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, 2023

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 for common stock	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, 2023, 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 $14.2 million, based on the closing price of the registrant's common stock.

As of March 11, 2024, there were 5,089,413 shares outstanding of the registrant's common stock, par value $0.001 per share.

DOCUMENTS INCORPORATED BY REFERENCE:

Portions of the registrant's Proxy Statement relative to the Annual Meeting of Stockholders for the year ended December 31, 2023 are incorporated by reference into Part III of this Form 10-K.

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BASIS OF PRESENTATION

As used in this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 (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"). 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 "*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. As of December 31, 2023, Biofrontera AG owned 26.4% of our Common Stock. Accordingly, the entities in the Biofrontera Group are related parties to us.

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 The Nasdaq Stock Market, LLC ("Nasdaq") continued listing standards;
- our ability to comply with the requirements of being a public company;
- the progress, timing and completion of our Licensors' research, development and preclinical studies and clinical trials for our licensed products and our Licensors' ability to obtain the regulatory approvals necessary for the marketing of our licensed products in the United States;
- any impact of extraordinary events, including those resulting from the 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 with PDT contribution to the largest amount of our business. The Company's licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions, as well as impetigo, a bacterial skin infection.

In May 2023, we began research and development ("R&D") activities to support PDT growth and will continue to opportunistically invest in these activities going forward. Our R&D program currently aims to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists. Our goal is to improve the effectiveness of our commercial team by allowing sales representatives to carry approved devices with them allowing for easier product demonstrations and evaluations.

Effective June 1, 2024, we will take control of all clinical trials relating to Ameluz® in the US, allowing for more effective cost management and direct oversight of trial efficiency.

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, 2023, Biofrontera AG held 26.4% 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, 2023, the company had 85 employees, of which 83 were full-time employees and two were part-time employees. 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, 2023, no customer represented more than 10% of the net accounts receivable balance. For the year ended December 31, 2023, 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 focusing on acquisition of new customers and growth of the therapy in our current customer base;

- 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 PDT 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 (as amended the "Ameluz LSA") between Biofrontera, Inc. and the Ameluz Licensors.

AKs are superficial potentially pre-cancerous skin lesions caused by chronic sun exposure that may, if left untreated, develop into a form of potentially life-threatening skin cancer called squamous cell carcinoma. AKs typically appear on sun-exposed areas, such as the face, bald scalp, arms or the back of the hands, and are often elevated, flaky, and rough in texture, and appear on the skin as hyperpigmented spots. AKs are typically treated with cryotherapy, topicals, or PDT. These treatments can be used in combination, which is the number one indication for those 45 years of age and older.

In general, PDT 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 PDT, 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. PDT 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 PDT 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 - efficacy is up to 91% clearance after one or two treatments[3] with limited or no scarring. 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, constitute approximately 12% of the market. PDT is approximately 2% of the market. The total market size is estimated to be roughly $4 billion for the three therapy types. Our primary competitor in the PDT space is Levulan® and the associated light, Blu-U®.

Our goal is to continue expansion in the current PDT market share and focus on converting cryotherapy treatments of more than 14 lesions as a field therapy such as Ameluz® PDT could be more effective and lead to better patient outcomes. This targeted market is about 11% or $500 million of the total AK market.[6] Ameluz® PDT is competitive in the market. We are leveraging medical affairs, advisory boards, reimbursement resources, and key opinion leaders in order to educate the market on the use and benefits of Ameluz® PDT.

[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 $273.00 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' R&D programs

We are a sales organization with focus on commercializing our portfolio of licensed products that are already FDA-approved. R&D 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 (available in the second quarter of 2024) in the United States for all indications currently approved by the FDA as well as all future FDA-approved indications identified under the Ameluz LSA.

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

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

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

			Clinical Phase			
Product	**Indication**	**Pre-clinical**	I	II	III	**Status**
Ameluz®	Superficial basal cell carcinoma				•	Last-patient-in treatment phase in August 2023; Last-patient-out of treatment phase expected in March 2024; Clinical Study Report (CSR) expected Q4 – 2024
Ameluz®	Actinic keratosis		•			Phase I safety study applying 3 tubes of Ameluz® to an expanded treatment area of 60 cm²; completed and submitted to FDA
Ameluz®	Moderate to severe acne			•		Phase II is recruiting; CSR expected in Q3 2025
Ameluz®	Actinic keratosis				•	Trunk & extremities applying 1-3 tubes of Ameluz®; First patient dosed in Jan 2023; CSR expected in Q1-2026
Ameluz®	Actinic keratosis				•	Combination daylight and conventional PDT, plan to start enrollment in 2025

Ameluz®	Squamous cell carcinoma in situ	•	Plan to start enrollment in 2026

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

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 (the "Cutanea Acquisition").

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' R&D 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.

There has been limited revenue during the current reporting periods and issues with the third-party manufacturer that was providing our supply of Xepi® impacting the timing of sales expansion and improved market positioning. However, Ferrer is in the process of qualifying a new third-party manufacturer in North America. The expectation is that this process will be completed in the second half of 2024. Once the new third-party manufacturer is qualified, we expect the supply of Xepi® will enable us to market and increase demand. 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. Additionally, a new patent regarding an Ameluz formulation without propylene glycol filed at USPTO in 2023, if granted, extends protection to 2043.

