Loan agreement with the European Investment Bank

In May 2017, a loan agreement for up to EUR 20.0 million was arranged with the European Investment Bank (EIB). The loan is unsecured and guaranteed by our main subsidiaries. It is available in tranches over a two-year period. In July 2017, the company drew down a first tranche of EUR 10.0 million. Two further tranches of EUR 5.0 million each can be drawn down after certain milestones have been achieved. Each tranche must be repaid five years after it was made available. The loan incurs interest in three components, whereby some of the interest payments must be paid in cash quarterly, some of the interest payments are initially deferred and are to be paid at the end of the term, and a further portion of the interest payments are also to be paid at the end of the term depending on the company's market capitalisation.

Employee stock option program 2015

After the end of the 2010 employee share option program, the company's Annual General Meeting on 28 August 2015 authorized the Management and Supervisory boards until 27 August 2020 to issue to Management Board members and employees up to 1,814,984 subscription rights to up to EUR 1,814,984 million of the company's ordinary registered shares according to the more detailed specifics of the authorization resolutions.

On April 18, 2016, a total of 425,000 options were issued for the first time from the potential 1,814,914 share options (exercise price: EUR 2.49 per option). On 1 December 2016, a further 130,500 options (second tranche) were issued with an exercise price of EUR 3.28 each. On April 28, 2017, a further 329,000 options (third tranche) were issued at an exercise price of EUR 4.02 each. A total of 38,500 options were forfeited by employees leaving the company during the six months ended June 30, 2017. Due to the vesting period, no options have yet been exercised or forfeited. As a consequence, 891,983 options are still outstanding on June 30, 2017. The cost expensed in the reporting period amounted to EUR 56 thousand (prior-year period: EUR 16 thousand).

Shares/Earnings per share

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

	June 30, 2017	June 30, 2016
Number of weighted ordinary shares in circulation (on average)	37,730,066	29,194,771
Net loss for the year in € thousands	(8,737)	(3,472)
Earnings per share in EUR based on the net loss for the year	(0.23)	(0.12)

Reporting on financial instruments

In the course 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. 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.

Credit risk: A credit risk arises for the Group if transaction partners cannot meet their obligations within 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 first half of 2017, no individual value adjustments were made to other financial assets (prior-year period: EUR 0); in addition, no individual value adjustments were applied to trade receivables in the first half of 2017 (prior-year period: EUR 0).

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 only has financial instruments at levels 1 and 2. During the first half of 2017, no reclassifications between the individual levels of the fair value hierarchy were implemented. With regard to financial liabilities, the full amount of non-current and current financial liabilities (EUR 6.3 million; 31 December 2016: EUR 3.9 million) are classified as level 1, except for the residual value of warrant bond 2016 (EUR 81 thousand). This involves financial debt arising from warrant and convertible bonds.

The financial assets and liabilities can be subdivided into measurement categories with the following carrying amounts, and net gains and losses:

		Carrying amounts			
Financial assets on 30.06.2017 € thousands	**Fair value**	**Loans and receivables**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**Financial assets available-for-sale**	**TOTAL CARRYING AMOUNTS**
Financial assets					
Liquid assets	11,452	11,452			11,452
Trade receivables	1,202	1,202			1,202
Other current financial receivables and assets	1,136	1,136			1,136
TOTAL	13,790	13,790	—	—	13,790

		Carrying amounts		
Financial liabilities on 30.06.2017 € thousands	**Fair value**	**Other liabilities**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**TOTAL CARRYING AMOUNTS**
Financial liabilities current	3,593	3,665		3,665
Trade payables	448	448		448
Other financial liabilities current	48	48		48
Other financial liabilities non-current	2,928	2,654		2,654
TOTAL	7,017	6,815	—	6,815

		Carrying amounts			
Financial assets on 31.12.2016 € thousands	**Fair value**	**Loans and receivables**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**Financial assets available-for-sale**	**TOTAL CARRYING AMOUNTS**
Financial assets					
Liquid assets	15,126	15,126			15,126
Trade accounts receivable	1,624	1,624			1,624
Miscellaneous current financial receivables and assets	1,377	1,377			1,377
TOTAL	18,127	18,127	—	—	18,127

		Carrying amounts		
Financial liabilities on 31.12.2016 € thousands	**Fair value**	**Other liabilities**	**Financial instruments recognized at fair value in profit or loss (excluding "held-for-trading")**	**TOTAL CARRYING AMOUNTS**
Financial liabilities current	274	274		274
Trade accounts payable	2,093	2,093		2,093
Other financial liabilities current	59	59		59
Other financial liabilities non-current	3,660	3,597		3,597
TOTAL	6,086	6,023	—	6,023

Members of the Supervisory Board

One change relating to the following Supervisory Board member occurred during the first half of 2017:

Hansjörg Plaggemars is a Supervisory Board member of Biofrontera AG and to date has been employed as a member of the Management Board of Deutsche Balaton Aktiengesellschaft, Heidelberg, resident in Stuttgart, and is now a member of the Management Board of Delphi Unternehmensberatung AG, Heidelberg, resident in Stuttgart.

Related party disclosures

In July 2016, Biofrontera AG entered into a collaboration and partnership agreement with Maruho Co., Ltd., a pharmaceutical company based in Japan specializing in dermatology that is also an affiliate of Maruho Deutschland GmbH, a major shareholder of Biofrontera AG. This agreement provides for the joint development of up to four branded generic pharmaceutical product candidates for the European market using Biofrontera AG's proprietary formulation technology. The current agreement covers the initial part of the collaboration, in which the feasibility of the product development is tested, which Biofrontera AG expects to be completed by the end of 2017. Under this agreement, Maruho will bear all costs connected with the development of these pharmaceutical product candidates (subject to a cap of €2.3 million).

