

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

BIOFRONTERA INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

2834
(Primary Standard Industrial
Classification Code Number)

47-3765675
(I.R.S. Employer
Identification No.)

**120 Presidential Way, Suite 330
Woburn, MA 01801
Telephone: 781-245-1325**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Prof. Dr. Hermann Luebbert
Chairman and Chief Executive Officer
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**APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: FROM TIME TO TIME AFTER THIS REGISTRATION
STATEMENT IS DECLARED EFFECTIVE.**

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☒

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Smaller reporting company ☒ Emerging growth company ☒

If an emerging growth company, that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act. ☐

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

securities in any jurisdiction where the offer or sale is not permitted.

**Subject to Completion.
Dated May 2, 2024**

Up to 11,309,019 Shares of Common Stock Offered by the Selling Stockholders



This prospectus relates to the offering and resale, from time to time, by the selling stockholders identified herein (the “Selling Stockholders”) of up to 11,309,019 shares of common stock issuable upon the conversion of Series B-3 Convertible Preferred Stock, par value \$0.001 per share (the “Series B-3 Preferred”). The Series B-3 Preferred may be issued upon the exercise of up to 8,000 warrants to purchase the Series B-3 Preferred at an exercise price of \$1,000 per share (the “Preferred Warrants”) issued to the Selling Stockholders by us on February 22, 2024 in a private placement (the “Private Placement”) pursuant to a securities purchase agreement dated February 19, 2024. Please see “*Private Placement of the Preferred Stock and Warrants*” beginning on page 23 of this prospectus for more information.

We will not receive any proceeds from the sale of shares of common stock by the Selling Stockholders. However, we will receive up to \$7.4 million in net proceeds if the Preferred Warrants are exercised in full.

The Selling Stockholders may sell all or a portion of the shares of common stock beneficially owned by them and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. Please see the section entitled “*Plan of Distribution*” on page 25 of this prospectus for more information. For information on the Selling Stockholders, see the section entitled “*Selling Stockholders*” on page 24 of this prospectus. We will bear all fees and expenses incident to our obligation to register the shares of common stock.

Our common stock is quoted on the Nasdaq Capital Market under the symbol “BFRI.” On May 2, 2024, the last reported sale price per share of our common stock was \$1.79.

The Selling Stockholders will offer their shares at prevailing market prices or privately negotiated prices.

We are an “emerging growth company,” as defined in the Jumpstart Our Business Startups Act of 2012, and a “smaller reporting company,” as defined under applicable federal securities laws and, as such, we have elected to comply with certain reduced public company reporting requirements. See “*Summary—Implications of Being an Emerging Growth Company and a Smaller Reporting Company.*”

Investing in our securities involves a high degree of risk. See “**Risk Factors**” beginning on page 8 to read about factors you should consider before buying our securities.

Neither the Securities and Exchange Commission nor any other regulatory body 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.

Prospectus dated , 2024.

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ABOUT THIS PROSPECTUS

We and the Selling Stockholders have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus. We and the Selling Stockholders take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. This prospectus is an offer to sell only the shares offered by this prospectus, but only under circumstances and in jurisdictions where it is lawful to do so. The information contained in this prospectus is current only as of its date. Our business, financial condition, results of operations and prospects may have changed since that date.

For investors outside the United States: We and the Selling Stockholders have not done anything that would permit the sale of our common stock being offered by the Selling Stockholders in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares and the distribution of this prospectus outside the United States.

BASIS OF PRESENTATION

As used in this prospectus, unless the context otherwise requires, references to “we,” “us,” “our,” the “Company,” “Biofrontera” and similar references refer to Biofrontera Inc. which includes its wholly owned subsidiary Bio-Fri GmbH. References in this prospectus to the “Biofrontera Group” (a related party) refer to Biofrontera AG and its consolidated subsidiaries, Biofrontera Pharma GmbH (individually, “Biofrontera Pharma”), Biofrontera Bioscience GmbH (individually “Biofrontera Bioscience”), Biofrontera Neuroscience GmbH Biofrontera Development GmbH. References in this prospectus to “Ferrer” refer to Ferrer Internacional S.A. References in this prospectus to “Licensors” refer collectively to Biofrontera Pharma, Biofrontera Bioscience and Ferrer. References in this prospectus to “Ameluz Licensor” refer collectively to Biofrontera Pharma and Biofrontera Bioscience. References in this prospectus to “Cutanea” refer to Cutanea Life Sciences, Inc.

Our financial statements have been prepared in accordance with generally accepted accounting principles in the United States, or GAAP. Our fiscal year ends on December 31 of each year. Our most recent fiscal year ended on December 31, 2023.

Certain monetary amounts, percentages and other figures included in this prospectus have been subject to rounding adjustments. Percentage amounts included in this prospectus have not in all cases been calculated on the basis of such rounded figures, but on the basis of such amounts prior to rounding. For this reason, percentage amounts in this prospectus may vary from those obtained by performing the same calculations using the figures in our financial statements included elsewhere in this prospectus. Certain other amounts that appear in this prospectus may not sum due to rounding.

TRADEMARKS

We 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. 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 annual report are listed without the ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights, or the rights of the applicable licensor, to such trademarks and trade names.

SUMMARY

This summary highlights selected information contained elsewhere in this prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our securities. You should read the entire prospectus, including the information incorporated by reference herein, carefully, including the section titled “Risk Factors,” included elsewhere in this prospectus and in the sections entitled “Risk Factors” and “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and our financial statements and the related notes included in our most recent Annual Report on Form 10-K, or Form 10-K, which is incorporated by reference herein, before making an investment decision. Some of the statements in this prospectus constitute forward-looking statements. See “Special Note Regarding Forward-Looking Statements.”

Overview

We are a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy (“PDT”) and topical antibiotics with PDT contributing to the largest amount of our business. The Company’s licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions, as well as impetigo, a bacterial skin infection. In May 2023, the Company began research and development (“R&D”) activities to support PDT growth and will continue to opportunistically invest in these activities going forward. Our research and development program currently aims to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists. Our goal is to improve the effectiveness of our commercial team by allowing sales representatives to carry approved devices with them allowing for easier product demonstrations and evaluations. Effective June 1, 2024, we will take control of all clinical trials relating to Ameluz® in the US, allowing for more effective cost management and direct oversight of trial efficiency.

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® lamp series, for PDT (when used together, “Ameluz® PDT”). In the United States, the Ameluz® PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses (“AK”) of mild-to-moderate severity on the face and scalp. AKs are premalignant lesions of the skin that can potentially develop into skin cancer (squamous cell carcinoma) if left untreated.¹ International treatment guidelines list photodynamic therapy as the strongly recommended treatment for multiple AK, and the suggested recommendation for single AK.² We are currently selling Ameluz® for this indication in the United States under an exclusive license and supply agreement (as amended, the “Ameluz LSA”) between Biofrontera Inc. and the Ameluz Licensors.

AKs 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. AKs 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. AKs are typically treated with cryotherapy, topicals, or PDT. These treatments can be used in combination, which is the number one indication for those 45 years of age or older.

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 accumulate 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 highly reactive oxygen species (“ROS”), which destroys or alters the sensitized cells. Photodynamic therapy can be a highly selective treatment that targets specific cells while minimizing damage to normal surrounding tissues. It also can allow for multiple courses of therapy. Hence the mode of action of photodynamic therapy requires destruction of the altered cells. Temporary local skin reactions and inflammation of the treated area might be expected. The Ameluz® PDT therapy is highly effective with patients experiencing up to 91% clearance after one or two treatments³ with limited or no scarring.⁴ The therapy also may provide protection from potentially fatal progress of mild or invisible AKs.

AK currently affects approximately 58 million Americans which lead to roughly 13 million treatments annually.⁵ Cryotherapy is the traditional and most common form of treatment but may not be as effective and may leave scarring; cryotherapy is estimated to be approximately 86% of the market. Topical medications which patients apply to the lesion multiple times per day for up to several weeks, constitute approximately 12% of the market. PDT is approximately 2% of the market. The total market size is estimated to be roughly \$4 billion for the three therapy types. Our primary competitor in the PDT space is Levulan® and the associated light, Blu-U®.

Our goal is to continue expansion in the current PDT market share and focus on converting cryotherapy treatments of more than 14 lesions as a field therapy such as Ameluz® PDT could be more effective. Between the current PDT market and the >14 lesion cryotherapy market, our targeted market is about 11% or \$500 million of the total AK market (consisting of the current PDT market at \$100 million and the portion of the market attributed to cryotherapy treatments of more than 14 lesions at \$400 million, assuming a tube price of \$346).⁶

Our second prescription drug licensed product in our portfolio is Xepi® (ozenoxacin cream, 1%), a topical non-fluorinated quinolone that inhibits bacterial growth. Currently, no antibiotic resistance against Xepi® is known and it has been approved by the FDA for the treatment of impetigo, a common skin infection, due to Staphylococcus aureus or Streptococcus pyogenes. It is approved for use in the United States in adults and children 2 months and older. We are currently selling Xepi® for this indication in the United States under an exclusive license and supply agreement, as amended ("Xepi LSA"), with Ferrer that was assumed by Biofrontera on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. There has been limited revenue during the current reporting periods and recent developments with the third-party manufacturer that was providing our supply of Xepi® impacting the timing of sales expansion and improved market positioning. However, Ferrer is qualifying a new third-party contract manufacturer in North America. The expectation is that this process will be completed in the second half of 2024. Once the new third-party manufacturer is qualified, we expect the supply of Xepi® will enable us to market and increase demand.

¹ Fuchs & Marmur, Dermatol Surg. 2007 Sep; 33(9):1099-101. doi: 10.1111/j.1524-4725.2007.33224.x
² Werner RN, et al.. J Eur Acad Dermatol Venereol. 2015 Nov;29(11):2069-2079. doi:10.1111/jdv.13180.
³ For full prescribing information for Ameluz, please see <https://bit.ly/AmeluzPI>.
⁴ Reinhold et al. Br. J. Derm. 2016 Oct; 175(4): 696-705. DOI 10.1111/bjd. 14498.
⁵ www.skincancer.org/skin-cancer-information/actinic-keratosis.
⁶ Market data accessible from CMS and IQVIA, 2020.

Impetigo is a common and highly contagious bacterial skin infection caused by bacteria. The bacteria that can cause impetigo include Group A beta-hemolytic streptococcus and Staphylococcus aureus. It occurs most frequently in children 2 to 5 years old, but people of any age can be affected and even more than once. Impetigo causes red sores that most often appear on the face, neck, arms, and legs. These sores can turn into blisters that open and form a yellowish crust. Transmission of the disease is by direct contact and poor hygiene can increase the spread. Although impetigo is a year-round disease, it occurs most often during the warm weather months.⁷ Although impetigo rarely leads to serious complications, effective treatment with drugs like Xepi® can shorten how long impetigo lasts.

We are a sales organization with focus on commercializing our portfolio of licensed products that are already FDA-approved. Predefined research and development efforts for label extensions in order to optimize the market positioning of the products are currently the responsibility of the respective licensor and responsibility for research and development efforts for Ameluz® will be transitioning to us effective June 1, 2024 in accordance with Ameluz LSA.

Under the Ameluz LSA, we hold the exclusive license to sell Ameluz® and the RhodoLED® lamp series comprising the RhodoLED® and the new, more advanced RhodoLED® XL (targeted launch in Q2 2024) in the United States for all indications currently approved by the FDA as well as all future FDA-approved indications identified under the Ameluz LSA.

On February 19, 2024, the Ameluz LSA was amended with the Second Amended and Restated License and Supply Agreement (the "Second A&R Ameluz LSA"), effective February 13. The Second A&R Ameluz LSA amends and restates the Ameluz LSA, originally dated as of October 1, 2016, between the Company and Amulez Licensor, which was subsequently amended on July 1, 2019, June 16, 2021, October 8, 2021, December 5, 2023, and January 26, 2024. Among other things, the Second A&R Ameluz LSA reduces the transfer price of Ameluz® from 50% to 25% for all purchases in 2024 and 2025. Starting on January 1, 2026, until 2032 there will be stepwise increases in the transfer price from 25% to 35% for sales related to actinic keratosis and, if approved by the FDA, basal cell carcinoma and squamous cell carcinoma. The transfer price for sales related to acne, another indication currently in development, will remain at 25% indefinitely. The transfer price covers the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance, and patent administration.

Effective June 1, 2024, the Company will take control of all clinical trials relating to Ameluz® in the US, allowing for more effective cost management and direct oversight of trial efficiency. The reduced Ameluz LSA transfer price will allow the Company to finance such R&D activities and continue our commercial growth trajectory.

A summary of our understanding of the Ameluz Licensor's clinical trials is below:

Product	Indication / comments	Clinical Phase				Approval process	Status
		Pre-clinical	I	II	III		
Ameluz®	Superficial basal cell carcinoma				•		Last-patient-in treatment phase in August 2023; Last-patient-out of treatment phase expected in March 2024; Clinical Study Report ("CSR") expected Q4 2024
Ameluz®	Actinic Keratosis		•				Phase 1 safety study applying 3 tubes of Ameluz® to an expanded treatment area of 60 cm ² ; completed and submitted to FDA
Ameluz®	Moderate to severe acne			•			Phase II is recruiting; CSR expected in Q3 2025
Ameluz®	Actinic Keratosis				•		Trunk & extremities applying 1-3 tubes of Ameluz®; First patient dosed in January 2023; CSR expected Q1 2026
Ameluz®	Actinic Keratosis				•		Combination daylight and conventional PDT; Plan to start enrollment in 2025

In late October 2021, the new, larger RhodoLED® XL was approved by the FDA in combination with Ameluz® for the treatment of mild and moderate actinic keratoses on the face and scalp, which corresponds to the current approval of Ameluz®. The new PDT-lamp enables the illumination of larger areas, thus allowing the simultaneous treatment of several actinic keratoses distant from each other. The smaller BF-RhodoLED® model will continue to be offered in the U.S. market. In addition to the patents listed in the Orange Book, our licensor has been granted two patents for pain-reduced PDT procedures. One patent combines daylight and conventional PDT and, if the respective Phase III trial leads to inclusion of the procedure into the Ameluz® label, may provide further patent protection until 2039. The other patent reduces pain by various modifications of light intensity during PDT and expires in 2040. Furthermore, the FDA recently approved a new formulation of Ameluz® that lacks propylene glycol and reduces the accumulation of certain contaminants over time. The new formulation will be implemented in all US productions of Ameluz® starting in 2024. A corresponding patent application has been filed which, if granted by the U.S. Patent and Trademark Office, will extend protection of Ameluz® to 2043.

