UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2022

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

FOR THE TRANSITION PERIOD FROM _____TO_____

COMMISSION FILE NUMBER 001-40943

BIOFRONTERA INC.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**47-3765675** **(I.R.S. Employer Identification No.)**
120 Presidential Way, Suite 330 **Woburn, Massachusetts** **(Address of principal executive offices)**	**01801** **(Zip code)**

(781) 245-1325
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class:	Trading symbol(s)	Name of Each Exchange on Which Registered:
Common Stock, par value $0.001 per share	BFRI	The Nasdaq Stock Market LLC
Preferred Stock Purchase Rights		The Nasdaq Stock Market LLC
Warrants, each warrant exercisable for one share of common stock, each at an exercise price of $5.00 per share	BFRIW	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:
None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

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, 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 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of June 30, 2022, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the common stock held by non-affiliates of the registrant was approximately $35.4 million, based on the closing price of the registrant's common stock.

As of March 13, 2023, there were 26,699,002 shares outstanding of the registrant's common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE:

None.

TABLE OF CONTENTS

BASIS OF PRESENTATION

As used in this Annual Report on Form 10-K for the fiscal year ended December 31, 2022 (the "Form 10-K"), 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 ("Bio-FRI" or "subsidiary"). References in this Form 10-K to the "*Biofrontera Group*" refer to Biofrontera AG and its consolidated subsidiaries, Biofrontera Pharma GmbH (individually, *"Biofrontera Pharma"*), Biofrontera Bioscience GmbH (individually *"Biofrontera Bioscience"*), Biofrontera Neuroscience GmbH, and Biofrontera Development GmbH. References in this Form 10-K to "*Ferrer*" refer to Ferrer Internacional S.A. References in this Form 10-K to Biofrontera's "*Licensors*" refer collectively to Biofrontera Pharma, Biofrontera Bioscience and Ferrer. References in this Form 10-K to "*Ameluz Licensor"* refer collectively to Biofrontera Pharma and Biofrontera Bioscience. References in this Form 10-K to "*Maruho*" refer to Maruho Co., Ltd. References in this Form 10-K to "*Cutanea*" refer to Cutanea Life Sciences, Inc., which was acquired by Biofrontera in 2019 ("*Cutanea acquisition*").

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The following discussion of our financial condition and results of operations should be read in conjunction with our audited consolidated financial statements and the related notes, which appear elsewhere in this Form 10-K. This Form 10-K, including the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations," may contain predictive or "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, in this annual report, including statements 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.

You should read this Form 10-K and the documents that we have filed as exhibits completely and with the understanding that our actual future results may be materially different from what we expect. While we have based these forward-looking statements on our current expectations and projections about future events, we may not actually achieve the plans, intentions or expectations disclosed in or implied by our forward-looking statements, and you should not place undue reliance on our forward-looking statements. These forward-looking statements are subject to risks, uncertainties and assumptions about us and accordingly, 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 the 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 licensed products if coverage, reimbursement and pricing from third-party payors for our products or procedures using our products significantly declines;
- our Licensors' ability to adequately protect their 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 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 sunsetting of the COVID-19 Public Health Emergency ("PHE") on May 11, 2023; and
- those risks listed in the sections of this Form 10-K entitled "*Risk Factors*" and elsewhere in this Form 10-K.

Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly

update or revise any forward-looking statements to reflect events or circumstances that may arise after the date of this Form 10-K, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

PART I

Item 1. Business

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. 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.

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.

Company Overview

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 December 31, 2022, Biofrontera AG held 30% of the outstanding shares of our common stock. With our national commercial team, we generate revenue by selling our licensed products directly to dermatology offices and groups.

Employees

As of December 31, 2022, the company had 81 employees all of which were full-time employees and approximately 57% are focused on marketing and sales activities. Our commercial team covers the continental United States, and our headquarters is in Woburn, MA.

Significant customers

We have a wide and diverse customer base with no single customer dominating our revenues. At December 31, 2022, no customer represented more than 10% of the net accounts receivable balance. For the year ended December 31, 2022, no customer represented more than 10% of net revenues.

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 BF-RhodoLED® lamp series for the treatment of minimally to moderately thick actinic keratoses of the face and scalp and positioning Ameluz® to be standard of care in the United States by growing our dedicated sales and marketing infrastructure in the United States;

- expand sales of Xepi® for treatment of impetigo by improving the market positioning of the licensed product;

- 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 our license and supply agreements with the Licensors; and

- opportunistically add complementary products or services to our portfolio by acquiring or licensing IP to further leverage our commercial infrastructure and customer relationships.

By executing these four 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.

Ameluz® and RhodoLED® Lamp Series

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 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 "gold standard" for treating AK, especially multiple AKs and the surrounding photodamaged skin.[2] We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement ("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. Actinic keratoses typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots. AKs are typically treated with cryotherapy, topicals, or PDT and these treatments can be used in combination.

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 a 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 treatments[3] with limited or no scaring. The therapy also may provide protection from potentially fatal progress of mild or invisible AKs.[4]

Market and competitive landscape

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. Topicals, medications which patients apply to the lesion multiple times per day for up to several weeks, constitutes 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. This targeted market is about 11% or $440 million of the total AK market.[6] Ameluz® PDT is competitive in the market. We are leveraging medical affairs, advisory boards, and key opinion leaders in order to educate the market on the use and benefits of Ameluz® PDT.

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[1] Fuchs & Marmur, Dermatol Surg. 2007 Sep; 33(9):1099-101

[2] Werner RN, Stockfleth E, Connolly SM, et al. Evidence- and consensus-based (S3) Guidelines for the Treatment of Actinic Keratosis - International League of Dermatological Societies in cooperation with the European Dermatology Forum - Short version. J Eur Acad Dermatol Venereol. 2015;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. 2016 Br. J. Derm. DOI 10.1111/bjd. 14498

[5] www.skincancer.org/skin-cancer-information/actinic-keratosis

[6] Market data accessible from CMS and IQVIA, 2020

Sales, marketing and distribution

We are currently selling our portfolio of licensed products in the United States through the use of our own commercial organization. We have a single sales force who markets all our licensed products across the dermatology space. We launched the commercialization of Ameluz® in combination with the RhodoLED® lamp for the treatment of actinic keratosis in the United States in October 2016. Ameluz® PDT is an in-office procedure. Ameluz® is distributed as a "buy-and-bill" drug that is purchased by the dermatologist, rather than distribution through pharmacies. Our customers will purchase our device and Ameluz® which will be held in inventory. When a dermatologist uses our product in a treatment, a payor will be billed, and the provider will be paid for both the product and light treatment. There are well established PDT CPT Codes. Ameluz® PDT is covered by code number 96574 which has an average reimbursement of $286.00 per light treatment and has to be performed by a qualified healthcare professional. Public information regarding CPT reimbursement is available at https://www.cms.gov/medicare/physician-fee-schedule/search?Y=0&T=4&HT=0&CT=3&H1=96574&M=5.

Our licensors' research and development programs

We are a sales organization with focus on commercializing our portfolio of licensed products that are already FDA-approved. Research and development efforts for label extensions in order to optimize the market positioning of the products are the responsibility of the respective licensor and are governed by the respective LSAs.

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 (when available) 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.

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

			Clinical Phase			
Product	**Indication**	**Pre-clinical**	I	II	III	**Status**
Ameluz®	Superficial basal cell carcinoma				●	Clinical Study Report (CSR) expected Q2 – 2024
Ameluz®	Actinic keratosis		●			Safety study with 3 tubes of Ameluz®; CSR expected Q3 – 2023
Ameluz®	Moderate to severe acne			●		CSR expected Q2 – 2024
Ameluz®	Actinic keratosis				●	Trunk & extremities with 1-3 tubes First patient dosed 01/23; CSR expected Q1 - 2025
Ameluz®	Actinic keratosis				●	Combination daylight + conventional PDT, plan to start enrollment in 2023
Ameluz®	Squamous cell carcinoma in situ				●	Plan to start enrollment in 2024

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 BF-RhodoLED® model will continue to be offered in the U.S. market.

Principal suppliers

Our source for the Ameluz® and the RhodoLED® lamp series is our Licensor, Biofrontera Pharma. Biofrontera Pharma is considered the responsible manufacturer for Ameluz® by the FDA. Biofrontera Pharma currently manufactures through a single unaffiliated contract manufacturer in Switzerland, Glaropharm AG, and has recently signed an agreement with a second unaffiliated contract manufacturer located in Germany, Pharbil Waltrop GmbH, to ensure stability of the supply chain. Our Licensor is responsible for all raw materials, product, and shipment of products to our third-party logistics partner ("3PL"), Cardinal Health for warehousing and distribution. We centralize our customer sales support and back-office functions through our headquarters in Woburn, Massachusetts.

We intend to continue our development of our sales and marketing infrastructure to effectively target the broad range of dermatologic prescribers. To further our development, we plan to expand our headcount, increase our investment in market research and brand development, further develop our distribution capabilities and explore broader payer relationships and coverage.

Xepi®

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 specifically 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.

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]

Possible complications of impetigo[8] can include:

- Worsening or spreading of the infection
- Scarring, which is more common with ecthyma
- Impetigo caused by beta-hemolytic strep bacteria can cause:
- Kidney damage (poststreptococcal glomerulonephritis)
- Fever, joint, and other problems (rheumatic fever)

Although impetigo rarely leads to serious complications, effective treatment with drugs like Xepi® can shorten how long impetigo lasts.

Market and competitive landscape

There are more than 3 million cases of impetigo in the United States every year.[5] The market for topical antibiotics is driven by generics with mupirocin being the top choice of topical antibiotics across all specialties. In 2021, over 13 million prescriptions were written for mupirocin for a range of conditions. According to prescription data from IQVIA, dermatologists account for approximately 12% of the annual topical antibiotic prescriptions written or about 1.4 million prescriptions. Xepi® is a prescription product that is filled by specialty pharmacies nationwide and orders to these specialty pharmacies are fulfilled by our 3PL, Cardinal Health. Sales to the specialty pharmacies are recognized net of sales deductions, which include expected returns, discounts and incentives such as payments made under patient assistance programs.

Our licensors' research and development programs

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.

Sales, marketing and distribution

We are currently selling our portfolio of licensed products in the United States through the use of our own commercial organization. We have a single sales force who markets all our licensed products across the dermatology space.

Although recent developments with respect to the third-party manufacturer that was providing our supply of Xepi® have impacted the timing of sales expansion and improved market positioning, Ferrer is in the process of qualifying a new third-party manufacturer in North America. The expectation is that this process will be completed by early 2024. Once the new third-party manufacturer is qualified, we expect the supply of Xepi® will meet future needs. Xepi®, is distributed through specialty pharmacies and generally covered by most commercial payers without pre-approval or similar requirements. Our contracts with third-party payers/pharmacy benefit managers ("PBMs") generally require us to provide rebates based on utilization by the patients they cover. We believe that Xepi® has the potential to be another innovative product with a large market potential.

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

[8] From CLS link to Johns Hopkins Impetigo | Johns Hopkins Medicine

Intellectual Property

We do not own any material patents or trademarks. We license the rights and trademarks related to the products we sell.

Ameluz® and the RhodoLED® lamp series are approved by the FDA as a combination product, such that the label requires the use of both products together. The Licensor has patent protection on its nanoemulsion technology in the United States until 2028 and three new patent family applications on the BF-RhodoLED® lamps and general PDT illumination procedures, two of which are already granted and one is listed in the Orange Book, that could jointly extend protection until 2040.

Xepi® is protected by four patents in the United States held by Ferrer. The primary patent protecting the active ingredient in Xepi® expires in November 2023. However, there are treatment specific patents for the treatment of impetigo due to Staphylococcus aureus or Streptococcus pyogenes and a method of treating nasopharynx infections in asymptomatic nasal carriers expiring in 2032 and 2029, respectively.

Commercial Partners and Agreements

Ameluz® and RhodoLED® Lamp Series License Service Agreement

On June 16, 2021, we entered into the Ameluz LSA with Biofrontera Pharma and Biofrontera Bioscience. Under the terms of the Ameluz LSA, we were granted an exclusive, non-transferable license to use Biofrontera Pharma and Biofrontera Bioscience technology to use, import, export, distribute, market, offer for sale and sell Ameluz® and the RhodoLED® lamp series for its approved indications within the United States and certain of its territories and agreed to purchase a minimum number of units according to an agreed schedule.

On October 8, 2021, we entered into an amendment to the Ameluz LSA under which the price we pay per unit will be based upon our sales history, although the minimum number of units to purchase per year remains unchanged.
The amendment to the Ameluz LSA that became effective on October 8, 2021, also shifted the costs of clinical development for FDA-approved indications that are not currently being sought by the Ameluz Licensor, as described below.

In addition, under the Ameluz LSA, the Ameluz Licensor agrees to sell us the RhodoLED® lamp series at cost plus a low double digit handling fee. There are no milestone or royalty obligations associated with this agreement. Any changes to pricing of supply of Ameluz® or RhodoLED® lamps would require agreement by both contract parties.

The Ameluz LSA will remain in effect until June 2036, at which time the Ameluz LSA may automatically renew depending on Biofrontera's achievement of certain revenue goals. Both parties may terminate the agreement early for a material breach after a 60-day cure period.

The Ameluz LSA also provides that we will indemnify the Ameluz Licensor, subject to certain conditions, for any claims related to a breach of our representations and covenants under the agreement or any other gross negligent, willful or intentionally wrongful act, error or omission on our part. Under the terms of the agreement, the Ameluz Licensor will indemnify us, subject to certain conditions, against claims related to the licensed products.

Under the Ameluz LSA, the Ameluz Licensor is responsible for obtaining and maintaining the rights to all FDA approvals (and any required maintenance thereafter) needed for the Ameluz Licensor to manufacture Ameluz® and/or the RhodoLED® lamp series and/or for Biofrontera to sell Ameluz® and/or the RhodoLED® lamp series in the United States. Likewise, the Ameluz Licensor is responsible to maintain a pharmacovigilance database and to respond appropriately to all relevant queries of any regulatory authority pertaining to pharmacovigilance (Biofrontera is required to provide reasonable support relating to any regulatory issues relating to pharmacovigilance and/or product recalls). Furthermore, the Ameluz Licensor will, in agreement with Biofrontera, perform and finance clinical trials to promote the Ameluz® market positioning in the U.S. market for indications that are identified in the amendment signed on October 8, 2021, including the clinical studies. With respect to the indications currently pursued by the Ameluz Licensor, we have the authority under the Ameluz LSA, in certain circumstances, to take over clinical development from the Ameluz Licensor, if they are unable or unwilling to perform these functions appropriately and subtract the cost from the transfer price of future shipments. The pursuit of any additional indications would need to be separately negotiated between us and the Ameluz Licensor.

Conversely, under the Ameluz LSA, Biofrontera is responsible for obtaining all state licenses or any other similar approvals required to market Ameluz® and/or the RhodoLED® lamp in the United States. Biofrontera must also carry out all mandatory reporting responsibilities under federal and state law with respect to compliance with the Prescription Drug Marketing Act, the Sunshine Act, or any other similar laws and regulations. Biofrontera is also responsible for all activities related to reimbursement and pricing of the products within the United States. Biofrontera is required by the Ameluz LSA to use commercially reasonable efforts and resources to exploit the license and market Ameluz® and the RhodoLED® lamp in the United States ("commercially reasonable efforts" being defined in terms of comparison against industry standards and practices for a company of comparable size and capability and active in the same business area).

Under the Ameluz LSA, if product or lamps are not delivered in conformance with certain specifications of this Agreement and the Quality Assurance Agreement, and the Ameluz Licensor does not remedy its failure, then we will have the right to organize manufacturing on our own, and step into contracts with the Ameluz Licensor's manufacturers, such that we will replace the Ameluz Licensor as a party to these contracts. If we pursue this option, the Ameluz Licensor must use its best efforts to assist with the transferring of these manufacturing contracts without delay and at its own cost. No transfer price will be paid to the Ameluz Licensor thereafter for products or lamps that are manufactured by third parties.

Ferrer Internacional S.A.

On March 25, 2019, we assumed the rights, duties and obligations of Cutanea under the Xepi LSA as part of the acquisition of Cutanea. Under the terms of the Xepi LSA, we have been granted an exclusive, royalty-bearing license in the United States and certain of its territories, including the right to sublicense under certain conditions, to develop, make, have made, use, register, market, promote, sell, have sold, offer for sale and import Xepi®.

Under the Xepi LSA, we are obligated to make payments to Ferrer upon the occurrence of certain milestones. Specifically, we must pay Ferrer (i) $2,000,000 upon the first occasion when annual net sales of Xepi® under the Xepi LSA exceed $25,000,000, and (ii) $4,000,000 upon the first occasion annual net sales of Xepi® under the Xepi LSA exceed $50,000,000. The maximum potential milestone payments remaining under this agreement total $6,000,000. These are both sales-based milestones. There are no development milestones within the agreement.

The terms of the Xepi LSA also provide for us to purchase Xepi® from Ferrer and pay royalties at a high single digit percentage based on net sales. Royalties are paid quarterly when the related sales occur. There are no other performance obligations required for royalties to be incurred. Furthermore, while Ferrer is approval holder for Xepi®, the administration of the NDA is managed by Biofrontera Bioscience. We are fully dependent on our collaboration with Ferrer for our supply of Xepi® from their sole supplier.

The Xepi LSA will continue for the longer of (a) 12 years following the first commercial sale of Xepi® or (b) 12 years from the date of latest product to launch under the Xepi LSA, concluding in 2030. However, the Xepi LSA will automatically terminate concurrently with the termination of Ferrer's license with Toyama Chemical Co., Ltd., also in 2030. Ferrer covenants under the agreement to make commercially reasonable efforts to extend its license agreement with Toyama. Although recent developments with respect to the third-party manufacturer that was providing our supply of Xepi® have impacted the timing of sales expansion and improved market positioning, we believe that Xepi® has the potential to be another innovative product with a large market potential in our portfolio. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Critical Accounting Estimates —Intangible Assets and Impairment Assessment*" in this Form 10-K.

Under the Xepi LSA, Biofrontera is required to obtain and maintain all "Marketing Authorizations and Regulatory Approvals" in Ferrer's name, as well as to obtain and maintain all other licenses and certificates required for the wholesale and/or retail sale of Xepi® in the United States. Biofrontera must also participate in a "Joint Steering Committee," which is intended, in part, to ensure (among other things) that Biofrontera uses commercially reasonable efforts to market and sell Xepi® in the United States. This joint steering committee is required to meet at least once per year, unless agreed otherwise by the parties.

Government and Industry Regulation

Governmental authorities in the United States, at the federal, state and local level, extensively regulate, among other things, the research, development, testing, manufacture, safety surveillance, efficacy, quality control, labeling, packaging, distribution, record keeping, promotion, storage, advertising, distribution, marketing, sale, export and import, pricing (including discounts and rebates), and the reporting of safety and other post-market information of the products we distribute. These laws and regulations may require administrative guidance for implementation, and a failure to comply could subject us to legal and administrative actions. Enforcement measures may include substantial fines and/or penalties, orders to stop non-compliant activities, criminal charges, warning letters, product recalls or seizures, delays in product approvals, exclusion from participation in government programs or contracts as well as limitations on conducting business in applicable jurisdictions and could result in harm to our reputation and business. Compliance with these laws and regulations may be costly and may require significant technical expertise and capital investment to ensure compliance.

FDA Regulation for Medical Devices

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

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

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

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

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

Fraud and Abuse Laws

We are subject to healthcare anti-fraud and abuse regulations that are enforced by the U.S. federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

- the federal healthcare programs' Anti-Kickback Law;
- federal false claims laws;
- federal criminal laws that prohibit executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters;
- the federal Civil Monetary Penalties Law, which imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent; and
- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payor, including commercial insurers.

The federal Anti-Kickback Statute makes it illegal for any person or entity, including a prescription drug manufacturer (or a party acting on its behalf) to knowingly and willfully, directly or indirectly, solicit, receive, offer, or pay any remuneration that is intended to induce the referral of business, including the purchase, order, or lease of any good, facility, item or service for which payment may be made under a federal health care program, such as Medicare or Medicaid. The term "remuneration" has been broadly interpreted to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, formulary managers, and beneficiaries on the other. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal health care covered business, the Anti-Kickback Statute has been violated. Violations of this law are punishable by up to five years in prison, and can also result in criminal fines, civil monetary penalties, administrative penalties and exclusion from participation in federal health care programs.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the Affordable Care Act to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the Affordable Care Act codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act. Because of the breadth of these laws and the narrowness of the safe harbors, it is possible that some of our business activities could be subject to challenge under one or more of such laws.

Federal false claims and false statement laws, including the federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers, promoting a product off-label, or for providing medically unnecessary services or items. In addition, activities relating to the sale and marketing of products are subject to scrutiny under this law. Penalties for the federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties for each separate false claim, the potential for exclusion from participation in federal health care programs, and, although the federal civil False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

Healthcare Privacy and Security Laws

We may be subject to, or our marketing activities may be limited by, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, and its implementing regulations, which established uniform standards for certain "covered entities" (healthcare providers, health plans and healthcare clearinghouses) governing the conduct of certain electronic healthcare transactions and protecting the security and privacy of protected health information. The American Recovery and Reinvestment Act of 2009, commonly referred to as the economic stimulus package, included sweeping expansion of HIPAA's privacy and security standards called the Health Information Technology for Economic and Clinical Health Act, or HITECH, which became effective on February 17, 2010. Among other things, the new law makes HIPAA's privacy and security standards directly applicable to "business associates," independent contractors or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also increased the civil and criminal penalties that may be imposed against covered entities, business associates and possibly other persons, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorney's fees and costs associated with pursuing federal civil actions.

Available Information

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Exchange Act requires us to file periodic reports, proxy statements and other information with the Securities and Exchange Commission (the "SEC"). The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC. These materials may be obtained electronically by accessing the SEC's website at http://www.sec.gov.

We also maintain a website at https://www.biofrontera-us.com. The Information on our website is not incorporated by reference into this Form 10-K and does not constitute a part of this Form 10-K. We make available, free of charge, on our website our annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after we electronically file such with, or furnish it to, the SEC.

Item 1A. Risk Factors

Summary of Material Risk Factors

Our business, results of operations and financial condition and the industry in which we operate are subject to various risks. We have listed below (in order of importance or probability of occurrence) the most significant risk factors applicable to us, but they do not constitute all of the risks that may be applicable to us. New risks may emerge from time to time, and it is not possible for us to predict all potential risks or to assess the likely impact of all risks. You should read this summary together with the more detailed description of each risk factor contained below. Some of these material risks include:

Risks Related to the License and Supply Agreements and our Licensed Products

- 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 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.

Risks Related to Our Business and Strategy

- The COVID-19 global pandemic still affects our business and presents new challenges.
- 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.
- 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.
- 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 U.S. market size for Ameluz® for the treatment of actinic keratosis may be smaller than we have estimated.
- If our Licensors face allegations of noncompliance with the law and encounter sanctions, their reputation, revenues and liquidity may suffer, and our licensed products could be subject to restrictions or withdrawal from the market.
- Even if our Licensors obtain regulatory approvals for our licensed products and product candidates, or approvals extending their indications, they may not gain market acceptance among hospitals, physicians, health care payors, patients and others in the medical community.
- A recall of our licensed drug or medical device products, or the discovery of serious safety issues with our licensed drug or medical device products, could have a significant negative impact on us.
- Our licensed medical device product, the RhodoLED® lamp, is subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.
- We are highly dependent on our key personnel, and if we are not successful in attracting and retaining highly qualified personnel, we may be unable to successfully implement our business strategy.
- Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Risks Related to Our Financial Position and Capital Requirements

- We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never sustain profitability.
- If we fail to obtain additional financing, we may be unable to pursue our plans for strategic growth, including completing the commercialization of Xepi® and other products we may license.
- Our existing and any future indebtedness could adversely affect our ability to operate our business.
- The valuation of our equity investments is subject to volatility.

Risks Related to Corporate Governance, Including Being a Public Company

- 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.
- We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.
- As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal controls over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.
- We are an emerging growth company and smaller reporting company we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

Risks Related to Our Securities and the Ownership of Our Common Stock

- As of December 31, 2022, Biofrontera AG beneficially owns 30.0% of our outstanding shares of common stock and will be able to exert significant control over matters subject to stockholder approval and its interests may conflict with ours or other stockholders in the future.
- 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.
- If we fail to regain compliance with applicable listing standards, our common stock and/or our publicly-traded warrants could be delisted from Nasdaq.
- 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.

Risks Related to the License and Supply Agreements and Our Licensed Products

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.

We are a party to license agreements with Biofrontera Pharma and Biofrontera Bioscience (for Ameluz® and the RhodoLED® lamp series) and with Ferrer (for Xepi®) and expect to enter into additional licenses in the future. Our existing license agreements impose, and we expect that future license agreements will impose, on us various development, regulatory diligence obligations, payment of milestones or royalties and other obligations. If we fail to comply with our obligations under our license agreements, or we are subject to a bankruptcy or insolvency, the licensor may have the right to terminate the license. In the event that any of our existing or future important licenses were to be terminated by the licensor, we would likely need to cease further commercialization of the related licensed product or be required to spend significant time and resources to modify the licensed product to not use the rights under the terminated license. In the case of marketed products that depend upon a license agreement, we could be required to cease our commercialization activities, including sale of the affected product. For a summary of the terms of the license agreements, see "*Business—Commercial Partners and Agreements*".

Disputes may arise between us and any of our Licensors regarding intellectual property subject to such agreements, including:

- the scope of rights granted under the agreement and other interpretation-related issues;
- whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the agreement;
- our right to sublicense patent and other rights to third parties;
- our diligence obligations with respect to the use of the licensed intellectual property, and what activities satisfy those diligence obligations;
- the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our Licensors and us, should any such joint creation occur;
- our right to transfer or assign the license; and
- the effects of termination.

These, or other disputes over intellectual property that we have licensed may prevent or impair our ability to maintain our current arrangements on acceptable terms or may impair the value of the arrangement to us. Any such dispute, or termination of a necessary license, could have a material adverse effect on our business, financial condition and results of operations.

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.

The patent family that protected the technology relating to nanoemulsion of 5-aminolevulinic acid, the active ingredient in Ameluz®, against copying by competitors expired on November 12, 2019. This patent family included U.S. Patent No. 6,559,183, which, prior to its expiration, served as a material, significant and possibly the only barrier to entry into the U.S. market by generic versions of Ameluz®. Although the process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors, Patent No. 6,559,183 no longer prevents generic versions of Ameluz® from entering the U.S. market and competing with Ameluz®. If generic competitors do enter the market, this may cause a significant drop in the price of Ameluz® and, therefore, a significant drop in our profits. We may also lose significant U.S. market share for Ameluz®.

The Ameluz Licensor holds another patent family protecting the technology relating to nanoemulsions for which they have been issued patents in various jurisdictions and which expire in December 2027. A corresponding U.S. patent application has been filed by the Ameluz Licensor but is still pending. We cannot guarantee that this U.S. patent will be issued or, if issued, will adequately protect us against copying by competitors.

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.

Although the Ameluz Licensor has received marketing approval in the United States for Ameluz® for lesion- and field-directed treatment of actinic keratosis in combination with photodynamic therapy using the BF-RhodoLED® lamp series, there remains a significant risk that we will fail to generate sufficient revenue or otherwise successfully commercialize the product in the United States. The success of our product will depend on several factors, including:

- successful completion of further clinical trials by the Ameluz Licensor;
- receipt by the Ameluz Licensor of further regulatory approvals, including for the marketing of Ameluz® for additional indications;
- the contract manufacturing facility maintaining regulatory compliance;
- compliance with applicable law for our sales force and marketing efforts;
- the contract manufacturing facility manufacturing sufficient quantities in acceptable quality;
- the Ameluz Licensor sourcing sufficient quantities of raw materials used to manufacture our licensed products;
- continued acceptable safety and effectiveness profiles for our licensed products;
- the Ameluz Licensor obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- the Ameluz Licensor protecting its intellectual property rights.

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

Because the Ameluz Licensor received approval from the FDA to market in the United States Ameluz® in combination with photodynamic therapy using the BF-RhodoLED® lamp, any new lamp we may license would require new approval from the FDA. We cannot assure you that the Biofrontera Group will develop any new lamps (beyond the BF-RhodoLED® XL lamp which was approved by the FDA on October 21, 2021) or obtain any such new approval.

The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer to manufacture Ameluz® and has 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.

Pursuant to the Ameluz LSA, the Ameluz Licensor supplies us with Ameluz®. The Ameluz Licensor currently depends on a single unaffiliated contract manufacturer located in Switzerland to manufacture Ameluz®, Glaropharm AG, and has signed an agreement with a second unaffiliated contract manufacturer located in Germany, Pharbil Waltrop GmbH, to begin to supply it with Ameluz® to ensure stability of the supply chain. If the Ameluz Licensor fails to maintain its relationships with both of these manufacturers or if the Ameluz Licensor fails to maintain its relationship with its current manufacturer and the second manufacturer has not yet completed the necessary steps to begin manufacturing Ameluz®, the Ameluz Licensor may be unable to obtain an alternative manufacturer of Ameluz® that could deliver the quantity of the product at the quality and cost levels that we require. Even if an acceptable alternative manufacturer could be found, we would expect long delays in transitioning the manufacturing from the existing manufacturer to a new manufacturer. Problems of this kind could cause us to experience order cancellations and loss of market share. The failure of either manufacturer to supply the Ameluz Licensor with Ameluz® that satisfies quality, quantity and cost requirements in a timely manner could impair our ability to deliver Ameluz® to the U.S. market and could increase costs, particularly if the Ameluz Licensor is unable to obtain Ameluz® from alternative sources on a timely basis or on commercially reasonable terms. In addition, each manufacturer is regulated by the country in which it is located and by the FDA and must comply with applicable laws and regulations. Finding a suitable replacement of these particular partners would therefore be extremely difficult for the Ameluz Licensor. If the Ameluz Licensor lost these manufacturers, this could have a material adverse effect on our business, prospects, financial condition and/or results of operations. If the suppliers fail to comply, this could harm our business.

If our Licensor 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.

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

Furthermore, while our Licensors take reasonable precautions to ensure the successful production of our commercially licensed products, their contract manufacturers may experience a myriad of business difficulties (i.e., workforce instability, supply chain issues, erosion of customer base, etc.) that could impact their financial solvency. Ferrer's manufacturer of Xepi® (Teligent, Inc.) filed for Chapter 11 bankruptcy on October 14, 2021, and on February 23, 2022 Teligent, Inc. filed a motion to convert their bankruptcy into a Chapter 7 liquidation. Ferrer is in the process of qualifying a new third-party manufacturer in North America. The process will require significant time and expense, including the time it will take the new contract manufacturer to reach a level of production to meet our commercial needs. Although we have inventory of Xepi® on hand, we do not expect it will be enough to complete the commercialization of Xepi® in accordance with the originally planned timeline. If there are any significant delays to, or changes in, our plans for the completion of the commercialization of Xepi®, this could have a material adverse effect on our business, prospects, financial condition and/or results of operations. See "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Key factors affecting our performance — Supply Chain*" in this Form 10-K.

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

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

In addition, we are subject to regulations in various jurisdictions, including the Federal Drug Quality and Security Act and the Drug Supply Chain Security Act in the United States, which require us to develop electronic systems to serialize, track, trace and authenticate units of our licensed products through the supply chain and distribution system. Compliance with these regulations may result in increased expenses for our company or impose greater administrative burdens on our organization, and failure to meet these requirements could result in fines or other penalties.