If these product candidates progress to clinical development, the collaboration and partnership agreement provides that Biofrontera AG will negotiate in good faith a new agreement with Maruho, without any obligation to enter into it. Maruho has not been granted any rights to Biofrontera AG's formulation technology in the first phase of the project. The collaboration and partnership agreement provides that, if the parties ultimately determine to enter into a new agreement, Biofrontera AG

would be granted an exclusive sublicensable right to market the product in Europe. As the agreement is related to Europe only, there are currently no firm understandings with respect to other geographical regions. The collaboration and partnership agreement further specifies that all results, information and data developed during the term of such agreement will be the property of Maruho. Any intellectual property (such as trade secrets, copyrights, patents and other patent rights, trademarks and moral rights) developed during the term of such agreement will be the joint property of Biofrontera AG and Maruho. We do not currently expect any such intellectual property to be developed during the term of the agreement. The collaboration and partnership agreement prohibits Biofrontera AG from manufacturing, selling or otherwise dealing in any products similar to and competitive with the product candidates developed under the agreement without Maruho's consent. Maruho has the right to terminate the collaboration and partnership agreement for any or no reason.

This development partnership generated revenue of EUR 785 thousand in the first half of 2017 (prior-year period: EUR 0 thousand). Receivables due from Maruho amounted to EUR 0.2 million as of June 30, 2017 (31 December 2016: EUR 0.5 million).

During the reporting period, the company availed itself of additional advisory services from Supervisory Board member Dr. Ulrich Granzer. Dr. Granzer assisted the 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 first half of 2017, advisory services amounting to EUR 33 thousand (previous-year period: EUR 2 thousand) were provided by Granzer Regulatory Consulting & Services. Accounts payable to Granzer Regulatory Consulting & Services amounted to EUR 0 thousand on June 30, 2017 (December 31, 2016: EUR 7 thousand). The amounts stated here do not include statutory VAT at the current rate of 19 %. The underlying consultancy contract was approved in consideration of the statutory provisions.

In the first half of 2017, no further significant reportable transactions or relationships with related parties existed beyond the aforementioned facts and circumstances.

Significant events after the interim reporting date

Management evaluated events after the interim reporting date of 30 June 2017 through 4 October 2017 and noted the following events that occurred during that period:

In July 2017, the Cologne District Court served a lawsuit on the company dated 23 June 2017 and brought by Deutsche Balaton AG for the rescission and nullity of two resolutions passed at the AGM on 24 May 2017.

In August 2017, the company received the written opinion of the American drugs regulator, the FDA, on the terms for the approval of Ameluz® for basal cell carcinoma in the U.S., on which the company had reached agreement with the FDA at a formal meeting in July. According to the agreed development plan, the approval expansion for superficial basal cell carcinoma can be applied for based on a single supplementary Phase III trial conducted in the U.S., comparing Ameluz® with a placebo. The FDA expects from Biofrontera a combined evaluation of the clinical and histological healing rates. The clinical investigation of patients with different ethnic backgrounds or children is not required. As far as safety information and long-term data are concerned, the FDA has accepted the existing European trial for review.

In July 2017, a first tranche of EUR 10.0 million from the loan from the European Investment Bank was drawn down.

In July 2017 a further patent for the development project BF-1 was granted by the United States Patent and Trademark Office.

Following a resolution by our supervisory board on 19 July 2017 the service contract with Christoph Dünwald and his appointment to the management board have been extended until 30 November 2020.

The 2009/2017 bond with warrants with stepped interest rates and with final maturity on 31 December 2017 was fully repaid early on 3 August 2017 with a total payment of €5.5 million including principal amount and accumulated interest.

On 2 August 2017, the company announced the market launch of Ameluz® and BF-RhodoLED® in Israel by its partner Perrigo Israel Ltd.

Marketing activities in Slovenia were discontinued as of 31 August 2017 due to low market volume.

Management evaluated events after 4 October 2017 through 13 February 2018 and noted the following events that occurred during that period;

On 13 September 2017, we terminated our license and supply agreement with BiPharma B.V., effective as of 31 October 2017.

In a ruling dated December 1, 2017, the Court of Cologne dismissed the lawsuit filed by Deutsche Balaton AG in June 2017.

On 21 December 2017 Deutsche Balaton AG appealed this ruling.

On January 23, 2018, we were informed by the Cologne District Court that Deutsche Balaton AG has initiated a proceeding pursuant to article 142 para 2 AKtG (German Stock Corporation Act) to appoint a special auditor. The subject of this special audit would be the collaboration and partnership agreement between us and Maruho entered into in July 2016. The annual shareholder meeting held in May 2017 had already rejected a similar action brought forward at that meeting.

On 7 February 2018, Mr. Reinhart Eyring was appointed to the Company's supervisory board. His term commenced on 7 February, 2018, and will end on the date of our next annual shareholders' meeting.

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

1,215,000 American Depositary Shares
Representing 2,430,000 Ordinary Shares

BIOFRONTERA AG

Prospectus dated February 13, 2018

Benchmark

Dawson James Securities, Inc. **Lake Street Capital Markets**

Until March 10, 2018 (the 25th day after the date of this prospectus), all dealers that effect transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to the dealers' obligation to deliver a prospectus when acting as underwriters and with respect to their unsold allotments or subscriptions.