⁷ How to Treat Impetigo and Control This Common Skin Infection | FDA

Currently, there are no clinical trials being conducted for Xepi®, and we are unaware of any immediate or near-term plans of Ferrer for a U.S.-market focused development pipeline.

Our Strategy

Our principal objective is to improve patient outcomes by increasing the sales of our licensed products. The key elements of our strategy include the following:

- expand our sales in the United States of Ameluz® in combination with the RhodoLED® lamp series for the treatment of minimally to moderately thick actinic keratosis of the face and scalp and positioning Ameluz® to be standard of care in the United States by focusing on acquisition of new customers and growth of the therapy in our current customer base;
- leverage the potential for future approvals and label extensions of our licensed portfolio products that are in the pipeline for the U.S. market through the LSAs with the Licensors and, with respect to Ameluz® after June 1, 2024, further the clinical development of this product after taking over responsibility for certain ongoing clinical trials pursuant to the amended and restated Ameluz LSA; and
- Strategically manage our licensed portfolio, including opportunistically adding complementary products or services to our portfolio by acquiring or licensing IP to further leverage our commercial infrastructure and customer relationships as well as availing ourselves of strategic opportunities, including potential divestitures, with respect to our existing portfolio.

By executing these three strategic objectives, we will fuel company growth, deepen our trusted relationships in the dermatology community, and above all, help patients live healthier, more fulfilling lives.

Company History and Management Team

We were formed in March 2015 as Biofrontera Inc., a Delaware corporation, and a wholly owned subsidiary of Biofrontera AG, a stock corporation organized under the laws of Germany. On November 2, 2021, we consummated our initial public offering and subsequently we ceased to be deemed a company controlled by Biofrontera AG. As of March 19, 2024, Biofrontera AG holds approximately 7.9% of the outstanding shares of our common stock.

Biofrontera Inc. includes its wholly owned subsidiary Bio-FRI GmbH, a limited liability company organized under the laws of Germany. Our subsidiary, Bio-FRI was formed on February 9, 2022, as a German presence to facilitate our relationship with the Ameluz Licensor.

Our management team includes Prof. Dr. Hermann Luebbert as Chairman and Chief Executive Officer and Fred Leffler as Chief Financial Officer.

Summary Risk Factors

Investing in our common stock involves substantial risk. Our ability to execute our strategy is also subject to certain risks. The risks described under the heading "Risk Factors" included elsewhere in this prospectus and in our most recent Annual Report on Form 10-K, which is incorporated by reference herein, may cause us not to realize the full benefits of our strengths or may cause us to be unable to successfully execute all or part of our strategy. Some of the most significant challenges and risks include the following:

- Currently, our sole source of revenue is from sales of products we license from other companies. If we fail to comply with our obligations in the agreements under which we license rights from such third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.
- Certain important patents for our licensed product Ameluz® expired in 2019. Although the process of developing generic topical dermatological products for the first time presents specific challenges that may deter potential generic competitors, generic versions of Ameluz® may enter the market following the recent expiration of these patents. If this happens, we may need to reduce the price of Ameluz® significantly and may lose significant market share.
- Our business depends substantially on the success of our principal licensed product Ameluz®. If the Ameluz Licensor is unable to successfully obtain and maintain regulatory approvals or reimbursement for Ameluz® for existing and additional indications, our business may be materially harmed.

- The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer to manufacture Ameluz[®] and has recently contracted with a second unaffiliated contract manufacturer to begin producing Ameluz[®]. If the Ameluz Licensor fails to maintain its relationships with these manufacturers or if both of these manufacturers are unable to produce product for the Ameluz Licensor, our business could be materially harmed.
- If our Licensors or our Licensors' manufacturing partners, as applicable, fail to manufacture Ameluz[®], RhodoLED[®] lamps, Xepi[®] or other marketed products 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 the products under license to us or we will be unable to meet market demand, and lose potential revenues.
- The Biofrontera Group has been involved in lawsuits to defend or enforce patents related to our licensed products and they or another licensor may become involved in similar suits in the future, which could be expensive, time-consuming and unsuccessful.
- We are fully dependent on our collaboration with the Ameluz Licensor for our supply of Ameluz[®] and RhodoLED[®] lamps and future development of the Ameluz[®] product line, on our collaboration with Ferrer for our supply of Xepi[®] and future development of Xepi[®] and may depend on the Ameluz Licensor, Ferrer or additional third parties for the supply, development and commercialization of future licensed products or product candidates. Although we have the authority under the Ameluz LSA with respect to the indications that the Ameluz Licensor is currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA) in certain circumstances to take over clinical development, regulatory work and manufacturing from the Ameluz Licensor if they are unable or unwilling to perform these functions appropriately, the sourcing and manufacture of our licensed products as well as the regulatory approvals and clinical trials related to our licensed products are currently controlled, and will likely continue to be controlled for the foreseeable future, by our existing and future collaborators. Our lack of control over some of these functions could adversely affect our ability to implement our strategy for the commercialization of our licensed products.
- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products.
- Healthcare legislative changes may have a material adverse effect on our business and results of operations.
- 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.
- The results of our research and development efforts are uncertain and there can be no assurance they will enhance the commercial success of our products.
- There is substantial doubt about our ability to continue as a "going concern", which has been alleviated through managements plans to mitigate these conditions and obtain additional liquidity.

- We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never sustain profitability.
- If we fail to obtain additional financing, we may be unable to support the levels of marketing we currently spend on Ameluz or complete the commercialization of Xepi[®] and other products we may license.
- We previously identified a material weakness in our internal control over financial reporting, resulting from control deficiencies related to management's review of work performed by specialists. If we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price.
- If we fail to regain compliance with applicable listing standards, our common stock and publicly-traded warrants could be delisted from Nasdaq.
- Future sales of our common stock in the public market could cause our share price to fall.
- We have issued several warrants, which are exercisable for our common stock, and issued Series B Convertible Preferred Stock, which, if exercised or converted, as applicable, could substantially increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.
- Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.
- Our stockholder rights plan, or "poison pill," includes terms and conditions which could discourage a takeover or other transaction that stockholders may consider favorable.
- Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.
- Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.
- Many of the warrants to purchase shares of our common stock are accounted for as a warrant liability and recorded at fair value with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stock.

Our Corporate Information

We were incorporated in March 2015 and commenced operations in May 2016. Our first commercial licensed product launch was in October 2016. Our corporate headquarters are located at 120 Presidential Way, Suite 330, Woburn, Massachusetts 01801. Our telephone number is 781-245-

1325. Our principal website address is www.biofrontera-us.com. The information on or accessed through our website is not incorporated in this prospectus or the registration statement of which this prospectus forms a part.

Implications of Being an Emerging Growth Company and a Smaller Reporting Company

We qualify as an “emerging growth company” as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. An emerging growth company may take advantage of certain reduced reporting and other requirements that are otherwise generally applicable to public companies. As a result:

- we are permitted to provide only two years of audited financial statements and Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure in any registration statement or report prior to the filing of our first annual report on Form 10-K;
- we are not required to engage an auditor to report on our internal control over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act of 2002, or the Sarbanes-Oxley Act;
- we are not required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board, or the PCAOB, regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements (i.e., critical audit matters);

- we are not required to submit certain executive compensation matters to stockholder advisory votes, such as “say-on-pay,” “say-on-frequency” and “say-on-golden parachutes;” and
- we are not required to comply with certain disclosure requirements related to executive compensation, such as the requirement to disclose the correlation between executive compensation and performance and the requirement to present a comparison of our Chief Executive Officer’s compensation to our median employee compensation.

We may take advantage of these reduced reporting and other requirements until the last day of our fiscal year following the fifth anniversary of the completion of our initial public offering, or such earlier time that we are no longer an emerging growth company. However, if certain events occur prior to the end of such five-year period, including if we have greater than or equal to \$1.235 billion in annual gross revenue, have greater than or equal to \$700 million in market value of our common stock held by non-affiliates, or issue more than \$1.0 billion of non-convertible debt over a three-year period, we will cease to be an emerging growth company prior to the end of such five-year period. We may choose to take advantage of some but not all of these reduced burdens. We have elected to adopt the reduced requirements with respect to our financial statements and Management’s Discussion and Analysis of Financial Condition and Results of Operations disclosure in this prospectus. As a result, the information that we provide to stockholders may be different from the information you may receive from other public companies in which you hold equity.

In addition, under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards until such time as those standards apply to private companies. We have elected to take advantage of the longer phase-in periods for the adoption of new or revised financial accounting standards under the JOBS Act until we are no longer an emerging growth company. Our election to use the phase-in periods permitted by this election may make it difficult to compare our financial statements to those of non-emerging growth companies and other emerging growth companies that have opted out of the longer phase-in periods permitted under the JOBS Act and who will comply with new or revised financial accounting standards. If we were to subsequently elect instead to comply with public company effective dates, such election would be irrevocable pursuant to the JOBS Act.

We are also a “smaller reporting company” as defined in the rules promulgated under the Securities Exchange Act of 1934, as amended, or the Exchange Act. We may continue to be a smaller reporting company even after we are no longer an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies and will be able to take advantage of these scaled disclosures for so long as our voting and non-voting common stock held by non-affiliates on the last business day of our second fiscal quarter is less than \$250.0 million, or our annual revenue is less than \$100.0 million during the most recently completed fiscal year and our voting and nonvoting common stock held by non-affiliates on the last business day of our second fiscal quarter in that fiscal year is less than \$700.0 million.

The Offering

Issuer	Biofrontera Inc.
Securities offered by the Selling Stockholders	11,309,019 shares of common stock issuable upon the conversion of up to 8,000 shares of the Series B-3 Preferred that may be issued to the Selling Stockholders upon the exercise of the Preferred Warrants in full
Common stock outstanding	5,089,413 shares as of May 2, 2024
Common stock outstanding assuming the conversion of all Series B-3 Preferred whose underlying shares are being offered hereby	16,398,432 Shares.
Use of proceeds	We will not receive any of the proceeds from the sale of the shares being offered by the Selling Stockholders. We will receive up to \$7.4 million in net proceeds upon the exercise of the Preferred Warrants in full.
Plan of distribution	The Selling Stockholders may sell all or a portion of the shares of common stock beneficially owned by it and offered hereby from time to time directly or through one or more underwriters, broker-dealers or agents. Registration of the common stock covered by this prospectus does not mean, however, that such shares necessarily will be offered or sold. See “Plan of Distribution.”

Risk factors

See “*Risk Factors*” beginning on page 8 of this prospectus and the other information included or incorporated by reference in this prospectus for a discussion of factors you should carefully consider before deciding to invest in shares of our common stock.

Nasdaq Capital Market symbol for common stock

“BFRI”

The number of shares of common stock to be outstanding after this offering is based on 5,089,413 shares of our common stock outstanding as of May 2, 2024, and assumes the conversion of the Series B-3 Preferred into 11,309,019 shares of common stock. The number of shares of common stock to be outstanding after this offering excludes:

- 6,793,893 shares of common stock issuable upon the conversion of the Series B-1 Preferred (as defined below) held by the Selling Stockholders;
- 2,269,356 shares of common stock issuable upon the exercise of warrants issued in connection with our initial public offering and prior private placements;
- 94,181 shares of our common stock issuable upon the exercise of stock options and the vesting of restricted stock units awarded to employees under our 2021 Omnibus Incentive Plan as of April 30, 2024;
- 151,900 shares of our common stock available for future issuance under our 2021 Omnibus Incentive Plan; and
- 20,182 shares of our common stock that may be issued upon the full exercise of the Unit Purchase Options issued in connection with our initial public offering and a private placement in December 2021.

RISK FACTORS

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the risks and uncertainties set forth under the section titled “Risk Factors” in our most recent Annual Report on Form 10-K, which is incorporated by reference herein, as well as the other information in this prospectus and the documents incorporated by reference herein, including our financial statements and the related notes and the section “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” included in our Form 10-K, before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

Risks Related to This Offering and Ownership of Our Common Stock

Provisions of our outstanding warrants could discourage an acquisition of us by a third party.

In addition to the discussion of the provisions of our certificate of incorporation, our bylaws, certain provisions of our outstanding warrants could make it more difficult or expensive for a third party to acquire us. The warrants prohibit us from engaging in certain transactions constituting “fundamental transactions” unless, among other things, the surviving entity assumes our obligations under the warrants. These and other provisions of our outstanding warrants could prevent or deter a third party from acquiring us even where the acquisition could be beneficial to you.

Our share price may be volatile, and you may be unable to sell your shares and/or warrants at or above the offering price.

The market price of our common stock is likely to be volatile and could be subject to wide fluctuations in response to many risk factors listed in this section, and others beyond our control, including:

- the success of existing or new competitive products or technologies;
- regulatory actions with respect to Ameluz[®], the BF-RhodoLED[®] lamp (and its successors) or Xepi[®] or our competitors’ products;
- actual or anticipated fluctuations in our financial condition and operating results, including fluctuations in our quarterly and annual results;
- announcements of innovations by us, our Licensors or our competitors;
- overall conditions in our industry and the markets in which we operate;
- market conditions or trends in the biotechnology industry or in the economy as a whole;
- addition or loss of significant healthcare providers or other developments with respect to significant healthcare providers;
- changes in laws or regulations applicable to Ameluz[®], the BF-RhodoLED[®] lamp (and its successors) or Xepi[®];
- actual or anticipated changes in our growth rate relative to our competitors;
- announcements by us, our Licensors or our competitors of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- additions or departures of key personnel;
- issuance of new or updated research or reports by securities analysts;
- fluctuations in the valuation of companies perceived by investors to be comparable to us;
- disputes or other developments related to the patents covering our licensed products, and our Licensors’ ability to obtain intellectual property protection for our licensed products;
- security breaches;
- litigation matters;
- announcement or expectation of additional financing efforts;
- sales of our common stock by us or our stockholders;
- share price and volume fluctuations attributable to inconsistent trading volume levels of our shares;
- the expiration of contractual lock-up agreements with our executive officers, directors and stockholders; and
- general economic and market conditions.