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

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

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

In addition, the patent applications that they own may fail to result in issued patents in the United States. Even if the patents do successfully issue, third parties may challenge the validity, enforceability or scope thereof, which may result in such patents being narrowed, invalidated or held unenforceable. Furthermore, even if they are unchallenged, their patents and patent applications may not adequately protect their intellectual property or prevent others from designing around their claims. If the breadth or strength of protection provided by the issued patents and patent applications our Licensors hold with respect to our licensed products is threatened, it could threaten our ability to commercialize our licensed products. Further, if our Licensors encounter delays in their clinical trials, the period of time during which we could market our licensed products under patent protection would be reduced. Since patent applications in the United States are confidential for a period of time after filing, we cannot be certain that our Licensors were the first to file any patent application related to the products we license. Furthermore, for applications in which all claims are entitled to a priority date before March 16, 2013, an interference proceeding can be provoked by a third party or instituted by the U.S. Patent and Trademark Office, or USPTO, to determine who was the first to invent any of the subject matter covered by the patent claims of our applications. For applications containing a claim not entitled to priority before March 16, 2013, there is greater level of uncertainty in the patent law with the passage of the America Invents Act (2012) which brings into effect significant changes to the U.S. patent laws that are yet untried and untested, and which introduces new procedures for challenging pending patent applications and issued patents. A primary change under this reform is creating a "first to file" system in the United States. This will require us to be cognizant going forward of the time from invention to filing of a patent application.

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

Third party claims of intellectual property infringement may affect our ability to sell our licensed products and may also prevent or delay our Licensors' product discovery and development efforts.

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

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

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

In March 2018, DUSA Pharmaceuticals, Inc., or DUSA, brought a lawsuit against Biofrontera AG and its subsidiaries, including us, before the District Court of Massachusetts (18-cv-10568-RGS) alleging patent infringement and other claims related to sales practices.

On November 29, 2021, before the trial began, we entered into a confidential settlement and release agreement with the respect to the DUSA Litigation with DUSA. See "*Commitments and Contingencies—Legal proceedings*" in Note 24 to the audited financial statements as of and for the years ended December 31, 2022 and 2021 as included in this Form 10-K

While Biofrontera AG has agreed to pay a portion of the settlement, we remain jointly and severally liable to DUSA for the full settlement amount, meaning that in the event Biofrontera AG does not pay all or a portion of the amount it owes under the Agreement, DUSA could compel us to pay Biofrontera AG's share. If either we or Biofrontera AG violates the terms of the settlement agreement, this could nullify certain aspects of the settlement and we may lose certain benefits of the settlement and be liable for a greater amount. If we become liable for more than our agreed share of the aggregate settlement amount, either of these events could have a material adverse effect on our business, prospects, financial condition and/or results of operations. As of December 31, 2022, the Company has a receivable of $6.4 million due from Biofrontera AG for its share of the settlement amount.

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.

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

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

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

The trade secrets of our Licensors are difficult to protect.

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

Our success depends upon the skills, knowledge and experience of our Licensors' scientific and technical personnel, consultants and advisors as well as our partners, Licensors and contractors. Because drug development is a highly competitive technical field, our Licensors may rely in part on trade secrets to protect their proprietary technology and processes. However, trade secrets are difficult to protect. We enter into confidentiality agreements with our Licensors, corporate partners, employees, consultants and other advisors. These agreements typically require that the receiving party keep confidential and not disclose to third parties all confidential information developed by the receiving party or made known to the receiving party during the course of the receiving party's relationship.

Our Licensors' trade secrets also could be independently discovered by their competitors, in which case, they would not be able to prevent use of such trade secrets by their competitors. The enforcement of a claim alleging that a party illegally obtained and was using our trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. There exists a risk that we or our Licensors may not be able to detect when misappropriation of trade secrets has occurred or where a third party is using such trade secrets without our or their knowledge. The failure to obtain or maintain meaningful trade secret protection could adversely affect the competitive position of our licensed products.

Our subsidiary and certain third-party employees and our licensed patents are subject to foreign laws.

All employees of our wholly owned subsidiary, Bio-FRI GmbH, and a majority of the employees of Biofrontera AG, the parent company of the Ameluz Licensor, work in Germany and are subject to German employment law. Ideas, developments, discoveries and inventions made by such employees and consultants are subject to the provisions of the German Act on Employees' Inventions, which regulates the ownership of, and compensation for, inventions made by employees. We face the risk that disputes can occur between Biofrontera AG and its employees or former employees pertaining to alleged non-adherence to the provisions of this act that may impact our license depending on whether Biofrontera AG prevails or fails in any such dispute. There is a risk that the compensation Biofrontera AG provided to employees who assign patents to them may be deemed to be insufficient and Biofrontera AG may be required under German law to increase the compensation due to such employees for the use of the patents. In those cases where employees have not assigned their interests to Biofrontera AG, Biofrontera AG may need to pay compensation for the use of those patents. If Biofrontera AG is required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, the impact on our license could adversely affect our results of operations.

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

Our operating results may be affected by volatility in currency exchange rates and our ability to effectively manage our currency transaction risks. In general, we conduct our business with our Licensors and any third-party vendors in the local currency of the country in which such licensor or vendor operates. We do not manage our foreign currency exposure in a manner that would eliminate the effects of changes in foreign exchange rates. Therefore, changes in exchange rates between these foreign currencies, the dollar and the euro will affect our selling, general and administrative, related party, and the recorded levels of assets and liabilities held in a foreign currency and could result in exchange losses in any given reporting period.

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

Risks Related to Our Business and Strategy

The COVID-19 global pandemic still affects our business and presents new challenges.

Since the beginning of 2020, COVID-19 has become a global pandemic. As a result of the measures implemented by governments around the world, our business operations have been directly affected. In particular, we experienced a significant decline in demand for our licensed products as a result of different priorities for medical treatments emerging, thereby causing a delay of actinic keratosis treatment for most patients. Our revenue was directly affected by the global COVID-19 pandemic starting in mid-March of 2020. From that point on, rising infection rates and the resulting American Academy of Dermatology's official recommendation to care for patients through remote diagnosis and treatment (telehealth) led to significantly declining patient numbers and widespread, albeit temporary, physician practice closures. As COVID-19 vaccines started to roll-out to the general public in March 2021, we experienced an increase in patients willing to undergo treatment for actinic keratosis. In the fourth quarter of 2021 continuing through 2022, we again saw a seasonally strong increase in sales, indicating a revenue recovery from the global COVID-19 pandemic. We are optimistic that our business will continue to thrive throughout 2023 as a result of the COVID-19 PHE sunsetting on May 11, 2023. However, the ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, including the effectiveness of vaccination and booster vaccination campaigns, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will continue to be affected. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19 and variants thereof.

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.

We do not own or operate manufacturing facilities for clinical or commercial manufacture of any of our licensed products. We outsource all manufacturing and packaging of our licensed products to our Licensors, who may in turn contract with third parties to provide these services. We have no direct control over the manufacturing process of our licensed products. This lack of control may increase quality or reliability risks and could limit our ability to quickly increase or decrease production rates. See *"—If our Licensors' manufacturing partners 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"* for more information on the risks related to the manufacture of our licensed products. Although under the Ameluz LSA we are entitled to enter into a direct agreement with the Ameluz Licensor's supplier under certain circumstances, this is only with respect to the indications that the Ameluz Licensor is currently seeking from the FDA (as well as certain other clinical studies identified in the Ameluz LSA) and there is no guarantee that we will be able to do so under terms similar to the Ameluz Licensor's existing agreement or without delays or difficulties, each of which could have an adverse impact on our business or results of operations.

We currently do not have the ability to conduct any clinical trials. Under the Ameluz LSA and the Xepi LSA, our Licensors' control clinical development as well as the regulatory approval process for our licensed products. Our lack of control over the clinical development and regulatory approval process for our licensed products could result in delays or difficulties in the commercialization of our licensed products and/or affect the development of future indications for our licensed products. Although under the Ameluz LSA we are entitled to take over clinical trial and regulatory work under certain circumstances with respect to the indications that the Ameluz Licensor is currently seeking from the FDA (as well as certain other clinical studies identified in the Ameluz LSA) and subtract the cost of the trials from the transfer price of Ameluz®, there is no guarantee that we will be able to do so without delays or difficulties that could have an adverse impact on our business or results of operations and we do not have that right with respect to indications for Ameluz® that we may desire the Ameluz Licensor to pursue in the future.

In addition, under the Ameluz LSA and the Xepi LSA, we are not obligated or tasked with the duty to defend the intellectual property related to our licensed products and rely on our Licensors to defend the relevant intellectual property. This lack of control may increase the litigation risks and could limit our ability to utilize the relevant intellectual property. See *"—If our Licensors' efforts to protect the proprietary nature of their intellectual property related to our licensed products are not adequate, we may not be able to compete effectively in our market"* for more information on the risks related to the defense of the intellectual property related to our licensed products.

Biofrontera AG is a significant stockholder of the Company and, as a result of its control of the manufacture, clinical development and regulatory approval of Ameluz® may exert greater influence on the Company relative to the percentage of its ownership of the Company's outstanding common stock. See *"—Risks Related to Our Securities and Ownership of Our Common Stock— As of December 31, 2022, Biofrontera AG beneficially owns 30.0% of our stock after the completion of the initial public offering and will be able to exert significant control over matters subject to stockholder approval, and its interests may conflict with ours or other stockholders' in the future"* for more information on the risks related to Biofrontera AG's beneficial ownership of the Company's common stock.

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.

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

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

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

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

In the United States and certain other countries, there have been a number of legislative and regulatory changes to the health care system that could impact our ability to sell our licensed products profitably. In particular, the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 revised the payment methodology for many products under Medicare in the United States, which has resulted in lower rates of reimbursement. In March 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 the ("PPACA" or collectively, the "ACA"), was signed into law, which substantially changed the way healthcare is financed by both governmental and private insurers in the United States.

Since its enactment, there have been executive, judicial and Congressional challenges to certain aspects of the ACA, and we expect there will be additional challenges and amendments to the ACA in the future. On January 20, 2017, President Donald Trump signed an executive order stating that the administration intended to seek prompt repeal of the Affordable Care Act, and, pending repeal, directed by the U.S. Department of Health and Human Services and other executive departments and agencies to take all steps necessary to limit any fiscal or regulatory burdens of the Affordable Care Act. On January 28, 2021, President Joseph R. Biden, Jr. signed the Executive Order on Strengthening Medicaid and stated his administration's intentions to reverse the actions of his predecessor and strengthen the Affordable Care Act. As part of this Executive Order, the Department of Health and Human Services, United States Treasury, and the Department of Labor are to review all existing regulations, orders, guidance documents, policies, and agency actions to consider if they are consistent with ensuring both coverage under the Affordable Care Act and if they make high-quality healthcare affordable and accessible to Americans. On March 11, 2021, President Joseph R. Biden Jr. signed into law the American Rescue Plan Act of 2021 to further strengthen Medicaid and the ACA and on April 5, 2022, President Joseph R. Biden Jr. signed the Executive Order on Continuing to Strengthen Americans' Access to Affordable, Quality Health Coverage in which he celebrated the significant progress across the U.S. in making healthcare more affordable and accessible. In this Executive Order, President Joseph R. Biden Jr. directed agencies "with responsibilities related to Americans' access to health coverage" to "review agency actions to identify ways to continue to expand the availability of affordable health coverage." The continued expansion of the government's role in the U.S. healthcare industry may further lower rates of reimbursement for pharmaceutical products. While we are unable to predict the likelihood of changes to the Affordable Care Act or other healthcare laws which may negatively impact our profitability, we continue to closely monitor all changes.

President Biden intends, as his predecessor did, to take action against drug prices which are considered "high." The most likely time to address this would be in the reauthorization of the Prescription Drug User Fee Act ("PDUFA") in 2022 as part of a package bill. Drug pricing continues to be a subject of debate at the executive and legislative levels of U.S. government. The American Rescue Plan Act of 2021 signed into law by President Biden on March 14, 2021 includes a provision that will eliminate the statutory cap on rebates drug manufacturers pay to Medicaid beginning in January 2024. With the elimination of the cap, manufacturers may be required to compensate states in an amount greater than what the state Medicaid programs pay for the drug. Additionally, the Inflation Reduction Act of 2022 contains substantial drug pricing reforms, including the establishment of a drug price negotiation program within the U.S. Department of Health and Human Services that would require manufacturers to charge a negotiated "maximum fair price" for certain selected drugs or pay an excise tax for noncompliance, the establishment of rebate payment requirements on manufacturers of certain drugs payable under Medicare Parts B and D to penalize price increases that outpace inflation, and requires manufacturers to provide discounts on Part D drugs. Substantial penalties can be assessed for noncompliance with the drug pricing provisions in the Inflation Reduction Act of 2022. The Inflation Reduction Act of 2022 could have the effect of reducing the prices we can charge and reimbursement we receive for our products, if approved, thereby reducing our profitability, and could have a material adverse effect on our financial condition, results of operations and growth prospects. The effect of Inflation Reduction Act of 2022 on our business and the pharmaceutical industry in general is not yet known.

Following the passage of the Inflation Reduction Act of 2022, President Biden signed The Executive Order on Lowering Prescription Drug Costs for Americans, effective October 14, 2022. This Executive Order is intended to drive down prescription drug costs and attempts to make use of HHS's Center for Medicare and Medicaid Innovation ("Innovation Center"). The Innovation Center tests health care payment and delivery models with the goal of improving health care quality and ensuring the efficiency of health care delivery. This Executive Order further requires that HHS consider utilizing the Innovation Center's testing to identify payment and delivery models that would "lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in Medicare and Medicaid programs, including models that may lead to lower cost-sharing for commonly used drugs and support value-based payment that promotes high-quality care."

At the state level, legislatures have increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

We expect that additional federal, state and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures. Additionally, third-party payors, including governmental payors, managed care organizations and private health insurers, are increasingly challenging the prices charged for medical products and services and examining their cost effectiveness. The continuing efforts of governments, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare and/or impose price controls may adversely affect:

- the demand for our licensed products,
- if our Licensors obtain regulatory approvals;
- our ability to set a price or obtain reimbursement that we believe is fair for our licensed products;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

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

To date, we have a relatively short history of sales of our licensed products in the United States.

We have limited relatively short history of sales of our licensed products to date. The Biofrontera Group, including Biofrontera as a wholly owned subsidiary of Biofrontera AG at the time, launched the commercialization of Ameluz® and the RhodoLED® lamp for actinic keratosis in the United States in October 2016 and we have a limited history of marketing our licensed products in the United States. In addition, we began marketing the drug Xepi® in the United States following our acquisition of Cutanea in March 2019 and have a limited history of marketing Xepi® in the United States. While our licensed products have gained acceptance in the markets we serve, our licensed products may never generate substantial revenue or profits for us. We must establish a larger market for our licensed products and build that market through marketing campaigns to increase awareness of, and confidence by doctors in, our licensed products. We expect this to continue to be even more challenging in the near term as a result of current measures and regulations implemented by governments worldwide in an attempt to control the COVID-19 pandemic, which may lead to declining demand in some of our markets in the foreseeable future for our licensed products as different priorities for medical treatments emerge, thereby causing a delay of actinic keratosis treatment for most patients. If we are unable to expand our current customer base and obtain market acceptance of our licensed products, our operations could be disrupted and our business may be materially adversely affected. Even if we achieve profitability, we may not be able to sustain or increase profitability.

Competing products and future emerging products may erode sales of our licensed products.

Reimbursement issues affect the economic competitiveness of our licensed products as compared to other therapies. See "*—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*."

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

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

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

We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

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

Our competitors may succeed in developing, acquiring or licensing products that are more effective or less costly than our licensed products and product candidates. In addition, our licensed products compete with other therapies, such as simple curettage and, particularly in the United States, cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

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

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

In order to grow the market for our licensed products, especially a newer licensed product like Xepi®, we must continue to build our marketing, sales and distribution capabilities in the United States. The development and training of our sales force and related compliance plans to market our licensed products are expensive and time consuming and can potentially delay the growth of sales of our licensed products. In the event we are not successful in expanding our marketing and sales infrastructure, we may not be able to successfully grow the market our licensed products, which would limit our revenue growth.

The U.S. market size for Ameluz® for the treatment of actinic keratosis may be smaller than we have estimated.

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

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

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

Even if our Licensors obtain regulatory approvals for our licensed products, or approvals extending their indications, they may not gain market acceptance or become widely accepted among hospitals, physicians, health care payors, patients and others in the medical community.

In May 2016, Biofrontera Bioscience received approval from the FDA to market in the United States. Ameluz® in combination with photodynamic therapy using the BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We launched the commercialization of Ameluz® and the BF-RhodoLED® lamp for actinic keratosis in the United States in October 2016. Even with regulatory approval, Ameluz® may not receive wide acceptance among hospitals, physicians, health care payors, patients and others in the medical community. In addition, Xepi® received approval from the FDA in 2017 and may not gain market acceptance over time. Market acceptance of any of our licensed products depends on a number of factors, including:

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

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

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

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

Increased Health and Human Services, Office of Inspector General (OIG), scrutiny on the sale of products through specialty pharmacies or through physician practices by means of direct investigation or by issuance of unfavorable Opinion Letters which may curtail or hinder the sales of our licensed products based on risk of enforcement upon ourselves or our buyers. The OIG continues to make modifications to existing Anti-Kickback Statute, or AKS, safe harbors which may increase liability and risk for our company as well as adversely impact sales relationships. On November 20, 2020, OIG issued the final rule for Safe Harbors under the Federal AKS. This new final rule creates additional safe harbors including ones pertaining to patient incentives. OIG is able to modify safe harbors as well as regulatory compliance requirements which could impact out business adversely.

The majority of states also have statutes or regulations similar to these federal laws, which apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payer. In addition, some states have laws that require pharmaceutical companies to adopt comprehensive compliance programs. Certain states also mandate the tracking and require reporting of gifts, compensation, and other remuneration paid by us to physicians and other health care providers.

In September 2010, OIG issued a Special Advisory Bulletin to notify drug manufacturers that OIG intended to pursue enforcement actions against drug manufacturers that failed to submit timely average manufacturer price, or AMP, and average sales price, or ASP, information. The Medicaid Drug Rebate Program requires manufacturers to enter into and have in effect a national rebate agreement with the Secretary of Health and Human Services in order for Medicaid payments to be available for the manufacturer's covered outpatient drugs. Companies with such rebate agreements are required to submit certain drug pricing information to CMS, including quarterly and monthly pricing data. There has been an increased level of federal enforcement against drug manufacturers that have failed to provide timely and accurate pricing information to the government. Since September 2010, OIG has settled 13 cases against drug manufacturers relating to drug price reporting issues, totaling approximately $18.5 million. We expect continued enforcement directed at companies that fail to make accurate and timely price reports. If we were found to make the required pricing disclosures, we could incur significant expense and delay.

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

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

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

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

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

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

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

We are working to commercialize a new lamp, the "RhodoLED® XL," which was approved by the FDA on October 21, 2021 and allows use of Ameluz® on more distant Actinic Keratosis lesions. Management believes that this new lamp, could provide new business growth opportunities for our company. In the United States, according to FDA guidance, products for PDT, such as Ameluz® gel and its corresponding lamp(s), must be approved as combination products that cover both the drug and the lamp. In May 2016, the Biofrontera Group (which included Biofrontera prior to our initial public offering) received approval from the FDA to market in the United States Ameluz® in combination with photodynamic therapy using the BF-RhodoLED® lamp for lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. The applicable office of the FDA has determined that if the Ameluz Licensor develops a new lamp to be used with Ameluz®, beyond the existing approved RhodoLED® lamp series, the Ameluz Licensor must seek a new approval utilizing the "New Drug Application" procedure. As part of a drug/device combination, the lamp is by definition classified as a class III medical device and as such requires a premarket approval, or PMA, by the FDA. A new lamp will also require changes in the "Prescribing Information" of the drug. If the Ameluz Licensor develops this new lamp, once the Ameluz Licensor's PMA application is submitted to the FDA as part of this approval process, it may take more than six months, plus, if needed, time required to answer questions or provide additional data. Prior to submission, the Ameluz Licensor will need to perform final tests on the lamp prototype, including technical tests by a certified laboratory and a usability study. During the process, there is a risk that the FDA might ask for additional tests or even clinical trials, and there is no assurance that the Ameluz Licensor will be able to satisfy the FDA's requests for additional tests or trials in a timely manner, or at all, and there is no assurance that the Ameluz Licensor will be able to develop this new lamp, or obtain approval to use it in the United States for PDT treatment of actinic keratosis in combination with Ameluz®.

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

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

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

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

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

As a result of our current IT infrastructure and German-based subsidiary, we are subject to governmental regulation and other legal obligations in the EU and European Economic Area, or EEA, related to privacy, data protection and data security and, as a result of our sales in California, the California Consumer Privacy Act (CCPA). Our actual or perceived failure to comply with such obligations could harm our business.

We are subject to diverse laws and regulations relating to data privacy and security in the EU and eventually in the EEA, including Regulation 2016/679, known as the GDPR. The GDPR applies extraterritorially and implements stringent operational requirements for controllers and processors of personal data. New global privacy rules are being enacted and existing ones are being updated and strengthened. We are likely to be required to expend capital and other resources to ensure ongoing compliance with these laws and regulations.

Complying with these numerous, complex and often changing regulations is expensive and difficult. Failure by us, any partners, our service providers, or our employees or contractors to comply with the GDPR could result in regulatory investigations, enforcement notices and/or fines of up to the higher of €20 million or up to 4% of our total worldwide annual revenue. In addition to the foregoing, a breach of privacy laws or data security laws, particularly those resulting in a significant security incident or breach involving the misappropriation, loss or other unauthorized use or disclosure of sensitive or confidential patient or consumer information, could have a material adverse effect on our business, reputation and financial condition.

As a data controller, we are accountable for any third-party service providers we engage to process personal data on our behalf. We attempt to mitigate the associated risks by performing security assessments and due diligence of our vendors and requiring all such third-party providers with data access to sign agreements and obligating them to only process data according to our instructions and to take sufficient security measures to protect such data. There is no assurance that these contractual measures and our own privacy and security-related safeguards will protect us from the risks associated with the third-party processing, storage and transmission of such information. Any violation of data or security laws by our third-party processors could have a material adverse effect on our business and result in the fines and penalties outlined above.

Where we transfer personal data of EU citizens or anyone residing in the EU out of the EU and EEA, we do so in compliance with the relevant data export requirements from time to time. There is currently ongoing litigation challenging the commonly used transfer mechanism, the EU Commission approved model clauses. On July 16, 2020, the Court of Justice of the European Union, or CJEU, issued a judgment which annulled, without granting a grace or transition period, the European Commission's Decision (EU) 2016/1250 of July 12, 2016 on the adequacy of the protection provided by the U.S. Privacy Shield (a mechanism for complying with data protection requirements when transferring personal data from the EU to the United States). Accordingly, such framework is not a valid mechanism to comply with EU data protection requirements when transferring personal data from the European Union to the United States. To the extent that we were to rely on the EU-U.S. Privacy Shield Framework, we will not be able to do so in the future, which could increase our costs and limit our ability to process personal data from the EU. The same decision also cast doubt on the viability of one of the primary alternatives to the U.S. Privacy Shield, namely, the European Commission's Standard Contractual Clauses, as a vehicle for such transfers in all circumstances. Use of the standard contractual clauses must now be assessed on a case-by-case basis taking into account the legal regime applicable in the destination country, in particular applicable surveillance laws and rights of individuals and additional measures and/or contractual provisions may need to be put in place, however, the nature of these additional measures is currently uncertain. The CJEU went on to state that if a competent supervisory authority believes that the Standard Contractual Clauses cannot be complied with in the destination country and the required level of protection cannot be secured by other means, such supervisory authority is under an obligation to suspend or prohibit that transfer. At present, there are few, if any, viable alternatives to the Standard Contractual Clauses, and the law in this area remains dynamic. These changes may require us to find alternative bases for the compliant transfer of personal data outside the EEA and we are monitoring developments in this area.

The GDPR is directly applicable in each EU Member State, however, it provides that EU Member States may introduce further conditions, including limitations which could limit our ability to collect, use and share personal data (including health and medical information), or could cause our compliance costs to increase, ultimately having an adverse impact on our business. The GDPR imposes onerous accountability obligations requiring data controllers and processors to maintain a record of their data processing and implement policies as part of its mandated privacy governance framework. It also requires data controllers to be transparent and disclose to data subjects (in a concise, intelligible and easily accessible form) how their personal information is to be used, imposes limitations on retention of personal data; defines for the first time pseudonymized (*i.e.*, key-coded) data; introduces mandatory data breach notification requirements; and sets higher standards for data controllers to demonstrate that they have obtained valid consent for certain data processing activities. In addition to the foregoing, a breach of the GDPR could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm.

On January 1, 2020, California enacted the California Consumer Privacy Act, or CCPA, which, among other things, requires new disclosures to California consumers and affords such consumers new abilities to opt out of certain sales of personal information. This Act also applies to any information of certain patients that a drug company may possess. It remains unclear what, if any, modifications will be made to this legislation or how it will be interpreted in the years to come. The effects of the CCPA potentially are significant, however, and may require us to modify our data processing practices and policies and to incur substantial costs and expenses in an effort to comply. As a general matter, compliance with laws, regulations, and any applicable rules or guidance from self-regulatory organizations relating to privacy, data protection, information security and consumer protection, may result in substantial costs and may necessitate changes to our business practices, which may compromise our growth strategy, adversely affect our ability to acquire customers, and otherwise adversely affect our business, financial condition and operating results. Noncompliance with CCPA could result in regulatory investigations, reputational damage, orders to cease/change our use of data, enforcement notices, as well potential civil claims including class action type litigation where individuals suffer harm. Since its enactment, four (4) additional states – Colorado, Connecticut, Utah, and Virginia – have enacted comprehensive consumer data privacy laws similar to the CCPA, indicating a potential trend that may continue to spread across the U.S.

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

Our ability to compete in the highly competitive pharmaceutical industry depends upon our ability to attract and retain highly qualified managerial, scientific and medical personnel with specialized scientific and technical skills. We are highly dependent on our management, scientific, medical and operations personnel, including Erica Monaco, our Chief Executive Officer, Prof. Dr. Hermann L✔bbert, our Executive Chairman and Fred Leffler, our Chief Financial Officer. The loss of the services of any of our executive officers or other key employees and our inability to find suitable replacements could potentially harm our business, prospects, financial condition or results of operations.

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

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

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

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards we have established, comply with healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices in the United States as well as in any other jurisdictions where we conduct our business. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions, inability to obtain product approval and serious harm to our reputation. It is not always possible to identify and deter employee misconduct, and any precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

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

As of December 31, 2022, we had 81 employees. In the longer term, as our development and commercialization plans and strategies develop, and as we continue operating as a public company, we expect to need additional managerial, operational, sales, marketing, financial and other personnel. Future growth would impose significant added responsibilities on members of management, including:

- identifying, recruiting, integrating, maintaining and motivating existing or additional employees; and
- improving our operational, financial and management controls, reporting systems and procedures.

Our future financial performance and our ability to commercialize and market our licensed products will depend, in part, on our ability to effectively manage any future growth, and our management may also have to divert a disproportionate amount of its attention away from day-to-day activities in order to devote a substantial amount of time to managing these growth activities. If we are not able to effectively expand our organization by hiring new employees and expanding our groups of consultants and contractors, we may not be able to successfully implement the tasks necessary to commercialize our licensed products and, accordingly, may not achieve our commercialization goals.

Due to our ongoing assessment of the size of the required sales force, we may be required to hire substantially more sales representatives to adequately support the commercialization and marketing of our licensed products or we may incur excess costs as a result of hiring more sales representatives than necessary. We may be competing with companies that currently have extensive and well-funded marketing and sales operations.

Our business and operations would suffer in the event of system failures, cyber-attacks or a deficiency in our cyber-security.

Despite the implementation of security measures, our internal computer systems and those of our current and future contract and research organizations, or CROs, and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. The risk of a security breach or disruption, particularly through cyber-attacks or cyber-intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity and sophistication of attempted attacks and intrusions from around the world have increased. While we have not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our licensed products and product candidates could be delayed.

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

We face an inherent risk of product liability as a result of the clinical testing of our licensed products and face an even greater risk if we commercialize our licensed products on a larger scale. For example, we may be sued if our licensed products allegedly cause injury or are found to be otherwise unsuitable during clinical testing, manufacturing, marketing or sale. Any such product liability claims may include allegations of defects in manufacturing; defects in design; a failure to warn of dangers inherent in the product, negligence, strict liability; and a breach of warranties. Claims could also be asserted under state consumer protection acts. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our licensed products and product candidates. Even a successful defense would require significant financial and management resources. Regardless of the merits or eventual outcome, liability claims may result in:

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

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

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

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

Our licensed products will be subject to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties.

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

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

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

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

To the extent that such adverse actions impact our rights under our license and supply agreements or otherwise restrict our ability to market our licensed products, they could adversely impact our business and results of operation.

Generic manufacturers may launch products at risk of patent infringement.

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

Risks Related to Our Financial Position and Capital Requirements

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

We have incurred losses in each year since inception. Our net loss for the fiscal years ended December 31, 2022 and December 31, 2021 was $0.6 million and $37.7 million, respectively. As of December 31, 2022, we had an accumulated deficit of $79.5 million.

Our ability to become profitable depends on our ability to further commercialize our principal licensed product Ameluz®. Even if we are successful in increasing our licensed product sales, we may never achieve or sustain profitability. In the long term, we anticipate increasing our sales and marketing expense as we attempt to exploit the regulatory approvals to market Ameluz® in the United States for the photodynamic therapy treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. There can be no assurance that our sales and marketing efforts will generate sufficient sales to allow us to become profitable. Moreover, because of the numerous risks and uncertainties associated with commercializing pharmaceutical products, we are unable to predict the extent of any future losses or when we will become profitable, if ever.

We cannot rule out the possibility that we may engage in additional equity or debt financing in the future, which could dilute the voting rights of stockholders and the value of their shares. If we are unable to achieve profitability over time or to obtain additional equity or debt financing in such a scenario, this would have a material adverse effect on our financial condition.

If we fail to obtain additional financing, we may be unable to pursue our plans for strategic growth, including completing the commercialization of Xepi® and other products we may license.

Our operations have consumed substantial amounts of cash since inception. Going forward, we expect that we will require significant funds in order to pursue our plans for strategic growth, including completing the commercialization of the drug Xepi®, the rights to which we acquired in March 2019 through our purchase of Cutanea, and the subsequent merger of Biofrontera and Cutanea.

During the year ended December 31, 2022, we received an aggregate of $14 million, including $9.4 million from a private placement, net of issuance costs, and $4.6 million from warrants exercised for common stock. We believe with the funds available from these transactions and availability under a working capital line of credit, that we will have sufficient funds to support the operating, investing, and financing activities of the Company through at least twelve months from the date of the issuance of this Form 10-K. However, changing circumstances may cause us to consume capital significantly faster than currently anticipated, and we may need to spend more money than currently expected because of circumstances beyond our control. In addition, if we choose to take significant steps towards the realization during the current fiscal year of longer-term goals for our strategic growth, we may need to raise additional capital through debt or equity financing in order to complete those steps during the current fiscal year. Our future funding requirements, both near- and long-term, will depend on many factors, including, but not limited to:

- the effects of competing technological and market developments;
- the cost and timing of completion of commercial-scale manufacturing activities;
- the cost of establishing or maintaining sales, marketing and distribution capabilities for Ameluz® photodynamic therapy or other licensed products or potential products in the United States; and
- the impact of COVID-19 on our licensor's clinical trials, the timing of regulatory approvals obtained by our Licensors, demand for our licensed products, our ability to market and sell our licensed products and other matters.

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

Any of the above events could prevent us from realizing business opportunities or prevent us from growing our business or responding to competitive pressures, which could have a material adverse effect on our business, prospects, financial condition and/or results of operations and could cause the price of our shares to decline.