Furthermore, the stock markets have experienced price and volume fluctuations that have affected and continue to affect the market prices of equity securities of many companies. These fluctuations often have been unrelated or disproportionate to the operating performance of those companies. These broad market and industry fluctuations, as well as general economic, political and market conditions such as recessions, interest rate changes or international currency fluctuations, may negatively affect the market price of our common stock. In the past, companies that have experienced volatility in the market price of their stock have been subject to securities litigation. This risk is especially relevant for biopharmaceutical companies, which have experienced significant stock price volatility in recent years. We may be the target of this type of litigation in the future. Securities litigation against us could result in substantial costs and divert our management’s attention from other business concerns, which could seriously harm our business.

Future sales of our common stock in the public market could cause our share price to fall.

Sales of a substantial number of shares of our common stock in the public market or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. Based on 5,089,413 shares of common stock outstanding as of May 2, 2024, upon the closing of the sale of our common stock being offered by the Selling Stockholders, we will have 16,398,432 shares of common stock outstanding.

All of the common stock sold by the Selling Stockholders will be freely tradable without restrictions or further registration under the Securities Act.

We have issued several warrants, which are exercisable for our common stock, and issued Series B Convertible Preferred Stock, which, if exercised or converted, as applicable, could substantially increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of May 2, 2024, we have a total of 2,269,356 outstanding warrants which may each be exercised for one share of our common stock. All of the shares issuable upon exercise of these warrants have been registered on effective registration statements and therefore, when issued, will be freely tradable without restriction or further registration required under the Securities Act. Any shares of our common stock issued upon exercise of outstanding warrants will result in dilution to the then existing holders of our common stock and increase the number of shares eligible for resale in the public market. In addition, in the closing of the Private Placement on February 22, 2024 we issued shares of Series B-1 Preferred Convertible Preferred Stock, par value \$0.001 per share (the "Series B-1 Preferred") to the Selling Stockholders. Each share of Series B-1 Preferred may be converted into approximately 1,413 shares of our common stock (based on the conversion price of \$0.7074 per share and a liquidation preference of \$1,000 per share of Series B-1 Preferred) without taking into account any beneficial ownership limitations. At the time of issuance, the holders of the Series B-1 Preferred converted some of their shares resulting in the issuance of 2,516,785 shares of common stock. However, 4,806 shares of Series B-1 Preferred remain outstanding, which could be converted into up to 6,793,893 shares of common stock (including the conversion of any B-2 Preferred (as defined below) that may be issued upon the automatic conversion of the Series B-1 Preferred). The 2,516,785 shares of common stock issued upon conversion of the Series B-1 Preferred and the up to 6,793,893 shares of common stock issuable upon conversion of the remaining Series B-1 Preferred or Series B-2 Preferred, as applicable, were registered for resale by the Selling Stockholders on a registration statement on Form S-1 filed with the Securities and Exchange Commission on March 19, 2024 and declared effective by the Securities and Exchange Commission on April 22, 2024.

We also issued the Preferred Warrants, which if exercised, would result in the issuance of Series B-3 Preferred. Each share of Series B-3 Preferred may convert into approximately 1,413 shares of our common stock (based on the conversion price of \$0.7074 per share and a liquidation preference of \$1,000 per share of Series B-3 Preferred). While it is not certain that any of the Preferred Warrants will be exercised, if they are exercised in full, the Series B-3 Preferred issued could be converted into up to 11,309,019 shares of common stock.

Although the Series B-1 Preferred, Series B-2 Preferred and Series B-3 Preferred each have a beneficial ownership limitation that prevents the holder from converting if it would result in the holder's beneficial ownership exceeding 9.99% of the then outstanding common stock and although the initial conversion into 2,516,785 shares is close to the beneficial ownership limitation for all current holders of the Series B-1 Preferred and the Preferred Warrants, the remaining Series B-1 Preferred, any Series B-2 Preferred issued upon conversion of the Series B-1 Preferred and any Series B-3 Preferred issued upon exercise of the Preferred Warrants could be converted into common stock at a future date if the total number of outstanding shares of our common stock increases, if the beneficial ownership limitation is removed or if the holders of the Series B-1 Preferred, Series B-2 Preferred and Series B-3 Preferred sell any of the common stock they currently hold. Sales of substantial numbers of any such shares described above in the public market could adversely affect the market price of our common stock.

If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.

The trading market for our common stock will be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts ceases coverage of our company or fails to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. Moreover, if our operating results do not meet the expectations of the investor community, one or more of the analysts who cover our company may change their recommendations regarding our company, and our stock price could decline.

Future sales and issuances of our common stock or rights to purchase our common stock, including pursuant to our equity incentive plans, could result in additional dilution of the percentage ownership of our stockholders and could cause the stock price of our common stock to decline.

In the future, we may sell common stock, convertible securities or other equity securities in one or more transactions at prices and in a manner we determine from time to time. We also expect to issue common stock to employees, consultants and directors pursuant to our equity incentive plans. If we sell common stock, convertible securities or other equity securities in subsequent transactions, or common stock is issued pursuant to equity incentive plans or the Unit Purchase Option, investors may be materially diluted. New investors in such subsequent transactions could gain rights, preferences and privileges senior to those of holders of our common stock.

Our stockholder rights plan, or "poison pill," includes terms and conditions which could discourage a takeover or other transaction that stockholders may consider favorable.

On October 24, 2022, stockholders of record at the close of business on that date received a dividend of one right (a "Right") for each outstanding share of common stock. Each Right entitles the registered holder to purchase one one-thousandth of a share of Series A Junior Participating Cumulative Preferred Stock of the Company (the "Preferred Stock"), at a price of \$5.00 per one thousandth of a share of Preferred Stock, subject to adjustment (the "Exercise Price"). The Rights are not exercisable until the Distribution Date (as defined below). The description and terms of the Rights are set forth in the Stockholder Rights Agreement between the Company and Computershare Trust Company, N.A., as rights agent, dated as of October 13, 2022, as amended by Amendment No. 1 to the Stockholder Rights Agreement, dated as of April 26, 2023.

The Rights will not be exercisable until the earlier of ten days after a public announcement by us that a person or group has become an Acquiring Person and ten business days (or a later date determined by our board of directors) after a person or group begins a tender or an exchange offer that, if completed, would result in that person or group becoming an Acquiring Person (the earlier of such dates being herein referred to as the "Distribution Date"). At any time after a person becomes an Acquiring Person, the Board of Directors may, at its option, exchange all or any part of the then outstanding and exercisable Rights for shares of Common Stock at an exchange ratio of one share of Common Stock for each Right, subject to adjustment as specified in the Rights Agreement. Notwithstanding the foregoing, the Board of Directors generally will not be empowered to effect such exchange at any time after any person becomes the beneficial owner of 50% or more of the Common Stock of the Company.

The Rights will expire at the earlier of (a) June 30, 2026 or (b) the first day after the Company's 2025 annual meeting, if stockholder approval has not been obtained prior to such date, the Rights will expire at such time, in each case, unless previously redeemed or exchanged by the Company.

The Rights have certain anti-takeover effects, including potentially discouraging a takeover that stockholders may consider favorable. The Rights will cause substantial dilution to a person or group that attempts to acquire us on terms not approved by the board of directors.

We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases.

We have never declared or paid any dividends on our common stock and do not intend to pay any dividends in the foreseeable future. We anticipate that we will retain all of our future earnings for use in the operation of our business and for general corporate purposes. Any determination to pay dividends in the future will be at the discretion of our board of directors. Accordingly, investors must rely on sales of their common stock after price appreciation, which may never occur, as the only way to realize any future gains on their investments. For more information, see the section of our Form 10-K captioned "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources*."

Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.

Our amended and restated certificate of incorporation and our amended and restated bylaws contains provisions that could delay or prevent a change in control of our company. These provisions could also make it more difficult for stockholders to elect directors and take other corporate actions.

These provisions may frustrate or prevent any attempts by our stockholders to replace or remove our current management by making it more difficult for stockholders to replace members of our board of directors, which is responsible for appointing the members of our management.

In addition, we are subject to the anti-takeover provisions contained in Section 203 of the Delaware General Corporation Law, or the DGCL. Under Section 203 of the DGCL, a corporation may not, in general, engage in a business combination with any holder of 15% or more of its capital stock unless the holder has held the stock for three years or, among other exceptions, the board of directors has approved the transaction.

These and other provisions in our amended and restated certificate of incorporation and our amended and restated bylaws and under Delaware law could discourage potential takeover attempts, reduce the price investors might be willing to pay in the future for shares of our common stock and result in the market price of our common stock being lower than it would be without these provisions.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for substantially all disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware is, to the fullest extent permitted by applicable law, the exclusive forum for:

- any derivative action or proceeding brought on our behalf;
- any action asserting a claim of breach of a fiduciary duty owed by, or other wrongdoing by, any of our current or former directors, officers, employees or stockholders;

- any action asserting a claim against us arising under the DGCL, our amended and restated certificate of incorporation, or our amended and restated bylaws (as either may be amended from time to time) or as to which the DGCL confers jurisdiction on the Court of Chancery of the State of Delaware; and
- any action asserting a claim against us that is governed by the internal-affairs doctrine.

However, Section 27 of the Exchange Act creates exclusive federal jurisdiction over all claims brought to enforce any duty or liability created by the Exchange Act or the rules and regulations thereunder. Consequently, the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction.

Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Our amended and restated certificate of incorporation will further provide that, unless we consent in writing to the selection of an alternative forum, the federal district courts are the sole and exclusive forum for the resolution of any complaint asserting a right under the Securities Act. The Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the provision should be enforced in a particular case, application of the provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court.

By becoming a stockholder in our Company, you will be deemed to have notice of and have consented to the provisions of our amended and restated certificate of incorporation related to choice of forum. This exclusive forum provision may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees, which may discourage lawsuits against us and our directors, officers and other employees and result in increased costs for investors to bring a claim. If a court were to find the exclusive forum provision in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving the dispute in other jurisdictions, which could seriously harm our business.

Claims for indemnification by our directors and officers may reduce our available funds to satisfy successful third-party claims against us and may reduce the amount of money available to us.

Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our directors and officers, in each case to the fullest extent permitted by Delaware law.

In addition, as permitted by Section 145 of the DGCL, our amended and restated bylaws and our indemnification agreements that we have entered into with our directors and officers provide that:

- we will indemnify our directors and officers for serving us in those capacities or for serving other business enterprises at our request, to the fullest extent permitted by Delaware law. Delaware law provides that a corporation may indemnify such person if such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to the best interests of the registrant and, with respect to any criminal proceeding, had no reasonable cause to believe such person's conduct was unlawful;
- we may, in our discretion, indemnify employees and agents in those circumstances where indemnification is permitted by applicable law;

- we are required to advance expenses, as incurred, to our directors and officers in connection with defending a proceeding, except that such directors or officers shall undertake to repay such advances if it is ultimately determined that such person is not entitled to indemnification;
- we will not be obligated pursuant to our amended and restated bylaws to indemnify a person with respect to proceedings initiated by that person against us or our other indemnitees, except with respect to proceedings authorized by our board of directors or brought to enforce a right to indemnification;
- the rights conferred in our amended and restated bylaws are not exclusive, and we are authorized to enter into indemnification agreements with our directors, officers, employees and agents and to obtain insurance to indemnify such persons; and
- we may not retroactively amend our amended and restated bylaw provisions to reduce our indemnification obligations to directors, officers, employees and agents.

Many of the warrants to purchase shares of our common stock are accounted for as a warrant liability and recorded at fair value with changes in fair value each period reported in earnings, which may have an adverse effect on the market price of our common stock.

Under U.S. GAAP, we are required to, evaluate the outstanding warrants to purchase our common stock to determine whether they should be accounted for as a warrant liability or as equity. At each reporting period (1) the accounting treatment of the warrants will be reevaluated for proper accounting treatment as a liability or equity and (2) the fair value of the liability of the warrants will be re-measured and the change in the fair value of the liability will be recorded as other income (expense) in our consolidated statement of operations. Such accounting treatment may adversely affect the market price of our securities. In addition, changes in the inputs and assumptions for the valuation model we use to determine the fair value of such liability may have a material impact on the estimated fair value of the warrant liability. As a result, our financial statements and results of operations will fluctuate quarterly, based on various factors, such as the share price of our common stock, many of which are outside of our control. If our share price is volatile, we expect that we will recognize non-cash gains or losses on our warrants or any other similar derivative instruments in each reporting period and that the amount of such gains or losses could be material. The impact of changes in fair value on earnings may have an adverse effect on the market price of our common stock.

The warrants issued in connection with our initial public offering, the ("IPO Warrants") were accounted for as equity as these instruments meet all of the requirements for equity classification under ASC 815-40. (See Note 19. Stockholders' Equity).

The warrants issued in connection with the private placement offerings (completed on December 1, 2021, May 16, 2022, July 26, 2022 and November 2, 2023) (collectively "PIPE Warrants") were accounted for as liabilities as these warrants provide for a redemption right in the case of a fundamental transaction which fails the requirement of the indexation guidance under ASC 815-40. The resulting warrant liabilities are re-measured at each balance sheet date until their exercise or expiration, and any change in fair value is recognized in the Company's consolidated statement of operations. Refer to *Note 4. Fair Value Measurements* in our audited financial statements for the fiscal year ended December 31, 2023 incorporated by reference in this prospectus.

As of the date of this prospectus, up to 2,269,356 shares are issuable upon the exercise of IPO Warrants and the PIPE Warrants that remain outstanding. See *Note 19. Stockholders' Equity* in our audited financial statements for the fiscal year ended December 31, 2023 incorporated by reference in this prospectus for more information on the IPO Warrants and PIPE Warrants.

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.

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. We have based these forward-looking statements on our current expectations and projections about future events, nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. Factors that could cause such differences include, but are not limited to:

- our ability to achieve and sustain profitability;
- our ability to compete effectively in selling our licensed products;
- changes in our relationship with our Licensors;
- our Licensors' ability to manufacture our licensed products;
- our ability to expand, manage and maintain our direct sales and marketing organizations, including our ability to obtain financing to develop our marketing strategy, if needed;
- 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;
- 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 Licensors' ability to adequately protect the intellectual property and operate their business without infringing upon the intellectual property rights of others;
- our ability to market, commercialize, achieve market acceptance for and sell our licensed products;
- the fact that product quality issues or product defects may harm our business;
- any product liability claims;
- our ability to regain compliance with The Nasdaq Stock Market, LLC ("Nasdaq") continued listing standards;
- our ability to comply with the requirements of being a public company;
- the progress, timing and completion of our Licensors' research, development and preclinical studies and clinical trials for our licensed products and our Licensors' ability to obtain the regulatory approvals necessary for the marketing of our licensed products in the United States;
- any impact of extraordinary events, including those resulting from the sunset of the COVID-19 Public Health Emergency on May 11, 2023; and
- those risks listed in the sections of our Form 10-K entitled "Risk Factors" and in our other filings with the Securities and Exchange Commission, or SEC.

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 incorporate by reference in this prospectus and have filed with the SEC, and the documents attached as exhibits to the registration statement of which this prospectus is a part with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We do not assume any obligation to update any

USE OF PROCEEDS

We will not receive any of the proceeds from the sale of the shares of our common stock being offered for sale by the Selling Stockholders.

Upon the exercise of the Preferred Warrants for an aggregate of 8,000 shares of Series B-3 Preferred assuming all payments are made in cash and there is no reliance on cashless exercise provisions, we will receive the exercise price of the Preferred Warrants, or an aggregate amount of approximately \$7.4 million in net proceeds.

We will bear all fees and expenses incident to our obligation to register the shares of common stock. Brokerage fees, commissions and similar expenses, if any, attributable to the sale of shares offered hereby will be borne by the Selling Stockholders.

DIVIDEND POLICY

We have never declared or paid cash dividends on our capital stock. We currently intend to retain all available funds and future earnings, if any, to fund the development and expansion of our business, and we do not anticipate paying any cash dividends in the foreseeable future. Any future determination regarding the declaration and payment of dividends will be at the discretion of our board of directors and will depend on then-existing conditions, including our financial condition, operating results, contractual restrictions, capital requirements, business prospects and other factors our board of directors may deem relevant.

SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth information with respect to the beneficial ownership of our common stock as of May 2, 2024, for each person or group known to us who beneficially owns more than 5% of our common stock, each of our directors and director nominees, each of our named executive officers and all of our directors, director nominees and executive officers as a group.

Beneficial ownership for the purposes of the following table is determined in accordance with the rules and regulations of the SEC. These rules generally provide that a person is the beneficial owner of securities if such person has or shares the power to vote or direct the voting thereof, or to dispose or direct the disposition thereof or has the right to acquire such powers within 60 days. Common stock subject to options that are currently exercisable or exercisable, restricted stock units that have vested or will vest, and shares of common stock issuable upon conversion of the Series B-1 Preferred subject to any beneficial ownership limitations, in each case, within 60 days of May 2, 2024 are deemed to be outstanding and beneficially owned by the person holding the options or restricted stock units. These shares, however, are not deemed outstanding for the purposes of computing the percentage ownership of any other person. Except as disclosed in the footnotes to this table (or in the notes to the Selling Stockholders table included in this prospectus) and subject to applicable community property laws, we believe that each shareholder identified in the table possesses sole voting and investment power over all common stock shown as beneficially owned by the shareholder.

Unless otherwise noted below, the address of each person listed on the table is c/o Biofrontera Inc., 120 Presidential Way, Suite 330, Woburn, Massachusetts 01801. For the address of each Selling Stockholder listed on the table below and more information about the holdings of each such Selling Stockholder, see "Selling Stockholders" beginning on page 24.

Name of beneficial owner	Common Stock beneficially owned	% of Common Stock Owned	Options exercisable and restricted stock units vesting within 60 days⁽¹⁾
5% or more stockholders:			
Biofrontera AG Hemmelrather Weg 201 D-51377 Leverkusen, Germany ⁽²⁾	400,000	7.9%	—
Investor Company ITF Rosalind Master Fund LP	508,895	9.9%	—
Lytton-Kambara Foundation	508,905	9.9%	—
The Hewlett Fund LP	508,905	9.9%	—
Entities affiliated with District 2 Capital Fund LP	509,062	9.9%	—
Entities affiliated with AIGH Capital Management, LLC	509,209	9.9%	—
Named executive officers and directors:			
Hermann Lübbert	10,440	*	6,891
Fred Leffler	—	—	1,650
John J. Borer	—	—	1,100
Heikki Lanckriet	—	—	—
Beth J. Hoffman, Ph.D.	—	—	1,100
Kevin D. Weber	—	—	1,100
All current directors and executive officers as a group (6 persons)	10,440	*	11,841

* Represents less than 1% of the Company's outstanding shares of common stock.

- (1) On December 9, 2021, the Company granted to Prof. Dr. Luebbert options (the “2021 Options”) to purchase shares of common stock at an exercise price of \$95.40 per share up to 5,669 shares. The 2021 Options vest in three equal annual installments beginning on December 9, 2022. In addition, on May 18, 2022, the Company granted options to Prof. Dr. Luebbert (the “2022 Options”) to purchase shares of common stock at an exercise price of \$52.20 up to 9,542 shares. The 2022 Options vest in three equal annual installments beginning on May 18, 2023. At the same time the Company granted the 2022 Options, it also granted restricted stock units to Prof. Luebbert, in the amounts of 9,542 restricted stock units. The restricted stock units vest in two equal annual installments beginning on May 18, 2023. Each vested restricted stock unit will be settled, at the Company's discretion, in shares, cash or a combination of shares and cash within 60 days of the applicable vesting date. The 6,891 shares for Prof. Luebbert represent the options and restricted stock units under such grants that will have vested within 60 days of the date of this prospectus. On January 10, 2023, the Company granted to Mr. Leffler options to purchase shares of common stock at an exercise price of \$19.40 per share up to 5,000 shares. The options granted to Mr. Leffler vest in three equal installments beginning on January 10, 2024. The 1,650 shares for Mr. Leffler represent the options that will have vested within 60 days after the date of this prospectus.
- (2) Information is based upon a Schedule 13G/A filed with the SEC on February 10, 2022 by Biofrontera AG. According to a Schedule 13D/A (“Zours Schedule 13D”) filed by Deutsche Balaton Aktiengesellschaft (“DB”), VV Beteiligungen Aktiengesellschaft (“VVB”), Delphi Unternehmensberatung Aktiengesellschaft (“DU”), Wilhelm Konrad Thomas Zours, Alexander Link and Rolf Birkert on September 19, 2022, Mr. Zours owns a majority interest in DU and is the sole member of the boards of management of VVB and DU. DU owns a majority interest in VVB. VVB owns a majority interest in DB and DB held 1,177,676 shares of common stock at the time of the Zours Schedule 13D's filing, which represented 4.41% of the Company's outstanding stock at that time. In the Zours Schedule 13D, Mr. Zours also includes the shares of Biofrontera Inc. held by Biofrontera AG, but disclaims beneficial ownership. If Mr. Zours was deemed to have voting and dispositive voting power over the shares held by Biofrontera AG, then Mr. Zours would be the beneficial owner of 9% of the Company's outstanding stock.

DESCRIPTION OF SECURITIES AND CERTIFICATE OF INCORPORATION

General

Our amended and restated certificate of incorporation authorizes capital stock consisting of (i) 15,000,000 shares of common stock, par value \$0.001 per share and (ii) 20,000,000 shares of preferred stock, par value \$0.001 per share. There are currently issued and outstanding 4,806 shares of Series B-1 Preferred.

The following summary describes the material provisions of our common stock and Series B Convertible Preferred Stock. We urge you to read our amended and restated certificate of incorporation and our amended and restated bylaws, which are included as exhibits to the registration statement of which this prospectus forms a part.

Certain provisions of our amended and restated certificate of incorporation and our amended and restated bylaws summarized below may be deemed to have an anti-takeover effect and may delay or prevent a tender offer or takeover attempt that a stockholder might consider in its best interest, including those attempts that might result in a premium over the market price for the shares of common stock.

Common Stock

The holders of our common stock are entitled to one vote for each share held on all matters submitted to a vote of the stockholders. The holders of our common stock do not have any cumulative voting rights. Holders of our common stock are entitled to receive ratably any dividends declared by our board of directors out of funds legally available for that purpose, subject to any preferential dividend rights of any outstanding preferred stock. Our common stock has no preemptive rights, conversion rights or other subscription rights or redemption or sinking fund provisions.

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock.

Upon our dissolution or liquidation, after payment in full of all amounts required to be paid to creditors and to the holders of preferred stock having liquidation preferences, if any, the holders of shares of our common stock will be entitled to receive pro rata our remaining assets available for distribution for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the prior rights of any preferred stock then outstanding.

Series B Convertible Preferred Stock

Pursuant to the terms of the Purchase Agreement, on February 20, 2024, the Company filed the Certificate of Designation with the Delaware Secretary of State designating 6,586 shares of its authorized and unissued preferred stock as Series B-1 Preferred, 6,586 shares as Series B-2 Preferred and 8,000 shares as Series B-3 Preferred (referred to herein collectively as “Series B Preferred Stock”), each with a stated value of \$1,000 per share (the “Original Per Share Price”). The Certificate of Designation sets forth the rights, preferences and limitations of the shares of Series B Preferred Stock. Terms not otherwise defined in this item shall have the meanings given in the Certificate of Designation.

The following is a summary of the terms of the Series B Preferred Stock:

Voting Rights. Subject to certain limitations described in the Certificate of Designation, the Series B Preferred Stock is voting stock. Holders of the Series B Preferred Stock are entitled to vote together with the Common Stock on an as-if-converted-to-Common-Stock basis. Holders of Common Stock are entitled to one vote for each share of Common Stock held on all matters submitted to a vote of stockholders. Accordingly, holders of Series B Preferred Stock will be entitled to one vote for each whole share of Common Stock into which their Series B Preferred Stock is then-convertible on all matters submitted to a vote of stockholders.

Unless and until the Company has obtained the stockholder approvals required pursuant to the Certificate of Designation (the “Stockholder Approval”), the number of shares of Common Stock that shall be deemed issued upon conversion of the Series B Preferred Stock (for purposes of calculating the number of aggregate votes that the holders of Series B Preferred Stock are entitled to on an as-converted basis) will be equal to that number of shares equal to 9.9% of the Company's outstanding Common Stock as of the Signing Date (excluding for purposes of the calculation, any securities issued on the Signing Date) (the “**Cap**”), which each such holder being able to vote the number of shares of Series B Preferred Stock held by it relative to the total number of shares of Series B Preferred Stock then outstanding multiplied by the Cap. Notwithstanding the foregoing, the holders of the Series B Preferred Stock are not entitled to vote together with the Common Stock on an as-if-converted-to-Common-Stock-basis with regard to the approval of the issuance of units upon conversion of the Series B-1 Preferred and the issuance of all Common Stock upon conversion of the Series B Preferred Stock.

Conversion. Prior to the Stockholder Approval, the Series B Preferred Stock is not convertible in excess of the Cap. Following the Stockholder Approval, each share of Series B-1 Preferred will automatically convert into either Common Stock or, to the extent the conversion would cause a holder to exceed their beneficial ownership limitation, shares of Series B-2 Preferred. In addition, following the Stockholder Approval, Series B-2 Preferred and Series B-3 Preferred may be converted into Common Stock at the election of the holder up to such holder's beneficial ownership limitation.

Liquidation. Prior to the Stockholder Approval, in the event of any voluntary or involuntary liquidation, dissolution or winding up of the Company, including a change of control transaction, or Deemed Liquidation Event (any such event, a "Liquidation") the holders of shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the assets of the Company available for distribution to its stockholders, and in the event of a Deemed Liquidation Event, the holders of shares of Series B Preferred Stock then outstanding shall be entitled to be paid out of the consideration payable to stockholders in such Deemed Liquidation Event or the other proceeds available for distribution to stockholders, before any payment shall be made to the holders of any other shares of capital stock of the Company by reason of their ownership thereof, an amount per share equal to the greater of (i) three times the Original Per Share Price, together with any dividends accrued but unpaid thereon (the "Liquidation Preference") or (ii) such amount per share as would have been payable had all shares of Series B Preferred Stock been converted into Common Stock (without regard to any limitations on conversion set forth in the Certificate of Designation or otherwise) immediately prior to such Liquidation (the amount payable pursuant to this sentence is hereinafter referred to as the "Series B Liquidation Amount"). If upon any such Liquidation, the assets of the Company available for distribution to its stockholders shall be insufficient to pay the holders of shares of Series B Preferred Stock the full Liquidation Preference, the holders of shares of Series B Preferred Stock shall share ratably in any distribution of the assets available for distribution in proportion to the respective amounts which would otherwise be payable in respect of the shares held by them upon such distribution if all amounts payable on or with respect to such shares were paid in full. After the payment in full of all Series B Liquidation Amount, the remaining assets of the Company available for distribution to its stockholders or, in the case of a Deemed Liquidation Event, the consideration not payable to the holders of shares of Series B Preferred Stock pursuant to the Certificate of Designation shall be distributed among the holders of shares of Common Stock, pro rata based on the number of shares held by each such holder.

Following the Stockholder Approval, upon any Liquidation, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series B Preferred Stock and Common Stock, pro rata based on the number of shares held by each such holder, treating for this purpose all shares of Series B Preferred Stock as if they had been converted to Common Stock pursuant to the terms of the Certificate of Designation immediately prior to such Liquidation, without regard to any limitations on conversion set forth in the Certificate of Designation or otherwise.

Redemption. Unless prohibited by Delaware law governing distributions to stockholders, in the event the Stockholder Approval is not obtained within one year following the Issuance Date, shares of Series B-1 Preferred shall be redeemed by the Company at a price equal to the then Liquidation Preference at any time for up to three years following the Issuance Date commencing not more than 60 days after receipt by the Company at any time on or after the one year anniversary of the Issuance Date of written notice from the holders of a majority of the then outstanding shares of Series B-1 Preferred, voting together as a single class (the "Redemption Request") requesting redemption of all shares of Series B-1 Preferred (such date, the "Redemption Date"). Upon receipt of a Redemption Request, the Company shall apply all of its assets to any such redemption, and to no other corporate purpose, except to the extent prohibited by Delaware law governing distributions to stockholders. On the Redemption Date, the Company shall redeem, on a pro rata basis in accordance with the number of shares of Series B-1 Preferred owned by each holder, the total number of shares of Series B-1 Preferred outstanding immediately prior to the Redemption Date; provided, however, that Excluded Shares (as defined in the Certificate of Designation) shall not be redeemed and shall be excluded from the calculations set forth in this sentence. If, on the Redemption Date, Delaware law governing distributions to stockholders prevents the Company from redeeming all shares of Series B-1 Preferred to be redeemed, the Company shall ratably redeem the maximum number of shares that it may redeem consistent with such law, and shall redeem the remaining shares as soon as it may lawfully do so under such law.