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

Under the Share Purchase and Transfer Agreement dated March 25, 2019 (as amended, the "Share Purchase Agreement"), by and among Biofrontera Newderm LLC, Biofrontera AG, Maruho Co., Ltd. and Cutanea, pursuant to which Biofrontera Newderm Inc. LLC, a wholly owned subsidiary of Biofrontera Inc., acquired Cutanea from Maruho Co., Ltd., we are required to repay to Maruho Co., Ltd., $3.6 million on December 31, 2022 and $3.7 million on December 31, 2023 in start-up costs that Maruho Co., Ltd. paid to us, in connection with such acquisition (not to exceed $7.3 million in the aggregate).

We have filed for arbitration against Maruho with the International Chamber of Commerce ("ICC") regarding issues with Maruho's contract manufacturer that were not disclosed at the time of the Agreement and therefore are evaluating the repayment of the $7.3 million of start-up costs. The arbitration notes that Maruho breached the agreement with Cutanea due to the undisclosed manufacturing issues and seeks damages as well as a declaration that we are not obligated to repay Maruho

In addition, on March 9, 2023, we entered into a commitment letter (the "Commitment Letter") with MidCap Business Credit LLC ("MidCap"), in respect of MidCap's commitment to provide us with a senior secured asset based revolving line of credit, subject to the borrowing base formula, minimum excess availability and other terms and conditions thereof, in the aggregate principal amount of up to $6.5 million (the "Revolving Facility"). The Revolving Facility shall be secured by a lien on substantially all of the assets of the Company, subject to customary exceptions. For additional details regarding the Revolving Facility see *Item 9.B. Other Information* in this Form 10-K. Entry into the Revolving Facility will be subject to customary closing conditions, including the execution and delivery of appropriate definitive documentation related to the Revolving Facility, to include customary representations, warranties, covenants, events of default and other terms and conditions, and there can be no assurance that such closing conditions will be satisfied or that the Revolving Facility will be entered into prior to the expiration of MidCap's commitment or at all.

Our indebtedness could have significant adverse consequences, including:

- requiring us to dedicate a portion of our cash to the payment of interest and principal, reducing money available for working capital, capital expenditure, product development and other general corporate purposes;
- increasing our vulnerability to adverse changes in general economic, industry and market conditions;
- increasing the risk of dilution to the holders of our shares in the event any of these bonds are exercised for or converted into our ordinary shares;
- limiting our flexibility in planning for, or reacting to, changes in our business and the industry in which we compete, including changes arising as a result of the COVID-19 pandemic; and
- placing us at a competitive disadvantage to competitors that are better capitalized than we are.

We may not have sufficient funds and may be unable to arrange for additional financing to pay the amounts due under our existing debt obligation to Maruho Co. Ltd. under the terms of such Share Purchase Agreement, and which must be repaid if certain profits from the sale of Cutanea products the Biofrontera Group agreed to share with Maruho are less than the amount of such start-up costs.

We may also engage in debt financing in the future. Failure to make payments or comply with covenants under such debt could result in an event of default and acceleration of amounts due. If an event of default occurs and the lender or lenders accelerate the amounts due, we may not be able to make accelerated payments, and such lenders could file suit against us to collect the amounts due under such obligations or pursue other remedies. In addition, the covenants under such debt obligations could limit our ability to obtain additional debt financing. If we are unable to satisfy such debt obligations it could have material adverse effect on our business, prospects, financial condition and/or results of operations.

The valuation of our equity investments is subject to volatility.

The market valuation of our equity investments, especially as it relates to our investment in Biofrontera AG which is publicly traded, may experience substantial price volatility which, when accounted for under GAAP, could have a material adverse effect on our financial condition and results of operations. Refer to Note 6, *Investments in Equity Securities*, to our consolidated financial statements for information on our equity investments. As of December 31, 2022, our investment in Biofrontera AG, a foreign publicly held company and significant shareholder, had a balance of $10.5 million. Our shares of Biofrontera AG are carried in our consolidated balance sheets at fair value based on the closing price of the shares owned on the last trading day of the reporting period. Those investments can be negatively affected by market and economic factors including liquidity, credit deterioration, financial results, interest rate fluctuations, or other factors. Although we intend to liquidate our investment in Biofrontera AG within the next twelve months, we cannot guarantee that we will able to do so within that timeframe. As a result, as long as we hold these equity investments, future fluctuations in their value could result in significant losses and could have a material adverse impact on the Company's financial condition and results of operations.

Risks Related to Corporate Governance, Including Being a Public Company

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.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the audit of our financial statements as of and for the year ended December 31, 2021, we identified a material weakness in our internal control over financial reporting. The material weakness we identified pertains to management's review of work performed by specialists; as the Company's management review control over information provided to and produced by a third-party specialist was not sufficiently precise to identify errors in the valuation of an intangible asset. Specifically, as part of the initial valuation of an intangible asset in connection with the Cutanea acquisition we failed to identify a computational error within the valuation model for the Xepi® intangible asset. In addition, in 2021 an error in the valuation of the same intangible asset was identified relating to insufficient information being provided to the third-party specialist in connection with an impairment assessment.

We have taken steps to enhance our internal control environment and continue to address the underlying cause of the material weakness with the implementation of additional controls including those designed to strengthen our review and validation of the work product from third-party service providers. As of December 31, 2022, the steps we have taken to date were determined to be sufficient to remediate this material weakness. As a result, management has concluded that the material weakness was fully remediated as of December 31, 2022.

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 investor confidence in us and, as a result, our stock price.

We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management is required to devote substantial time to compliance with our public company responsibilities and corporate governance practices.

As a public company, and particularly after we are no longer an "emerging growth company," we have incurred and will continue to incur significant legal, accounting and other expenses that we did not incur as a private company. The Sarbanes-Oxley Act of 2002, or the Sarbanes Oxley Act, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of Nasdaq, and other applicable securities rules and regulations impose various requirements on public companies. Our management and other personnel will need to devote a substantial amount of time to compliance with these requirements. Moreover, these rules and regulations will increase our legal and financial compliance costs and will make some activities more time-consuming and costly. If, notwithstanding our efforts to comply with new or changing laws, regulations and standards, we fail to comply, regulatory authorities may initiate legal proceedings against us, and our business may be harmed. Further, failure to comply with these laws, regulations and standards may make it more difficult and more expensive for us to obtain directors' and officers' liability insurance, which could make it more difficult for us to attract and retain qualified members to serve on our board of directors or committees or as members of senior management. We cannot predict or estimate the amount of additional costs we will incur as a public company or the timing of such costs.

As a result of becoming a public company, we are obligated to develop and maintain proper and effective internal control over financial reporting and any failure to maintain the adequacy of these internal controls may adversely affect investor confidence in our company and, as a result, the value of our common stock.

We will be required, pursuant to Section 404 of the Sarbanes Oxley Act, or Section 404, to furnish a report by management on, among other things, the effectiveness of our internal controls over financial reporting for the fiscal year ended December 31, 2022. This assessment will need to include disclosure of any material weaknesses identified by our management in our internal controls over financial reporting. Our independent registered public accounting firm will not be required to attest to the effectiveness of our internal controls over financial reporting until our first annual report required to be filed with the SEC following the date we are no longer an emerging growth company, as defined in the JOBS Act. At such time as we are required to obtain auditor attestation, if we then have a material weakness, we would receive an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm. We will be required to disclose significant changes made in our internal control procedures on a quarterly basis.

We have already begun the process of compiling the system and processing documentation necessary to perform the evaluation needed to comply with Section 404 and anticipate we will be able to complete our evaluation, testing and any required remediation in a timely fashion. Our compliance with Section 404 will require that we incur additional legal, accounting and other compliance expense and expend significant management efforts. We currently do not have an internal audit group, and although we have accounting and finance staff with appropriate public company experience and technical accounting knowledge, we may need to hire additional consultants or staff to perform the evaluation needed to comply with Section 404.

During the evaluation and testing process of our internal controls, if we identify one or more material weaknesses in our internal control over financial reporting, we will be unable to assert that our internal control over financial reporting are effective. For example, in connection with the audits of our financial statements as of and for the years ended December 31, 2021 and 2020, we identified a material weakness in our internal control over financial reporting. See "*—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.*"

We cannot assure you that the measures we have taken to date, and are continuing to implement, will be sufficient to avoid additional material weaknesses or significant deficiencies in our internal controls over financial reporting in the future. Any failure to maintain effective internal controls over financial reporting could severely inhibit our ability to accurately report our financial condition or results of operations. If we are unable to conclude that our internal control over financial reporting is effective, or if our independent registered public accounting firm determines we have a material weakness or significant deficiency in our internal control over financial reporting, we could lose investor confidence in the accuracy and completeness of our financial reports, the market price of shares of our common stock could decline, and we could be subject to sanctions or investigations by Nasdaq, the SEC or other regulatory authorities. Failure to remedy any material weakness in our internal control over financial reporting, or to implement or maintain other effective control systems required of public companies, could also negatively impact our ability to access to the capital markets.

In addition, effective disclosure controls and procedures enable us to make timely and accurate disclosure of financial and non-financial information that we are required to disclose. As a public company, if our disclosure controls and procedures are ineffective, we may be unable to report our financial results or make other disclosures accurately on a timely basis, which could cause our reported financial results or other disclosures to be materially misstated and result in the loss of investor confidence and cause the market price of our securities.

We are an emerging growth company and a smaller reporting company and we cannot be certain if the reduced disclosure requirements applicable to emerging growth companies or smaller reporting companies will make our common stock less attractive to investors.

We are an "emerging growth company" as defined in the JOBS Act. 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 use this exemption from new or revised accounting standards and, therefore, we will not be subject to the same new or revised accounting standards as other public companies that have not made this election.

For as long as we continue to be an emerging growth company, we also intend to take advantage of certain other exemptions from various reporting requirements that are applicable to other public companies including, but not limited to, reduced disclosure obligations regarding executive compensation in our periodic reports and proxy statements, and exemptions from the requirements of holding a non-binding advisory vote on executive compensation and stockholder approval of any golden parachute payments not previously approved. We cannot predict if investors will find our common stock less attractive because we will rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

We will remain an emerging growth company until the earliest of (i) the last day of the fiscal year in which we have total annual gross revenue of $1.235 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the closing of our initial public offering; (iii) the date on which we have issued more than $1.0 billion in nonconvertible debt during the previous three fiscal years; or (iv) the date on which we are deemed to be a "large accelerated filer" under the rules of the SEC.

Additionally, we are a "smaller reporting company" as defined in Item 10(f)(1) of Regulation S-K. Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company," which would allow us to continue to take advantage of many of the same exemptions from disclosure requirements, including presenting only the two most recent fiscal years of audited financial statements and reduced disclosure obligations regarding executive compensation in this Form 10-K and our periodic reports and proxy statements. We will remain a smaller reporting company until the last day of the fiscal year in which (1) the market value of our shares of common stock held by non-affiliates exceeds $250 million as of the prior the end of our second fiscal quarter ending December 31st of each year, or (2) our annual revenues exceeded $100 million during such completed fiscal year and the market value of our ordinary shares held by non-affiliates exceeds $700 million as of the prior to the end of our second fiscal quarter ending December 31st of each year. To the extent we take advantage of such reduced disclosure obligations, it may also make comparison of our financial statements with other public companies difficult or impossible.

Risks Related to Our Securities and Ownership of Our Common Stock

As of December 31, 2022, Biofrontera AG beneficially owns 30.0% of our outstanding shares of common stock and will be able to exert significant control over matters subject to stockholder approval, and its interests may conflict with ours or other stockholders in the future.

As of December 31, 2022, Biofrontera AG beneficially owns in the aggregate approximately 30.0% of our outstanding voting stock and will continue to exert significant influence on the company. In addition, Biofrontera AG's beneficial ownership would be further reduced by the exercise of any of the 9,197,109 outstanding warrants issued in connection with our initial public offering and private placements. However, it would likely continue to have a significant portion (and perhaps even a majority) of the voting power in a shareholder meeting. As a result, Biofrontera AG will have the ability to significantly influence us through this ownership position. Biofrontera AG may be able to determine all matters requiring stockholder approval. For example, Biofrontera AG may be able to control elections of directors, amendments of our organizational documents, our financing and dividend policy and approval of any merger, sale of assets or other major corporate transaction. This may prevent or discourage unsolicited acquisition proposals or offers for our common stock that you may feel are in your best interest as one of our stockholders.

Moreover, because of the significant ownership position held by Biofrontera AG and our classified board structure, new investors may not be able to effect a change in the Company's business or management, and therefore, stockholders would be subject to decisions made by management and Biofrontera AG.

Biofrontera AG's interests may differ from our interests and the interests of our other stockholders, and therefore actions Biofrontera AG takes with respect to us, as a significant shareholder, including under the Ameluz LSA, may not be favorable to us or our public stockholders. For a discussion of the risks related to our license agreement with Biofrontera AG, see "*Risks Related to the License and Supply Agreements and Our Licensed Products*."

Furthermore, Biofrontera AG is a public company with a comparatively low amount of shares that are regularly traded and several shareholders who each hold a significant stake in Biofrontera AG. Any of these shareholders may exert their influence on Biofrontera AG by voting in favor of proposals that are in their individual interest or electing members to Biofrontera AG's supervisory board who could act to align Biofrontera AG's actions with the interests of such shareholders. Under German law, company management must obtain the consent of the supervisory board for certain actions. Since 2017, several legal actions have been filed by one of Biofrontera AG's significant shareholders opposing resolutions passed at the shareholders' meetings, including actions for annulment and rescission of resolutions related to financing transactions undertaken by Biofrontera AG and they could seek to cause Biofrontera AG to take actions as our significant shareholder that no longer support our strategy as set forth in this Form 10-K and may be contrary to the interests of our other stockholders.

If Biofrontera AG sells a controlling interest in our company to a third party in a private transaction, you may not realize any change-of-control premium on shares of our common stock and we may become subject to the control of a presently unknown third party.

Although Biofrontera AG holds less than the majority of the voting power of our common stock, it may still exert a controlling influence over us, since many shares of our common stock are held by retail investors who may not vote at shareholder meetings. The ability of Biofrontera AG to privately sell its shares of our common stock, with no requirement for a concurrent offer to be made to acquire all of the shares of our common stock held by our other stockholders, could prevent you from realizing any change-of-control premium on your shares of our common stock that may otherwise accrue to Biofrontera AG on its private sale of our common stock. Additionally, if Biofrontera AG privately sells its controlling equity interest in our company, we may become subject to the control of a presently unknown third party. Such third party may have conflicts of interest with those of other stockholders. In addition, if Biofrontera AG sells a controlling interest in our company to a third party, our indebtedness may be subject to acceleration, and our other commercial agreements and relationships, including any remaining agreements with Biofrontera AG, could be impacted, all of which may adversely affect our ability to run our business as described herein and may have a material adverse effect on our business, financial condition and results of operations.

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 and 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.

If we fail to regain compliance with applicable listing standards, our common stock and publicly-traded warrants could be delisted from Nasdaq.

Nasdaq requires listing issuers to comply with certain standards in order to remain listed on its exchange. If, for any reason, Nasdaq should delist our common stock from trading on its exchange and we are unable to obtain listing on another reputable national securities exchange, a reduction in some or all of the following may occur, each of which could materially adversely affect our stockholders:

- the liquidity and marketability of our common stock and/or publicly-traded warrants;
- the market price of our common stock;
- our ability to obtain financing for the continuation of our operations;
- the number of institutional and general investors that will consider investing in our common stock;
- the number of market makers in our common stock;
- the availability of information concerning the trading prices and volume of our common stock; and
- the number of broker-dealers willing to execute trades in shares of our common stock.

On February 24, 2023, we received a letter (the "Notice") from the Listing Qualifications Staff of the Nasdaq Stock Market, LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we are no longer in compliance with the requirement to maintain a minimum bid price of $1.00 per share for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2) . We were provided a compliance period of 180 calendar days from the date of the Notice, or until August 23, 2023, to regain compliance with the minimum closing bid requirement, pursuant to Nasdaq Listing Rule 5810(c)(3)(A). If we fail to regain compliance within the allotted compliance periods, including any extensions that may be granted by Nasdaq, Nasdaq will provide notice that our common stock and publicly-traded warrants will be subject to delisting. We would then be entitled to appeal Nasdaq's determination, but there can be no assurance that Nasdaq would grant our request for continued listing.

We will continue to monitor the closing bid price of our common stock and seek to regain compliance with all applicable Nasdaq requirements within the allotted compliance periods and may, if appropriate, consider available options, including implementation of a reverse stock split of our common stock, to regain compliance with the minimum closing bid requirement. If we seek to implement a reverse stock split in order to remain listed on Nasdaq, the announcement or implementation of such a reverse stock split could negatively affect the price of our common stock and/or publicly-traded warrants.

In addition, if we fail to regain compliance to be eligible to trade on Nasdaq or obtain listing on another reputable national securities exchange, we may have to pursue trading on a less recognized or accepted market, such as the over the counter markets, our stock may be traded as a "penny stock" which would make transactions in our stock more difficult and cumbersome, and we may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to further decline.

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. We had 26,699,002 shares of common stock outstanding as of December 31, 2022, of which 18,699,002 shares are freely tradable without restrictions or further registration required under the Securities Act. The remaining 8,000,000 million shares are currently unregistered and held by Biofrontera AG.

Warrants are exercisable for our common stock, which would increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders.

As of March 10, 2023, we have a total of 9,197,109 outstanding warrants which may each be exercised for one share of our common stock. All of the shares issuable upon exercise of the 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. Sales of substantial numbers of such shares 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.

Our quarterly operating results may fluctuate significantly.

We expect our operating results to be subject to quarterly fluctuations. Our net loss and other operating results will be affected by numerous factors, including:

- variations in the level of expenses related to our marketing efforts;
- any litigation, including intellectual property infringement lawsuits related to our licensed products, in which we may become involved;
- regulatory developments affecting Ameluz®, the BF-RhodoLED® lamp (and its successors) or Xepi®;
- our execution of any licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- the timing of milestone payments under our existing license agreements; and
- the level of underlying demand for Ameluz® and Xepi® and customers' buying patterns.

If our quarterly operating results fall below the expectations of investors or securities analysts, the price of our common stock could decline substantially. Furthermore, any quarterly fluctuations in our operating results may, in turn, cause the price of our stock to fluctuate substantially.

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.

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 this Form 10-K captioned "*Management's Discussion and Analysis of Financial Condition and Results of Operations—Liquidity and Capital Resources*."

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.

The Rights Agreement imposes a significant penalty upon any person or group that acquires 20% or more (but less than 50%) of our then-outstanding common stock without the prior approval of our board of directors. A person or group that acquires shares of our common stock in excess of the applicable threshold, subject to certain limited exceptions, is called an "Acquiring Person." Any rights held by an Acquiring Person are void and may not be exercised. A person or group who beneficially owned 20% or more of our outstanding Common Stock prior to the first public announcement of the adoption of the Rights Agreement will not trigger the Rights Agreement so long as they do not acquire beneficial ownership of any additional shares of Common Stock at a time when they still beneficially own 20% or more of such Common Stock.

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 close of business on October 13, 2023; provided that if the Company's stockholders have not ratified the Stockholder Rights Agreement by the close of business on the first day after the Company's 2023 annual meeting of stockholders (including any adjournments or postponement thereof), 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.

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 our 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 and May 16, 2022), as well as the Inducement Warrants issued on July 26, 2022 were accounted for as liabilities as these warrants provide for a cashless settlement provision which fails the requirement of the indexation guidance under ASC 815-40 (collectively "PIPE Warrants"). 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.*

As of the date of this Form 10-K, 7,704,715 PIPE Warrants remain outstanding. See Note 19. Stockholders' Equity in our audited financial statements for the fiscal year ended December 31, 2022 included in this Form 10-K for more information on the Warrants.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

Our headquarters is located in Woburn, Massachusetts, where we lease approximately 16,128 square feet under a lease agreement that has an initial term expiring in September 2025.

Item 3. Legal Proceedings

From time to time, we may be involved in legal proceedings arising in the ordinary course of our business. Information regarding our material legal proceedings is included in Note 24, *Commitments and Contingencies*, to the consolidated financial statements in Item 8 of this Form 10-K, which is incorporated herein by reference. Given the inherent uncertainties of litigation, the ultimate outcome of any such matters cannot be predicted at this time, nor can the amount of possible loss or range of loss, if any, be reasonably estimated, except in circumstances where an aggregate litigation accrual has been recorded for probable and reasonably estimable loss contingencies.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Market Information

Our common stock is traded on the NASDAQ Capital Market, under the symbol "**BFRI**," and our warrants are traded on the NASDAQ Capital Market, under the symbol "**BFRIW**."

Holders

As of December 31, 2022, there were three holders of record of our common stock. Holders of record are defined as those stockholders whose shares are registered in their names in our stock records and do not include beneficial owners of common stock whose shares are held in the names of brokers, dealers or clearing agencies.

Dividend Policy

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all future earnings for the operation of our business, and we do not currently intend to pay any cash dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this Item 5 regarding securities authorized for issuance under our equity compensation plan is contained under the caption "Securities Authorized for Issuance Under Equity Compensation Plan" in Item 12 of this Form 10-K, which information under such caption is incorporated herein by reference.

Recent Sales of Unregistered Securities

We do not have any sales of unregistered securities to report that have not been previously included in a Quarterly Report on Form 10-Q or in a Current Report on Form 8-K.

Issuer Purchases of Equity Securities

There were no repurchases made by us, or on our behalf, of shares of our common stock during the year ended December 31, 2022.

Use of Proceeds

Use of Proceeds from our Initial Public Offering

On October 28, 2021, our registration statement on Form S-1 (File No. 333-257722) relating to the initial public offering ("IPO") of our common stock became effective.

As of December 31, 2022, we have used all of the proceeds received from our IPO for working capital and general corporate purposes. There was no material change in the planned use of proceeds from the IPO of our common stock from that described in the Prospectus filed with SEC pursuant to rule 424b(4) under the Securities Act on November 1, 2021.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following section contains statements that are not statements of historical fact and are forward-looking statements within the meaning of the federal securities laws. These statements involve known and unknown risks, uncertainties, and other factors that may cause our actual results, performance, or achievement to differ materially from anticipated results, performance, or achievement, expressed or implied in such forward-looking statements. These statements reflect our current views with respect to future events, are based on assumptions, and are subject to risks and uncertainties. We discuss many of these risks and uncertainties at the beginning of this Form 10-K and under the sections captioned "Business" and "Risk Factors." The following discussion should also be read in conjunction with the financial statements and the Notes thereto appearing elsewhere in this Form 10-K.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain statements in this Form 10-K constitute "forward-looking statements". Such statements include statements regarding the timeline for regulatory review and approval of our products, the availability of funding sources for continued development of such products, and other statements that are not historical facts, including statements which may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guaranties of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements.

See Part I, Item 1A, "Risk Factors" of this Form 10-K for list of factors that may cause such differences.

We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

Overview

Biofrontera Inc. (the "Company") includes its wholly owned subsidiary Bio-FRI GmbH ("Bio-FRI" or "subsidiary"). Our subsidiary, Bio-FRI was formed on February 9, 2022, as a German presence to facilitate our relationship with our Ameluz Licensor.

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. 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.

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the BF-RhodoLED® lamp series, for photodynamic therapy, or PDT (when used together, "Ameluz® PDT"). In the United States, the 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. International treatment guidelines list photodynamic therapy as the "gold standard" for treating AK, especially multiple AK and the surrounding photodamaged skin.[3] We are currently selling Ameluz® for this indication in the U.S. under the Ameluz LSA.

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 specifically 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. ("Cutanea").

Our principal objective is to increase the sales of our licensed products in the United States. The key elements of our strategy include the following:

- expanding our sales in the United States of Ameluz® in combination with the BF-RhodoLED® lamp for the treatment of minimally to moderately thick actinic keratoses of the face and scalp and positioning Ameluz® to be the standard of care in the United States by growing our dedicated sales and marketing infrastructure in the United States;

- expanding sales of Xepi® for treatment of impetigo by improving the market positioning of the licensed product;

- leveraging the potential for future approvals and label extensions of our portfolio products that are in the pipeline for the U.S. market through the LSAs with our Licensors; and

- opportunistically adding complementary products or services to our portfolio by acquiring or licensing IP to further leverage our commercial infrastructure and customer relationships.

We devote a substantial portion of our cash resources to the commercialization of our licensed products, Ameluz® and the BF-RhodoLED® lamp series. We have financed our operating and capital expenditures through cash proceeds generated from our product sales and proceeds received in equity financings.

We believe that important measures of our results of operations include product revenue, operating income (loss) and adjusted EBITDA (a non-GAAP measure as defined below). Our sole source of product revenue is sales of products that we license from certain related and unrelated companies. Our long-term financial objectives include consistent revenue growth and expanding operating margins. Accordingly, we are focused on licensed product sales expansion to drive revenue growth and improve operating efficiencies, including effective resource utilization, information technology leverage, and overhead cost management.

Key factors affecting our performance

As a result of a number of factors, our historical results of operations may not be comparable to our results of operations in future periods, and our results of operations may not be directly comparable from period to period. Set forth below is a brief discussion of the key factors impacting our results of operations.

Seasonality

Because traditional photodynamic therapy treatments using a lamp are performed more frequently during the winter, our revenue is subject to some seasonality and has historically been higher during the first and fourth quarters than during the second and third quarters.

COVID-19

Since the beginning of 2020, COVID-19 has become a global pandemic. As a result of the measures implemented by governments around the world, our business operations have been directly affected. In particular, we experienced a significant decline in demand for our licensed products as a result of different priorities for medical treatments emerging, thereby causing a delay of actinic keratosis treatment for most patients. Our revenue was directly affected by the global COVID-19 pandemic starting in mid-March of 2020. From that point on, rising infection rates and the resulting American Academy of Dermatology's official recommendation to care for patients through remote diagnosis and treatment (telehealth) led to significantly declining patient numbers and widespread, albeit temporary, physician practice closures. As COVID-19 vaccines started to roll-out to the general public in March 2021, we experienced an increase in patients willing to undergo treatment for actinic keratosis. In the fourth quarter of 2021 continuing through 2022, we again saw a seasonally strong increase in sales, indicating a revenue recovery from the global COVID-19 pandemic, despite some residual effects such as reduced capacity or staffing shortages at physicians' offices. We are optimistic that our business will continue to thrive throughout 2023 as a result of the COVID-19 PHE sunsetting on May 11, 2023. However, the ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, including the effectiveness of vaccination and booster vaccination campaigns, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will continue be affected. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19 and variants thereof.

Supply Chain

While our Licensors take reasonable precautions to ensure the successful production of our commercially licensed products, their contract manufacturers may experience a myriad of business difficulties (i.e., workforce instability, supply chain issues, erosion of customer base, etc.) that could impact their financial solvency. In December 2021, we were notified by Ferrer of third-party manufacturing delays for the Xepi® product. Although we have inventory of Xepi® on hand, we expect a delay in further shipments of Xepi® for the next 9 to 12 months. Despite these delays, our total revenues will not be significantly impacted since the majority of our revenues are from sales of Ameluz®. We continue to monitor the impacts of the supply chain on our business and are focused on ensuring the stability of the supply chains for Ameluz® and BF-RhodoLED®.

Components of Our Results of Operations

Product Revenue, net

We generate product revenues through the third-party sales of our licensed products Ameluz®, BF-RhodoLED® lamps and Xepi® covered by our exclusive LSAs with our Licensors as described in the section "*Business—Commercial Partners and Agreements."* Revenues from product sales are recorded net of discounts, rebates and other incentives, including trade discounts and allowances, product returns, government rebates, and other incentives such as patient co-pay assistance. Revenue from the sales of our BF-RhodoLED® lamp and Xepi® are relatively insignificant compared with revenues generated through our sales of Ameluz®.

The primary factors that determine our revenue derived from our licensed products are:

- the level of orders generated by our sales force;
- the level of prescriptions and institutional demand for our licensed products; and
- unit sales prices.

Related Party Revenues

We also generate insignificant related party revenue in connection with an agreement with Biofrontera Bioscience to provide BF-RhodoLED® lamps, associated services for the clinical trials performed by Biofrontera Bioscience and accounting services provided to Biofrontera AG.

Cost of Revenues, Related Party

Cost of revenues, related party, is comprised of purchase costs of our licensed products, Ameluz® and BF-RhodoLED® lamps from Biofrontera Pharma GmbH and insignificant inventory adjustments due to scrapped, expiring and excess products.

On October 8, 2021, we entered into an amendment to the Ameluz LSA under which the price we pay per unit will be based upon our sales history. As a result of this amendment, the purchase price we pay the Ameluz Licensor for Ameluz® will be determined in the following manner:

- fifty percent of the anticipated net price per unit until we generate $30 million in revenue from sales of the products we license from the Ameluz Licensor during a given Commercial Year (as defined in the Ameluz LSA);
- forty percent of the anticipated net price per unit for all revenues we generate between $30 million and $50 million from sales of the products we license from the Ameluz Licensor; and
- thirty percent of the anticipated net price per unit for all revenues we generate above $50 million from sales of the products we license from the Ameluz Licensor.

Cost of Revenues, Other

Cost of revenues, other, is comprised of purchase costs of our licensed product, Xepi®, third-party logistics and distribution costs including packaging, freight, transportation, shipping and handling costs, inventory adjustment due to expiring Xepi® products, as well as sales-based Xepi® royalties.

Selling, General and Administrative Expense

Selling, general and administrative expenses consist principally of costs associated with our sales force, commercial support personnel, personnel in executive and other administrative functions, as well as medical affairs professionals. Other selling, general and administrative expenses include marketing, trade, and other commercial costs necessary to support the commercial operation of our licensed products and professional fees for legal, consulting and accounting services. Selling, general and administrative expenses also include the amortization of our intangible asset and our legal settlement expenses.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party, primarily relate to the services provided by our significant stockholder, Biofrontera AG, for accounting consolidation, IT support, and pharmacovigilance. These expenses were charged to us based on costs incurred plus 6% in accordance with the 2016 Services Agreement. During 2021, we entered into the Services Agreement which provides for the execution of statements of work that supersede the applicable provisions of the 2016 Services Agreement. The Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us, including IT and pharmacovigilance support for as long as we deem necessary. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, pharmacovigilance, and Investor Relations services, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine 1) if they will be needed, and 2) whether they can or should be obtained from other third-party providers. During 2022, we hired additional IT personnel and developed our IT infrastructure, enabling us to commence work on our IT separation from Biofrontera AG.

Restructuring Costs

We restructured the business of Cutanea and incurred restructuring costs through 2021, which were subsequently reimbursed by Maruho Co., Ltd, ("Maruho"). Restructuring costs primarily relate to Aktipak® discontinuation, personnel costs related to the termination of all Cutanea employees, and the winding down of Cutanea's operations.

Change in Fair Value of Contingent Consideration

In connection with the Cutanea acquisition, we recorded contingent consideration related to the estimated profits from the sale of Cutanea products to be shared equally with Maruho. The fair value of such contingent consideration was determined to be $6.5 million on the acquisition date of March 25, 2019 and is re-measured at each reporting date until the contingency is resolved.

Change in Fair Value of Warrant Liabilities

Common stock warrants issued in conjunction with private placement financing transactions are accounted for as liabilities in accordance with ASC 815-40.

The warrant liability is measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statements of operations.

Change in Fair Value of Investment in Equity Securities

Our investments are comprised of equity securities, which are initially recorded at cost, plus transaction costs, and subsequently measured at fair value, based on quoted market prices, with the gains and losses reported in the Company's consolidated statement of operations. For the investments held in foreign currencies, the change in fair value attributable to changes in foreign exchange rates is included in gains and losses in the consolidated statement of operations.

The Company may sell its equity securities in response to changes in interest rates, risk/reward characteristics, liquidity needs or other factors.

Interest Expense, net

Interest expense, net, primarily consists of amortization of the contract asset related to the start-up cost financing from Maruho under the Share Purchase and Transfer Agreement dated March 25, 2019 (as amended, the "Share Purchase Agreement") offset by interest income of 6% per annum for each day that any reimbursement is past due related to the Amended Settlement Allocation Agreement with Biofrontera AG, and immaterial amounts of interest income earned on our financing of customer purchases of BF-RhodoLED® lamps.

Other Income, net

Other income, net primarily includes (i) gain on sale of leased assets, and (ii) gain (loss) on foreign currency transactions.

Income Taxes

As a result of the net losses we have incurred in each fiscal year since inception, we have recorded no provision for federal income taxes during such periods. Income tax expense incurred relates to state income taxes.

Results of Operations

Comparison of the Years Ended December 31, 2022 and December 31, 2021

The following table summarizes our results of operations for the years ended December 31, 2022 and December 31, 2021:

	For the Year Ended December 31,			
(*in thousands*)	**2022**	**2021**	**Change**	**%Change**
Product revenues, net	$ 28,541	$ 24,043	$ 4,498	18.7%
Related party revenues	133	57	76	132.5%
Revenues, net	**28,674**	**$ 24,100**	**4,574**	**19.0%**
Operating expenses:				
Cost of revenues, related party	14,618	12,222	2,396	19.6%
Cost of revenues, other	567	520	47	9.1%
Selling, general and administrative	35,137	36,512	(1,375)	-3.8%
Selling, general and administrative, related party	733	697	36	5.1%
Restructuring costs	-	752	(752)	-100.0%
Change in fair value of contingent consideration	(3,800)	(1,402)	(2,398)	171.0%
Total operating expenses	47,255	49,301	(2,046)	-4.1%
Loss from operations	**(18,581)**	**(25,201)**	**6,620**	**-26.3%**
Change in fair value of warrant liabilities	16,388	(12,801)	29,189	-228.0%
Change in fair value of investments	1,747	-	1,747	n/a
Interest expense, net	(195)	(344)	149	-43.3%
Other income, net	33	689	(656)	-95.2%
Loss before income taxes	**(608)**	**(37,657)**	**37,049**	**-98.4%**
Income tax expenses	32	56	(24)	-42.9%
Net loss	**$ (640)**	**$ (37,713)**	**$ 37,073**	**-98.3%**

Revenues, net

Our net revenue was $28.7 million and $24.1 million 2022 and 2021, respectively, an increase of $4.6 million, or 19.0%. Net product revenue was $28.5 million and $24.0 million for 2022 and 2021, respectively, an increase of $4.5 million, or 18.7%. The increase was primarily driven by: (i) higher volume of Ameluz® orders, which resulted in an increase in Ameluz® revenue of $3.7 million, and (ii) an increase in the price of Ameluz®, which further increased Ameluz® revenue by $0.6 million.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party was $14.6 million and $12.2 million for 2022 and 2021, respectively, an increase of $2.4 million, or 19.6%. The increase was primarily driven by the increase in Ameluz® product revenue. Cost of Ameluz® is directly correlated to the selling price under the Ameluz LSA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $35.1 million and $36.5 million for 2022 and 2021, respectively, a decrease of $1.4 million, or 3.8%. This decrease was driven by the one-time legal settlement expense of $11.3 million recognized in 2021. This decrease was offset by an increase in headcount costs as a result of resumed hiring in 2022 and a broad increase in the costs to comply with corporate governance, regulatory reporting, risk management and other requirements applicable to us as a public company.

Restructuring Costs

There were no restructuring costs for the twelve months ended December 31, 2022. Restructuring costs were $0.8 million for the twelve months ended December 31, 2021, all of which related to facility exit costs.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was a decrease of $3.8 million and a decrease of $1.4 million for 2022 and 2021, respectively. The change in fair value of contingent consideration is driven by the estimated profit share the Company is required to pay under the Share Purchase Agreement. During 2022, the estimated profit share was reduced in response to supply chain delays experienced by the supplier.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a decrease of $29.2 million and an increase of $12.8 million for 2022 and 2021, respectively. The change was driven by changes in the underlying value of the common stock. The change in 2022 was also driven by the modification and exercise of the 2021 Purchase Warrant.

Change in fair value of investments in equity securities

The change in fair value of investments in equity securities of $1.7 million was driven by changes in the quoted market price of the common stock.

Other Income, net

Other income, net was negligible and $0.7 million in 2022 and 2021, respectively, a decrease of $0.7 million or 95.2%. The decrease is primarily related to the decrease in reimbursed costs under the Share Purchase Agreement with Maruho of $0.5 million.

Net Income to Adjusted EBITDA Reconciliation for years ended December 31, 2022 and 2021

We define adjusted EBITDA as net income or loss before interest income and expense, income taxes, depreciation and amortization, and other non-operating items from our statements of operations as well as certain other items considered outside the normal course of our operations specifically described below. Adjusted EBITDA is not a presentation made in accordance with GAAP. Our definition of adjusted EBITDA may vary from the use of similarly-titled measures by others in our industry due to the potential inconsistencies in the method of calculation and differences due to items subject to interpretation. Adjusted EBITDA should not be considered as an alternative to net income or loss, operating income/(loss), cash flows from operating activities or any other performance measures derived in accordance with GAAP as measures of operating performance or liquidity. Adjusted EBITDA has limitations as an analytical tool and should not be considered in isolation or as a substitute for analysis of our results as reported under GAAP.

Change in fair value of contingent consideration: Pursuant to the Share Purchase Agreement, the profits from the sale of Cutanea products will be shared equally between Maruho and Biofrontera until 2030. The fair value of the contingent consideration was determined to be $6.5 million on the acquisition date and is re-measured at each reporting date. We exclude the impact of the change in fair value of contingent consideration as this is non-cash.

Change in fair value of warrant liabilities: The Warrants issued in conjunction with our private placement offerings were accounted for as liabilities in accordance with ASC 815-40. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statement of operations. We exclude the impact of the change in fair value of warrant liabilities as this is non-cash.

Change in fair value of investment in equity securities: The Company accounts for its investments in equity securities in accordance with ASC 321, *Investments — Equity Securities* ("ASC 321"). Equity securities, which are comprised of investments in common stock, are initially recorded at cost, plus transaction costs, and subsequently measured at fair value, based on quoted market prices, with the gains and losses reported in the Company's consolidated statement of operations. For the investments held in foreign currencies, the change in fair value attributable to changes in foreign exchange rates is included in gains and losses in the consolidated statement of operations. We exclude the impact of the change in fair value of investments as this is non-cash.

Legal settlement expenses: To measure operating performance, we exclude legal settlement expenses. We do not expect to incur these types of legal expenses on a recurring basis and believe the exclusion of such amounts allows management and the users of the financial statements to better understand our financial results.

Stock Based Compensation: To measure operating performance, we exclude the impact of costs relating to share-based compensation. Due to the subjective assumptions and a variety of award types, we believe that the exclusion of share-based compensation expense, which is typically non-cash, allows for more meaningful comparisons of our operating results to peer companies. Share-based compensation expense can vary significantly based on the timing, size and nature of awards granted.

Expensed issuance costs: To measure operating performance, we exclude the portion of issuance costs allocated to our warrant liabilities. We do not expect to incur this type of expense on a recurring basis and believe the exclusion of these costs allows management and the users of the financial statements to better understand our financial results.

Adjusted EBITDA margin is adjusted EBITDA for a particular period expressed as a percentage of revenues for that period.

We use adjusted EBITDA to measure our performance from period to period and to compare our results to those of our competitors. In addition to adjusted EBITDA being a significant measure of performance for management purposes, we also believe that this presentation provides useful information to investors regarding financial and business trends related to our results of operations and that when non-GAAP financial information is viewed with GAAP financial information, investors are provided with a more meaningful understanding of our ongoing operating performance.

The below table presents a reconciliation from net loss to Adjusted EBITDA for the years ended December 31, 2022 and 2021:

	Years ended December 31,	
	2022	**2021**
Net loss	**$ (640)**	**$ (37,713)**
Interest expense, net	195	344
Income tax expenses	32	56
Depreciation and amortization	519	540
EBITDA	**106**	**(36,773)**
Change in fair value of contingent consideration	(3,800)	(1,402)
Change in fair value of warrant liabilities	(16,388)	12,801
Change in fair value of investments	(1,747)	-
Legal settlement expenses	870	11,250
Stock based compensation	1,852	129
Expensed issuance costs	1,045	1,383
Adjusted EBITDA	**$ (18,062)**	**$ (12,612)**
Adjusted EBITDA margin	-63.0%	-52.3%

Adjusted EBITDA

Adjusted EBITDA decreased from ($12.7) million for the year ended December 31, 2021 to ($18.1) million for the year ended December 31, 2022. The decrease was primarily driven by an increase in Selling, general, and administrative expenses (excluding legal settlement expenses) due to increased headcount and compliance costs. Our adjusted EBITDA margin decreased from (52.8%) for the year ended December 31, 2021 to (63.0%) for the year ended December 31, 2022, as the decline in our Adjusted EBITDA outpaced our increase in revenues.

Liquidity and Capital Resources

The Company's primary sources of liquidity are its existing cash balances, cash collected from the sales of its products, and cash flows from financing transactions. During the year ended December 31, 2022, we received proceeds of $9.4 million from the issuance of common stock and warrants in private placement, net of issuance costs, and $4.6 million from the exercise of common stock warrants (See *Note 19. Stockholders' Equity*). As of December 31, 2022, we had cash and cash equivalents of $17.2 million, compared to $24.5 million as of December 31, 2021.

Since we commenced operations in 2015, we have generated significant losses. For the years ended December 31, 2022 and 2021, we incurred net losses of $0.6 million and $37.7 million, respectively. We incurred net cash outflows from operations of $16.2 million and $26.7 million, for the same periods, respectively. We had an accumulated deficit as of December 31, 2022 of $79.5 million.

The Company's short-term material cash requirements include working capital needs and satisfaction of contractual commitments including facility and auto leases (see *Note 24, Commitments and Contingencies*), Maruho start-up payments of $7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG of $2.5 million. Long-term material cash requirements include potential milestone payments to Ferrer Internacional S.A and contingent consideration payments to Maruho connected with Xepi sales.

Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing efforts as we seek to expand the commercialization of our licensed products in the United States. We also expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. In addition, we expect to incur costs to continue to comply with corporate governance, regulatory reporting and other requirements applicable to us as a public company in the U.S.

Our future growth is dependent on our ability to obtain additional equity or debt financing. Based on current operating plans and financial forecasts, we expect that our current capital resources, including investments in equity securities which we intend to liquidate within the next twelve months, and availability under a working capital line of credit, will be sufficient to fund our operations for at least the next twelve months from the date of issuance of our financial statements. However, if our current operating plans or financial forecasts change, or we are unable to obtain additional financing, we may need to reduce the discretionary spend on promotional expenses, branding, marketing consulting and defer some hiring. While we expect to continue being flexible in our spending over the next twelve months, we do not consider there to be a need to significantly revise our operations currently.

Cash Flows

The following table summarizes our cash provided by and (used in) operating, investing and financing activities:

	For the Year Ended December 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (16,199)	$ (26,715)
Net cash used in investing activities	(5,156)	(11)
Net cash provided by financing activities	14,021	43,191
Net increase in cash and restricted cash	$ (7,334)	$ 16,465

Operating Activities

During the year ended December 31, 2022, operating activities used $16.2 million of cash, primarily resulting from our net loss of $0.6 million, adjusted for the add back of non-cash income of $18.3 million and offset by net cash provided by changes in our operating assets and liabilities of $2.7 million. Non-cash items include stock-based compensation of $1.9 million, non-cash interest expense of $0.4 million, and depreciation and amortization in the aggregate of $1.2 million, netted against a change in fair value of investment of warrant liabilities of $16.4 million, change in fair value of contingent consideration of $3.8 million, and change in fair value of equity securities of $1.7 million.

Investing Activities

During the year ended December 31, 2022, investing activities used $5.2 million, primarily resulting from the purchase of shares of Biofrontera AG (See *Note 4. Fair Value Measurements and Note 6. Investment in Equity Securities)*

Financing Activities

During the years ended December 31, 2022 and 2021, net cash provided by financing activities was $14.0 million and $43.2 million, respectively. Financing activities during year ended December 31, 2022 consisted of proceeds of $9.4 million from the issuance of common stock and warrants in private placement, net of issuance costs, and $4.6 million from the exercise of common stock warrants. Financing activities during year ended December 31, 2021 consisted of proceeds from the issuance of common stock upon an initial public offering of $14.9 million, issuance of common stock in private placement of $15.0 million, and the exercise of warrants of $13.2 million.

On March 9, 2023, we entered into the Commitment Letter with MidCap, in respect of MidCap's commitment to provide us with the Revolving Facility, subject to the borrowing base formula, minimum excess availability and other terms and conditions thereof, in the aggregate principal amount of up to $6.5 million. The Revolving Facility shall be secured by a lien on substantially all of the assets of the Company, subject to customary exceptions and, if drawn upon, the proceeds of the Revolving Facility will be used for working capital. For additional details regarding the Revolving Facility see *Item 9.B. Other Information* in this Form 10-K.

Entry into the Revolving Facility will be subject to customary closing conditions, including the execution and delivery of appropriate definitive documentation related to the Revolving Facility, to include customary representations, warranties, covenants, events of default and other terms and conditions.

Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with generally accepted accounting principles of the United States, or GAAP. The preparation of the financial statements in accordance with GAAP requires the use of estimates and assumptions by management that affect the value of assets and liabilities, as well as contingent assets and liabilities, as reported on the balance sheet date, and revenues and expenses arising during the reporting period. The main areas in which assumptions, estimates and the exercising of a degree of judgment are appropriate relate to contingent consideration, fair value measurements, valuation of intangible assets and impairment assessment, and stock compensation. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary from the actual values.

Our significant accounting policies are described in more detail in *Note 2 – Summary of Significant Accounting Policies*, to our consolidated financial statements included in *Item 8, "Financial Statements and Supplementary Data*," of this Form 10-K.

Critical Accounting Estimates

We believe that the following accounting policies are those that are most critical to the judgments and estimates used in the preparation of our financial statements.

Contingent Consideration

We record contingent consideration resulting from a business combination at its fair value on the acquisition date. Each reporting period thereafter, we revalue the remaining obligations and record increases or decreases in their fair value as an adjustment to contingent consideration expense in our statements of operations. We considered a number of factors, including information provided by an outside valuation advisor in performing the valuation. Contingent consideration is reported at the estimated fair values based on the probability-adjusted present value of the consideration expected to be paid, using significant inputs and estimates. Changes in the fair value of our contingent consideration obligations can result from changes to one or multiple inputs, including forecasted product profit amounts, metric risk premium and discount rates consistent with the level of risk of achievement as further discussed in *Note 4, Fair Value Measurements* to the audited financial statements as of and for the years ended December 31, 2022 and 2021 as included in this Form 10-K. The fair value of the contingent consideration is remeasured each reporting period, with changes in the fair value included in current operations. These fair value measurements represent Level 3 measurements as they are based on significant inputs not observable in the market.

Significant judgment is employed in determining the appropriateness of these assumptions as of the acquisition date and for each subsequent period. Accordingly, changes in assumptions described above, could have a material impact on the amount of contingent consideration expense we record in any given period.

Intangible Assets and Impairment Assessment

The Company regularly reviews the carrying amount of its long-lived assets to determine whether indicators of impairment may exist, which warrant adjustments to carrying values or estimated useful lives. In connection with this review, assets are grouped at the lowest level at which identifiable cash flows are largely independent of other asset groupings. If indications of impairment exist, projected future undiscounted cash flows associated with the asset grouping are compared to the carrying amount to determine whether the asset's value is recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group are less than its carrying amount. The impairment loss would be based on the excess of the carrying value of the impaired asset group over its fair value, determined based on discounted cash flows.

In determining future cash flows, we take various factors into account, including the remaining useful life of each asset group, forecasted growth rates, pricing, working capital, capital expenditures, and other cash needs specific to the asset group. Additional considerations when assessing impairment include changes in our strategic operational and financial decisions, economic conditions, demand for our product and other corporate initiatives which may eliminate or significantly decrease the realization of future benefits from our long-lived assets. Since the determination of future cash flows is an estimate of future performance, future impairments may arise in the event that future cash flows do not meet expectations.

We perform an impairment assessment in accordance with FASB ASC Topic 360-10-S99, *Impairment or Disposal of Long-Lived Assets*. Management's review for the presence of indicators of impairment include events or changes in circumstances that indicate the carrying amount of an asset may not be recoverable. In October 2022, upon receiving notification of further third-party manufacturing delays that impacted the timing of sales expansion and improved market positioning of the Xepi® product, we deemed it necessary to assess the recoverability of our Xepi® asset group. As of the date of notification, future undiscounted cash flows were estimated over the expected remaining useful life using revenue and operating expense growth rates. Also, the expected cash flows were based on the assumption that sales levels would grow considerably for the first two years after resolution of the manufacturing delays as a result of expanding the sales force and marketing efforts related to the asset group. While we believe these assumptions were reasonable, the level of future sales may vary significantly from the levels assumed. Also, the timeframe over which activity levels grow is highly uncertain. Potential events that could affect our assumptions are affected by factors such as those described in "*Risks Related to Our Business and Strategy*". After the assessment we performed, we determined that, on an undiscounted basis, expected cash flows exceeded the carrying amount of the asset group. For additional information on our impairment assessment, refer *Note 12*, *"Intangible Assets, Net*", to our financial statements included in this Form 10-K.

Fair Value – Warrant Liability

The Warrants issued in conjunction with our private placement offerings were accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities in the accompanying consolidated balance sheet. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statement of operations.

The Company utilizes a Black-Scholes option pricing model to estimate the fair value of the Warrants which is considered a Level 3 fair value measurement. The Black-Scholes option-pricing model considers several variables and assumptions in estimating the fair value of financial instruments, including the per-share fair value of the underlying common stock, exercise price, expected term, risk-free interest rate, expected stock price volatility over the expected term, and expected annual dividend yield. Certain inputs utilized in our Black-Scholes pricing model may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of our warrant liability which could also result in material non-cash gain or loss being reported in our consolidated statement of operations.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in *Note 2, Summary of Significant Accounting Policies—Recently Issued Accounting Pronouncements Not Yet Effective*.

Off-balance Sheet Arrangements

Besides the contractual obligations and commitments as discussed in the *Liquidity and Capital Resources*, we did not have during the periods presented, and we do not currently have, any other off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when an accounting standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

As a "smaller reporting company," we are not required to provide the information required by this Item.

Item 8. Financial Statements and Supplementary Data

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

Board of Directors and Stockholders

Biofrontera Inc.

Opinion on the financial statements

We have audited the accompanying consolidated balance sheets of Biofrontera Inc. (a Delaware corporation) and subsidiary (the "Company") as of December 31, 2022 and 2021, the related consolidated statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2022, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, in conformity with accounting principles generally accepted in the United States of America.

Change in accounting principle

As discussed in Note 2 to the financial statements, the Company changed its method of accounting for leases as of January 1, 2022, due to adoption of Financial Accounting Standards Board Accounting Standards Codification No. 842, Leases.

Basis for opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ GRANT THORNTON LLP

We have served as the Company's auditor since 2021.

Boston, Massachusetts

March 13, 2023

BIOFRONTERA INC.
CONSOLIDATED BALANCE SHEETS
(*In thousands, except par value and share amounts*)

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,208	$ 24,545
Investment in equity securities	10,548	-
Accounts receivable, net	3,748	3,784
Other receivables, related party	3,658	8,647
Inventories	7,168	4,458
Prepaid expenses and other current assets	810	4,987
Total current assets	**43,140**	**46,421**
Other receivables long term, related party	2,813	2,813
Property and equipment, net	204	267
Operating lease right-of-use assets	1,375	-
Intangible asset, net	3,032	3,450
Other assets	320	268
Total assets	**$ 50,884**	**$ 53,219**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,278	658
Accounts payable, related parties	1,312	282
Acquisition contract liabilities, net	6,942	3,242
Operating lease liabilities	498	-
Accrued expenses and other current liabilities	10,864	9,654
Total current liabilities	**20,894**	**13,836**
Long-term liabilities:		
Acquisition contract liabilities, net	2,400	9,542
Warrant liabilities	2,843	12,854
Operating lease liabilities, non-current	848	-
Other liabilities	21	5,649
Total liabilities	**27,006**	**41,881**
Commitments and contingencies (see Note 24)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2022 and 2021	-	-
Common Stock, $0.001 par value, 300,000,000 shares authorized; 26,699,002 and 17,104,749 shares issued and outstanding as of December 31, 2022 and 2021	27	17
Additional paid-in capital	103,370	90,200
Accumulated deficit	(79,519)	(78,879)
Total stockholders' equity	**23,878**	**11,338**
Total liabilities and stockholders' equity	**$ 50,884**	**$ 53,219**

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

BIOFRONTERA INC.
CONSOLIDATED STATEMENTS OF OPERATIONS
(*In thousands, except per share amounts and number of shares*)

	December 31,	
	2022	**2021**
Products revenues, net	$ 28,541	$ 24,043
Revenues, related party	133	57
Total revenues, net	**28,674**	**24,100**
Operating expenses		
Cost of revenues, related party	14,618	12,222
Cost of revenues, other	567	520
Selling, general and administrative	35,137	36,512
Selling, general and administrative, related party	733	697
Restructuring costs	-	752
Change in fair value of contingent consideration	(3,800)	(1,402)
Total operating expenses	**47,255**	**49,301**
Loss from operations	**(18,581)**	**(25,201)**
Other income (expense)		
Change in fair value of warrant liabilities	16,388	(12,801)
Change in fair value of investments	1,747	-
Interest expense, net	(195)	(344)
Other income, net	33	689
Total other income (expense)	**17,973**	**(12,456)**
Loss before income taxes	**(608)**	**(37,657)**
Income tax expense	32	56
Net loss	**$ (640)**	**$ (37,713)**
Loss per common share:		
Basic and diluted	$ (0.03)	$ (4.28)
Weighted-average common shares outstanding:		
Basic and diluted	21,139,765	8,808,233

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

BIOFRONTERA INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
(In thousands, except number of shares)

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance at December 31, 2020	8,000,000	$ 8	46,986	$ (41,166)	$ 5,828
Issuance of common stock and warrants under IPO, net of issuance costs of $3.1 million	3,600,000	4	14,939	-	14,943
Issuance of common stock and warrants under private placement offering, net of issuance costs of $0.3 million	1,350,000	1	2,689	-	2,690
Exercise of common stock warrants	2,647,606	3	13,235	-	13,238
Exercise of pre-funded warrants	1,507,143	1	12,222	-	12,223
Stock-based compensation			129		129
Net loss	-	-	-	(37,713)	(37,713)
Balance at December 31, 2021	17,104,749	$ 17	$ 90,200	$ (78,879)	$ 11,338
Issuance of common stock in exchange for investments in equity securities	3,148,042	3	3,680	-	3,683
Issuance of common stock and warrants under private placement, net of negligible issuance costs	1,850,000	2	115	-	117
Exercise of pre-funded warrants	1,569,000	2	2,840		2,842
Exercise of PIPE warrants	2,857,143	3	4,683	-	4,686
Issuance of shares for vested restricted stock units	170,068	-	-	-	-
Stock based compensation	-	-	1,852	-	1,852
Net loss	-	-	-	(640)	(640)
Balance, December 31, 2022	26,699,002	$ 27	$ 103,370	$ (79,519)	$ 23,878

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

BIOFRONTERA INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Years ended December 31,	
	2022	**2021**
Cash Flows From Operating Activities:		
Net loss	$ (640)	$ (37,713)
Adjustments to reconcile net loss to cash flows used in operations		
Depreciation	101	122
Amortization of right-of-use assets	653	-
Amortization of acquired intangible assets	418	418
Change in fair value of investment in equity securities	(1,747)	-
Change in fair value of contingent consideration	(3,800)	(1,402)
Change in fair value of warrant liabilities	(16,388)	12,801
Stock-based compensation	1,852	129
Provision for inventory obsolescence	100	33
Provision for doubtful accounts	106	44
Non-cash interest expense	358	358
Changes in operating assets and liabilities:		
Accounts receivable	(70)	(612)
Other receivables, related party	4,990	(11,387)
Prepaid expenses and other assets	4,154	(3,809)
Inventories	(2,810)	2,592
Accounts payable and related party payables	912	(773)
Operating lease liabilities	(781)	-
Accrued expenses and other liabilities	(3,607)	12,484
Cash flows used in operating activities	**(16,199)**	**(26,715)**
Cash flows from investing activities		
Purchases of investment in equity securities	(5,118)	-
Purchases of property and equipment	(38)	(11)
Cash flows used in investing activities	**(5,156)**	**(11)**
Cash flows from financing activities		
Proceeds from issuance of common stock and warrants upon initial public offering, net of issuance costs	-	14,943
Proceeds from issuance of common stock and warrants in private placement, net of issuance costs	9,391	14,995
Proceeds from exercise of warrants	4,630	13,253
Cash flows provided by financing activities	**14,021**	**43,191**
Net (decrease) increase in cash and cash equivalents	**(7,334)**	**16,465**
Cash, cash equivalents and restricted cash, at the beginning of the year	**24,742**	**8,277**
Cash, cash equivalents and restricted cash, at the end of the year	**$ 17,408**	**$ 24,742**
Supplemental disclosure of cash flow information		
Interest paid	$ 1	$ 2
Income tax paid, net	$ 32	$ 56
Supplemental non-cash investing and financing activities		
Conversion of warrant liability to equity in connection with exercise of warrants	$ 6,840	$ 12,208
Issuance of common shares in exchange for investments in equity securities	$ 3,683	$ -
Addition of right-of-use assets in exchange for operating lease liabilities	$ 234	$ -
Issuance costs included in accrued expenses and other liabilities	$ -	$ 44
Non-cash purchase of fixed assets	$ -	$ 8

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

1. Business Overview

Biofrontera Inc. (the "Company") includes its wholly owned subsidiary Bio-FRI GmbH ("Bio-FRI" or "subsidiary").

Biofrontera Inc. is a U.S.-based biopharmaceutical company specializing in the commercialization of pharmaceutical products for the treatment of dermatological conditions, in particular, diseases caused primarily by exposure to sunlight that result in sun damage to the skin. Our principal licensed products focus on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer. We also market a licensed topical antibiotic for treatment of impetigo, a bacterial skin infection.

Our principal product is Ameluz®, which is a prescription drug approved for use in combination with our licensor's FDA-approved medical devices, the BF-RhodoLED® lamp series, consisting of the BF-RhodoLED® and the RhodoLED® XL lamps, for photodynamic therapy ("PDT") (when used together, "Ameluz® PDT") in the U.S. for the lesion-directed and field-directed treatment of actinic keratosis of mild-to-moderate severity on the face and scalp. We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement ("Ameluz LSA"), by and among us and Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH (collectively, the ("Ameluz Licensor") originally dated as of October 1, 2016, and as subsequently amended on October 8, 2021. Refer to *Note 17, Related Party Transactions*, for further details.

Our second prescription drug product 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 specifically approved by the FDA for the treatment of impetigo due to staphylococcus aureus or streptococcus pyogenes. The approved indication is impetigo, a common skin infection. It is approved for use in adults and children 2 months and older. We are currently selling Xepi® for this indication in the U.S. under an exclusive license and supply agreement ("Xepi LSA") with Ferrer Internacional S.A. ("Ferrer") that was acquired by Biofrontera Inc. on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. Refer to *Note 17, Related Party Transactions*, for further details.

Our subsidiary, Bio-FRI was formed on February 9, 2022, as a German presence to facilitate our relationship with the Ameluz Licensor.

Liquidity and Going Concern

The Company's primary sources of liquidity are its existing cash balances, cash collected from the sales of its products, and cash flows from financing transactions. During the year ended December 31, 2022, we received proceeds of $9.4 million from the issuance of common stock and warrants in a private placement, net of issuance costs, and $4.6 million from the exercise of common stock warrants (See *Note 19. Stockholders' Equity*). As of December 31, 2022, we had cash and cash equivalents of $17.2 million, compared to $24.5 million as of December 31, 2021.

Since we commenced operations in 2015, we have generated significant losses. For the years ended December 31, 2022 and 2021, we incurred net losses of $0.6 million and $37.7 million, respectively. We incurred net cash outflows from operations of $16.2 million and $26.7 million, for the same periods, respectively. We had an accumulated deficit as of December 31, 2022 of $79.5 million.

The Company's short-term material cash requirements include working capital needs and satisfaction of contractual commitments including facility and auto leases (see *Note 24, Commitments and Contingencies*), Maruho start-up payments of $7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG of $2.5 million. Long-term material cash requirements include potential milestone payments to Ferrer Internacional S.A, and contingent consideration payments to Maruho connected with Xepi sales.

Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing efforts as we seek to expand the commercialization of our licensed products in the United States. We also expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. In addition, we expect to incur costs to continue to comply with corporate governance, regulatory reporting and other requirements applicable to us as a public company in the U.S.

Our future growth is dependent on our ability to obtain additional equity or debt financing. Based on current operating plans and financial forecasts, we expect that our current capital resources, including investments in equity securities, which we intend to liquidate within the next twelve months, and availability under a working capital line of credit, will be sufficient to fund our operations for at least the next twelve months from the date of issuance of our financial statements. However, if our current operating plans or financial forecasts change, or we are unable to obtain additional financing, we may need to reduce the discretionary spend on promotional expenses, branding, marketing consulting and defer some hiring. While we expect to continue being flexible in our spending over the next twelve months, we do not consider there to be a need to significantly revise our operations currently.

2. Summary of Significant Accounting Policies

Basis for Preparation of the Consolidated Financial Statements

The accompanying consolidated financial statements have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP"). These consolidated financial statements include the accounts of our wholly owned subsidiary. All intercompany balances and transactions have been eliminated in consolidation. The information presented reflects the application of significant accounting policies described below.

All amounts shown in these financial statements and tables are in thousands and amounts in the notes are in millions, except percentages and per share and share amounts.

Segment Reporting

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision-maker in deciding how to allocate resources and assess performance. The Company's chief operating decision maker (determined to be the Chief Executive Officer) does not manage any part of the Company separately, and the allocation of resources and assessment of performance are based on the Company's operating results.

We operate in a single reporting segment, the commercialization of pharmaceutical products for the treatment of dermatological conditions and diseases within the U.S. All business operations focus on the products Ameluz®, including the complementary product BF-RhodoLED®, and Xepi®. We monitor and manage our business operations across these products collectively as one reporting segment.

Use of Estimates

The preparation of the consolidated financial statements in accordance with U.S. GAAP requires the use of estimates and assumptions by management that affect the reported amounts of assets and liabilities, as well as disclosure of contingent assets and liabilities, as reported on the balance sheet date, and the reported amounts of revenues and expenses arising during the reporting period. The main areas in which assumptions, estimates and the exercising of judgment are appropriate relate to valuation allowances for receivables and inventory, valuation of contingent consideration and warrant liabilities, realization of intangible and other long-lived assets, product sales allowances and reserves, share-based payments and income taxes including deferred tax assets and liabilities. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary from the actual values.

Cash and Cash Equivalents

The Company considers all highly liquid investments purchased with an original maturity of three months or less at the time of purchase to be cash equivalents.

Restricted Cash

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards, in addition to one deposit held for a sublease *(see Note 13. Statement of Cash Flows Reconciliation)*.

Investment in Equity Securities

The Company accounts for its investments in equity securities in accordance with ASC 321, *Investments — Equity Securities* ("ASC 321"). Equity securities, which are comprised of investments in common stock with a readily determinable fair value, are initially recorded at cost, plus transaction costs, and subsequently measured at fair value, based on quoted market prices, with the gains and losses reported in the Company's consolidated statement of operations. As the fair value of the Company's investments is reported in a foreign currency, the change in fair value attributable to changes in foreign exchange rates is included in other income, net in the consolidated statement of operations.