Participation Right. For a period of one year following closing of the transactions, the purchasers will have the right to participate as an investor in any securities offering consummated by the Company.

Outstanding Warrants

At May 2, 2024, we had outstanding warrants to purchase an aggregate of 2,269,356 shares of common stock with an exercise price range from \$3.55 per share to \$100.00 per share. These warrants have expiration dates ranging from November 2026 to November 2028.

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Number of Share Purchase Warrants	Exercise Price (USD\$)	Expiry Date
2,192,736	3.55	11/02/2028
76,620	\$ 100.00	11/02/2026

In addition, at May 2, 2024, we had outstanding Preferred Warrants to purchase Series B-3 Preferred. The aggregate exercise price of the Preferred Warrants is approximately \$8.0 million in gross proceeds, exercisable for an aggregate of 8,000 shares of Series B-3 Preferred commencing on the Exercisability Date (as defined in the Form of Preferred Warrant) until the earlier of (i) 5 days following the date of completion of (A) the Company's public announcement of (I) at least 95% of the Company's territory managers, medical science liaisons, and reimbursement employees are using the Company's customer relationship management system routinely or on a performance improvement plan and (II) the Company's revenue for the period starting on January 1, 2024 and ending no earlier than April 30, 2024 excluding revenue from related parties (including Biofrontera AG) is at least 5% higher than the Company's revenue excluding revenue from related parties (including Biofrontera AG) for the corresponding period of the same length, starting on January 1, 2023, which announcement shall be made promptly after certification by the Company's board of directors that such targets have been completed, and (B) the Stockholder Approval, and (C) the effectiveness of a registration statement with the U.S. Securities and Exchange Commission covering the resale of the Common Stock underlying all shares of Series B-3 Preferred and (ii) February 22, 2027. If the Preferred Warrants are exercised in full, the resulting 8,000 shares of Series B-3 Preferred would be convertible into 11,309,019 shares of common stock.

Stockholder Rights Plan

On October 13, 2022, the Board of Directors of Biofrontera adopted a stockholder rights plan, as set forth in the Stockholder Rights Agreement, dated October 13, 2022, between the Company and Computershare Trust Company, N.A., as Rights Agent. The information regarding the stockholder rights plan contained in Item 1 of the Company's Registration Statement on Form 8-A filed with the SEC on October 14, 2022 is incorporated herein by reference.

Forum Selection

Our amended and restated certificate of incorporation provides that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware will, to the fullest extent permitted by applicable law, be the sole and exclusive forum for: (i) any derivative action or proceeding brought on our behalf; (ii) any action asserting a claim of breach of a fiduciary duty owed by any of our directors, officers, other employees or stockholders to us or our stockholders; (iii) any action asserting a claim arising pursuant to any provision of the DGCL, our amended and restated certificate of incorporation or our amended and restated bylaws, or as to which the DGCL confers exclusive jurisdiction on the Court of Chancery; or (iv) any action asserting a claim governed by the internal affairs doctrine; provided that the exclusive forum provisions will not apply to suits brought to enforce any liability or duty created by the Exchange Act or to any claim for which the federal courts have exclusive jurisdiction.

Moreover, Section 22 of the Securities Act creates concurrent jurisdiction for federal and state courts over all claims brought to enforce any duty or liability created by the Securities Act or the rules and regulations thereunder. Unless the Company consents in writing to the selection of an alternative

forum, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. The Supreme Court of the State of Delaware has held that such provisions are facially valid under Delaware law. While there can be no assurance that federal or state courts will follow the holding of the Delaware Supreme Court or determine that the provision should be enforced in a particular case, application of the provision means that suits brought by our stockholders to enforce any duty or liability created by the Securities Act must be brought in federal court and cannot be brought in state court. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder. Any person or entity purchasing or otherwise acquiring or holding any interest in shares of our capital stock will be deemed to have notice of and consented to this provision.

Dividends

Declaration and payment of any dividend will be subject to the discretion of our board of directors. The time and amount of dividends will be dependent upon our business prospects, results of operations, financial condition, cash requirements and availability, debt repayment obligations, capital expenditure needs, contractual restrictions, covenants in the agreements governing our current and future indebtedness, industry trends, the provisions of Delaware law affecting the payment of distributions to stockholders and any other factors our board of directors may consider relevant. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business, and therefore do not anticipate declaring or paying any cash dividends on our common stock in the foreseeable future. See *"Dividend Policy"* and *"Risk Factors—Risks Related to the Offering and Ownership of our Common Stock—We have never paid dividends on our common stock and we do not intend to pay dividends for the foreseeable future. Consequently, any gains from an investment in our common stock will likely depend on whether the price of our common stock increases."*

Anti-Takeover Provisions

Our amended and restated certificate of incorporation and amended and restated bylaws, contain provisions that may delay, defer or discourage another party from acquiring control of us. We expect that these provisions, which are summarized below, will discourage coercive takeover practices or inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors, which we believe may result in an improvement of the terms of any such acquisition in favor of our stockholders. However, they also give our board of directors the power to discourage acquisitions that some stockholders may favor. See *"Risk Factors—Risks Related to the Offering and Ownership of Our Common Stock—Our charter documents and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock."*

Authorized but Unissued Shares

The authorized but unissued shares of our common stock are available for future issuance without stockholder approval, subject to any limitations imposed by the listing standards of Nasdaq. These additional shares may be used for a variety of corporate finance transactions, acquisitions and employee benefit plans. The existence of authorized but unissued and unreserved common stock and preferred stock could make more difficult or discourage an attempt to obtain control of us by means of a proxy contest, tender offer, merger or otherwise.

Stockholder Action; Special Meeting of Stockholders

Our amended and restated certificate of incorporation provides that our stockholders will not be able to take action by written consent for any matter and may only take action at annual or special meetings. As a result, a holder controlling a majority of our capital stock would not be able to amend our amended and restated bylaws or remove directors without holding a meeting of our stockholders called in accordance with our amended and restated bylaws, unless previously approved by our board of directors. Our amended and restated certificate of incorporation will further provide that special meetings of our stockholders may be called only by (i) the president or (ii) the president or secretary acting upon the written request of a majority of our board of directors, thus limiting the ability of a stockholder to call a special meeting. These provisions might delay the ability of our stockholders to force consideration of a proposal, including the removal of directors.

Classified Board of Directors

Our board of directors is divided into three classes, Class I, Class II and Class III, with members of each class serving staggered three-year terms. Our amended and restated certificate of incorporation provides that the authorized number of directors may be changed only by resolution of the board of directors. Subject to the terms of any preferred stock, any or all of the directors may be removed from office at any time, but only for cause and only by the affirmative vote of holders of 66-2/3% of the voting power of all then outstanding shares of our capital stock entitled to vote generally in the election of directors, voting together as a single class.

Advance Notice Requirements for Stockholder Proposals and Director Nominations

In addition, our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of stockholders, including proposed nominations of candidates for election to our board of directors. In order for any matter to be "properly brought" before a meeting, a stockholder will have to comply with advance notice and duration of ownership requirements and provide us with certain information. Stockholders at an annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board of directors or by a qualified stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has delivered timely written notice in proper form to our secretary of the stockholder's intention to bring such business before the meeting. These provisions could have the effect of delaying stockholder actions that are favored by the holders of a majority of our outstanding voting securities until the next stockholder meeting.

Amendment of Certificate of Incorporation or Bylaws

The DGCL provides generally that the affirmative vote of the holders of a majority in voting power of the shares entitled to vote is required to amend a corporation's certificate of incorporation, unless a corporation's certificate of incorporation requires a greater percentage. Our bylaws may be amended or repealed by a majority vote of our board of directors or by the affirmative vote of the holders a majority of the votes which all our stockholders would be eligible to cast in an election of directors. In addition, the affirmative vote of the holders of at least 66-2/3% of the votes that all our stockholders would be entitled to cast in any election of directors is required to amend or repeal or to adopt any provisions inconsistent with any of the provisions of our certificate of incorporation described above.

Section 203 of the DGCL

We are subject to Section 203 of the DGCL, which prohibits persons deemed "interested stockholders" from engaging in a "business combination" with a publicly held Delaware corporation for three years following the date these persons become interested stockholders unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another

prescribed exception applies. Generally, an “interested stockholder” is a person who, together with affiliates and associates, owns, or within three years prior to the determination of interested stockholder status did own, 15% or more of a corporation’s voting stock. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. The existence of this provision may have an anti-takeover effect with respect to transactions not approved in advance by the board of directors, such as discouraging takeover attempts that might result in a premium over the market price of our common stock.

Limitations on Liability and Indemnification of Officers and Directors

Our amended and restated bylaws provide indemnification for our directors and officers to the fullest extent permitted by the DGCL, along with the right to have expenses incurred in defending proceedings paid in advance of their final disposition. We have indemnification agreements with each of our directors and executive officers that may, in some cases, be broader than the specific indemnification and advancement provisions contained under our amended and restated bylaws and provided under Delaware law. In addition, as permitted by Delaware law, our amended and restated certificate of incorporation includes provisions that eliminate the personal liability of our directors for monetary damages resulting from breaches of certain fiduciary duties as a director. The effect of this provision is to restrict our rights and the rights of our stockholders to recover monetary damages against a director for breach of fiduciary duties as a director.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act, and is, therefore, unenforceable.

Corporate Opportunity Doctrine

Delaware law permits corporations to adopt provisions renouncing any interest or expectancy in certain opportunities that are presented to the corporation or its officers, directors or stockholders. Our amended and restated certificate of incorporation will, to the maximum extent permitted from time to time by Delaware law, renounce any interest or expectancy that we have in, or right to be offered an opportunity to participate in, specified business opportunities that are from time to time presented to our officers, directors or certain of our stockholders or their respective affiliates, other than those opportunities our officers, directors, stockholders or affiliates are presented with while acting in their capacity as an employee, officer or director of us or our affiliates. Our amended and restated certificate of incorporation provides that, to the fullest extent permitted by law, any director or stockholder who is not employed by us or our affiliates will not have any duty to refrain from (i) engaging in a corporate opportunity in the same or similar lines of business in which we or our affiliates now engage or propose to engage; or (ii) otherwise competing with us or our affiliates. In addition, to the fullest extent permitted by law, if any director or stockholder, other than a director or stockholder who is employed by us or our affiliates acting in their capacity as an employee or director of us or our affiliates, acquires knowledge of a potential transaction or other business opportunity which may be a corporate opportunity for itself or himself or its or his affiliates or for us or our affiliates, such person will have no duty to communicate or offer such transaction or business opportunity to us or any of our affiliates and they may take any such opportunity for themselves or offer it to another person or entity. To the fullest extent permitted by Delaware law, no potential transaction or business opportunity may be deemed to be a corporate opportunity of ours or any subsidiary. Our amended and restated certificate of incorporation will not renounce our interest in any business opportunity that is expressly offered to an employee director, employee officer or employee in his or her capacity as a director, officer or employee of Biofrontera Inc.

Dissenters’ Rights of Appraisal and Payment

Under the DGCL, with certain exceptions, our stockholders will have appraisal rights in connection with a merger or consolidation of Biofrontera Inc. Pursuant to the DGCL, stockholders who properly demand and perfect appraisal rights in connection with such mergers or consolidations will have the right to receive payment of the fair value of their shares as determined by the Delaware Court of Chancery, subject to certain limitations.

Stockholders’ Derivative Actions

Under the DGCL, any of our stockholders may bring an action in our name to procure a judgment in our favor, also known as a derivative action, in certain circumstances. Among other things, either the stockholder bringing any such action must be a holder of our shares at the time of the transaction to which the action relates or such stockholder’s stock must have thereafter devolved by operation of law, and such stockholder must continuously hold shares through the resolution of such action.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Computershare Trust Company, N.A.

Trading Symbol and Market

Our common stock is traded on The Nasdaq Capital Market under the symbol “BFRI.”

PRIVATE PLACEMENT OF THE COMMON STOCK AND WARRANTS

On February 19, 2024, we entered into the Purchase Agreement with Selling Stockholders, pursuant to which the Company agreed to issue and sell, in the Private Placement, (i) 6,586 shares of Series B-1 Preferred and (ii) the Preferred Warrants, for an aggregate offering price of \$8.0 million. Each share of Series B-1 Preferred was sold for \$1,000 per share and the consideration for each Preferred Warrant was \$0.125 per share of common stock that each share of Series B-3 Preferred may be converted into. The Offering closed on February 22, 2024. Concurrent with the closing of the Private Placement, each Selling Stockholder delivered a notice of initial conversion requesting that the Company convert the Series B-1 Preferred they had acquired in the Private Placement up to the Cap (as defined in the Certificate of Designation) for each Selling Stockholder.

Subject to the terms and limitations contained in the Certificate of Designation, the shares of the Series B-1 Preferred issued in the Private Placement are immediately convertible and the Series B-3 Preferred issuable upon exercise of the Warrants issued in the Offering will not become convertible until the Company’s stockholders approve an increase to the Company’s authorized share capital. Following receipt of such stockholder approval, each outstanding share of Series B-1 Preferred shall automatically convert into Common Stock, at the conversion price of \$0.7074 per share, subject to the terms and limitations contained in the Certificate of Designation. The Company’s stockholders approved an increase in the Company’s authorized share capital from 15,000,000 to 35,000,000 at a special meeting of the Company’s stockholders on April 24, 2024. If issuing common stock to the Selling Stockholder would cause such Selling Stockholder to exceed their beneficial ownership limitation, then the Selling Stockholder would receive Series B-2 Preferred Convertible Stock, par value \$0.001 convertible into the equivalent amount of common shares they would have received but for the beneficial ownership limitation. This prospectus is only registering the resale of the shares of common stock that could be issued upon conversion of the Series B-3 Preferred that may be issued upon exercise of the Preferred Warrants. The resale of any shares of common stock that are issuable upon conversion of the Series B-3 Preferred or Series B-2 Preferred, as applicable, was registered pursuant to a prospectus included in a registration

statement on Form S-1 that was filed with the Securities and Exchange Commission on March 19, 2024 and declared effective on April 22, 2024.

The Preferred Warrants are exercisable for an aggregate of 8,000 shares of the Series B-3 Preferred commencing on the Exercisability Date (as defined in the Form of Preferred Warrant) until the earlier of (i) 5 days following the date of completion of (A) the Company's public announcement of (I) at least 95% of the Company's territory managers, medical science liaisons, and reimbursement employees are using the Company's customer relationship management system routinely or on a performance improvement plan and (II) the Company's revenue for the period starting on January 1, 2024 and ending no earlier than April 30, 2024 excluding revenue from related parties (including Biofrontera AG) is at least 5% higher than the Company's revenue excluding revenue from related parties (including Biofrontera AG) for the corresponding period of the same length, starting on January 1, 2023, which announcement shall be made promptly after certification by the Company's board of directors that such targets have been completed, and (B) the Stockholder Approval, and (C) the effectiveness of a registration statement with the U.S. Securities and Exchange Commission covering the resale of the Common Stock underlying all shares of Series B-3 Preferred Stock (as defined below) and (ii) February 22, 2027.

SELLING STOCKHOLDERS

The common stock being offered by the Selling Stockholders hereby, includes shares of common stock issuable upon conversion of the Series B-3 Preferred that may be issued to the Selling Stockholders upon exercise of the Preferred Warrants. For additional information regarding the issuances of those shares of common stock, see "Private Placement of the Preferred Stock and Warrants" above. We are registering the shares of common stock in order to permit the Selling Stockholders to offer the shares for resale from time to time. Except for the ownership of the shares of common stock issued in the closing of the Private Placement upon conversion of the Series B-1 Preferred and the Preferred Warrants, the Selling Stockholders have not had any material relationship with us within the past three years.

The table below lists the Selling Stockholders and other information regarding the beneficial ownership of the shares of common stock by the Selling Stockholders. The second column lists the number of shares of common stock beneficially owned by the Selling Stockholders, based on their ownership of the shares of common stock and warrants, as of May 2, 2024, including shares that may be issued upon the conversion of Series B-1 up to the applicable beneficial ownership limitation. As of the date of this prospectus, all Selling Stockholders have elected a beneficial ownership limitation of 9.99%. The third column lists the shares of common stock being offered by the Selling Stockholders as part of this public offering. The fourth column assumes the sale of all of the shares offered by the Selling Stockholders pursuant to this prospectus.

In accordance with the terms of the Purchase Agreement with the Selling Stockholders, this prospectus covers the resale of the maximum number of shares of common stock issuable upon conversion of the Series B-3 Preferred, determined as if the Preferred Warrants were exercised in full and the outstanding shares of Series B-3 Preferred were then converted in full as of the trading day immediately preceding the date this registration statement was initially filed with the SEC, each as of the trading day immediately preceding the applicable date of determination and all subject to adjustment as provided in the Purchase Agreement, without regard to any limitations on the conversion of the Series B-3 Preferred.

The number of shares in the third and fourth column does not reflect shares of common stock currently held by the Selling Stockholders or that may be issued upon conversion of the Series B-1 Preferred held by the Selling Stockholders as such shares are not being registered in this prospectus. In addition, the fourth column assumes that the Selling Stockholders have not sold any shares of common stock other than those shares issued upon the conversion of the Series B-3 Preferred. The Selling Stockholders may sell all, some or none of their shares registered in this offering. See "Plan of Distribution."

Name of Selling Stockholder	Number of shares of Common Stock Owned Prior to Offering ⁽¹⁾	Maximum Number of shares of Common Stock to be Sold Pursuant to this Prospectus	Number of shares of Common Stock Owned After Offering
Entities affiliated with AIGH Capital Management, LLC ⁽²⁾	509,209	4,594,289	509,209
Investor Company ITF Rosalind Master Fund LP ⁽³⁾	508,895	4,594,289	508,895
Lytton-Kambara Foundation ⁽⁴⁾	508,905	706,814	508,905
The Hewlett Fund LP ⁽⁵⁾	508,905	706,814	508,905
Bigger Capital Fund LP ⁽⁶⁾⁽⁷⁾	254,531	353,406	254,531
District 2 Capital Fund LP ⁽⁷⁾⁽⁸⁾	254,531	353,407	254,531

(1) This column does not include any shares of common stock that might be acquired by conversion of the Series B-1 Preferred.

(2) Number of Shares of Common Stock Owned Prior to Offering includes 7,775 shares of Common Stock issuable upon conversion of Series B-1 Preferred held by the entities affiliated with such Selling Stockholder. Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 4,594,289 shares of common stock that is issuable upon conversion of the Series B-3 Preferred that may be issued to one or more of the entities affiliated with AIGH Capital Management, LLC upon the exercise of their Preferred Warrants. Orin Hirschman is the managing member of AIGH Capital Management, LLC, who is an advisor with respect to the securities held by AIGH Investment Partners, L.P. and a sub-advisor with respect to the securities held by WVP Emerging Manager Onshore Fund, LLC – AIGH Series and WVP Emerging Manager Onshore Fund, LLC – Optimized Equity Series. Mr. Hirschman has voting and investment control over the securities indirectly held by AIGH Capital Management, LLC and directly held by AIGH Investment Partners, L.P. As such, Mr. Hirschman may be deemed to be the beneficial owner of the securities set forth in (i), (ii) and (iii) above. The address for Mr. Hirschman and each of the affiliated entities is 6006 Berkeley Avenue, Baltimore, Maryland 21209.

(3) Number of Shares of Common Stock Owned Prior to Offering includes 4,634 shares of Common Stock issuable upon conversion of Series B-1 Preferred held by such Selling Stockholder. Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 4,594,289 shares of common stock that is issuable upon conversion of the Series B-3 Preferred that may be issued to Investor Company ITF Rosalind Master Fund LP upon the exercise of their Preferred Warrants. Each of Rosalind Advisors, Inc., Steven Salamon, and Gilad Aharon have shared voting and dispositive power with respect to these securities. The address for Rosalind Advisors, Inc., Mr. Salamon and Mr. Aharon is 15 Wellesley Street West, Suite 326, Toronto, Ontario, M4Y 0G7 Canada. The address of Investor Company ITF Rosalind Master Fund L.P. is c/o TD Waterhouse, 77 Bloor Street West, 3rd Floor, Toronto, ON M5S 1M2 Canada.

(4) Number of Shares of Common Stock Owned Prior to Offering includes 4,737 shares of Common Stock issuable upon conversion of Series B-1 Preferred held by such Selling Stockholder. Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 706,814 shares of common stock that is issuable upon conversion of the Series B-3 Preferred that may be issued to LKF upon exercise of their Preferred Warrants. Laurence Lytton, President of LKF, has voting and investment power over the Shares held by LKF. The business address of LKF and Mr. Lytton is 467 Central Park West 17-A, New York, NY 10025.

(5) Number of Shares of Common Stock Owned Prior to Offering includes 4,737 shares of Common Stock issuable upon conversion of Series B-1 Preferred held by such Selling Stockholder. Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 706,814 shares of common stock that is issuable upon conversion of the Series B-3 Preferred that may be issued to The Hewlett Fund LP upon exercise of their

Preferred Warrants. Martin Chopp has voting and investment control over the securities held by The Hewlett Fund LP. The address of The Hewlett Fund LP is 100 Merrick Road, Suite 400W, Rockville Centre, NY 11570.

(6) Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 353,406 shares of common that is issuable upon conversion of the Series B-3 Preferred that may be issued to Bigger Capital (as defined below) upon exercise of their Preferred Warrants. The address of Bigger Capital Fund, LP is 11700 W Charleston Blvd 170-659, Las Vegas, NV 89135.

(7) Bigger Capital Fund GP, LLC ("Bigger GP") is a general partner of Bigger Capital Fund, LP ("Bigger Capital") and District 2 Capital LP ("District 2") is the investment manager of District 2 Capital Fund LP ("District 2 CF"). Michael Bigger is the managing member of Bigger GP and District and District 2 Holdings LLC ("District 2 Holdings"), which is the managing member of District 2 GP LLC ("District 2 GP"), the general partner of District 2 CF. Therefore, Mr. Bigger, District 2, District 2 Holdings and District 2 CF may be deemed to be the beneficial owner, and have the shared power to dispose of or direct the disposition, of the shares reported as beneficially owned by District 2 CF and Mr. Bigger and Bigger GP may be deemed to be the beneficial owner, and have the shared power to dispose of or direct the disposition, of the shares reported as beneficially owned by Bigger Capital and District 2 CF. Number of Shares of Common Stock Owned Prior to Offering includes 6,308 shares of Common Stock issuable upon conversion of Series B-1 Preferred held by Bigger Capital and District 2 CF. For purposes of the table, the number is split evenly between Bigger Capital and District 2 CF.

(8) Maximum Number of Shares of Common Stock to be Sold Pursuant to this Prospectus contains 353,407 shares of common stock that is issuable upon conversion of the Series B-3 Preferred that may be issued to District 2 upon exercise of their Preferred Warrants. The address of District 2 Capital Fund, LP is 14 Wall Street, 2nd Floor, Huntington, NY 11743.

PLAN OF DISTRIBUTION

The Selling Stockholders of the securities and any of their respective pledgees, assignees and successors-in-interest may, from time to time, sell any or all of their securities covered hereby on the Nasdaq Capital Market or any other stock exchange, market or trading facility on which the securities are traded or in private transactions. These sales may be at fixed or negotiated prices. The Selling Stockholders may use any one or more of the following methods when selling securities:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the securities as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales;
- in transactions through broker-dealers that agree with the Selling Stockholders to sell a specified number of such securities at a stipulated price per security;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- a combination of any such methods of sale; or
- any other method permitted pursuant to applicable law.

The Selling Stockholders may also sell securities under Rule 144 or any other exemption from registration under the Securities Act, if available, rather than under this prospectus. Broker-dealers engaged by one or more of the Selling Stockholders may arrange for other brokers-dealers to participate in sales. Broker-dealers may receive commissions or discounts from a Selling Stockholder (or, if any broker-dealer acts as agent for the purchaser of securities, from the purchaser) in amounts to be negotiated, but, except as set forth in a supplement to this Prospectus, in the case of an agency transaction not in excess of a customary brokerage commission in compliance with FINRA Rule 2121; and in the case of a principal transaction a markup or markdown in compliance with FINRA Rule 2121.

In connection with the sale of the securities or interests therein, the Selling Stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the securities in the course of hedging the positions they assume. The Selling Stockholders may also sell securities short and deliver these securities to close out their short positions, or loan or pledge the securities to broker-dealers that in turn may sell these securities. The Selling Stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or create one or more derivative securities which require the delivery to such broker-dealer or other financial institution of securities offered by this prospectus, which securities such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The Selling Stockholders and any broker-dealers or agents that are involved in selling the securities may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the securities purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The Selling Stockholders has informed the Company that they do not have any written or oral agreement or understanding, directly or indirectly, with any person to distribute the securities.

The Company is required to pay certain fees and expenses incurred by the Company incident to the registration of the securities. The Company has agreed to indemnify the Selling Stockholder holding the Inducement Warrants against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the securities may be resold by both of the Selling Stockholders without registration and without regard to any volume or manner-of-sale limitations by reason of Rule 144, without the requirement for the Company to be in compliance with the current public information under Rule 144 under the Securities Act or any other rule of similar effect or (ii) all of the securities have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The resale securities will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the resale securities covered hereby may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

Under applicable rules and regulations under the Exchange Act, any person engaged in the distribution of the resale securities may not

simultaneously engage in market making activities with respect to the common stock for the applicable restricted period, as defined in Regulation M, prior to the commencement of the distribution. In addition, the Selling Stockholders will be subject to applicable provisions of the Exchange Act and the rules and regulations thereunder, including Regulation M, which may limit the timing of purchases and sales of the common stock by the Selling Stockholders or any other person. We will make copies of this prospectus available to the Selling Stockholders and have informed them of the need to deliver a copy of this prospectus to each purchaser at or prior to the time of the sale (including by compliance with Rule 172 under the Securities Act).

LEGAL MATTERS

The validity of the securities offered hereby will be passed upon for us by McGuireWoods LLP, New York, New York.

EXPERTS

The audited financial statements for the fiscal years ended December 31, 2023 and 2022, incorporated by reference in this prospectus and elsewhere in the registration statement have been so incorporated by reference in reliance upon the report of Marcum LLP, independent registered public accountants, upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the securities offered hereby. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement or the exhibits and schedules filed with the registration statement. For further information about us and the securities offered hereby, we refer you to the registration statement and the exhibits filed with the registration statement. Statements contained in this prospectus regarding the contents of any contract or any other document that is filed as an exhibit to the registration statement are not necessarily complete, and each such statement is qualified in all respects by reference to the full text of such contract or other document filed as an exhibit to the registration statement. The SEC also maintains an internet website that contains reports, proxy statements and other information about registrants, like us, that file electronically with the SEC. The address of that website is www.sec.gov.

We are required to file periodic reports, proxy statements, and other information with the SEC pursuant to the Exchange Act. These reports, proxy statements, and other information will be available on the website of the SEC referred to above.

We maintain a website at www.biofrontera-us.com, through which you may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on or accessed through our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INCORPORATION BY REFERENCE

The SEC allows us to “incorporate by reference” information from other documents that we file with it, which means that we can disclose important information to you by referring you to those documents. The information incorporated by reference is considered to be part of this prospectus. Information in this prospectus supersedes information incorporated by reference that we filed with the SEC prior to the date of this prospectus.