Accounts Receivable

Accounts receivables are reported at their net realizable value. Any value adjustments are booked directly against the relevant receivable. We have standard payment terms that generally require payment within approximately 30 to 90 days. Management performs ongoing credit evaluations of its customers. An allowance for potentially uncollectible accounts is provided based on history, economic conditions, and composition of the accounts receivable aging. In some cases, the Company makes allowances for specific customers based on these and other factors. Provisions for the allowance for doubtful accounts are recorded in selling, general and administrative expenses in the accompanying statements of operations.

Concentration of Credit Risk and Off-Balance Sheet Risk

Financial instruments that potentially expose the Company to concentrations of credit risk consist primarily of cash, cash equivalents, accounts receivable and other receivables, related party. The Company maintains all of its cash and cash equivalents at a single accredited financial institution, in amounts that exceed federally insured limits. The Company has no significant off-balance sheet risk such as foreign exchange contracts, option contracts, or other foreign hedging arrangements.

Concentrations of credit risk with respect to receivables, which are typically unsecured, are somewhat mitigated due to the wide variety of customers using our products. We monitor the financial performance and creditworthiness of our customers so that we can properly assess and respond to changes in their credit profile. We continue to monitor these conditions and assess their possible impact on our business.

Other receivables, related party consists of a receivable due from Biofrontera AG for its 50% share of a legal settlement and related costs for which they are jointly and severally liable for the total settlement amount. The Company has a contractual right to repayment of its share of the settlement payment from Biofrontera AG under the Settlement Allocation Agreement entered into on December 9, 2021, which provided that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share. Although this receivable has credit risk, it is mitigated by the Settlement Allocation Agreement as amended on March 31, 2022, which provides certain remedies to the Company, if Biofrontera AG fails to make timely reimbursements, which the Company may implement in its sole discretion, including the ability to charge interest at a rate of 6.0% per annum for each day that any reimbursement is past due and the ability to offset any overdue reimbursement amounts against payments owed to Biofrontera AG by the Company (including amounts owed under the Company's license and supply agreement for Ameluz®).

We are dependent on two suppliers, Biofrontera Pharma GmbH and Ferrer Internacional S.A., to supply drug products, including all underlying components, for our commercial efforts. These efforts could be adversely affected by a significant interruption in the supply of our finished products.

Inventories

Finished goods consist of pharmaceutical products purchased for resale and are stated at the lower of cost or net realizable value. Cost is calculated by applying the first-in-first-out method (FIFO). Inventory costs include the purchase price of finished goods and freight-in costs. The Company regularly reviews inventory quantities on hand and writes down to its net realizable value any inventory that it believes to be impaired. Management considers forecast demand in relation to the inventory on hand, competitiveness of product offerings, market conditions and product life cycles when determining excess and obsolescence and net realizable value adjustments. Once inventory is written down and a new cost basis is established, it is not written back up if demand increases.

Property and Equipment

Property and equipment are recorded at cost less accumulated depreciation. Depreciation is generally applied straight-line over the estimated useful life of assets. Leasehold improvements are amortized over the shorter of the asset's estimated useful life or the lease term. The estimated useful lives of property and equipment are:

	Estimated Useful Life in Years
Computer equipment	3 years
Computer software	3 years
Furniture and fixtures	3-5 years
Leasehold improvements	Shorter of estimated useful lives or the term of the lease
Machinery & equipment	3-4 years

The cost and accumulated depreciation of assets retired or sold are removed from the respective asset category, and any gain or loss is recognized in our statements of operations.

Intangible Assets

Intangible assets with finite lives are amortized over their estimated useful lives. Intangible assets with indefinite lives are not amortized.

Leases

In February 2016, the Financial Accounting Standards Board ("FASB") issued ASU No. 2016-02, Leases (Topic 842), to enhance the transparency and comparability of financial reporting related to leasing arrangements. The Company adopted the standard effective January 1, 2022. Using the optional transition method, prior period financial statements have not been recast to reflect the new lease standard. The adoption of the new lease standard resulted in the addition of an operating lease right-of-use asset and an operating lease liability in the amount of $1.8 million to the consolidated balance sheet as of January 1, 2022.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected lease term. The interest rate implicit in lease contracts is typically not readily determinable. As such, the Company utilizes its incremental borrowing rate ("IBR"), which is the rate incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment. Given the absence of an outstanding debt agreement, a synthetic credit rating analysis was used in estimating the Company's IBR. Based on a synthetic credit rating of Ba3 and a term of 3.33 to six years, the IBR was determined to be 6% for leased liabilities at inception and 8.5% for 2022 leased liabilities. No adjustments to the right-of-use asset were required for items such as initial direct costs paid or incentives received.

The Company has elected to adopt the practical expedient provided in ASC 842 and not reassess, for leases that existed prior to the commencement date, 1). whether any expired or existing contracts are or contain leases, 2). lease classification, or 3). initial indirect costs for any existing leases. The Company has elected to combine lease and non-lease components as a single component for certain asset classes, when applicable. Operating leases are recognized on the balance sheet as operating lease right-of-use assets, operating lease liabilities current and operating lease liabilities non-current. The Company also elected to utilize the short-term lease recognition exemption and for those leases that qualified, the Company did not recognize right-of-use assets or lease liabilities. These leases are recognized on a straight-line basis over the expected term.

Impairment of Long-Lived Assets

The Company considers whether events or changes in facts and circumstances, both internally and externally, may indicate that an impairment of long-lived assets held for use, including right-of-use assets, are present. To the extent indicators or impairment exist, the determination of recoverability is based on an estimate of undiscounted future cash flows resulting from the use of the asset and its eventual disposition. In the event that such cash flows are not expected to be sufficient to recover the carrying amount of the asset, the assets are written down to their estimated fair values and the loss is recognized in the statements of operations.

Contingent Consideration

Contingent consideration in a business combination is included as part of the acquisition cost and is recognized at fair value as of the acquisition date. For contingent consideration, management is responsible for determining the appropriate valuation model and estimated fair value, and in doing so, considers a number of factors, including information provided by an outside valuation advisor. Contingent consideration liabilities are reported at their estimated fair values based on probability-adjusted present values of the consideration expected to be paid, using significant inputs and estimates. Key assumptions used in these estimates include probability assessments with respect to the likelihood of achieving certain milestones and discount rates consistent with the level of risk of achievement. The fair value of contingent consideration liabilities are remeasured each reporting period, with changes in the fair value included in current operations. The remeasured liability amount could be significantly different from the amount at the acquisition date, resulting in material charges or credits in future reporting periods.

Contingencies

Loss contingency provisions are recorded if the potential loss from any claim, asserted or unasserted, or legal proceeding is considered probable, and the amount can be reasonably estimated or a range of loss can be determined. These accruals represent management's best estimate of probable loss. Disclosure also is provided when it is reasonably possible that a loss will be incurred or when it is reasonably possible that the amount of a loss will exceed the recorded provision. On a quarterly basis, we review the status of each significant matter and assess its potential financial exposure. Significant judgment is required in both the determination of probability and as to whether an exposure is reasonably estimable. Because of uncertainties related to these matters, accruals are based only on the best information available at the time. As additional information becomes available, we reassess the potential liability related to pending claims and litigation and may change our estimates. Legal costs associated with legal proceedings are expensed when incurred.

Derivative Instruments

The Company accounts for common stock warrants as either equity-classified or liability-classified instruments based on an assessment of the specific terms of the warrants and applicable authoritative guidance in FASB Accounting Standards Codification ("ASC") 480, Distinguishing Liabilities from Equity ("ASC 480") and Derivatives and Hedging ("ASC 815"). Warrants classified as equity are recorded at fair value as of the date of issuance on the Company's consolidated balance sheets and no further adjustments to their valuation are made. Warrants classified as derivative liabilities that require separate accounting as liabilities are recorded on the Company's consolidated balance sheets at their fair value on the date of issuance and are revalued on each subsequent balance sheet date until such instruments are exercised or expire, with any changes in the fair value between reporting periods recorded as other income or expense. Management estimates the fair value of these liabilities using the Black-Scholes-Merton ("BSM") model and assumptions that are based on the individual characteristics of the warrants or instruments on the valuation date, as well as assumptions for future financings, expected volatility, expected life, yield, and risk-free interest rate.

At their issuance date in October 2021, the IPO Warrants (see Note 19. Stockholders' Equity) were accounted for as equity as these instruments meet all of the requirements for equity classification under ASC 815-40.

The Purchase Warrants issued in connection with the private placement offerings completed on December 1, 2021 and May 16, 2022 as well as the Inducement Warrants issued on July 26, 2022 were accounted for as liabilities as these warrants provide for a cashless settlement provision 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.*

Fair Value Measurements

The Company is required to disclose information on all assets and liabilities reported at fair value that enables an assessment of the inputs used in determining the reported fair values. ASC 820, *Fair Value Measurements and Disclosures*, or ASC 820, establishes a hierarchy of inputs used in measuring fair value that maximizes the use of observable inputs and minimizes the use of unobservable inputs by requiring that the observable inputs be used when available. Observable inputs are those that market participants would use in pricing the asset or liability based on market data obtained from sources independent of the Company. Unobservable inputs reflect the Company's assumptions about the inputs that market participants would use in pricing the asset or liability and are developed based on the best information available in the circumstances. The three levels of the fair value hierarchy are described below:

Level 1 – Quoted prices in active markets for identical assets or liabilities.

Level 2 – Inputs other than quoted prices included within Level 1 that are observable for the asset or liability, either directly or indirectly.

Level 3 – Unobservable inputs using estimates or assumptions developed by the Company, which reflect those that a market participant would use in pricing the asset or liability.

To the extent that valuation is based on models or inputs that are less observable or unobservable in the market, the determination of fair value requires more judgment. Accordingly, the degree of judgment exercised by the Company in determining fair value is greatest for instruments categorized in Level 3. A financial instrument's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement.

Fair Value of Financial Instruments

The carrying amounts reflected in the consolidated balance sheets for cash and cash equivalents, accounts receivable, other receivables, accounts payable and start-up cost financing included in acquisition contract liabilities approximate their fair values, due to their short-term nature.

Revenue Recognition

The Company accounts for revenue in accordance with ASC Topic 606, *Revenue from Contracts with Customers*. Under ASC Topic 606, revenue is recognized when a customer obtains control of promised goods or services in an amount that reflects the consideration to which the Company expects to be entitled in exchange for those goods or services. We recognize revenue when the customer obtains control of our product, which occurs at a point in time, typically upon delivery to the customer.

To determine revenue recognition, we perform the following five steps: (i) identify the contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price, including variable consideration, if any; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) we satisfy a performance obligation. We only apply the five-step model to contracts when collectability of the consideration to which we are entitled in exchange for the goods or services we transfer to the customer is determined to be probable.

The Company realizes its revenue primarily through the sale of its pharmaceutical products. Sales of Ameluz® are made directly to physicians, hospitals or other qualified healthcare providers. Sales are recognized, net of sales deductions, when ownership and control are transferred to the customer, which is generally upon delivery. Sales deductions include expected trade discounts and allowances, product returns, and government rebates. These discounts and allowances are estimated at the time of sale based on the amounts incurred or expected to be received for the related sales.

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

The payment terms for sales of our pharmaceutical products are generally short-term payment terms with the possibility of volume-based discounts, co-pay assistance discounts, or other rebates.

BF RhodoLED® is also sold directly to physicians, hospitals or other qualified healthcare providers through (i) direct sales or (ii) an evaluation period up to six-month for a fee, after which a customer can decide to purchase or return the lamp. For direct sales, revenue is recognized only after complete installation has taken place. As directed by the instruction manual, the lamp may only be used by the customer once it has been professionally installed. A final decision to purchase the lamps that are within the evaluation period does not need to be made until the end of the evaluation period. Lamps that are not returned at the end of the evaluation period are converted into sales in accordance with the contract terms. The Company generates immaterial revenues from the monthly fees during the evaluation period and from the sale of lamps at the end of the evaluation period.

Variable Consideration

Revenues from product sales are recorded at the net sales price (transaction price), which includes estimates of variable consideration for which sales reserves are established and which result from discounts, rebates and other incentives that are offered within contracts between the Company and its customers. Components of variable consideration include trade discounts and allowances, product returns, government rebates, and other incentives such as patient co-pay assistance. Variable consideration is recorded on the balance sheet as either a reduction of accounts receivable, if expected to be claimed by a customer, or as a current liability, if expected to be payable to a third party other than a customer. Where appropriate, these estimates take into consideration relevant factors such as the Company's historical experience, current contractual and statutory requirements, specific known market events and trends, industry data and forecasted customer buying and payment patterns. These reserves reflect the Company's best estimates of the amount of consideration to which it is entitled based on the terms of the contract. Actual amounts of consideration ultimately received may differ from the Company's estimates. If actual results in the future vary from the Company's estimates, the Company will adjust these estimates, and record any necessary adjustments in the period such variances become known.

Trade Discounts and Allowances – The Company provides customers with trade discounts, rebates, allowances and/or other incentives. The Company records estimates for these items as a reduction of revenue in the same period the revenue is recognized.

Government and Payor Rebates – The Company contracts with, or is subject to arrangements with, certain third-party payors, including pharmacy benefit managers and government agencies, for the payment of rebates with respect to utilization of its commercial products. The Company is also subject to discount and rebate obligations under state and federal Medicaid programs and Medicare. The Company records estimates for these discounts and rebates as a reduction of revenue in the same period the revenue is recognized.

Other Incentives – The Company maintains a co-pay assistance program which is intended to provide financial assistance to qualified patients with the cost of purchasing Xepi®. The Company estimates and records accruals for these incentives as a reduction of revenue in the period the revenue is recognized. The Company estimates amounts for co-pay assistance based upon the number of claims and the cost per claim that the Company expects to receive associated with products sold to customers but remaining in the distribution channel at the end of each reporting period.

Royalties

For arrangements that include sales-based royalties, the Company recognizes royalty expense at the later of (i) when the related sales occur, or (ii) when the performance obligation to which some or all of the royalty has been allocated has been satisfied (or partially satisfied). Royalty expense is recognized as cost of revenues.

Product Warranty

The Company generally provides a 36-month warranty for sales of BF-RhodoLED® for which estimated contractual warranty obligations are recorded as an expense at the time of installation. Customers do not have the option to purchase the warranty separately and the warranty does not provide the customer with a service beyond the assurance that BF-RhodoLED® complies with agreed-upon specifications. Therefore, the warranty is not considered to be a performance obligation. The lamps are subject to regulatory and quality standards. Future warranty costs are estimated based on historical product performance rates and related costs to repair given products. The accounting estimate related to product warranty expense involves judgment in determining future estimated warranty costs. Should actual performance rates or repair costs differ from estimates, revisions to the estimated warranty liability would be required. Warranty expenses incurred in 2022 and 2021 were negligible and are recognized as selling, general and administrative expenses.

Contract Costs

Incremental costs of obtaining a contract with a customer may be recorded as an asset if the costs are expected to be recovered. As a practical expedient, we recognize the incremental costs of obtaining a contract as an expense when incurred if the amortization period of the asset that we otherwise would have recognized is one year or less. Sales commissions earned by the Company's sales force are considered incremental costs of obtaining a contract. To date, we have expensed sales commissions as these costs are generally attributed to periods shorter than one year. Sales commissions are included in selling, general and administrative expenses.

Cost of Revenues

Cost of revenues is comprised of purchase costs of our products, third party logistics and distribution costs including packaging, freight, transportation, shipping and handling costs, and inventory adjustment due to expiring products, as well as sales-based royalties. Logistics and distribution costs totaled $0.5 million and $0.4 million for the years ended December 31, 2022 and 2021, respectively.

Share-Based Compensation

The Company measures and recognizes share-based compensation expense for equity awards based on fair value at the grant date. The Company uses the Black-Scholes-Merton ("BSM") option pricing model to calculate fair value of its stock option grants. The compensation cost for restricted stock awards is based on the closing price of the Company's common stock on the date of grant. Share-based compensation expense recognized in the statements of operations is based on the period the services are performed and recognized as compensation expense on a straight-line basis over the requisite service period. The Company accounts for forfeitures as they occur.

The BSM option pricing model requires the input of subjective assumptions, including the risk-free interest rate, the expected volatility of the value of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the share-based compensation expense could be materially different in the future. These assumptions are estimated as follows:

Risk-Free Interest Rate. The risk-free rate is based on the interest rate payable on United States Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.

Expected Volatility. The Company based the volatility assumption on a weighted average of the peer group re-levered equity volatility with 80% weight and the warrant implied volatility with 20% weight. The peer group was developed based on companies in the biotechnology industry whose shares are publicly traded. Due to our limited historical data and the long-term nature of the awards, the peer group volatility was much more heavily weighted.

Expected Term. The expected term represents the period of time that options are expected to be outstanding. Due to the lack of historical exercise data and given the plain vanilla nature of the options granted by the Company, the expected term is determined using the "simplified" method, as prescribed in SEC Staff Accounting Bulletin ("SAB") No. 107 ("SAB 107"), whereby the expected life equals the average of the vesting term and the original contractual term.

Dividend Yield. The dividend yield is 0% as the Company has never declared or paid, and for the foreseeable future does not expect to declare or pay, a dividend on its common stock.

Foreign Currency Transactions

Transactions realized in currencies other than USD are reported using the exchange rate on the date of the transaction.

Selling, General and Administrative Expense

Selling, general and administrative expenses are primarily comprised of compensation and benefits associated with our sales force, commercial support personnel, personnel in executive and other administrative functions, as well as medical affairs professionals. Other selling, general and administrative expenses include marketing, advertising, and other commercial costs to support the commercial operation of our product and professional fees for legal, consulting, and other general and administrative costs.

Advertising costs are expensed as incurred. For the years ended December 31, 2022 and 2021, advertising costs totaled $0.1 million and $0.5 million, respectively.

Income Taxes

The Company accounts for income taxes using the asset and liability method in accordance with ASC 740, *Income Taxes*, which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been recognized in the financial statements or in the Company's tax returns. Deferred taxes are determined based on the difference between the financial reporting and tax basis of assets and liabilities using enacted tax rates in effect in the years in which the differences are expected to reverse. Changes in deferred tax assets and liabilities are recorded in the provision for income taxes. The Company assesses the likelihood that its deferred tax assets will be recovered from future taxable income and, to the extent it believes, based upon the weight of available evidence, that it is more likely than not that all or a portion of deferred tax assets will not be realized, a valuation allowance is established through a charge to income tax expense. Potential for recovery of deferred tax assets is evaluated by estimating the future taxable profits expected and considering prudent and feasible tax planning strategies.

The Company accounts for uncertainty in income taxes recognized in the financial statements by applying a two-step process to determine the amount of tax benefit to be recognized. First, the tax position must be evaluated to determine the likelihood that it will be sustained upon external examination by the taxing authorities. If the tax position is deemed more likely-than-not to be sustained, the tax position is then assessed to determine the amount of benefit to recognize in the financial statements. The amount of the benefit that may be recognized is the largest amount that has a greater than 50% likelihood of being realized upon ultimate settlement. The provision for income taxes includes the effects of any resulting tax reserves, or unrecognized tax benefits, that are considered appropriate as well as the related net interest and penalties.

Net Loss per Share

Basic and diluted net income (loss) per common share is computed by dividing net income (loss) attributable to common stockholders by the weighted average number of common shares outstanding. When the effects are not anti-dilutive, diluted earnings per share is computed by dividing the Company's net income attributable to common stockholders by the weighted average number of common shares outstanding and the impact of all dilutive potential common shares outstanding during the period, including stock options, restricted stock units, and warrants, using the treasury stock method.

Recently Issued Accounting Pronouncements

In September 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments*, which requires entities to record expected credit losses for certain financial instruments, including trade receivables, as an allowance that reflects the entity's current estimate of credit losses expected to be incurred. The new standard will be effective for us on January 1, 2023. The Company does not believe this will have a material effect on its consolidated financial statements.

3. Acquisition Contract Liabilities

On March 25, 2019, we entered into an agreement (as amended, the "Share Purchase Agreement") with Maruho Co, Ltd. ("Maruho") to acquire 100% of the shares of Cutanea Life Sciences, Inc. ("Cutanea"). As of the date of the acquisition, Maruho Co, Ltd. owned approximately 29.9% of Biofrontera AG through its fully owned subsidiary Maruho Deutschland GmbH. Biofrontera AG is our former parent, and currently a significant shareholder.

Pursuant to the Share Purchase Agreement, Maruho agreed to provide $7.3 million in start-up cost financing for Cutanea's redesigned business activities ("start-up costs"). These start-up costs are to be paid back to Maruho by the end of 2023 in accordance with contractual obligations related to an earn-out arrangement. In addition, as part of the earn-out arrangement with Maruho, the product profit amount from the sale of Cutanea products as defined in the share purchase agreement will be shared equally between Maruho and Biofrontera until 2030 ("contingent consideration").

In connection with this acquisition in 2019, we recorded the $7.3 million in start-up cost financing, a $1.7 million contract asset related to the benefit associated with the non-interest bearing start-up cost financing and $6.5 million of contingent consideration related to the estimated profits from the sale of Cutanea products to be shared equally with Maruho.

The contract asset related to the start-up cost financing is amortized on a straight-line basis using a 6.0% interest rate over the 57-month term of the financing arrangement, which ends on December 31, 2023. The contract asset is shown net of the related start-up cost financing within acquisition contract liabilities, net.

The contingent consideration was recorded at acquisition-date fair value using a Monte Carlo simulation with an assumed discount rate of 6.0% over the applicable term. The contingent consideration is recorded within acquisition contract liabilities, net. The amount of contingent consideration that could be payable is not subject to a cap under the agreement. The Company re-measures contingent consideration and re-assesses the underlying assumptions and estimates at each reporting period utilizing a scenario-based method.

Acquisition contract liabilities, net consist of the following:

(in thousands)	December 31, 2022	December 31, 2021
Short-term acquisition contract liabilities:		
Contingent consideration	$ -	$ -
Start-up cost financing	7,300	3,600
Contract asset	(358)	(358)
Acquisition contract liabilities, net	$ 6,942	$ 3,242
Long-term acquisition contract liabilities:		
Contingent consideration	$ 2,400	$ 6,200
Start-up cost financing	-	3,700
Contract asset	-	(358)
Acquisition contract liabilities, net	$ 2,400	$ 9,542
Total acquisition contract liabilities:		
Contingent consideration	$ 2,400	$ 6,200
Start-up cost financing	7,300	7,300
Contract asset	(358)	(716)
Total acquisition contract liabilities, net	$ 9,342	$ 12,784

4. Fair Value Measurements

The following table presents information about the Company's assets that are measured at fair value on a recurring basis and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

(in thousands)	Level	December 31, 2022	December 31, 2021
Assets:			
Investment in equity securities	1	$ 10,548	$ -
Liabilities:			
Contingent Consideration	3	$ 2,400	$ 6,200
Warrant liability – 2021 Purchase Warrants	3	$ -	$ 12,854
Warrant liability - 2022 Purchase Warrants	3	$ 1,129	$ -
Warrant liability – 2022 Inducement Warrants	3	$ 1,714	$ -

Investment in equity securities

As of December 31, 2022, the Company had investments in common stock. The fair value of these investments was determined with Level 1 inputs through references to quoted market prices.

Contingent Consideration

Contingent consideration, which relates to the estimated profits from the sale of Cutanea products to be shared equally with Maruho, is reflected at fair value within acquisition contract liabilities, net on the consolidated balance sheets. The fair value is based on significant inputs not observable in the market, which represent a Level 3 measurement within the fair value hierarchy. The valuation of the contingent consideration utilizes a scenario-based method under which a set of payoffs are calculated using the term of the earnout, projections, and an appropriate metric risk premium. These payoffs are then discounted back from the payment date to the valuation date using a payment discount rate. Finally, the discounted payments are summed together to arrive at the value of the contingent consideration. The scenario-based method incorporates the following key assumptions: (i) the forecasted product profit amounts, (ii) the remaining contractual term, (iii) a metric risk premium, and (iv) a payment discount rate. The Company re-measures contingent consideration and re-assesses the underlying assumptions and estimates at each reporting period.

The following table provides a roll forward of the fair value of the contingent consideration:

(in thousands)	
Balance at December 31, 2020	**$ 7,602**
Change in fair value of contingent consideration	(1,402)
Balance at December 31, 2021	**$ 6,200**
Change in fair value of contingent consideration	(3,800)
Balance at December 31, 2022	**$ 2,400**

The decrease in fair value of the contingent consideration in the amount of $(3.8) million and $(1.4) million during the years ended December 31, 2022 and 2021 was recorded in operating expenses in the statements of operations.

Warrant Liabilities

The Purchase and Inducement Warrants were accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities in the accompanying consolidated balance sheets. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statement of operations.

The Company utilizes a Black-Scholes option pricing model to estimate the fair value of the Purchase and Inducement Warrants which is considered a Level 3 fair value measurement. Certain inputs utilized in our Black-Scholes pricing model may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of the fair value may cause a significant change to the fair value of our warrant liabilities which could also result in material non-cash gain or loss being reported in our consolidated statement of operations.

The fair value at issuance was estimated using a Black-Scholes pricing model based on the following assumptions at May 16, 2022 for the Purchase Warrants and July 26, 2022 for the Inducement Warrants:

	Purchase	Inducement
Stock price	$ 2.62	$ 1.64
Expiration term (in years)	5.50	4.34
Volatility	65.0%	70.0%
Risk-free Rate	2.83%	2.84%
Dividend yield	0.0%	0.0%

The fair value was estimated using Black-Scholes pricing model based on the following assumptions as of December 31, 2022 (outstanding warrants were all issued during 2022):

	Purchase	Inducement
Stock price	$ 0.92	$ 0.92
Expiration term (in years)	4.88	3.92
Volatility	70%	75%
Risk-free Rate	3.96%	4.07%
Dividend yield	0.0%	0.0%

The following table presents the changes in the warrant liabilities measured at fair value (in thousands):

	December 31, 2022	December 31, 2021
Fair value at beginning of year	$ 12,854	$ -
Issuance of new warrants	13,217	12,261
Exercise of warrants	(6,840)	(12,208)
Change in fair value of warrant liability	(16,388)	12,801
Fair value at end of year	$ 2,843	12,854

5. Revenue

We generate revenue primarily through the sales of our products Ameluz®, BF-RhodoLED® lamps and Xepi®. Revenue from the sales of our BF-RhodoLED® lamp and Xepi® are relatively insignificant compared with the revenues generated through our sales of Ameluz®.

Related party revenue relates to an agreement with Biofrontera Bioscience GmbH ("Bioscience") for BF-RhodoLED® leasing and installation service. Refer to *Note 17, Related Party Transactions*.

An analysis of the changes in product revenue allowances and reserves is summarized as follows:

(in thousands):	**Returns**	**Co-pay assistance program**	**Prompt pay discounts**	**Government and payor rebates**	**Total**
Balance at December 31, 2020	**$ 217**	**$ 52**	**$ 15**	**$ 43**	**$ 327**
Provision related to current period sales	6	423	40	168	637
Credit or payments made during the period	(180)	(374)	(7)	(157)	(718)
Balance at December 31, 2021	**$ 43**	**$ 101**	**$ 48**	**$ 54**	**$ 246**
Provision related to current period sales	10	574	19	210	813

Credit or payments made during the period	(5)	(666)	(62)	(244)	(977)
Balance at December 31, 2022	**$ 48**	**$ 9**	**$ 5**	**$ 20**	**$ 82**

6. Investment in Equity Securities

On October 25, 2022, the Company entered into private exchange agreements with certain holders of options to acquire common shares, nominal value €1.00 per share, of Biofrontera AG ("AG Options), a German stock corporation and significant shareholder of the Company, pursuant to which the parties agreed to a negotiated private exchange of 3,148,042 shares of the Company's common stock in exchange for the AG Options. There was no additional cost to exercise the AG Options. On November 8, 2022, the Company exercised the AG options in full to acquire 2,623,365 shares of Biofrontera AG. In addition, the Company purchased an additional 3,843,581 common shares of Biofrontera AG for a total of 6,446,946 shares or approximately 10% of Biofrontera AG's outstanding common shares as of December 31, 2022.

7. Accounts Receivable, net

Accounts receivable are mainly attributable to the sale of Ameluz®, the BF-RhodoLED® and Xepi®. It is expected that all trade receivables will be settled within twelve months of the balance sheet date.

The allowance for doubtful accounts was $0.1 million and negligible as of December 31, 2022 and 2021, respectively.

8. Other Receivables, Related Party

As of December 31, 2022, the Company has a receivable of $6.5 million ($3.7 short term and $2.8 long-term) due from the Biofrontera Group of which $6.4 million is due from Biofrontera AG for its 50% share of the balance of a legal settlement for which both parties are jointly and severally liable. The Company has a contractual right to repayment of its share of the settlement payments, plus interest and other miscellaneous settlement costs, from Biofrontera AG under the Settlement Allocation Agreement entered into on December 9, 2021 and as amended on March 31, 2022, which provides that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share. The March 31, 2022 Amended Settlement Allocation Agreement provides certain remedies to the Company, if Biofrontera AG fails to make timely reimbursements, which the Company may implement in its sole discretion, including the ability to charge interest at a rate of 6.0% per annum for each day that any reimbursement is past due and the ability to offset any overdue reimbursement amounts against payments owed to Biofrontera AG by the Company (including amounts owed under the Company's license and supply agreement for Ameluz®). As such, no reserve for the receivable has been recorded as of December 31, 2022 or December 31, 2021.

9. Inventories

Inventories are comprised of Ameluz®, Xepi® and the BF-RhodoLED® finished products.

In assessing the consumption of inventories, the sequence of consumption is assumed to be based on the first-in-first-out (FIFO) method. The provision related to BF-RhodoLED® devices was $0.1 million for the year ended December 31, 2022, and negligible for the year ended December 31, 2021. The provision for Xepi® inventory obsolescence was negligible for the years ended December 31, 2022 and December 31, 2021.

10. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	December 31, 2022	December 31, 2021
Receivable for common stock warrants proceeds	$ -	$ 3,258
Prepaid expenses	439	$ 824
Security deposits	85	149
Other	286	756
Total	$ 810	$ 4,987

11. Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	December 31, 2022	December 31, 2021
Computer equipment	$ 89	$ 85
Computer software	27	27
Furniture & fixtures	81	81
Leasehold improvement	368	368
Machinery & equipment	145	112
Property and equipment, gross	710	673
Less: Accumulated depreciation	(506)	(406)
Property and equipment, net	$ 204	$ 267

Depreciation expense was $0.1 million for each of the years ended December 31, 2022, and 2021, respectively, which was included in selling, general and administrative expense on the consolidated statements of operations.

12. Intangible Asset, Net

Intangible asset, net consists of the following:

(in thousands)	December 31, 2022	December 31, 2021
Xepi® license	$ 4,600	$ 4,600
Less: Accumulated amortization	(1,568)	(1,150)
Intangible asset, net	$ 3,032	$ 3,450

The Xepi® license intangible asset was recorded at acquisition-date fair value of $4.6 million and is amortized on a straight-line basis over the useful life of 11 years. Amortization expense was $0.4 million for each the years ended December 31, 2022 and 2021.

We review the Xepi® license intangible asset for impairment whenever events or changes in circumstances indicate that the carrying amount of the assets may not be fully recoverable. In October 2022, upon receiving notification of third-party manufacturing delays that impacted the timing of sales expansion and improved market positioning of the Xepi® product, we deemed it necessary to assess the recoverability of our Xepi® asset group. Future cash flows were estimated over the expected remaining useful life of the asset group and we determined that, on an undiscounted basis, expected cash flows exceeded the carrying amount of the asset group.

The Company did not recognize any impairment charges during the years ended December 31, 2022 or 2021.

13. Statement of Cash Flows Reconciliation

The following table provides a reconciliation of cash, cash equivalents, and restricted cash that sum to the total shown in the statements of cash flows:

(in thousands)	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 17,208	$ 24,545
Short-term restricted cash	-	47
Long-term restricted cash	200	150
Total cash, cash equivalent, and restricted cash shown on the statements of cash flows	$ 17,408	$ 24,742

14. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	December 31, 2022	December 31, 2021
Legal settlement (See Note 24)	$ 6,207	$ 5,625
Employee compensation and benefits	2,850	2,384
Professional fees	1,353	570
Product revenue allowances and reserves	82	246
Other	372	829
Total	$ 10,864	$ 9,654

15. Other Long-Term Liabilities

Other long-term liabilities consist of the following:

(in thousands)	December 31, 2022	December 31, 2021
Legal settlement – noncurrent (See Note 24)	$ -	$ 5,625
Other	21	24
Total	$ 21	$ 5,649

16. Income Taxes

As a result of the net losses, we have incurred in each fiscal year since inception, we have recorded no provision for federal income taxes for the years ended December 31, 2022 and December 31, 2021. Income tax expense incurred in 2022 and 2021 relates to state income taxes. At December 31, 2022 and December 31, 2021, the Company had no unrecognized tax benefits.

A reconciliation of the expected income tax (benefit) computed using the federal statutory income tax rate to the Company's effective income tax rate is as follows:

	Year ended December 31,	
	2022	**2021**
Income tax computed at federal statutory tax rate	21.00%	21.00%
State taxes	(5.85)%	(0.09)%
Permanent differences – non-deductible expenses	(37.93)%	(1.03)%
Change in fair value of contingent consideration	133.62%	0.78%
Change in fair value of warrant liabilities	576.27%	(7.13)%
True-ups	(7.42)%	-
Change in valuation allowance	(685.54)%	(13.62)%
Effective income tax rate	(5.85)%	(0.09)%

The principal components of the Company's deferred tax assets and liabilities consist of the following at December 31, 2022 and 2021:

(in thousands)	December 31, 2022	December 31, 2021
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 30,450	$ 24,307
Intangible assets	4,824	5,132
Acquisition contract liabilities	(96)	(187)
Property and equipment	123	103
Accrued expenses and reserves	890	1,693
Stock based compensation	449	-
Lease liability	361	-
Other	-	6
ROU asset	(369)	-
Investment revaluation	(469)	-
Total deferred tax assets	36,163	31,054
Less valuation allowance	(36,163)	(31,054)
Net deferred taxes	$ -	$ -

The Company has had no income tax expense due to operating losses incurred since inception. The Company has evaluated the positive and negative evidence bearing upon the realizability of its deferred tax assets. Based on this, the Company has provided a valuation allowance for the full amount of the net deferred tax assets as the realization of the deferred tax assets is not determined to be more likely than not. During 2022, the valuation allowance increased by $5.1 million, primarily due to the increase in the Company's net operating loss carryforwards during the period.

As of December 31, 2022, the Company had approximately $123.4 million and $89.2 million of Federal and state net operating loss carryforwards, respectively. $113.8 million of the federal NOLs are not subject to expiration and the remaining NOLs begin to expire in 2036. These loss carryforwards are available to reduce future federal taxable income, if any. These loss carryforwards are subject to review and possible adjustment by the appropriate taxing authorities. The amount of loss carryforwards that may be utilized in any future period may be limited based upon changes in the ownership of the Company's shareholders.

The Company follows the provisions of ASC 740-10, "Accounting for Uncertainty in Income Taxes," which specifies how tax benefits for uncertain tax positions are to be recognized, measured, and recorded in financial statements; requires certain disclosures of uncertain tax matters; specifies how reserves for uncertain tax positions should be classified on the balance sheet; and provides transition and interim period guidance, among other provisions. As of December 31, 2022, the Company has not recorded any amounts for uncertain tax positions. The Company's policy is to recognize interest and penalties accrued on any uncertain tax positions as a component of income tax expense, if any, in its statements of operations. As of December 31, 2022 the Company had no reserves for uncertain tax positions. For the year ended December 31, 2022 no estimated interest or penalties were recognized on uncertain tax positions.

The Company's tax returns 2019 through 2022 remain open and subject to examination by the Internal Revenue Service and state taxing authorities. Net operating loss carryovers from earlier years are also subject to exam and adjustment.

17. Related Party Transactions

License and Supply Agreement

On October 1, 2016, the Company executed an exclusive license and supply agreement with Biofrontera Pharma GmbH ("Pharma"), which was amended in July 2019 to increase the Ameluz® transfer price per unit from 35.0% to 50.0% of the anticipated net selling price per unit as defined in the agreement. It was further amended on October 8, 2021 so that the price we pay per unit will be based upon our sales history, although the minimum number of units to purchase per year remains unchanged. As a result of this amendment, the purchase price we pay Biofrontera Pharma for Ameluz® will range from 30% to 50% of the anticipated net price per unit based on our level of annual revenue. Under the agreement, the Company obtained an exclusive, non-transferable license to use Pharma's technology to market and sell the licensed products, Ameluz® and BF-RhodoLED® and must purchase the licensed products exclusively from Pharma. There was no consideration paid for the transfer of the license.

Purchases of the licensed products during the years ended December 31, 2022 and 2021 were $16.6 million and $9.4 million, respectively, and recorded in inventories in the consolidated balance sheets, and, when sold, in cost of revenues, related party in the consolidated statements of operations. Amounts due and payable to Pharma as of December 31, 2022 and 2021 were $1.3 million and $0.3 million, respectively, which were recorded in accounts payable, related parties in the consolidated balance sheets.

Service Agreements

In December 2021, we entered into an Amended and Restated Master Contract Services Agreement, or "Services Agreement", which provides for the execution of statements of work that will replace the applicable provisions of our previous intercompany services agreement dated January 1, 2016, or 2016 Services Agreement, by and among us, Biofrontera AG, Biofrontera Pharma and Biofrontera Bioscience, enabling us to continue to use the IT resources of Biofrontera AG and its wholly owned subsidiaries (the "Biofrontera Group") as well as providing access to the Biofrontera Group's resources with respect to quality management, regulatory affairs and medical affairs. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, pharmacovigilance, and investor relations services, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine 1) if they will be needed, and 2) whether they can or should be obtained from other third-party providers. Expenses related to the service agreement were $0.7 million and $0.7 million for the years ended December 31, 2022 and 2021, which were recorded in selling, general and administrative, related party. Amounts due to Biofrontera AG related to the service agreement were $0.2 million as of December 31, 2022 and 2021, which were recorded in accounts payable, related parties in the consolidated balance sheets.

Clinical Lamp Lease Agreement

On August 1, 2018, the Company executed a clinical lamp lease agreement with Biofrontera Bioscience GmbH ("Bioscience") to provide lamps and associated services.

Total revenue related to the clinical lamp lease agreements was approximately $0.1 million for each of the years ended December 31, 2022 and 2021 and recorded as revenues, related party. Amounts due from Bioscience for clinical lamp and other reimbursements were approximately $0.1 million for each of the years ended December 31, 2022 and 2021, which were recorded as accounts receivable, related party in the consolidated balance sheets.

Reimbursements from Maruho Related to Cutanea Acquisition

Pursuant to the Cutanea acquisition share purchase agreement, we received start-up cost financing and reimbursements for certain costs. These restructuring costs Maruho agreed to pay are referred to as "SPA costs" under the arrangement and are to be accounted for as other income. Refer to *Note 3, Acquisition Contract Liabilities*.

There were no amounts reimbursed relating to SPA costs for the year ended December 31, 2022. For the year ended December 31, 2021 the amounts reimbursed relating to SPA costs were $0.5 million and were recorded as other income in the consolidated statements of operations as the related expenses were incurred. There were no amounts due from Maruho for the year ended December 31, 2022. The amounts due from Maruho, primarily relating to SPA cost reimbursements, were $0.1 million as of December 31, 2021 and were recorded in other receivables, related parties in the consolidated balance sheets.

Others

The Company has recorded a receivable of $6.4 million and $11.3 million as of December 31, 2022 and December 31, 2021 due from Biofrontera AG for its 50% share of the balance of a legal settlement for which both parties are jointly and severally liable as of December 31, 2022. *Refer to Note 8, Other Receivables, Related Party*. The Company has recognized $0.1 and $0.0 million of interest income for the years ended December 31, 2022 and 2021, respectively in connection with this receivable.

As of December 31, 2022, our investment in equity securities valued at $10.5 million consists of 6,466,949 common shares of Biofrontera AG, a significant shareholder.

In accordance with a Share Purchase and Transfer Agreement dated, November 3, 2022, the Company purchased approximately 1,674,996 shares (of the total 6,466,949 shares) for $1.7 million from Maruho.

18. Restructuring costs

We restructured the business of Cutanea and incurred restructuring costs which were subsequently reimbursed by Maruho. Restructuring costs primarily relate to the winding down of Cutanea's operations. There were no restructuring costs for the year ended December 31, 2022. For the year ended December 31, 2021, restructuring costs were incurred in the amount of $0.8 million.

19. Stockholders' Equity

Under the Company's amended and restated certificate of incorporation, dated December 21, 2020, the Company is authorized to issue 300,000,000 shares of common stock, par value $0.001 per share and 20,000,000 shares of preferred stock, par value $.001 per share.

The holders of common stock are entitled to one vote for each share held. Common stockholders are not entitled to receive dividends, unless declared by the Board of Directors. The Company has not declared dividends since inception. In the event of liquidation of the Company, dissolution or winding up, the holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities. The common stock has no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to the common stock. The outstanding shares of common stock are fully paid and non-assessable.

Initial Public Offering. On November 2, 2021, the Company completed its initial public offering ("IPO") of 3,600,000 units ("Units") each consisting of (i) one share of common stock of the Company, par value $0.001 per share and (ii) one warrant (the "IPO Warrants") to purchase one common stock share at an exercise price of $5.00 per share. The IPO Warrants are immediately exercisable upon issuance for a period of five years after the issuance date. The common stock shares and Warrants were issued separately in the offering and may be transferred separately immediately upon issuance. The Units were sold at a price of $5.00 per Unit, with gross proceeds from the IPO of approximately $18 million, offset by $3.1 million in offering costs.

At the IPO date, the underwriters also exercised in full their option to purchase up to an additional 540,000 IPO Warrants at the purchase price of $0.01 per Warrant to cover over-allotments.

In connection with the IPO, the Company also issued to the underwriters Unit Purchase Options ("UPO") to purchase, in the aggregate, (a) 108,000 Units and (b) 16,200 Warrants (relating to the underwriters' exercise of the over-allotment option in full, with respect to the Warrants). The UPOs have an exercise price of $6.25 if exercisable for Units and $0.0125 if exercisable for Warrants. The UPOs are exercisable at any time from October 28, 2021 ("Effective Date") through the 5th anniversary of the Effective Date.

The UPOs issued to the underwriters were accounted for as equity under ASC 718, Compensation -Stock Compensation ("ASC 718"). The fair value of the UPOs, which were fully vested at the issuance date, was recognized as an offering cost against the proceeds from the IPO. The estimated fair value of the UPO Units of $0.3 million at the IPO date was determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $4.95, expected volatility of 60.0%, risk free rate of 1.15%, remaining contractual term of 5 years and a dividend yield of 0%. The estimated fair value of the UPO Warrants of $21,000 at the IPO date was determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $1.29, expected volatility of 60.0%, risk free rate of 1.15%, remaining contractual term of 5 years and a dividend yield of 0%.

Private Placement - On December 1, 2021, the Company settled the private placement in connection with a securities purchase agreement dated November 29, 2021 ("December 2021 PIPE"). In the December 2021 PIPE, the Company issued for the gross cash receipts of $15,000,000 (i) 1,350,000 shares of the common stock, (ii) a warrant to purchase up to 2,857,143 shares of the common stock ("Purchase Warrant") and (iii) a warrant to purchase up to 1,507,143 shares of the common stock ("Pre-Funded Warrant"). Each of the Purchase Warrant and the Pre-Funded Warrant is exercisable immediately and has an exercise term of five years and an exercise price of: (a) $5.25 per share with respect to the Purchase Warrant and (b) a nominal exercise price of $0.0001 per share with respect to the Pre-Funded Warrant. The shares of common stock and the accompanying warrants were issued separately and were immediately separable upon issuance. The combined purchase price for one share of common stock and one Purchase Warrant was $5.25 and the combined purchase price for one Pre-Funded Warrant and one common warrant was $5.24.

On December 28, 2021, 1,507,143 common stock shares were issued from the exercise of the Pre-Funded Warrant at an exercise price of $0.0001 per share of the Company's common stock.

In connection with the December 2021 PIPE, the Company, issued Unit Purchase Options ("PP-UPO") to the placement agents to purchase, in the aggregate, (a) 85,714 Units, consisting of one share of common stock and one warrant to purchase common stock. The PP-UPOs have an exercise price of $6.56 and are exercisable at any time for the period of 5 years.

The PP-UPOs issued to the underwriters were accounted for under ASC 718, Compensation -Stock Compensation ("ASC 718"). The fair value of the PP-UPOs, which were fully vested at the issuance date, was recognized as an offering cost of the December 2021 PIPE and allocated between warrants and common stock, based on the allocated proceeds. The Company estimated the fair value of the unit purchase options to be approximately $0.3 million at December 1, 2021 of which $0.2 million was allocated to the warrants and immediately expensed in the consolidated statement of operations and $0.1 million was allocated to the common stock and charged to equity. The fair value was determined using a Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $6.39, expected volatility of 60.0%, risk free rate of 1.15%, remaining contractual term of 5 years and a dividend yield of 0%.

Private Placement - On May 16, 2022, the Company entered into a Securities Purchase Agreement ("May 2022 PIPE"). In the May 2022 PIPE, the Company issued for the gross cash receipts of $9.4 million (i) 1,850,000 shares of the common stock, (ii) a warrant to purchase up to 3,419,000 shares of the common stock ("2022 Purchase Warrant") and (iii) a warrant to purchase up to 1,569,000 shares of the common stock ("2022 Pre-Funded Warrant"). The purchase price for one share of common stock (or common stock equivalent) and a warrant to purchase one share of common stock was $2.75. The 2022 Purchase Warrant will be exercisable nine months after the issue date, expires five and one-half years after the issue date and has an exercise price of: $2.77 per share. The Pre-Funded Warrant is exercisable immediately and has a term of exercise equal to five (5) years with a nominal exercise price of $0.001 per share.

Because the warrants are accounted for as liabilities, the May 2022 PIPE proceeds were allocated between the fair value of the warrants with the remaining proceeds allocated to common stock and additional paid in capital.

Exercise of 2022 Pre-Funded Warrant - On July 14, 2022, an investor exercised the 2022 Pre-Funded Warrant and purchased a total of 1,569,000 shares of common stock at an exercise price of $.001 per share, resulting in negligible net proceeds,

Exercise of 2021 Purchase Warrant and Issuance of July 2022 Inducement Warrant - On July 26, 2022, the Company entered into the Inducement Letter with the holder of the Company's 2021 Purchase Warrants (the "Investor"). The 2021 Purchase Warrants were originally issued on December 1, 2021 to purchase up to 2,857,143 shares of common stock, par value $0.001 per share. The Investor agreed to exercise for cash, the 2021 Purchase Warrants, in exchange for the Company's agreement to (i) lower the exercise price of the 2021 Purchase Warrants from $5.25 to $1.62 per share and (ii) issue a new warrant (the "Inducement Warrant") to purchase up to 4,285,715 shares of common stock. The Company received proceeds of $4.6 million, from the exercise of the 2021 Purchase Warrants and expensed the related issuance costs of $0.3 million.

The Inducement Warrant is exercisable on or after January 27, 2023 at a price per share of $1.66 and expires on December 1, 2026.

Adoption of a stockholder rights plan. On October 13, 2022 the Board of Directors ("Board") authorized and declared a dividend distribution of one Preferred Stock Purchase Right (a "Right") for each outstanding share of common stock to stockholders of record as of the close of business on October 24, 2022. In addition, one Right will automatically attach to each share of Common Stock issued between the record date of the distribution and the earlier of the distribution date and the expiration date of the Rights. Each Right entitles the registered holder to purchase from the Company a unit consisting of one ten-thousandth of a share (a "Unit") of Series A Junior Participating Cumulative Preferred Stock, par value $0.001 per share, of the Company at a cash exercise price of $5.00 per Unit, subject to adjustment, under certain conditions. The complete terms of the Rights are set forth in the Stockholder Rights Agreement, dated October 13, 2022, between the Company and Computershare Trust Company, N.A, as Rights agent.

While the stockholder rights plan described above (the "Rights Plan") is effective immediately, the Rights would become exercisable only if a person or group, or anyone acting in concert with such a person or group, acquires beneficial ownership, as defined in the Rights Agreement, of 20% or more of the Company's issued and outstanding common stock in a transaction not approved by the Company's Board of Directors. The Rights Plan will expire on October 13, 2023.

Under the Rights Plan, a person or group who beneficially owned 20% or more of the Company's outstanding Common Stock prior to the first public announcement of the Rights Plan on October 14, 2022 will not trigger the Rights so long as they do not acquire beneficial ownership of any additional shares of Common Stock at a time when they still beneficially own 20% or more of such Common Stock.

Series A Junior Participating Cumulative Preferred Stock. In connection with the adoption of the Rights Plan, the Board approved a Certificate of Designations of Series A Junior Participating Cumulative Preferred Stock which designates the rights, preferences and privileges of 5,000 shares of Preferred Stock. The Certificate of Designations was filed with the Secretary of State of Delaware and became effective on October 13, 2022.

Exchange Agreement – On October 25, 2022, the Company entered into private exchange agreements with certain holders of options to acquire ordinary shares, nominal value €1.00 per share, of Biofrontera AG, a German stock corporation, pursuant to which the parties agreed to a negotiated private exchange of 3,148,042 shares of the Company's common stock in exchange for the AG Options.

Warrants – The following table summarizes information with regard to the IPO Warrants, and the PIPE Warrants, which includes the Inducement and 2022 Pre-Funded Warrants (together, the "Warrants") share activity for the year ended December 31, 2022:

	Warrant - PIPE	Warrant - IPO	Total Warrants	Weighted Average Exercise Price
Balance, December 31, 2020	-	-	-	$ -
Issued	4,364,286	4,140,000	8,504,286	5.13
Exercised	(1,507,143)	(2,647,606)	(4,154,749)	5.09
Balance, December 31, 2021	2,857,143	1,492,394	4,349,537	5.16
Issued	9,273,715	-	9,273,715	1.79
Exercised	(4,426,143)	-	(4,426,143)	1.05
Balance, December 31, 2022	7,704,715	1,492,394	9,197,109	$ 2.61

20. Equity Incentive Plans and Share-Based Payments

2021 Omnibus Incentive Plan

In 2021, our Board of Directors adopted and our shareholders approved, the 2021 Omnibus Incentive Plan ("2021 Plan). Under the original 2021 Plan, 2,750,000 shares are reserved and authorized for awards and the maximum contractual term is 10 years for stock options issued under the 2021 Plan. On December 12, 2022, the 2021 Plan was amended by our stockholders and the number of shares authorized for awards under the 2021 Plan was increased by 2,589,800 to 5,339,800. As of December 31, 2022, there were 3,088,876 shares available for future awards under the amended 2021 Plan.

Non-qualified stock options

We maintain the 2021 Plan for the benefit of our officers, directors and employees. Employee stock options granted under the 2021 Plan generally vest in equal annual installments over three years and are exercisable for a period of up to ten years from the grant date. Non-employee director options vest in equal monthly installments following the date of grant and will be fully vested on the one-year anniversary of the date of grant. All stock options are exercisable at a price equal to the market value of the common shares underlying the option on the grant date.

The Company recognizes the grant-date fair value of share-based awards granted as compensation expense on a straight-line basis over the requisite service period. The fair value of stock options is estimated at the time of grant using the Black-Scholes option pricing model, which requires the use of inputs and assumptions such as the fair value of the underlying stock, exercise price of the option, expected term, risk-free interest rate, expected volatility and dividend yield. The Company elects to account for forfeitures as they occur.

The fair value of each option was estimated on the date of the grant using the BSM option pricing model with the following assumptions:

	2022	2021
Expected volatility	55% -70%	55.0%
Expected term (in years)	5.24 - 6.0	6.0
Risk-free interest rate	1.34% - 4.10%	1.34%
Expected dividend yield	0.0%	0.0%

Share-based compensation expense of approximately $0.8 million was recorded in selling, general and administrative expenses on the accompanying consolidated statement of operations for the year ended December 31, 2022. There was negligible share-based compensation expense for the year ended December 31, 2021.

Options outstanding and exercisable under the employee share option plan as of December 31, 2022 and December 2021, and a summary of option activity during the year then ended is presented below.

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding at December 31, 2020	-	$ -		
Granted	617,696	$ 4.77		
Exercised	-	$ -		
Canceled or forfeited	(4,082)	$ 4.77		
Outstanding at December 31, 2021	613,614	$ 4.77	9.94	$ 1,687
Granted	1,290,489	$ 2.41		
Exercised	-	$ -		
Canceled or forfeited	(166,759)	$ 3.80		
Outstanding at December 31, 2022	1,737,344	$ 3.11	9.27	$ 1
Exercisable at December 31, 2022	222,829	$ 4.27	8.99	$ -

(1) The aggregate intrinsic value is calculated as the difference between the exercise price of the underlying options and the fair value of the common stock for the options that were in the money at December 31, 2022 and December 31, 2021.

As of December 31, 2022, there was $2.2 million of unrecognized compensation cost related to unvested stock options held by employees and directors, which is expected to be recognized over a weighted-average period of approximately 2.3 years.

Share-Based Compensation (RSUs)

Restricted Stock Units ("RSUs") will vest annually over two years, subject to the recipient's continued service with the Company through the applicable vesting dates. The fair value of each RSU is estimated based on the closing market price of the Company's common stock on the grant date.

Share-based compensation expense of $1.0 million and $0.1 million for the RSUs was recorded in selling, general and administrative expenses in the accompanying consolidated statement of operations for the years ended December 31, 2022 and 2021.

As of December 31, 2022, there was $0.6 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 1.4 years. The total fair value of shares vested during the years ended December 31, 2022 and 2021 was $0.8 million and $0.0 million, respectively.

The following table summarizes the activity for RSUs during the year ended December 31, 2022 and December 31, 2021:

	Shares	Weighted Average Grant Date Fair Value
Outstanding balance at December 31, 2020	-	$ -
Granted	170,068	4.77
Issued	-	-
Forfeited	-	-
Outstanding balance at December 31, 2021	170,068	$ 4.77
Awarded	343,512	2.61
Issued	(170,068)	4.77
Forfeited	-	-
Outstanding balance at December 31, 2022	343,512	$ 2.61
Vested and expected to vest at December 31, 2022	343,512	2.61

21. Interest Expense, net

Interest expense, net consists of the following:

	For years ended December 31,	
(in thousands)	2022	2021
Interest expense	(12)	(2)
Contract asset interest expense	(358)	(358)
Interest income- related party	165	-
Interest income – other	10	16
Interest expense, net	$ (195)	$ (344)

Contract asset interest expense relates to the $1.7 million contract asset in connection with the $7.3 million start-up cost financing received from Maruho under the Cutanea acquisition share purchase agreement. The contract asset is amortized on a straight-line basis using a 6% interest rate over the financing arrangement contract term, which ends on December 31, 2023.

Related party interest income relates to the recorded receivable of $6.1 million from Biofrontera AG for its 50% share of the balance of a legal settlement.

22. Other Income, net

Other income, net consists of the following:

	For years ended December 31,	
(in thousands)	2022	2021
Reimbursed SPA costs	$ -	$ 539
Other, net	33	150
Other income, net	$ 33	$ 689

Other, net, primarily includes gain (loss) on foreign currency transactions and gain on termination of operating leases.

23. Net Loss per Share

Basic and diluted net loss per share attributable to common stockholders is calculated as follows (in thousands, except share and per share amounts):

	For years ended December 31,	
	2022	2021
Net loss	$ (640)	$ (37,713)
Weighted average common shares outstanding, basic and diluted	21,139,765	8,808,233
Net loss per share, basic and diluted	$ (0.03)	$ (4.28)

The following table sets forth securities that were anti-dilutive for diluted EPS for the periods presented but which could potentially dilute EPS in the future:

December 31,	2022	2021
Common stock warrants	9,197,109	4,349,537
Common stock options and RSUs	2,080,856	783,682
Unit Purchase Options	403,628	403,628

24. Commitments and Contingencies

Facility Leases

The Company leases its corporate headquarters under an operating lease that expires in August 2025. The Company has the option to extend the term of the lease for one five (5) year period upon written notice to the landlord. The extension period has not been included in the determination of the ROU asset or the lease liability as the Company concluded that it is not reasonably certain that it would exercise this option. The Company provided the landlord with a security deposit in the amount of $0.1 million, which was recorded as other assets in the consolidated balance sheets.

The Company has also entered into a master lease agreement for its vehicles. After an initial non-cancelable twelve-month period each vehicle is leased on a month to month basis. Based on historical retention experience of approximately three years, the vehicles have expiration dates ranging from February 2023 through September 2025.

In calculating the present value of the lease payments, the Company has elected to utilize its incremental borrowing rate based on the original lease term and not the remaining lease term. Given the absence of an outstanding debt agreement, a synthetic credit rating analysis was used in estimating the Company's IBR. Based on a synthetic credit rating of Ba3 and a term of 3.33 to six years, the IBR was determined to be 6% for leased liabilities at inception and 8.5% for 2022 leased liabilities.

The components of lease expense for the year ended December 31, 2022 was as follows (in thousands except lease term and discount rate):

Lease expense	Operating Leases
Amortization of ROU assets (operating lease cost)	$ 653
Interest on lease liabilities	99
Total lease expense	$ 752

Other Information	
Operational cash flow used for operating leases	$ 781
ROU assets obtained in exchange for lease liabilities	234
Weighted -average remaining lease term (in years)	2.54
Weighted -average discount rate	6.31%

Future lease payments under non-cancelable leases as of December 31, 2022 were as follows (in thousands):

Years ending December 31,	Future lease commitments
2023	565
2024	541
2025	349
Thereafter	-
Total future minimum lease payments	$ 1,455
Less imputed interest	$ (109)
Total lease liability	$ 1,346

Reported as:	
Operating lease liability, current	$ 498
Operating lease liability, non-current	848
Total	1,346

Cutanea payments

We have a contract in which we agreed to repay to Maruho $3.6 million on December 31, 2022 and $3.7 million on December 31, 2023 in start-up cost financing paid to us in connection with the Cutanea acquisition.

We have filed for arbitration against Maruho with the International Chamber of Commerce ("ICC") regarding issues with Maruho's contract manufacturer that were not disclosed at the time of the Agreement and therefore are evaluating the repayment of the $7.3 million of start-up costs. The arbitration notes that Maruho breached the agreement with Cutanea due to the undisclosed manufacturing issues and seeks damages as well as a declaration that we are not obligated to repay Maruho.

We are also obligated to share product profits with Maruho equally from January 1, 2020 through October 30, 2030. Refer to *Note 3, Acquisition Contract Liabilities*.

Milestone payments with Ferrer Internacional S.A.

Under the Xepi LSA, we are obligated to make payments to Ferrer upon the occurrence of certain milestones. Specifically, we must pay Ferrer i) $2,000,000 upon the first occasion when annual net sales of Xepi® under the Xepi LSA exceed $25,000,000, and ii) $4,000,000 upon the first occasion annual net sales of Xepi® under the Xepi LSA exceed $50,000,000. No payments were made in 2022 or 2021 related to Xepi® milestones.

Contingent liability related to shares of Biofrontera AG acquired from Maruho through subscription rights

Dependent on the outcome of legal proceedings between Biofrontera AG and Maruho, the Company may be liable for an additional payout of $0.9 million in relation to the shares of Biofrontera AG acquired from Maruho through a subscription rights agreement. In accordance with ASC 450-20-50-3, *Contingencies,* we have not accrued any liability associated with the subscription rights purchase, as the liability is not considered probable.

Legal proceedings

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, *Contingencies*. The Company expenses as incurred the legal costs related to such legal proceedings.

On November 29, 2021, the Company entered into a settlement and release agreement with respect to a lawsuit filed March 23, 2018 in the United States District Court for the District of Massachusetts in which we were alleged to have infringed on certain patents and misappropriated certain trade secrets. In the settlement, the Company and Biofrontera AG together agreed to make an aggregate payment of $22.5 million and engage a forensic expert to destroy data at issue in the litigation to settle the claims in the litigation.

While Biofrontera AG has agreed to pay fifty percent of the settlement costs, we remain jointly and severally liable to DUSA for the full cash settlement amount, meaning that in the event Biofrontera AG does not pay all or a portion of the amount it owes under the Agreement, DUSA could compel us to pay Biofrontera AG's share. If either we or Biofrontera AG violates the terms of the settlement agreement, we or Biofrontera AG may be liable for a greater amount. If we become liable for more than our agreed share of the aggregate settlement amount, either of these events could have a material adverse effect on our business, prospects, financial condition and/or results of operations. As of December 31, 2022, we have reflected a legal settlement liability in the amount of $6.2 million for the remaining payments due under the settlement, including the estimated remaining cost of the forensic expert and a related receivable from related party of $6.4 million for the remaining legal settlement costs to be reimbursed in accordance with the Settlement Allocation Agreement, which provided that the settlement payments, including the cost of the forensic expert, would first be made by the Company and then reimbursed by Biofrontera AG for its share.

25. Retirement Plan

The Company has a defined-contribution plan under Section 401(k) of Internal Revenue Code (the "401(k) Plan"). The 401(k) Plan covers all employees who meet defined minimum age and service requirements and allows participants to defer a portion of their annual compensation on a pre-tax basis. The Company matches 50% of employee contributions up to a maximum of 6% of employees' salary.

For each of the years ended December 31, 2022 and 2021, matching contribution costs paid by the Company were $0.2 million.

26. Subsequent Events

On March 9, 2023, we entered into the Commitment Letter with MidCap, in respect of MidCap's commitment to provide us with the Revolving Facility, subject to the borrowing base formula, minimum excess availability and other terms and conditions thereof, in the aggregate principal amount of up to $6.5 million. The Revolving Facility shall be secured by a lien on substantially all of the assets of the Company, subject to customary exceptions.

The proceeds of the loans under the Revolving Facility shall be used by the Company to provide working capital. The Revolving Facility shall bear interest at the 30-Day Adjusted Term SOFR Rate, set monthly on the first day of the month and subject to a floor of 2.25%, plus 4.00%. In the event of a called event of default, a default interest rate of 3.00% percent shall be added to the aforementioned rate. Under the terms of the Revolving Facility, amounts available for advances would be subject to a borrowing base, which is a formula based on certain eligible receivables and reserves.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Form 10-K, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2022, our disclosure controls and procedures were effective at the reasonable assurance level.

Previously Identified Material Weaknesses in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the audits of our financial statements as of and for the years ended December 31, 2021 and December 31, 2020, we identified a material weakness in our internal control over financial reporting. The previously identified material weakness pertains to our oversight of work being performed for the Company by third-party service providers; as the Company's management review control over information produced by third-party service providers was not sufficiently precise to identify errors. Specifically, as part of the valuation of an intangible asset in connection with the acquisition of Cutanea, we failed to identify a computational error within the valuation model for the Xepi® intangible asset. In addition, in 2021 an error in the valuation of the same intangible asset was identified relating to insufficient information being provided to the third-party consultant in connection with an impairment assessment.

We have continued our remediation work by adding steps to the engagement of third-party specialists who provide assistance with complex or judgmental accounting areas, including checks and balances over the proper flow of information to the specialist to allow for an adequate understanding of the transaction.

We have also continued to assess the competency of any third-party specialists prior to engagement to ensure that the Company is utilizing appropriate firms and individuals with regard to technical accounting matters. Annually, this assessment is documented to support the Company's assessment of third-party specialists used as part of the financial reporting process.