We incorporate by reference into this prospectus and the registration statement of which this prospectus is a part the information or documents listed below that we have filed with the SEC:

- our Annual Report on [Form 10-K](#) for the year ended December 31, 2023, filed with the SEC on March 15, 2024;
- our Current Reports on Form 8-K filed with the SEC [January 3, 2024](#), [January 9, 2024](#), [January 25, 2024](#), [February 2, 2024](#), [February 13, 2024](#), [February 20, 2024](#), [February 23, 2024](#), [March 26, 2024](#), [April 3, 2024](#), [April 25, 2024](#); and [April 30, 2024](#).
- the description of our common stock contained in our registration statement on [Form 8-A](#) filed with the SEC on October 20, 2021, including any amendments or reports filed for the purposes of updating this description; and
- the description of our stockholder rights plan contained in our registration statement on [Form 8-A](#) filed with the SEC on October 14, 2022, including any amendments or reports filed for the purposes of updating this description; and

In addition, all documents (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items) that are filed by us with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act after the date of the initial registration statement of which this prospectus is a part and prior to the effectiveness of such registration statement and all documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act prior to the termination of the offering (excluding any information furnished rather than filed) shall be deemed to be incorporated by reference into this prospectus.

Notwithstanding the statements in the preceding paragraphs, no document, report or exhibit (or portion of any of the foregoing) or any other information that we have “furnished” to the SEC pursuant to the Exchange Act shall be incorporated by reference into this prospectus.

We will furnish without charge to you, on written or oral request, a copy of any or all of the documents incorporated by reference in this prospectus, including exhibits to these documents. You should direct any requests for documents to Biofrontera Inc., 120 Presidential Way, Suite 330, Woburn, MA 01801 or call 781-245-1325. You also may access these filings on our website at www.biofrontera-us.com. We do not incorporate the information on our website into this prospectus and you should not consider any information on, or that can be accessed through, our website as part of this prospectus (other than those filings with the SEC that we specifically incorporate by reference into this prospectus).

Any statement contained in a document incorporated or deemed to be incorporated by reference in this prospectus will be deemed modified, superseded or replaced for purposes of this prospectus to the extent that a statement contained in this prospectus modifies, supersedes or replaces such statement.



PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

Item 13. Other expenses of issuance and distribution.

The following table sets forth all fees and expenses, other than the underwriting discounts and commissions payable solely by Biofrontera Inc. in connection with the offer and sale of the securities being registered. All amounts shown are estimated except for the SEC registration fee.

	Amount to be paid
SEC registration fee	\$ 2,746
Accounting fees and expenses	10,000
Legal fees and expenses	<u>35,000</u>
Total	\$ 47,746

Item 14. Indemnification of directors and officers.

Section 102 of the General Corporation Law of the State of Delaware permits a corporation to eliminate the personal liability of directors of a corporation to the corporation or its stockholders for monetary damages for a breach of fiduciary duty as a director, except where the director breached his duty of loyalty, failed to act in good faith, engaged in intentional misconduct or knowingly violated a law, authorized the payment of a dividend or approved a stock repurchase in violation of Delaware corporate law or obtained an improper personal benefit. Our amended and restated certificate of incorporation provides that no director of Biofrontera Inc. shall be personally liable to it or its stockholders for monetary damages for any breach of fiduciary duty as a director, notwithstanding any provision of law imposing such liability, except to the extent that the General Corporation Law of the State of Delaware prohibits the elimination or limitation of liability of directors for breaches of fiduciary duty.

Section 145 of the General Corporation Law of the State of Delaware provides that a corporation has the power to indemnify a director, officer, employee, or agent of the corporation, or a person serving at the request of the corporation for another corporation, partnership, joint venture, trust or other enterprise in related capacities against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by the person in connection with an action, suit or proceeding to which he was or is a party or is threatened to be made a party to any threatened, ending or completed action, suit or proceeding by reason of such position, if such person acted in good faith and in a manner he reasonably believed to be in or not opposed to the best interests of the corporation, and, in any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful, except that, in the case of actions brought by or in the right of the corporation, no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or other adjudicating court determines that, despite the adjudication of liability but in view of all of the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

Our amended and restated certificate of incorporation and amended and restated bylaws provide indemnification for our directors and officers to the fullest extent permitted by the General Corporation Law of the State of Delaware. We will indemnify each person who was or is a party or threatened to be made a party to any threatened, pending or completed action, suit or proceeding (other than an action by or in the right of us) by reason of the fact that he or she is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise (all such persons being referred to as an "Indemnitee"), or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding and any appeal therefrom, if such Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, and, with respect to any criminal action or proceeding, he or she had no reasonable cause to believe his or her conduct was unlawful. Our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify any Indemnitee who was or is a party to an action or suit by or in the right of us to procure a judgment in our favor by reason of the fact that the Indemnitee is or was, or has agreed to become, a director or officer, or is or was serving, or has agreed to serve, at our request as a director, officer, partner, employee or trustee of, or in a similar capacity with, another corporation, partnership, joint venture, trust or other enterprise, or by reason of any action alleged to have been taken or omitted in such capacity, against all expenses (including attorneys' fees) and, to the extent permitted by law, amounts paid in settlement actually and reasonably incurred in connection with such action, suit or proceeding, and any appeal therefrom, if the Indemnitee acted in good faith and in a manner he or she reasonably believed to be in, or not opposed to, our best interests, except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to us, unless a court determines that, despite such adjudication but in view of all of the circumstances, he or she is entitled to indemnification of such expenses. Notwithstanding the foregoing, to the extent that any Indemnitee has been successful, on the merits or otherwise, he or she will be indemnified by us against all expenses (including attorneys' fees) actually and reasonably incurred in connection therewith. Expenses must be advanced to an Indemnitee under certain circumstances.

We maintain a general liability insurance policy that covers certain liabilities of directors and officers of our corporation arising out of claims based on acts or omissions in their capacities as directors or officers.

Item 15. Recent sales of unregistered securities.

We do not have any sales of unregistered securities to report that have not been previously included in a periodic report or Current Report on Form 8-K filed with the SEC.

Item 16. Exhibits and financial statements.

Exhibit No.

- 2.1# [Share and Purchase Agreement dated March 25, 2019 between Biofrontera Newderm LLC, Biofrontera AG, Maruho Co. Ltd. And Cutanea Life Sciences, Inc. \(incorporated by reference to Exhibit 4.13 to Biofrontera AG's Form 20-F filed with the SEC on April 29, 2019\).](#)
- 3.1 [Amended and Restated Certificate of Incorporation of the Company \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on November 3, 2021\).](#)
- 3.2 [Amended and Restated Bylaws of the Company \(incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed with the SEC on November 3, 2021\).](#)
- 3.3 [Certificate of Designations of Series A Junior Participating Cumulative Preferred Stock of Biofrontera Inc. \(incorporated by reference to Exhibit 3.1 to the Company's Registration Statement on Form 8-A filed with the SEC on October 14, 2022\)](#)
- 3.4 [Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Biofrontera Inc. \(incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023\).](#)
- 3.5 [Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock of Biofrontera Inc. \(incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024\)](#)
- 4.1 [Specimen Stock Certificate evidencing the shares of common stock \(incorporated by reference to Exhibit 4.1 to Amendment No. 6 to the Company's Form S-1 filed with the SEC on October 12, 2021\).](#)
- 4.2 [Form of IPO Unit Purchase Option \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 3, 2021\)](#)
- 4.3 [Warrant Agent Agreement \(incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 3, 2021\)](#)
- 4.4 [Form of 2021 Purchaser Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on December 3, 2021\).](#)
- 4.5 [Form of 2021 Pre-Funded Warrant \(incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on December 3, 2021\).](#)
- 4.6 [Form of 2021 Private Placement Unit Purchase Option \(incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed with the SEC on December 3, 2021\)](#)
- 4.7 [Form of 2022 Purchaser Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022\)](#)
- 4.8 [Form of 2022 Pre-funded Warrant \(incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022\)](#)
- 4.9 [Form of Inducement Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on July 27, 2022\)](#)
- 4.10 [Stockholder Rights Agreement, dated as of October 13, 2022, between Biofrontera Inc. and Computershare Trust Company, N.A., as Rights Agent \(incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form 8-A filed with the SEC on October 14, 2022\)](#)

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- 4.11 [Amendment No. 1 to the Stockholder Rights Agreement, dated as of April 26, 2023, between Biofrontera Inc. and Computershare Trust Company, N.A., as Rights Agent \(incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed on April 28, 2023\).](#)
- 4.12 [Form of Common Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023\)](#)
- 4.13 [Form of Pre-Funded Warrant \(incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023\)](#)
- 4.14 [Form of Preferred Warrant \(incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024\)](#)
- 5.1* [Opinion of McGuireWoods LLP.](#)
- 10.1# [Amended and Restated License and Supply Agreement dated June 16, 2021 by and among Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH and Biofrontera Inc. \(incorporated by reference to Exhibit 10.1 to Company's Form S-1 filed with the SEC on July 6, 2021\).](#)
- 10.2# [License and Supply Agreement dated March 10, 2014 by and between Ferrer Internacional, S.A. and Medimetriks Pharmaceuticals, Inc., as amended by Amendment No. 1 and Consent and Acknowledgment Agreement with respect thereto \(incorporated by reference to Exhibit 4.14 to Biofrontera AG's Form 20-F filed with the SEC on April 29, 2019\).](#)
- 10.3# [Amendment No. 1 to License and Supply Agreement dated March 5, 2018 by and between Medimetriks Pharmaceuticals, Inc. and Ferrer Internacional, S.A. \(incorporated by reference to Exhibit 4.15 to Biofrontera AG's Form 20-F filed with the SEC on April 29, 2019\).](#)
- 10.4 [Consent and Acknowledgement Agreement dated March 5, 2018 by and between Medimetriks Pharmaceuticals, Inc. and Ferrer Internacional, S.A. \(incorporated by reference to Exhibit 4.16 to Biofrontera AG's Form 20-F filed with the SEC on April 29, 2019\).](#)
- 10.5# [Supply Agreement dated March _____, 2018 by and between Ferrer Internacional, S.A. and Cutanea Life Sciences, Inc. \(incorporated by reference to Exhibit 4.17 to Biofrontera AG's Form 20-F filed with the SEC on April 29, 2019\).](#)

- 10.6† [Employment Agreement – Erica Monaco \(incorporated by reference to Exhibit 10.6 to Amendment No. 2 to the Company's Form S-1 filed with the SEC on August 12, 2021\).](#)
- 10.7 [Second Intercompany Revolving Loan Agreement dated March 31, 2021 by and between the Company and Biofrontera AG \(incorporated by reference to Exhibit 10.7 to the Company's Form S-1 filed with the SEC on July 6, 2021\).](#)
- 10.8 [Amended and Restated Master Contract Services Agreement, by and among the Company, Biofrontera AG, Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH \(incorporated by reference to Exhibit 10.8 to the Company's Form S-1 filed with the SEC on July 6, 2021\).](#)

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- 10.9 [Quality Agreement dated November 1, 2016, between the Company and Biofrontera Pharma GmbH \(incorporated by reference to Exhibit 10.9 to Amendment No. 1 to the Company's Form S-1 filed with the SEC on July 26, 2021\).](#)
- 10.10 [Intercompany Services Agreement dated January 1, 2016, between the Company, Biofrontera AG, Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH \(incorporated by reference to Exhibit 10.10 to Amendment No. 4 to the Company's Form S-1 filed with the SEC on September 16, 2021\).](#)
- 10.11† [Amended Employment Agreement dated October 1, 2021 – Hermann Lübbert \(incorporated by reference to Exhibit 10.11 to Amendment No. 5 to the Company's Form S-1 filed with the SEC on October 1, 2021\).](#)
- 10.12† [2021 Omnibus Incentive Plan \(incorporated by reference to Exhibit 10.12 to Amendment No. 6 to the Company's Form S-1 filed with the SEC on October 12, 2021\).](#)
- 10.13† [Form of Restricted Stock Unit Executive Award Agreement under 2021 Omnibus Incentive Plan \(incorporated by reference to Exhibit 10.13 to Amendment No. 6 to the Company's Form S-1 filed with the SEC on October 12, 2021\).](#)
- 10.14† [Form of Nonqualified Stock Option Executive Award Agreement under 2021 Omnibus Incentive Plan \(incorporated by reference to Exhibit 10.14 to Amendment No. 6 to the Company's Form S-1 filed with the SEC on October 12, 2021\).](#)
- 10.15† [Form of Nonqualified Stock Option Award Agreement under 2021 Omnibus Incentive Plan \(incorporated by reference to Exhibit 10.15 to Amendment No. 6 to the Company's Form S-1 filed with the SEC on October 12, 2021\).](#)
- 10.16† [Employee Stock Purchase Plan \(incorporated by reference to Exhibit 10.16 filed with the SEC on October 12, 2021\).](#)
- 10.17# [Corrected Amendment to Amended and Restated License and Supply Agreement dated October 8, 2021 by and among Biofrontera Pharma GmbH, Biofrontera Bioscience GmbH and Biofrontera Inc. \(incorporated by reference to Exhibit 10.17 to Amendment No. 7 to the Company's Form S-1 filed with the SEC on October 13, 2021\).](#)
- 10.18 [Form of Securities Purchase Agreement for 2021 Private Placement \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on December 3, 2021\).](#)
- 10.19 [Form of Registration Rights Agreement for 2021 Private Placement \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on December 3, 2021\).](#)
- 10.20 [Amendment to Amended Employment Agreement effective as December 15, 2021 and dated March 2, 2022 — Herman Lübbert \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on March 8, 2022\).](#)
- 10.21 [Amended Settlement Allocation Agreement dated March 31, 2022 between the Company and Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on April 5, 2022\).](#)
- 10.22† [Amendment to Employment Agreement effective as April 1, 2022 — Erica Monaco \(incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on April 5, 2022\).](#)
- 10.23 [Form of Securities Purchase Agreement for 2022 Private Placement \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022\).](#)
- 10.24 [Form of Registration Rights Agreement for 2022 Private Placement \(incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022\).](#)

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- 10.25 [Form of Inducement Letter \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 27, 2022\).](#)
- 10.26 [Employment Agreement —Fred Leffler \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on October 24, 2022\).](#)
- 10.27 [Form of Exchange Agreement \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on October 31, 2022\).](#)
- 10.28# [Settlement Agreement dated April 11, 2023 between Biofrontera Inc., Hermann Luebbert, John J. Borer, Loretta M. Wedge, Beth J. Hoffman, Kevin D. Weber and Biofrontera AG \(incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the SEC on May 12, 2023\).](#)
- 10.29 [Securities Purchase Agreement, , dated October 30, 2023, by and between Biofrontera Inc. and an institutional investor \(incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023\).](#)
- 10.30 [Placement Agency Agreement, dated October 30, 2023, by and between Biofrontera Inc. and Roth Capital Partner, LLC \(incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on November 2, 2023\).](#)