We have implemented controls and procedures to ensure that an appropriate and sufficient review is being performed over both the data being provided to and from any third-party specialists. These checks are designed to ensure that the Company is providing all relevant data to third-party specialists, and that sufficient procedures are being performed to validate and challenge the assumptions in any valuation reports, validate that the detail in the valuation is accurate, and that any formulas and calculations are validated for clerical accuracy.

As a result of the remediation activities and controls in place as of December 31, 2022 described above, we have remediated this previously disclosed material weakness. However, completion of remediation does not provide assurance that our remediated controls will continue to operate properly or that our financial statements will be free from error.

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as defined in Rules 13a-15(f) and 15d-15(f) of the Exchange Act. Our management, under the supervision and with the participation of our principal executive officer and principal financial officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2022 based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (2013 Framework). Based on the results of its evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2022.

Remediation of Prior Material Weakness

Through effective implementation of the Company's remediation plan, the Company has strengthened its internal control environment and has addressed the material weaknesses that were identified at December 31, 2021. Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO, in Internal Control—Integrated Framework (2013). Based on our assessment, the Company concluded that the material weakness has been remediated as of December 31, 2022.

Attestation Report of the Registered Public Accounting Firm

As a smaller reporting company as defined in the Exchange Act, we are exempt from the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002. As a result, our independent registered public accounting firm has not audited or issued an attestation report with respect to the effectiveness of our internal control over financial reporting as of December 31, 2022.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended December 31, 2022 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act), other than the certain internal controls implemented in connection with our remediation efforts described above.

Item 9B. Other Information

On March 9, 2023, we entered into the Commitment Letter with MidCap, in respect of MidCap's commitment to provide us with the Revolving Facility, subject to the borrowing base formula, minimum excess availability and other terms and conditions thereof, in the aggregate principal amount of up to$6.5 million. The Revolving Facility shall be secured by a lien on substantially all of the assets of the Company, subject to customary exceptions.

The proceeds of the loans under the Revolving Facility shall be used by the Company to provide working capital.

Pursuant to the Commitment Letter, the final documentation for the Revolving Facility shall include conditions to borrowings, representations and warranties, affirmative and negative covenants and other terms and conditions, each to be negotiated and mutually agreed and customary for financings of this type and size.

The Revolving Facility shall bear interest at the 30-Day Adjusted Term SOFR Rate, set monthly on the first day of the month and subject to a floor of 2.25%, plus 4.00%. In the event of a called event of default, a default interest rate of 3.00% percent shall be added to the aforementioned rate. Under the terms of the Revolving Facility, amounts available for advances would be subject to a borrowing base, which is a formula based on certain eligible receivables and reserves.

The Company also is obligated to pay MidCap certain fees and charges, including (i) at closing, a facility fee equal to 2.00% times the commitments under the Revolving Facility, (ii) an annual fee equal to 1.00% times the commitments under the Revolving Facility, (iii) audit fees in connection with any audits or inspections by MidCap or its agents of collateral or the Company's operations or business (not to exceed $10,000 per year), (iv) a collateral monitoring charge of $2,000 per month and (v) an unused line fee of 0.375% per annum on the daily average of the undrawn portion of the commitments under the Revolving Facility.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Executive Officers and Directors

The following table provides information regarding our executive officers and members of our board of directors (ages as of the date of this Form 10-K):

Name	Age	Position(s)	Since
Executive Officers			
Prof. Hermann L✔bbert Ph.D.	66	Executive Chairman and Director	November 2021
Erica Monaco, CPA	38	Chief Executive Officer	November 2021
Eugene Frederick Leffler III	39	Chief Financial Officer	October 2022
Non-Employee Directors			
John J. Borer	65	Director	November 2021
Loretta M. Wedge, CPA, CCGMA	62	Director	November 2021
Beth J. Hoffman, Ph.D.	65	Director	November 2021
Kevin D. Weber	64	Director	March 2022

Executive Officers

Prof. Hermann L✔bbert, Ph.D. founded Biofrontera AG in 1997 and has served as Biofrontera Inc.'s Executive Chairman since November 2021 and as chairman of its board of directors since March 2015. Until December 2021, Prof. Dr. L✔bbert had served as the chief executive officer of Biofrontera AG, chairman of the management board of Biofrontera AG, and as a managing director of all subsidiaries of Biofrontera AG. Prof. Dr. L✔bbert has also served as the chief executive officer of Biofrontera Inc. (March 2015 – January 2020; March 2021-November 2021) and as the chairman of Biofrontera Inc.'s board of directors (March 2015-present). He studied biology in his hometown of Cologne and received his doctorate there in 1984. Following 3.5 years in academic research at the University of Cologne and the California Institute of Technology, he gained experience in managing a global research organization during 10 years at Sandoz, where he served as Head of Genome Research, and Novartis Pharma AG, where he served as a member of the global Neuroscience Research Management Team. He qualified as a university lecturer at the Swiss Federal Institute of Technology (ETH) Zurich and in addition to his engagements at Biofrontera held a professorship for animal physiology at the Ruhr-University Bochum from which he retired on February 28, 2022.

Erica Monaco has served as Biofrontera Inc.'s Chief Executive Officer since November 2021. She has held senior leadership positions since joining Biofrontera in 2016, including as Chief Financial Officer and Chief Operating Officer and acted as a member of Biofrontera Inc.'s Board of Directors from January 2020 until November 2021. Erica previously held financial leadership roles with SUN Pharma from 2013 to 2016 where she directed financial operations for two GMP facilities specializing in PDT, sterile injectable diagnostics and contract manufacturing. Prior to 2013, Erica worked for WGBH Educational Foundation managing financial planning and analysis for public media production and broadcasting and for Deloitte providing audit, assurance and tax consulting services for public companies. Erica received her Bachelor of Business Administration with an Accounting concentration and her Master of Science in Accounting (M.S.A) from The Isenberg School of Management at the University of Massachusetts. She holds an active CPA license.

Fred Leffler has served as Biofrontera Inc's Chief Financial Officer since October 2022. Mr. Leffler is an experienced financial executive with 15 years of leadership, financial management, consultancy and operations experience across a range of private and public organizations, including growth-stage, private equity and Fortune 100 companies. Prior to joining the Company, Mr. Leffler served as a Senior Manager at McKinsey & Company since January 2022 as well as in different capacities, including Associate and Senior Manager from September 2015 to November 2019. Prior to rejoining McKinsey & Company, Mr. Leffler served as the Senior Director, Corporate Finance & Restructuring of FTI Consulting from August 2020 to January 2022. Prior to joining FTI Consulting, he served as Vice President, Data & Analytics of Rockcreek from November 2019 to August 2020. Earlier in his career, Mr. Leffler held various financial positions at General Electric and Sun Edison. Fred received his Bachelor of Science, Business Administration (BSBA) degree from the Ohio State University Fisher School of Business, and his Master of Business Administration (MBA) from Duke University's Fuqua School of Business.

Non-Employee Directors

John J. Borer III, J.D. became a member of our board of directors in November 2021. Since 2012, he has been the Senior Managing Director and Co-Head of Investment Banking at The Benchmark Company, LLC. He was formerly the Chief Executive Officer and Head of Investment Banking at Rodman & Renshaw and has held senior positions at Security Pacific Business Credit and Barclays American Business Credit. Mr. Borer has also served on the Supervisory Board of Biofrontera AG since May 2016 until December 2021. He holds a Doctor of Law degree (J.D.) from Loyola Law School in Los Angeles, California and a degree in Agricultural Economics from The University of California, Davis.

Loretta M. Wedge, CPA, CCGMA became a member of our board of directors in November 2021. She has been the Managing Partner of SemperFi Accounting Services, LLC since July 2019. Prior to that, from February to October 2017 she was the Vice President, Finance & Controller of Velcro Companies and between June 2015 and February 2017, she was the Vice President & Controller of CRISPR Therapeutics. Ms. Wedge is a financial executive with over 25 years of both public and private sector experience including extensive manufacturing, utility, medical device, bio-pharma and experience. She has an M.B.A. from California State University in Sacramento, California. She holds an active CPA license and is also a Certified Chartered Global Management Accountant.

Beth J. Hoffman, Ph.D. became a member of our board of directors in November 2021. Dr. Hoffman is the founder, and, since 2015, has been the President and Chief Executive Officer, of Origami Therapeutics, Inc., in San Diego, California. Dr. Hoffman has over 20 years of experience in drug discovery and development. Dr. Hoffman has made major contributions to the launch of two first-in-class drugs and two best-in-class drugs for Cystic Fibrosis. Beth holds her Ph.D. in Biology from The Johns Hopkins University in Baltimore, Maryland.

Kevin D. Weber became a member of our board of directors in March 2022. Mr. Weber is an experienced pharmaceutical executive who brings to Biofrontera more than 30 years of executive and commercialization experience with a particular expertise in product marketing. He has worked in a range of therapeutic areas including clinical and aesthetic dermatology, pain management, inborn errors of metabolism and respiratory medicine. He recently retired from his position as a Principal at Skysis, a biotech-focused brand management consulting practice, and previously served as CEO of Paraffin International. Prior to Paraffin, Mr. Weber served in senior executive and marketing roles at Depomed, Hyperion Therapeutics and Medicis Pharmaceuticals. From 2016 to 2021 Mr. Weber served as a member of the supervisory board of Biofrontera AG. Mr. Weber previously served on the Boards of Directors of the American Academy of Pain Medicine Foundation, the American Chronic Pain Association and the Arizona Bioindustry Association. He holds a B.S. in Business Administration from Western Michigan University.

Family Relationships

There are no family relationships between any director or executive officer.

Involvement in Certain Legal Proceedings

None of our directors, executive officers or control persons have been involved in any of the following events during the past ten years:

1. any bankruptcy petition filed by or against any business of which such person was a general partner or executive officer either at the time of the bankruptcy or within two years prior to that time;

2. any conviction in a criminal proceeding or being subject to a pending criminal proceeding (excluding traffic violations and other minor offences);

3. being subject to any order, judgment, or decree, not subsequently reversed, suspended or vacated, of any court of competent jurisdiction, permanently or temporarily enjoining, barring, suspending or otherwise limiting his involvement in any type of business, securities or banking activities; or

4. being found by a court of competent jurisdiction (in a civil action), the SEC or the Commodity Futures Trading Commission to have violated a federal or state securities or commodities law, and the judgment has not been reversed, suspended, or vacated.

Delinquent Section 16(a) Reports

Section 16(a) of the Securities Exchange Act of 1934 requires our executive officers and directors and persons who own more than 10% of our common stock to file with the Securities and Exchange Commission initial statements of beneficial ownership, reports of changes in ownership and annual reports concerning their ownership of our common stock and other equity securities, on Forms 3, 4 and 5 respectively. Executive officers, directors and greater than 10% shareholders are required by the SEC regulations to furnish us with copies of all Section 16(a) reports that they file.

Based solely on our review of the copies of such forms received by us, or written representations from certain reporting persons, we believe that during fiscal year ended December 31, 2022 our officers, directors and greater than 10% percent beneficial owners were in compliance with all applicable filing requirements except for (a) a late Form 4 filed for Prof. Dr. L✔bbert on January 19, 2022 to report employee stock grants, (b) late Form 4s filed for Prof. Dr. L✔bbert, Ms. Monaco, Ms. Hoffman, Ms. Wedge, Mr. Weber and Mr. Borer on May 26, 2022 to report equity compensation and (c) a late Form 4 filed for Prof. Dr. L✔bbert and Ms. Monaco on September 19, 20222 to report the vesting of restricted stock units.

Code of Ethics and Code of Conduct

We have adopted a written code of business conduct and ethics that applies to our directors, officers and employees, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the code is posted on our website at *https://investors.biofrontera-us.com/wp-content/uploads/2021/10/Code-of-Conduct.pdf*. In addition, we post on our website all disclosures that are required by law or the Nasdaq listing standards concerning any amendments to, or waivers from, any provision of the code. The information on or accessed through our website is deemed not to be incorporated in this Form 10-K or to be part of this Form 10-K.

Procedures for Shareholders to Recommend Director Nominees

There have been no material changes to the procedures by which security holders may recommend nominees to our board of directors.

Audit Committee

We have an audit committee of the board of directors, which consists of Mr. Weber, Dr. Hoffman and Ms. Wedge. Before the expiration of the phase-in period applicable to initial public offerings under SEC and Nasdaq rules, all members of our audit committee will be independent for audit committee purposes. The board of directors has determined that Ms. Wedge qualifies as an "audit committee financial expert," as defined under rules and regulations of the SEC.

The audit committee's duties, which are specified in our Audit Committee Charter, include, but are not limited to:

- reviewing and discussing with management and the independent auditor the annual audited financial statements, and recommending to the board whether the audited financial statements should be included in our Form 10-K
- discussing with management and the independent auditor significant financial reporting issues and judgments made in connection with the preparation of our financial statements;
- discussing with management major risk assessment and risk management policies;
- monitoring the independence of the independent auditor;
- verifying the rotation of the lead (or coordinating) audit partner having primary responsibility for the audit and the audit partner responsible for reviewing the audit as required by law;

- reviewing and approving all related-party transactions;
- inquiring and discussing with management our compliance with applicable laws and regulations;
- pre-approving all audit services and permitted non-audit services to be performed by our independent auditor, including the fees and terms of the services to be performed;
- appointing or replacing the independent auditor;
- determining the compensation and oversight of the work of the independent auditor (including resolution of disagreements between management and the independent auditor regarding financial reporting) for the purpose of preparing or issuing an audit report or related work; and
- establishing procedures for the receipt, retention and treatment of complaints received by us regarding accounting, internal accounting controls or reports which raise material issues regarding our financial statements or accounting policies.

Item 11. Executive Compensation

Summary Compensation Table

Executive Compensation during the years ended December 31, 2022 and 2021 was as follows:

Name and principal position	Year	Salary ($)	Bonus ($)	Stock awards ($)	Option awards ($)	All other compensation ($)	Total ($)
Erica Monaco, CPA, Chief Executive Officer	2022	433,823	120,798	398,474	243,100	346	1,196,541
	2021	294,231	107,658	270,407	140,441	235	812,972
Eugene Frederick Leffler III	2022**	54,615	25,000	-	-	55	79,670
	2021	-	-	-	-	-	-
Prof. Hermann L✔bbert Ph.D., Executive Chairman	2022	474,739	-	498,092	303,785	1,616	1,278,232
	2021	18,019*	-	540,818	280,885	-	839,722

* for services during December 14, 2021 – December 31, 2021
**for services during October 24, 2022 – December 31, 2022

Refer to *Note: 20. Equity Incentive Plans and Share-Based Payments* of the Notes to the Financial Statements for all assumptions used in the valuation of the stock awards and option awards.

Narrative Disclosure to Summary Compensation Table

Executive Compensation Arrangements

The following summarizes the material terms of the employment offer letters and employment agreements with each of our named executive officers.

Monaco Employment Agreement

On October 21, 2019, we entered into an employment agreement with Erica Monaco pursuant to which she agreed to continue to serve as our Vice President of Finance and Operations. This agreement was amended on January 6, 2020, pursuant to which she agreed to serve as our Chief Financial Officer in consideration for an annual base salary of $270,000 and eligibility to receive a cash bonus of up to 30% of her base salary and to participate in any benefit programs we make available to our employees. Ms. Monaco's employment agreement is for no particular terms and provides "at will" employment, provided that, if we terminate Ms. Monaco without "cause" (as such term is defined in Ms. Monaco's employment agreement), we must provide her with ninety (90) days' notice.

On August 11, 2021, we entered into a new employment agreement with Ms. Monaco. The agreement provides that Ms. Monaco will serve as our Chief Executive Officer with a base salary of $300,000 as well as provides a signing bonus of $75,000 paid in two installments. The terms of this agreement are otherwise substantially the same with those of her current employment agreement.

On April 1, 2022, we entered into an amendment to the employment agreement with Ms. Monaco. The agreement was amended to provide for an annual base salary of $450,000 and eligibility to receive a cash bonus up to 60% of base salary upon the attainment of performance goals set in advance by the Board of Directors. The actual amount of the bonus shall depend upon the level of achievement of set targets, however, no bonus shall be paid if the level of target achievement is below 70%. Upon termination of employment by the Company other than termination for "Cause", Ms. Monaco shall be entitled to a severance payment equal to one twelfth of her then-current annual base salary for each full year of employment; provided, however, that such payment shall not exceed two full years of Ms. Monaco's then-current base salary.

L✔bbert Employment Agreement

On October 1, 2021, we entered into an amended employment agreement with Prof. Dr. L✔bbert that became effective on December 14, 2021, the day after his last day of employment with Biofrontera AG. The agreement provides that Prof. Dr. L✔bbert will continue to serve as our Executive Chairman and devote 100% of his time to his role as Executive Chairman. Subsequently, Prof Dr. L✔bbert's agreement was further amended on March 2, 2022 (effective retroactively to December 15, 2021) to establish his base salary of $468,500, with eligibility to receive a cash bonus of up to 65% of his base salary upon the attainment of performance goals set in advance by the Board. The actual amount of any bonus shall depend upon the level of achievement of set targets. No bonus will be paid if our board of directors determines that the target achievement of the respective year was below 70%. We also agree to allow Prof. Dr. L✔bbert to participate in any benefit programs we make available to our employees.

Upon termination of employment by the Company other than termination for "Cause", Mr. L✔bbert shall be entitled to a severance payment equal to one twelfth of his then-current annual base salary for each full year of employment (including Biofrontera AG, as a past affiliate of the Company); provided, however, that such payment shall not exceed two full years of Mr. L✔bbert's then-current base salary.

Leffler Employment Agreement

On October 3, 2022, we entered into an employment agreement with Mr. Leffler to serve as our Chief Financial Officer. The agreement provides for an annual base salary of $355,000, with a one-time signing bonus of $25,000, receipt of 100,000 stock options and eligibility to participate in any benefit programs we make available to our employees. Mr. Leffler may receive a bonus of up to 40% of his base salary upon attainment of performance goals set in advance by the Chief Executive Officer.

In the event that Mr. Leffler experiences a termination of his employment without "cause" or he resigns for "good reason" outside of a period during which provisions related to a "change in control" (as such terms are defined in the employment agreement) are in effect, provided that he executes and makes effective a release of claims against the Company and its affiliates, Mr. Leffler will become entitled to a lump sum payment in an amount equal to one-twelfth of his annual base salary for each full year of employment; further provided that such payment will not be less than six months of his then-current base salary, and shall not exceed two full years of, his then-current base salary. If Mr. Leffler experiences a termination of his employment without "cause" or he resigns for "good reason" within a certain period of a "change in control," he will be entitled to certain benefits and an enhanced severance payment.

2022 Equity Awards

Our Chief Executive Officer and Executive Chairman hold outstanding options and restricted stock unit awards that were awarded in the fiscal years ending December 31, 2022, and 2021, following our initial public offering. These awards are described in more detail in the "Outstanding Equity Awards at Fiscal Year End" table below and in Note 20, Equity Incentive Plans and Share-Based Payments of the Notes to the Financial Statements for additional information.

We maintain the 2021 Omnibus Incentive Plan, which provided for the issuance of stock option awards to our eligible employees (including our named executive officers). See additional details in the "*General Information About the 2021 Omnibus Incentive Plan"* below.

Ms. Monaco's Stock Option Award

On December 9, 2021, Ms. Monaco was granted an option to purchase 56,689 shares of our common stock under the terms of the 2021 Omnibus Incentive Plan, as described below, at an exercise price of $4.77 per share. Subject to Ms. Monaco's continued employment through the applicable vesting date, the option will vest and become exercisable in three equal annual installments, beginning on December 9, 2022. In the event of Ms. Monaco's death, disability, or termination for good reason while any portion of the option remains unvested, the option will become immediately vested and exercisable with respect to 100 percent of the option shares as of the date of such occurrence. In the event of termination for cause, Ms. Monaco will forfeit the vested and unvested portions of the option. In the event of termination for any other reason, the unvested portion of the option will be forfeited as of the termination date, and the vested portion will expire on the earlier of the last day of the applicable option period or the 90th day following the termination date.

Ms. Monaco's Award of Restricted Stock Units

On December 9, 2021, Ms. Monaco also received a grant of 56,689 restricted stock units under the terms of the 2021 Omnibus Incentive Plan, as described below, and subject to the applicable award agreement between Ms. Monaco and the Company. Each restricted stock unit represents a contingent right to receive one share of our common stock. The restricted stock units vest on June 9, 2022, subject to Ms. Monaco's continued employment through the vesting date. 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 vesting date. Ms. Monaco is entitled to dividend equivalents with respect to the restricted stock units. In the event of Ms. Monaco's death, disability, or termination for good reason while the restricted stock units remain unvested, 100 percent of the restricted stock units will become immediately vested as of the date of such occurrence. In the event of termination or cause, the unvested and vested portion of the restricted stock units will be cancelled immediately and any rights to the underlying shares of stock will be forfeited.

Prof. Dr. L✔bbert's Stock Option Award

On December 9, 2021, 2021, Prof. Dr. L✔bbert was granted an option to purchase 113,379 shares of our common stock under the terms of the 2021 Omnibus Incentive Plan, as described below, at an exercise price of $4.77 per share. Subject to Prof. Dr. L✔bbert's continued employment through the applicable vesting date, the options will vest in three equal annual installments beginning on December 9, 2022. In the event of the Prof. Dr. L✔bbert's death, disability, or termination for good reason while any portion of the option remains unvested, the option will become immediately vested and exercisable with respect to 100 percent of the option shares as of the date of such occurrence. In the event of termination for cause, Prof. Dr. L✔bbert will forfeit immediately the vested and unvested portions of the option. In the event of termination for any other reason, the unvested portion of the option will be forfeited as of the termination date, and the vested portion will expire on the earlier of the last day of the applicable option period or the 90th day following the termination date.

Prof. Dr. L✔bbert's Award of Restricted Stock Units

On December 9, 2021, Prof. Dr. L✔bbert also received a grant of 113,379 restricted stock units under the terms of the 2021 Omnibus Incentive Plan, as described below, and subject to the applicable award agreement between Prof. Dr. L✔bbert and the Company. Each restricted stock unit represents a contingent right to receive one share of our common stock. The restricted stock units vest on June 9, 2022, subject to Prof. Dr. L✔bbert's continued employment through the vesting date. 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 vesting date. Prof. Dr. L✔bbert is entitled to dividend equivalents with respect to the restricted stock units. In the event of Prof. Dr. L✔bbert's death, disability, or termination for good reason while the restricted stock units remain unvested, 100 percent of the restricted stock units will become immediately vested as of the date of such occurrence. In the event of termination for cause, the unvested and vested portions of the restricted stock units will be cancelled immediately and any rights to the underlying shares of stock will be forfeited.

General Information About the 2021 Omnibus Incentive Plan

On July 23, 2021, our board of directors adopted and our sole shareholder at the time approved the 2021 Omnibus Incentive Plan. The purpose of the 2021 Omnibus Incentive Plan is to enable the Company to attract, retain and motivate its employees by providing for or increasing their proprietary interests in the Company.

The 2021 Omnibus Incentive Plan is a stock incentive plan under which we may offer securities of the Company to our employees. The 2021 Omnibus Incentive Plan is not subject to any provisions of the U.S. Employee Retirement Income Security Act of 1974 and is not qualified under Section 401(a) of the Code. The 2021 Omnibus Incentive Plan permits Biofrontera to satisfy any awards under the 2021 Omnibus Incentive Plan by distributing to participants (1) authorized and unissued shares of Biofrontera common stock, (2) shares of common stock held in the Biofrontera treasury, (3) shares of Biofrontera common stock purchased on the open market or (4) shares of Biofrontera common stock acquired through private purchase.

Eligibility

Employees, directors, officers and consultants or advisors of the Company and its affiliates are eligible for awards under the 2021 Omnibus Incentive Plan. The Committee (as discussed below) has the sole and complete authority to determine who will be granted awards under the 2021 Omnibus Incentive Plan.

Administration

The 2021 Omnibus Incentive Plan is administered by the Committee, which consists of the members of our compensation committee, or if our board of directors is acting as our compensation committee, the individuals constituting "eligible" directors of our board of directors. The Committee administers the 2021 Omnibus Incentive Plan, except in the case of awards to non-employee directors. Awards to non-employee directors are administered by our board of directors. The Committee in its discretion may delegate any and all of its duties to officers of the Company. The Committee or, in the case of awards to non-employee directors, our board of directors, has the authority to determine the terms and conditions of any agreements relating to awards granted under the 2021 Omnibus Incentive Plan (agreements may differ among participants), and to adopt, alter and repeal rules, guidelines and practices relating to the 2021 Omnibus Incentive Plan. The Committee or, in the case of awards to non-employee directors, our board of directors, has full discretion to administer and interpret the 2021 Omnibus Incentive Plan, and to adopt whatever rules, regulations and procedures it deems necessary or advisable.

Duration; Plan Amendments

The 2021 Omnibus Incentive Plan expires by its terms on the tenth anniversary of the Plan Effective Date. However, our board of directors may terminate the 2021 Omnibus Incentive Plan before that date. No awards can be granted under the 2021 Omnibus Incentive Plan after the 2021 Omnibus Incentive Plan has terminated. However, awards granted prior to the date on which the 2021 Omnibus Incentive Plan terminates will not be affected by the termination and the terms and conditions of the 2021 Omnibus Incentive Plan will continue to apply to those awards.

Shares Available for Awards

Shares Available for Issuance

The maximum number of shares of common stock that may be issued pursuant to awards granted under the 2021 Omnibus Incentive Plan is 2,750,000, subject to certain adjustments for corporate transactions, as described in the section entitled "*—Adjustments*" below. On December 12, 2022, the stockholders of the Company approved an amendment to increase the number of shares authorized for issuance by 2,589,800 from 2,750,000 to 5,339,800 shares. No participant may be granted awards of options and/or stock appreciation rights or performance compensation awards with respect to more than 900,000 shares of common stock in any one year. On termination, forfeiture, or expiration of an unexercised stock option grant or other award, in whole or in part, the number of shares of common stock subject to such unexercised stock option grant or other award will become available again for grant under the 2021 Omnibus Incentive Plan. Also, shares subject to a stock option grant or other award that are not delivered to a participant because they are used to satisfy a tax withholding obligation or that are withheld to pay all or a portion of an option's exercise price will again become available for grant under the 2021 Omnibus Incentive Plan. In addition, shares of Biofrontera common stock will not be considered used if the award to which they relate is settled in cash. Further, shares subject to awards granted in assumption or substitution of outstanding awards of an acquired entity shall not be counted against the shares of our common stock available for issuance under the 2021 Omnibus Incentive Plan.

Awards

Stock Options

Nonqualified or incentive stock options may be granted under the 2021 Omnibus Incentive Plan. The Committee sets the terms of the stock option grant at the time the grant is made. These terms are described in a stock option agreement.

Restricted Stock Awards

Restricted stock awards may be granted under the 2021 Omnibus Incentive Plan. The Committee will set the terms of the restricted stock award at the time of grant and will describe these terms in a restricted stock award agreement.

If the specified performance criteria are not achieved within the established time frame, the shares will be forfeited, unless the terms of the applicable restricted stock award agreement also provide for service-based vesting, catch-up vesting or otherwise specifically alter this treatment.

Restricted Stock Units

Restricted stock unit awards may be granted under the 2021 Omnibus Incentive Plan. The Committee will set the terms of the restricted stock unit award at the time of grant and will describe these terms in a restricted stock unit agreement.

Stock Bonus Awards

Participants may receive under the 2021 Omnibus Incentive Plan a grant of unrestricted shares of Biofrontera common stock or other awards, including fully-vested deferred stock units, denominated in common stock, as determined by the Committee.

Cash Bonus Awards

Participants may also receive under the 2021 Omnibus Incentive Plan a cash bonus award. No cash bonus award to any one Participant (as defined in the 2021 Omnibus Incentive Plan) in any calendar year can exceed $1,500,000.

Additional Information

Adjustments

The 2021 Omnibus Incentive Plan provides for appropriate adjustments in the number of shares of common stock subject to awards and available for future awards, the exercise price of outstanding awards, as well as the maximum award limits under the 2021 Omnibus Incentive Plan, in the event of changes in our outstanding common stock by reason of a merger, stock split, reorganization, recapitalization or similar events. The Committee may also make these types of adjustments if a change in law or circumstances would result in any substantial dilution or enlargement of the rights of participants under the 2021 Omnibus Incentive Plan.

Repricing

Repricing of options and SARs is generally prohibited under the 2021 Omnibus Incentive Plan without approval of our stockholders.

Change in Control

Unless the applicable award agreement provides otherwise, in the event of a "change in control" of Biofrontera (as defined in the 2021 Omnibus Incentive Plan),

- the Committee may in its discretion determine that all options and SARs will become vested and immediately exercisable, and/or the restricted period with respect to any restricted shares or restricted stock units will expire immediately (including a waiver of any applicable performance goals); and

- all incomplete performance periods in effect on the date the change in control occurs will end on the date of the change in control, and the Committee will determine the extent to which performance goals with respect to each such award period have been met based upon such audited or unaudited financial information then available as it deems relevant; and each participant will be paid partial or full awards with respect to performance goals for each relevant award period based upon the Committee's determination of the degree of attainment of any performance goals; and

- with respect to a Senior Participant (as defined in the 2021 Omnibus Incentive Plan) who is terminated by the Company or its affiliates without "cause" (as defined in the 2021 Omnibus Incentive Plan): (i) within twelve months following a change in control or, (ii) in contemplation of a change in control, all awards will become fully vested and exercisable immediately, irrespective of vesting schedules and the restricted period shall end at the time of the termination.

In the event of a change in control, the Committee may in its discretion also make adjustments to the stock options and other awards granted under the 2021 Omnibus Incentive Plan. The Committee may substitute shares of the surviving entity or another corporation that is party to the transaction for shares of Biofrontera common stock. In connection with such an event, the Committee may also determine that outstanding awards will be cancelled in return for a cash payment equal to the value of the cancelled awards. In the event that the Committee decides to cancel outstanding awards, holders of outstanding awards will receive ten days' advance notice.

Tax withholding

Participants in the 2021 Omnibus Incentive Plan must make a cash payment to us, or make other arrangements satisfactory to the Committee, to satisfy the tax withholding obligations that arise under applicable law with respect to a stock option or other award granted under the Plan, including without limitation any U.S. federal income and employment taxes and other applicable state and local taxes. Under certain circumstances, participants may be permitted to satisfy their tax withholding obligation, in whole or in part, by having us withhold from the shares of common stock otherwise deliverable to them on the exercise of a stock option, restricted stock unit or SAR, or by surrendering shares having a fair market value on the date of exercise equal to the exercise price.

Transferability and assignment

In general, participants in the 2021 Omnibus Incentive Plan can exercise an option or other award received under the 2021 Omnibus Incentive Plan only during their lifetime. Unless the agreement under which the stock option or other award was granted provides otherwise, participants cannot transfer stock options or other awards (except for shares that are not subject to a restricted period), except by will or the laws of descent and distribution or pursuant to a domestic relations order issued by a court of competent jurisdiction.

Award Termination; Forfeiture; Disgorgement

The Committee will have full power and authority to determine whether, to what extent and under what circumstances any award will be terminated or forfeited. To the extent provided in the award agreement, if a participant is terminated for "cause" (as defined in the 2021 Omnibus Incentive Plan) or if they engage in certain activities after termination as determined by the Committee, then any outstanding stock options or other awards granted to such participant may be cancelled, and under certain circumstances, they may be required to return the gain received from certain awards. Awards granted under the 2021 Omnibus Incentive Plan are also subject to any compensation recovery policy or minimum stock holding period requirement adopted by Biofrontera.

Outstanding Equity Awards at Fiscal Year End

The following table sets forth as of the end of fiscal year 2022 all outstanding equity awards held by our named executive officers:

	Option Awards				Equity Incentive Plan Awards:	
Name	*Number of Securities Underlying Unexercised Options (#) Exercisable*	*Equity incentive plan awards: number of securities underlying unexercised unearned options (#)*	*Option Exercise Price*	*Option Expiration Date*	*Number of Unearned Shares or Units That Have Not Vested (#)*	*Market or Payout Value of Unearned Shares or Units That Have Not Vested ($)*
Erica Monaco						
Stock options (1)	18,707	37,982	4.77	12/9/2031	-	-
Stock options (3)	-	152,672	2.61	05/18/2032	-	-
Restricted stock units (2)	-	-	-	-	152,672	398,474
Hermann L✔bbert						
Stock options (1)	37,415	75,964	4.77	12/9/2031	-	-
Stock options (3)	-	190,840	2.61	05/18/2032	-	-
Restricted stock units (2)	-	-	-	-	190,840	498,092
Eugene Frederick Leffler III	-	-	-	-	-	-

(1) The option vests in three equal annual installments beginning on December 9, 2022.

(2) Each restricted stock unit represents a contingent right to receive one share of BFRI common stock. 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 vesting date.

(3) The option vests in three equal annual installments beginning on May 18, 2023.

Additional Narrative Disclosure

General Information About the Employee Stock Purchase Plan (the "ESPP")

We will use the ESPP to provide eligible employees with the opportunity to purchase our common stock, thereby encouraging employees to share in the economic growth and success of the Company through stock ownership. The ESPP was adopted by our board of directors on July 23, 2021 and became effective upon approval of our shareholders on July 23, 2021, although we have not allocated any shares to the program at this time. At a future date, we will seek shareholder approval to authorize the offering of shares of our common stock pursuant to the ESPP. The ESPP is not qualified under Section 401(a) of the Code, which deals with the tax treatment of qualified retirement plans. The ESPP is intended to constitute an "employee stock purchase plan" within the meaning of Section 423 of the Code. The ESPP is not subject to any provisions of the U.S. Employee Retirement Income Security Act of 1974, as amended. The ESPP is administered by our compensation committee, or a duly-authorized delegate. The administrator has full and exclusive authority to interpret the terms of the ESPP and determine eligibility.

In general, unless the administrator determines otherwise, all full and part-time employees who are employed by us or a designated subsidiary are eligible to participate in offerings under the ESPP. The administrator may exclude the following employees from offerings under the ESPP: employees who have been employed for less than two years, are highly compensated or subject to Section 16 of the Exchange Act, or who are citizens or residents of certain foreign jurisdictions. In addition, employees who beneficially own 5% or more of the total combined voting power of all classes of our capital stock, who are customarily employed 20 hours or less per week, or are customarily employed for not more than five months during the year are excluded from participating in the ESPP. When shares are available, employees may acquire shares of our common stock through payroll deductions, which may not exceed 15% of their compensation during any pay period. The purchase price of the shares in each qualified offering will be 85% of the fair market value of our closing common stock price on the last day of a designated offering period.

General Information About the 401(k) Plan

We sponsor a 401(k) defined contribution plan in which our named executive officers may participate, subject to limits imposed by the Code, to the same extent as our other full-time employees. Currently, we match 50% of contributions made by participants in the 401(k) plan up to a maximum of 6% of the employee's base salary per year. All matching contributions are subject to vesting at the rate of 25% per year of service.

Severance Benefits

Prof. Dr. L✔bbert, Mr. Leffler, and Ms. Monaco receive severance benefits pursuant to their employment agreements, which have been explained in detail starting on page 65 in the section “Narrative Disclosure to Summary Compensation Table.”

Director Compensation

Director compensation for the year ended December 31, 2022, which was pro-rated for board members who served less than the entire service period during fiscal 2022, are shown on the table below:

Name	Fees earned or paid in cash ($)	Stock awards ($)	Option Awards ($)	Total ($)
Hermann L✔bbert[(1)]	$ -	-	-	$ -
Kevin Weber	46,399		33,132	79,531
John J. Borer	60,416	-	33,132	93,548
Loretta M. Wedge, CPA, CCGMA	63,420	-	33,132	96,552
Beth J. Hoffman, Ph.D.	59,906	-	33,132	93,038

[(1)] As described above in this Item 11, Prof. Dr. L✔bbert was granted a stock option award and restricted stock units in his capacity as an employee of the Company, not for his service as a director.

Narrative to Director Compensation Table

Our non-employee director compensation policy is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy each director who is not an employee is paid cash compensation as set forth below as well as reimbursed for all reasonable travel and other expensed incurred in connection with attending Board and Committee meetings:

Annual Retainer	April 1 – May 18, 2022	May 19 – December 31, 2022
Board of Directors:		
All non-employee members	$ 35,000	$ 40,250
Additional retainer for non-executive chairperson	30,000	$ 30,000
Audit Committee:		
Members	$ 7,500	$ 8,000
Additional retainer for chair	$ 7,500	$ 8,000
Compensation Committee:		
Members	$ 5,000	$ 6.000
Additional retainer for chair	$ 5,000	$ 9,000
Nominating and Corporate Governance Committee:		
Members	$ 4,000	$ 5,000
Additional retainer for chair	$ 4,000	$ 5,000

These fees are payable in four equal quarterly installments, provided that the amount of such payment will be prorated for any portion of such quarter that the director is not serving on our board of directors or any committee of the board of directors. We also reimburse our non-employee directors for reasonable travel and other expenses incurred in connection with attending our board of directors and committee meetings.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

Equity Compensation Plan Information

The following table summarizes our equity compensation plan information as of December 31, 2021:

Plan Category	Number of Securities to Be Issued upon Exercise of Outstanding Options, Warrants and Rights (a)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (b)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a)) (c)
2021 Omnibus Incentive Plan	2,080,856	3.11	3,088,876

Security Ownership of Certain Beneficial Holders and Management

The following table sets forth information with respect to the beneficial ownership of our common stock as February 28, 2023, 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. Our common stock subject to options or RSUs that are currently exercisable or exercisable within 60 days of February 28, 2023 are deemed to be outstanding and beneficially owned by the person holding the options or RSUs. 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 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.

Name of beneficial owner	*Common Stock beneficially owned*	*% of Common Stock Owned*	*Options exercisable within 60 days(1) (2)*
5% or more stockholders:			
Biofrontera AG Hemmelrather Weg 201 D-51377 Leverkusen, Germany(3)	8,000,000	30.0	-
Abshagen Consulting GmbH Burgunderweg 8 Weinheim, Germany, 69469(4)	3,148,042	11.8	-
Named executive officers and directors:			
Erica Monaco	56,689	*	18,707
Eugene Frederick Leffler III	-	*	-
Hermann L✔bbert	113,379	-*	37,415
John J. Borer	-	-*	20,166
Loretta M. Wedge, CPA, CCGMA	-	-*	20,166
Beth J. Hoffman, Ph.D.	-	-*	20,166
Kevin D. Weber	-	*	20,166
All current directors and executive officers as a group (7 persons)	170,068	1.15	136,786

* Represents beneficial ownership of less than 1% of outstanding shares of our common stock.

(1) On December 9, 2021, the Company granted options to purchase shares of common stock at an exercise price of $4.77 per share up to (a) in the case of Prof. Dr. L✔bbert, 113,379 shares and (b) in the case of Ms. Monaco, 56,689 shares. The options vest in three equal annual installments beginning on December 9, 2022. The 37,415 shares for Prof. Dr. L✔bbert and the 18,707 shares for Ms. Monaco represent the options under such grants that will have vested within 60 days of the date of this proxy statement.

(2) On May 18, 2022, the Company granted non-qualified stock options to each of the non-employee directors to purchase 22,000 shares of common stock with an exercise price of $2.61. The non-employee director options vest in equal monthly installments following the date of grant. The 20,166 shares reported in the table above for each non-employee director represent the options that will have vested within 60 days of the date of this proxy statement.

(3) 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 holds 1,177,676 shares of common stock representing 4.41% of the Company's outstanding stock. 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 34.4% of the Company's outstanding stock.

(4) Information is based upon a Schedule 13G filed with the SEC on November 4, 2022 by Abshagen Consulting GmbH.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The following are summaries of certain provisions of transactions within the past three years to which we have been a party, in which the amount involved exceeds or will exceed $120,000 and in which any of our directors, executive officers or holders of more than 5% of our capital stock, or immediate family member thereof, had or will have a direct or indirect material interest, and are qualified in their entirety by reference to all of the provisions of such agreements.

We believe the terms obtained or consideration that we paid or received, as applicable, in connection with the transactions described below were comparable to terms available or the amounts that we would pay or receive, as applicable, in arm's-length transactions.

Management

Prof. Dr. L✔bbert used to be Chief Executive Officer and Chairman of the management board of Biofrontera AG, our former parent and currently a significant stockholder. Following his resignation from Biofrontera AG in December 2021, he will begin to receive compensation from us for his services to our company as determined in accordance with the terms of his amended employment agreement.

Related Party Agreements

License and Supply Agreement

On July 15, 2016, we executed an exclusive license and supply agreement with Biofrontera Pharma, which was amended in July 2019 to increase the Ameluz® transfer price per unit from 35.0% to 50.0% of the anticipated net selling price per unit as defined in the agreement. Under the agreement, we obtained an exclusive, non-transferable license to use Biofrontera Pharma's technology to market and sell the licensed products in the United States and certain of its territories, Ameluz® and the RhodoLED® lamp, and must purchase the licensed products exclusively from Biofrontera Pharma. There was no consideration paid for the transfer of the license.

On June 16, 2021, we entered into the Ameluz LSA with Biofrontera Pharma and Biofrontera Bioscience. Under the terms of the Ameluz LSA, we were granted an exclusive, non-transferable license to use Biofrontera Pharma and Biofrontera Bioscience technology to use, import, export, distribute, market, offer for sale and sell Ameluz® and the RhodoLED® lamp series for its approved indications within the United States and certain of its territories.

Under the terms of the Ameluz LSA as entered into on June 16, 2021, we agree to purchase from Biofrontera Pharma a minimum number of units of Ameluz® per year according to an agreed schedule at fifty percent of our anticipated net price per unit for Ameluz®. On October 8, 2021, we entered into an amendment to the Ameluz LSA under which the price we pay per unit will be based upon our sales history, although the minimum number of units to purchase per year remains unchanged. See "*Business—Commercial Partners and Agreements—Biofrontera Pharma and Biofrontera Bioscience"* for further details.

Purchases of the licensed products during the years ended December 31, 2022 and 2021 were $16.6 million and $9.4 million, respectively, and recorded in inventories in the consolidated balance sheets, and, when sold, in cost of revenues, related party in the consolidated statements of operations. Amounts due and payable to Biofrontera Pharma as of December 31, 2022 and 2021 were $1.3 million and $0.3 million, respectively, which were recorded in accounts payable, related parties in the consolidated balance sheets.

Service Agreements

In December 2021, we entered into an Amended and Restated Master Contract Services Agreement, or Services Agreement, which provides for the execution of statements of work that will replace the applicable provisions of our previous intercompany services agreement dated January 1, 2016, or 2016 Services Agreement, by and among us, Biofrontera AG, Biofrontera Pharma and Biofrontera Bioscience, enabling us to continue to use the Biofrontera Group's IT resources as well as providing access to the Biofrontera Group's resources with respect to quality management, regulatory affairs and medical affairs. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, pharmacovigilance, and investor relations services, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine 1) if they will be needed, and 2) whether they can or should be obtained from other third-party providers.

Expenses related to the service agreement were $0.8 million and $0.7 million for the years ended December 31, 2022 and 2021, which were recorded in selling, general and administrative, related party. Management asserts that these expenses represent a reasonable allocation from Biofrontera AG. Amounts due to Biofrontera AG related to the service agreement were $0.2 million for each of the years ended December 31, 2022 and 2021, which were recorded in accounts payable, related parties in the consolidated balance sheets.

Quality Assurance Agreement

On November 1, 2016, we entered into a quality assurance agreement ("QAA") with Biofrontera Pharma GmbH in connection with the Ameluz LSA. Under the Ameluz LSA, Biofrontera Pharma GmbH agreed to supply products under the LSA of the quality and according to the specifications agreed upon with the FDA in the respective approvals. The QAA allocates quality and regulatory responsibilities including, but not limited to manufacturing, packaging, labeling, complaints, change control and any applicable requirements and is incorporated by reference herein as Exhibit 10.9 to this Form 10-K. The QAA has remained in effect following our initial public offering.

Clinical Lamp Lease Agreement

On August 1, 2018, the Company executed a clinical lamp lease agreement with Biofrontera Bioscience to provide lamps and associated services.

Total revenue related to the clinical lamp lease agreements was approximately $0.1 million for each of the years ended December 31, 2022 and 2021 and is recorded as revenues, related party. Amounts due from Bioscience for clinical lamp and other reimbursements were approximately $0.1 million and $0.1 million as of December 31, 2021 and 2020, respectively, which were recorded as accounts receivable, related party in the consolidated balance sheets.

Reimbursements from Maruho Related to Cutanea Acquisition

Pursuant to the Cutanea acquisition share purchase agreement, we received start-up cost financing and reimbursements for certain costs. These restructuring costs Maruho agreed to pay are referred to as "SPA costs" under the arrangement and are to be accounted for as other income. Refer to Note 3, Acquisition Contract Liabilities.

There were no amounts reimbursed relating to SPA costs for the year ended December 31,2022. For the year ended December 31, 2021 the amounts reimbursed relating to SPA costs were $0.5 million and were recorded as other income in the consolidated statements of operations as the related expenses were incurred. The amounts due from Maruho, primarily relating to SPA cost reimbursements, were $0.1 million for each of the years ended December 31, 2022 and 2021 and were recorded in other receivables, related parties in the consolidated balance sheets.

Other Arrangements

The Company has recorded a receivable of $6.4 million and $11.3 million as of December 31, 2022 and December 31, 2021 due from Biofrontera AG for its 50% share of the balance of a legal settlement for which both parties are jointly and severally liable. Refer to Note 8, Other Receivables, Related Party. The Company has recognized $0.1 and $0.0 million of interest income for the years ended December 31, 2022 and 2021 in connection with this receivable.

Director Independence

Our board of directors has undertaken a review of the independence of our directors and considered whether any director has a material relationship with us that could compromise that director's ability to exercise independent judgment in carrying out that director's responsibilities. Our board of directors affirmatively determined that each of Dr. Hoffman, Mr. Weber, Mr. Borer and Ms. Wedge is an "independent director," as defined under the Exchange Act and the rules of Nasdaq.

Item 14. Principal Accountant Fees and Services

Audit Fees and Services

Grant Thornton LLP was our independent registered public accounting firm for the years ended December 31, 2022 and December 31, 2021. The following table summarizes the fees Grant Thornton billed to us for the last two fiscal years. All services and fees related to our 2022 and 2021 audits were either approved by our audit committee or our Board of Directors for work prior to November 2, 2021.

	Years Ended December 31,	
Fee Category	**2022**	**2021**
Audit Fees (1)	$ 438,194	$ 990,000
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 438,194	$ 990,000

(1) Audit fees consist of fees billed for professional services rendered by Grant Thornton LLP for the audits of our annual financial statements, the reviews of our interim financial statements, and related services that are normally provided in connection with statutory and regulatory filings or engagements, including our registration statements on Form S-1.

Pre-approval Policies

The formal written charter for our audit committee requires that the audit committee pre-approve all audit services to be provided to the Company, whether provided by the Company's principal auditor or other firms, and all other services (review, attest and non-audit) to be provided to the Company by its independent registered public accounting firm. During the approval process, our audit committee considers the impact of the types of services and the related fees on the independence of the independent registered public accounting firm. The services and fees must be deemed compatible with the maintenance of that firm's independence, including compliance with rules and regulations of the SEC.

PART IV

Item 15. Exhibit and Financial Statements

The following documents are filed as part of this report:

(1) Financial Statements, included in Part II, "*Item 8. Financial Statements and Supplementary Data*":

(2) Financial Statement Schedules:

Financial statement schedules have been omitted because either they are not applicable or the required information is included in the financial statements or the notes thereto.

(3) List of Exhibits:

The following exhibits are filed herewith or are incorporated by reference to exhibits previously filed with the SEC.

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 Form 8-K filed with the SEC on November 3, 2021).
3.2	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)
3.3	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).
4.1*	Description of Securities
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 Purchaser Warrant (incorporated by reference to Exhibit 4.1 to the Company's Form 8-K filed with the SEC on December 3, 2021).

4.5	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Form 8-K filed with the SEC on December 3, 2021).
4.6	Form of Unit Purchase Option (incorporated by reference to Exhibit 4.3 to the Company's 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 Form 8-K filed with the SEC on July 28, 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)
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).
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 L✔bbert (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 (as amended and restated on December 12, 2022) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 16, 2022).
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 (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on December 3, 2021).
10.19	Form of Registration Rights Agreement (incorporated by reference to Exhibit 10.1 to the Company's 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 L✔bbert (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)
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)
21.1*	List of Subsidiaries of the Company
23.1*	Consent of Grant Thornton LLP, independent registered public accounting firm
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

* 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.

Item 16. Form 10-K Summary

Not applicable.

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 March 13, 2023.

BIOFRONTERA INC.

By: */s/ Erica L Monaco*
Name: Erica L. Monaco
Title: Chief Executive Officer

Signature	Title	Date
/s/ Erica L Monaco Erica Monaco	Chief Executive Officer (*Principal Executive Officer)*	March 13, 2023
/s/ E. Fred Leffler E. Fred Leffler	Chief Financial Officer (*Principal Financial Officer)* *(Principal Accounting Officer)*	March 13, 2023
/s/ Hermann L✔bbert Hermann L✔bbert	Chairman of the Board of Directors	March 13, 2023
/s/ John J. Borer John J. Borer	Director	March 13, 2023
/s/ Loretta M. Wedge Loretta M. Wedge	Director	March 13, 2023
/s/ Kevin D. Weber Kevin D. Weber	Director	March 13, 2023
/s/ Beth J. Hoffman Beth J. Hoffman	Director	March 13, 2023

Exhibit 4.1

DESCRIPTION OF REGISTERED SECURITIES

The following summary describes the material provisions of our common stock and the warrants that are listed on The Nasdaq Capital Market LLC.

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. The shares as part of the units to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

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.

Our common stock is listed for trading on The NASDAQ Capital Market under the symbol “BFRI”.

Warrants

The following summary of certain terms and provisions of the warrants to purchase one share of our common stock issued in connection with our initial public offering is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement between us and Computershare Trust Company, N.A., as warrant agent, and the form of warrant, both of which are filed as exhibits to our Annual Report on Form 10-K for the fiscal year ended December 31, 2022 of which this exhibit is a part. There are currently 1,492,394 warrants outstanding that were issued in connection with our public offering and have not been exercised.

Exercisability

The warrants are immediately exercisable at any time following the consummation of this offering and at any time up to the date that is five years after their original issuance. The warrants will be exercisable, at the option of each holder, in whole or in part by delivering to us a duly executed exercise notice and, at any time a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is effective and available for the issuance of such shares, or an exemption from registration under the Securities Act is available for the issuance of such shares, by payment in full in immediately available funds for the number of shares of common stock purchased upon such exercise. If a registration statement registering the issuance of the shares of common stock underlying the warrants under the Securities Act is not effective or available and an exemption from registration under the Securities Act is not available for the issuance of such shares, the holder may, in its sole discretion, elect to exercise the warrant through a cashless exercise, in which case the holder would receive upon such exercise the net number of shares of common stock determined according to the formula set forth in the warrant. No fractional shares of common stock will be issued in connection with the exercise of a warrant. In lieu of fractional shares, we will pay the holder an amount in cash equal to the fractional amount multiplied by the exercise price.

We will not effect the exercise of any portion of these warrants, and the holder will not have the right to exercise any portion of the warrants, and any such exercise shall be null and void and treated as if never made, to the extent that after giving effect to such exercise, the holder together with its affiliates and certain other persons specified in these warrants collectively would own beneficially in excess of 4.99% (or, upon election by a holder prior to the issuance of any warrants, 9.99%) of the shares of common stock outstanding immediately after giving effect to such exercise.

Exercise Price

The exercise price per whole share of common stock purchasable upon exercise of the warrants is $5.00 per share. The exercise price is subject to appropriate adjustment in the event of certain stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock and also upon any distributions of assets, including cash, stock or other property to our stockholders.

Transferability

Subject to applicable laws, the warrants may be offered for sale, sold, transferred or assigned without our consent.

Exchange Listing

The warrants offered in connection with our initial public offering are listed for trading on The NASDAQ Capital Market under the symbol "BFRIW".

Warrant Agent

The warrants were issued in registered form under a warrant agent agreement between Computershare Trust Company, N.A., as warrant agent, and us. The warrants are represented by one or more global warrants deposited with the warrant agent, as custodian on behalf of The Depository Trust Company (DTC) and registered in the name of Cede & Co., a nominee of DTC, or as otherwise directed by DTC.

Fundamental Transactions

In the event of a fundamental transaction, as described in the warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the warrants will be entitled to receive upon exercise of the warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the warrants immediately prior to such fundamental transaction

Rights as a Stockholder

Except as otherwise provided in the warrants or by virtue of such holder's ownership of shares of our common stock, the holder of a warrant does not have the rights or privileges of a holder of our common stock, including any voting rights, until the holder exercises the warrant.

Governing Law

The warrants and the warrant agent agreement are governed by New York law.

Stockholder Rights Plan

On October 13, 2022, the Board of Directors of the Company 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 "Rights Agreement"). The following description of the terms of the Rights Agreement does not purport to be complete and is qualified in its entirety by reference to the Rights Agreement, which is attached as an exhibit to the Company's Annual Report on Form 10-K for the year ended December 31, 2022.

Rights Dividend

Pursuant to the terms of the Rights Agreement, the Board of Directors declared a dividend distribution of one Preferred Stock Purchase Right (a "Right") for each outstanding share of Common Stock, to stockholders of record as of the close of business on October 24, 2022 (the "Record Date"). In addition, one Right will automatically attach to each share of Common Stock issued between the Record Date and the earlier of the Distribution Date (as defined below) and the expiration date of the Rights. Each Right entitles the registered holder thereof to purchase from the Company a unit consisting of one ten-thousandth of a share (a "Unit") of Series A Junior Participating Cumulative Preferred Stock, par value $0.001 per share, of the Company (the "Preferred Stock") at a cash exercise price of $5.00 per Unit (the "Exercise Price"), subject to adjustment, under certain conditions specified in the Rights Agreement and summarized below.

Distribution Date

Initially, the Rights are not exercisable and are attached to and trade with all shares of Common Stock outstanding as of, and issued subsequent to, the Record Date. The Rights will separate from the Common Stock and will become exercisable upon the earlier of (i) the close of business on the tenth calendar day following the first public announcement that a person or group of affiliated or associated persons or any other person acting in concert with such persons (an "Acquiring Person") has acquired beneficial ownership of 20% or more of the outstanding shares of Common Stock, other than as a result of repurchases of stock by the Company or certain inadvertent actions by a stockholder (the date of such announcement being referred to as the "Stock Acquisition Date"), or (ii) the close of business on the tenth business day (or such later day as the Board of Directors may determine) following the commencement of a tender offer or exchange offer that could result upon its consummation in a person or group becoming an Acquiring Person (the earlier of such dates being herein referred to as the "Distribution Date").

A person or group who beneficially owned 20% or more of the Company's outstanding Common Stock prior to the first public announcement by the Company of the adoption of the Rights Agreement will not trigger the Rights Agreement so long as they do not acquire beneficial ownership of any additional shares of Common Stock at a time when they still beneficially own 20% or more of such Common Stock.

For purposes of the Rights Agreement, beneficial ownership is defined to include ownership of securities that are subject to a derivative transaction and acquired derivative securities. Swaps dealers unassociated with any control intent or intent to evade the purposes of the Rights Agreement are excepted from such imputed beneficial ownership.

Until the Distribution Date (or earlier redemption, exchange or expiration of the Rights), (i) the Rights will be evidenced by the Common Stock certificates (or, with respect to any uncertificated shares of Common Stock registered in book entry form ("Book Entry Shares"), by notation in book entry) and will be transferred with and only with such shares of Common Stock, (ii) new Common Stock certificates or Book Entry Shares issued after the Record Date will contain a notation incorporating the Rights Agreement by reference, and (iii) the surrender for transfer of any certificates for Common Stock or Book Entry Shares will also constitute the transfer of the Rights associated with the Common Stock represented thereby.

As soon as practicable after the Distribution Date, one or more certificates evidencing Rights (the "Right Certificates") will be mailed to holders of record of Common Stock as of the close of business on the Distribution Date and, thereafter, the separate Right Certificates alone will represent the Rights. Except as otherwise determined by the Board of Directors, only shares of Common Stock issued prior to the Distribution Date will be issued with Rights.

Subscription and Merger Rights

In the event that a Stock Acquisition Date occurs, proper provision will be made so that each holder of a Right (other than an Acquiring Person or its associates or affiliates or any other person acting in concert with such persons, whose Rights shall become null and void) will thereafter have the right to receive upon exercise, in lieu of a number of shares of Preferred Stock, that number of shares of Common Stock of the Company (or, in certain circumstances, including if there are insufficient shares of Common Stock to permit the exercise in full of the Rights, Units of Preferred Stock, other securities, cash or property, or any combination of the foregoing) having a market value of two times the Exercise Price of the Right (such right being referred to as the "Subscription Right"). In the event that, at any time following the Stock Acquisition Date, (i) the Company consolidates with, or merges with and into, any other person, and the Company is not the continuing or surviving corporation, (ii) any person consolidates with the Company, or merges with and into the Company and the Company is the continuing or surviving corporation of such merger and, in connection with such merger, all or part of the shares of Common Stock are changed into or exchanged for stock or other securities of any other person or cash or any other property, or (iii) 50% or more of the Company's assets or earning power is sold, mortgaged or otherwise transferred, each holder of a Right (other than an Acquiring Person or its associates or affiliates or any other person acting in concert with such persons, whose Rights shall become null and void) will thereafter have the right to receive, upon exercise, common stock of the acquiring company having a market value equal to two times the Exercise Price of the Right (such right being referred to as the "Merger Right"). The holder of a Right will continue to have the Merger Right whether or not such holder has exercised the Subscription Right. Rights that are or were beneficially owned by an Acquiring Person may (under certain circumstances specified in the Rights Agreement) become null and void.

Until a Right is exercised, the holder will have no rights as a stockholder of the Company (beyond those as an existing stockholder), including the right to vote or to receive dividends. While the distribution of the Rights will not be taxable to stockholders or to the Company, stockholders may, depending upon the circumstances, recognize taxable income in the event that the Rights become exercisable for shares of Common Stock, other securities of the Company, other consideration or for common stock of an acquiring company.

Exchange Feature

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.

Preferred Stock Provisions

Each share of Preferred Stock, if issued:

- will not be redeemable,
- will entitle the holder thereof to quarterly dividend payments equal to the greater of (a) $1.00 per share and (b) 10,000 times the amount of all cash dividends plus 10,000 times the amount of non-cash dividends or other distributions paid on one share of Common Stock,
- will entitle the holder thereof to receive the greater of (1) $10,000.00 per share or (2) an aggregate amount per share, subject to the provision for adjustment hereinafter set forth, equal to 10,000 times the aggregate amount of all cash or other property to be distributed per share to holders of Common Stock upon such liquidation, dissolution or winding up of the Corporation,
- will have the same voting power as 10,000 shares of Common Stock and,
- if shares of Common Stock are exchanged via merger, consolidation or a similar transaction, will entitle the holder thereof to a per share payment equal to the payment made on 10,000 shares of Common Stock.

Adjustments

The Exercise Price payable, and the number of shares of Common Stock or other securities or property issuable, upon exercise of the Rights are subject to adjustment from time to time to prevent dilution (i) in the event of a stock dividend on, or a subdivision, combination or reclassification of, the Preferred Stock, (ii) if holders of the Preferred Stock are granted certain rights or warrants to subscribe for Preferred Stock or convertible securities at less than the current market price of the Preferred Stock, or (iii) upon the distribution to holders of the Preferred Stock of evidences of indebtedness or assets (excluding regular quarterly cash dividends) or of subscription rights or warrants (other than those referred to above).

With certain exceptions, no adjustment in the Exercise Price will be required until cumulative adjustments amount to at least 1% of the Exercise Price. The Company is not obligated to issue fractional shares. If the Company elects not to issue fractional shares, in lieu thereof an adjustment in cash will be made based on the fair market value of the Preferred Stock on the last trading date prior to the date of exercise.

Redemption

The Rights may be redeemed in whole, but not in part, at a price of $0.0001 per Right (payable in cash, Common Stock or other consideration deemed appropriate by the Board of Directors) by the Board of Directors only until the earlier of (i) the time at which any person becomes an Acquiring Person or (ii) the expiration date of the Rights Agreement. Immediately upon the action of the Board of Directors ordering redemption of the Rights, the Rights will terminate and thereafter the only right of the holders of Rights will be to receive the redemption price.

Amendment

The Rights Agreement may be amended by the Board of Directors in its sole discretion at any time prior to the time at which any person becomes an Acquiring Person. After such time the Board of Directors may, subject to certain limitations set forth in the Rights Agreement, amend the Rights Agreement only to cure any ambiguity, defect or inconsistency, to shorten or lengthen any time period, or to make changes that do not adversely affect the interests of Rights holders (excluding the interests of an Acquiring Person or its associates or affiliates).

Expiration Date

The Rights are not exercisable until the Distribution Date and will expire at the close of business on October 13, 2023; provided that if the Company's stockholders have not ratified the Rights Agreement by the close of business on the first day after the Company's 2023 annual meeting of stockholders (including any adjournments or postponement thereof), the Rights will expire at such time, in each case, unless previously redeemed or exchanged by the Company.

Transfer Agent

The transfer agent for our common stock and our preferred stock is Computershare, Inc.

Exhibit 21.1

List of Subsidiaries of the Company

Bio-Fri GmbH	Germany

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We have issued our report dated March 13, 2023, with respect to the consolidated financial statements included in the Annual Report of Biofrontera Inc. on Form 10-K for the year ended December 31, 2022. We consent to the incorporation by reference of said report in the Registration Statements of Biofrontera Inc. on Forms S-1 (File No. 333-265467 and File No. 333-268124) and on Form S-8 (File No. 333-265463).

/s/ GRANT THORNTON LLP

Boston, Massachusetts

March 13, 2023

Exhibit 31.1

Certification

I, Erica L. Monaco, certify that:

1. I have reviewed this annual report on Form 10-K of Biofrontera Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/13/2023

By: */s/ Erica L. Monaco*

Erica L. Monaco
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

Certification

I, E. Fred Leffler, certify that:

1. I have reviewed this annual report on Form 10-K of Biofrontera Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: 3/13/2023

By: */s/ E. Fred Leffler*

E. Fred Leffler
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

Certification*

In connection with the Annual Report of Biofrontera Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.§ 1350), I, Erica L. Monaco, Chief Executive Officer of the Company, do hereby certify, to the best of my knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

Date: 3/13/2023

By: */s/ Erica L. Monaco*
Erica L. Monaco
Chief Executive Officer
(Principal Executive Officer)

* This certification accompanies the Annual Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Biofrontera Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.

Exhibit 32.2

Certification*

In connection with the Annual Report of Biofrontera Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2022 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.§ 1350), I, E. Fred Leffler, Chief Financial Officer of the Company, do hereby certify, to the best of my knowledge:

1. The Annual Report fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act, and

2. The information contained in the Annual Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Annual Report.

Date: 3/13/2023

By: */s/ E. Fred Leffler*
E. Fred Leffler
Chief Financial Officer
(Principal Financial Officer)

* This certification accompanies the Annual Report to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Biofrontera Inc. under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Annual Report), irrespective of any general incorporation language contained in such filing.