- 10.31 [Amendment to Common Stock Purchase Warrants, dated October 30, 2023, by and between Biofrontera Inc. and institutional investor \(incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the SEC on November 2, 2023\)](#)
- 10.32 [Amendment No. 1 to Settlement Agreement dated as of October 12, 2023, between Biofrontera Inc., Hermann Luebbert, John J. Borer, Loretta M. Wedge, Beth J. Hoffman, Kevin D. Weber and Biofrontera AG \(incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 13, 2023\)](#)
- 10.33 [Addendum to Amended and Restated License and Supply Agreement, dated as of December 12, 2023 \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 15, 2023\)](#)
- 10.34 [Confidential Settlement Agreement and Mutual Release, dated as of December 27, 2023 and effective as of December 22, 2023, by and between the Company and Maruho \(incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on January 3, 2024\)](#)
- 10.35 [Amended and Restated Addendum to Amended and Restated License and Supply Agreement, dated January 29, 2024 \(incorporated by reference to Exhibit 10.1 to the Company's 8-K filed with the SEC on February 2, 2024\)](#)
- 10.36 [Second Amended and Restated License and Supply Agreement, dated February 19, 2024, between the Company, Pharma and Bioscience \(incorporated by reference to Exhibit 10.1 to the Company's 8-K filed with the SEC on February 20, 2024\)](#)
- 10.37 [Release of Claims, dated February 13, 2024, between the Company, Pharma and Bioscience \(incorporated by reference to Exhibit 10.2 to the Company's 8-K filed with the SEC on February 20, 2024\)](#)
- 10.38 [Form of Securities Purchase Agreement, dated February 19, 2024, by and amount Biofrontera Inc. and the purchasers named therein \(incorporated by reference to Exhibit 10.1 to the Company's 8-K filed with the SEC on February 23, 2024\)](#)

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- 10.39 [Placement Agency Agreement, dated February 19, 2024, by and between Biofrontera Inc. and Roth Capital Partners, LLC \(incorporated by reference to Exhibit 10.2 to the Company's 8-K filed with the SEC on February 23, 2024\)](#)
- 10.40 [Amended and Restated Business Loan and Security Agreement between Biofrontera Inc. and Agile Capital Funding, LLC and Agile Lending, LLC, dated as of December 21, 2023 \(incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2024\)](#)
- 10.41 [Business Loan and Security Agreement between Biofrontera Inc. and Cedar Advance, LLC, dated as of December 21, 2023 \(incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K filed with the SEC on March 15, 2024\)](#)
- 21.1 [List of Subsidiaries of the Company \(incorporated by reference to Exhibit 21.1 of the Company's S-1 filed with the SEC on July 6, 2021\).](#)
- 23.1* [Consent of Marcum LLP, independent registered public accounting firm.](#)
- 23.2* [Consent of McGuireWoods LLP \(included in Exhibit 5.1\).](#)
- 24.1* [Power of Attorney \(included in the signature page\).](#)
- 107* [Filing Fees Exhibit](#)

* To be filed herewith.

† Indicates a management contract or compensatory plan or arrangement.

Certain confidential portions of this Exhibit were omitted by means of marking such portions with brackets ("****") because the identified confidential portions (i) are not material and (ii) would be competitively harmful if publicly disclosed.

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Item 17. Undertakings.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by section 10(a)(3) of the Securities Act;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

(2) That, for the purposes of determining any liability under the Securities Act, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of the securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act to any purchaser, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in

reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act, each filing of the registrant's annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in this registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(c) Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the SEC such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction, the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

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SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of Woburn, Commonwealth of Massachusetts, on May 2, 2024.

BIOFRONTERA INC.

By: /s/ E. Fred Leffler, III
Name: E. Fred Leffler, III
Title: Chief Financial Officer

SIGNATURES AND POWER OF ATTORNEY

Each of the undersigned, whose signature appears below, hereby constitutes and appoints Daniel Hakansson, his or her true and lawful agent, proxy and attorney-in-fact, with full power of substitution and resubstitution, for him or her and in his or her name, place and stead, in any and all capacities, to act on, sign and file with the Securities and Exchange Commission any and all amendments to this registration statement together with all schedules and exhibits thereto, and to take any and all actions which may be necessary or appropriate to be done, as fully for all intents and purposes as he or she might or could do in person, hereby approving, ratifying and confirming all that such agent, proxy and attorney-in-fact or any of his or her substitutes may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act, this registration statement has been signed by the following persons in the capacities held on the dates indicated.

Signature	Title	Date
<u>/s/ Hermann Luebbert</u> Hermann Luebbert	Chairman and Chief Executive Officer (Principal Executive Officer)	May 2, 2024
<u>/s/ E. Fred Leffler, III</u> E. Fred Leffler, III	Chief Financial Officer (Principal Financial Officer and Principal Accounting Officer)	May 2, 2024
<u>/s/ John J. Borer</u> John J. Borer	Director	May 2, 2024
<u>/s/ Heikki Lanckriet</u> Heikki Lanckriet	Director	May 2, 2024
<u>/s/ Beth J. Hoffman</u> Beth J. Hoffman	Director	May 2, 2024
<u>/s/ Kevin D. Weber</u> Kevin D. Weber	Director	May 2, 2024

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McGuireWoods LLP
1251 Avenue of the Americas
20th Floor
New York, NY 10020
Phone: 212.548.2100
www.mcguirewoods.com

May 2, 2024

Biofrontera Inc.
120 Presidential Way, Suite 330
Woburn, Massachusetts 01801

**RE: Biofrontera Inc., a Delaware corporation
Form S-1 Registration Statement**

Ladies and Gentlemen:

We have acted as special counsel to Biofrontera Inc., a Delaware corporation (the "Company"), in connection with the Company's Registration Statement on Form S-1 filed by the Company with the Securities and Exchange Commission ("SEC") (as amended or supplemented, the "Registration Statement"), under the Securities Act of 1933, as amended (the "Securities Act"), relating to the registration by the Company of the offer and sale from time to time by the selling stockholders listed in the Registration Statement under "Selling Stockholders" (the "Selling Stockholders") of up to 11,309,019 shares (the "Shares") of the Company's common stock, par value \$0.001 per share (the "Common Stock"), issuable upon the conversion of Series B-3 Convertible Preferred Stock, par value \$0.001 per share, of the Company (the "B-3 Preferred Stock") that may be issued to the Selling Stockholders upon the exercise of warrants to purchase B-3 Preferred Stock (the "Preferred Warrants"). This opinion letter is being furnished in accordance with the requirements of Item 16 of Form S-1 and Item 601(b)(5)(i) of Regulation S-K promulgated under the Securities Act. Capitalized terms used and not defined herein shall have the meanings assigned to them in the Registration Statement.

Documents Reviewed

In connection with this opinion letter, we have examined the following documents:

- (a) the Registration Statement, including the exhibits being filed therewith;
- (b) the securities purchase agreement dated as of February 19, 2024 by and between the Company and the Selling Stockholders (the "Purchase Agreement");
- (c) the Certificate of Designation of the Series B Convertible Preferred Stock filed with the Secretary of State of the State of Delaware on February 20, 2024 (the "Certificate of Designation"), which provides, in part, that each share of B-3 Preferred Stock is convertible into shares of Common Stock;
- (d) the form of Preferred Warrant.

McGuireWoods LLP | www.mcguirewoods.com

Atlanta | Austin | Baltimore | Charlotte | Charlottesville | Chicago | Dallas | Houston | Jacksonville | London | Los Angeles - Century City
Los Angeles - Downtown | New York | Norfolk | Pittsburgh | Raleigh | Richmond | San Francisco | Tysons | Washington, D.C.

Also, we have examined and relied upon the following:

- (i) (A) true and correct copies of the amended and restated certificate of incorporation and amended and restated bylaws of the Company, each as in effect the date hereof and as amended to date, and (B) the resolutions of the Board of Directors of the Company authorizing (1) the filing of the Registration Statement by the Company and (2) the issuance of the Shares, the Preferred Stock and the Preferred Warrants by the Company; and
- (ii) a certificate dated May 2, 2024 issued by the Secretary of State of the State of Delaware, attesting to the corporate status of the Company in the State of Delaware;
- (iii) originals, or copies identified to our satisfaction as being true copies, of such other records, documents and instruments as we have deemed necessary for the purposes of this opinion letter.

"Applicable Law" means the Delaware General Corporation Law.

Assumptions Underlying Our Opinions

For all purposes of the opinions expressed herein, we have assumed, without independent investigation, the following:

- (a) Factual Matters. To the extent that we have reviewed and relied upon (i) certificates of the Company or authorized representatives thereof, (ii) representations of the Company and the Selling Stockholders as set forth in the Purchase Agreement, and (iii) certificates and assurances from public officials, all of such certificates and assurances are accurate with regard to factual matters.
- (b) Signatures. The signatures of individuals who have signed the documents we have reviewed are genuine and (other than those of individuals signing on behalf of the Company at or before the date hereof) authorized.
- (c) Authentic and Conforming Documents. All documents submitted to us as originals are authentic, complete and accurate, and all documents submitted to us as copies conform to authentic original documents. All forms of documents are substantially identical to the corresponding documents that will be filed with the appropriate government agency or executed by the applicable parties.
- (d) Organizational Status, Power and Authority and Legal Capacity of Certain Parties. All parties to the Purchase Agreement are validly existing and in good standing in their respective jurisdictions of formation and have the capacity and full power and authority to execute, deliver and perform the Purchase Agreement and the documents required or permitted to be delivered and performed thereunder, including the Preferred Warrants, except that no such assumption is made as to the Company as of the date hereof. All individuals who have signed the Purchase Agreement have the legal capacity

to execute the applicable document.

(e) Authorization, Execution and Delivery of the Purchase Agreement and the Preferred Warrants. The Purchase Agreement, the Preferred Warrants and the other documents required or permitted to be delivered thereunder have been duly authorized by all necessary corporate, limited liability company, business trust, partnership or other action on the part of the parties thereto and have been duly executed and delivered by such parties, except that no such assumption is made as to the Company.

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(f) Registration. The Registration Statement shall have been declared effective under the Securities Act and such effectiveness shall not have been terminated or rescinded.

(g) No Mutual Mistake, Amendments, etc. There has not been, and will not be, any mutual mistake of fact, fraud, duress or undue influence in connection with the issuance of the Preferred Warrants, the B-3 Preferred Stock and the Shares as contemplated by the Registration Statement and the Purchase Agreement. There are and will be no oral or written statements or agreements that modify, amend or vary, or purport to modify, amend or vary, any of the terms of the Purchase Agreement or the Preferred Warrants.

Our Opinion

Based on and subject to the foregoing and the exclusions, qualifications, limitations and other assumptions set forth in this opinion letter, we are of the opinion that, (a) when the B-3 Preferred Stock has been issued as contemplated by the Preferred Warrants and (b) the Shares have been issued upon conversion of the B-3 Preferred Stock in accordance with the terms of the Certificate of Designation, the Shares will have been duly authorized and validly issued and will be fully paid and non-assessable.

Qualification and Limitation Applicable to Our Opinions

The opinions set forth above are subject to the following qualifications and limitations.

(a) Applicable Law. Our opinions are limited to the Applicable Law, and we do not express any opinion concerning any other law.

Miscellaneous

The foregoing opinions are being furnished only for the purpose referred to in the first paragraph of this opinion letter. Our opinions are based on statutes, regulations and administrative and judicial interpretations which are subject to change. We undertake no responsibility to update or supplement these opinions subsequent to the effective date of the Registration Statement. Headings in this opinion letter are intended for convenience of reference only and shall not affect its interpretation. We hereby consent to the filing of this opinion as Exhibit 5.1 to the Registration Statement and to the reference to our firm in the Registration Statement under the caption "Legal Matters." In giving this consent, we do not admit that we are within the category of persons whose consent is required by Section 7 of the Securities Act or the rules and regulations of the SEC promulgated thereunder.

Very truly yours,

/s/ McGuireWoods LLP

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INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in this Registration Statement of Biofrontera Inc. on Form S-1 of our report dated March 15, 2024, with respect to our audits of the consolidated financial statements of Biofrontera Inc. as of December 31, 2023 and 2022 and for the two years in the period ended December 31, 2023 appearing in the Annual Report on Form 10-K of Biofrontera Inc. for the year ended December 31, 2023. We also consent to the reference to our firm under the heading "Experts" in the Prospectus, which is part of this Registration Statement.

/s/ Marcum LLP

Marcum LLP
East Hanover, NJ
May 2, 2024

Calculation of Filing Fee Tables

Form S-1
(Form Type)

Biofrontera Inc.
(Exact Name of Registrant as Specified in its Charter)

Table 1: Newly Registered and Carry Forward Securities

Security Type	Security Class Title	Fee Calculation Rule	Amount Registered ⁽¹⁾	Proposed Maximum Offering Price Per Share	Maximum Aggregate Offering Price	Fee Rate	Amount of Registration Fee
Newly Registered Securities							
Equity	Common Stock, par value \$0.001 per share	Other	11,309,019 ⁽²⁾	\$ 1.645 ⁽³⁾	\$ 18,603,336	147.60 per \$1,000,000	\$ 2,746
Total Offering Amounts					<u>\$ 18,603,336</u>		<u>\$ 2,746</u>
Total Fees Previously Paid							
Total Fee Offsets							\$
Net Fee Due							<u>\$ 2,746</u>

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this registration statement also covers such additional shares of the common stock, par value \$0.001 per share (the "Common Stock") of the registrant, as may be issued to prevent dilution from stock splits, stock dividends and similar transactions.

(2) Represents up to 11,309,019 shares of Common Stock that may be issued to the selling stockholders upon conversion of shares of Series B-3 Convertible Preferred Stock which the Selling Stockholders may acquire upon the exercise of the warrants to purchase up to 8,000 shares of Series B-3 Convertible Stock issued to the Selling Stockholders on February 22, 2024.

(3) Pursuant to Rules 457(c) and (g) under the Securities Act, and solely for the purpose of calculating the registration fee, the proposed maximum offering price per share is the average of the high and low prices reported for the registrant's Common Stock quoted on The Nasdaq Capital Market LLC on April 26, 2024.