Xepi® is protected by four patents in the United States held by Ferrer. The primary patent protecting the active ingredient in Xepi® expired 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

Under the terms of the Ameluz LSA, we are 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. The price we pay per unit will be based upon our sales history. The Ameluz LSA will remain in effect for fifteen years and automatically renew for a period of five years, in perpetuity as long as certain minimum revenues are achieved. See Note *23. Commitments and Contingencies.*

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 milestones or royalty obligations associated with this agreement. Any changes to the pricing of supply of Ameluz® or RhodoLED® lamps would require agreement by both contract parties.

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.

On February 19, 2024, we entered into the Second A&R Ameluz LSA, which is discussed above in the section entitled "**Ameluz® and RhodoLED® Lamp Series** - *Our licensors' R&D programs*.

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

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, a related party. 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.

U.S. Drug Development and Review

Drug Development Process

General Information about the Drug Approval Process and Post-Marketing Requirements

The U.S. system of new drug and biologics approval is a rigorous process. The following general comments about the drug approval process are relevant to the development activities undertaken by our Licensors.

Investigational New Drug Application ("IND"): After certain pre-clinical studies are completed, an IND application is submitted to the FDA to request the ability to begin human testing of the drug or biologic. An IND becomes effective thirty days after the FDA receives the application (unless the FDA notifies the sponsor of a clinical hold), or upon prior notification by the FDA.

Phase 1 Clinical Trials: These trials typically involve small numbers of healthy volunteers or patients and usually define a drug candidate's safety profile, including the safe dosage range.

Phase 2 Clinical Trials: In Phase 2 clinical trials, controlled studies of human patients with the targeted disease are conducted to assess the drug's effectiveness. These studies are designed primarily to determine the appropriate dose levels, dose schedules and route(s) of administration, and to evaluate the effectiveness of the drug or biologic on humans, as well as to determine if there are any side effects on humans to expand the safety profile following Phase 1. These clinical trials, and Phase 3 trials discussed below, are designed to evaluate the product's overall benefit-risk profile, and to provide information for physician labeling.

Phase 3 Clinical Trials: This Phase usually involves a larger number of patients with the targeted disease. Investigators (typically physicians) monitor the patients to determine the drug candidate's efficacy and to observe and report any adverse reactions that may result from long-term use of the drug on a large, more widespread, patient population.

During the Phase 3 clinical trials, typically the drug candidate is compared to either a placebo or a standard treatment for the target disease.

NDA or Biologics License Application ("BLA"): After completion of all three clinical trial Phases, if the data indicates that the drug is safe and effective, an NDA or BLA is filed with the FDA requesting FDA approval to market the new drug as a treatment for the target disease.

Risk Evaluation and Mitigation Strategy Authority under the Food and Drug Administration Amendments Act ("FDAAA"): The FDAAA also gave the FDA authority to require the implementation of a Risk Evaluation and Mitigation Strategy ("REMS") for a product when necessary to minimize known and preventable safety risks associated with the product. The FDA may require the submission of a REMS before a product is approved, or after approval based on "new safety information," including new analysis of existing safety information. A REMS may include a medication guide, patient package insert, a plan for communication with healthcare providers, or other elements as the FDA deems are necessary to assure safe use of the product, which could include imposing certain restrictions on distribution or use of a product. A REMS must include a timetable for submission of assessments of the strategy at

specified time intervals. Failure to comply with a REMS, including the submission of a required assessment, may result in substantial civil or criminal penalties.

Other Issues Related to Product Safety: Adverse events that are reported after marketing approval also can result in additional limitations being placed on a product's use and, potentially, withdrawal of the product from the market. In addition, under the FDAAA, the FDA has authority to mandate labeling changes to products at any point in a product's life cycle based on new safety information derived from clinical trials, post-approval studies, peer-reviewed medical literature, or post-market risk identification and analysis systems data.

Clinical trials may experience delays or fail to demonstrate the safety and efficacy, which could prevent or significantly delay obtaining regulatory approval.

Clinical trials require the investment of substantial financial and personnel resources. The commencement and completion of clinical trials may be delayed by various factors, including scheduling conflicts with participating clinicians and clinical institutions, difficulties in identifying and enrolling patients who meet trial eligibility criteria, failure of patients to complete the clinical trial, delays in accumulating the required number of clinical events for data analysis, delay or failure to obtain the required approval to conduct a clinical trial at a prospective site, and shortages of available drug supply. Moreover, the outcome of a clinical trial is often uncertain. There may be numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval. In addition, the results of early-stage clinical trials do not necessarily predict the results of later-stage clinical trials. Later-stage clinical trials may fail to demonstrate that a drug product is safe and effective despite having progressed through initial clinical testing. Clinical trial data results are susceptible to varying interpretations, and such data may not be sufficient to support approval by the FDA. The ability to commence and complete clinical trials may be delayed by many factors that are beyond our licensors control, including:

- delays obtaining regulatory approval to commence a trial;
- delays in reaching agreement on acceptable terms with contract research organizations ("CROs") and clinical trial sites;
- delays in obtaining institutional review board ("IRB"), approval at each site;
- slower than anticipated patient enrollment or an inability to recruit and enroll patients to participate in clinical trials for various reasons;
- inability to retain patients who have initiated a clinical trial;
- lack of funding to start or continue the clinical trial, including as a result of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies;
- negative or inconclusive results;
- deficiencies in the conduct of the clinical trial, including failure to conduct the clinical trial in accordance with regulatory requirements, good clinical practice, or clinical protocols;
- deficiencies in the clinical trial operations or trial sites resulting in the imposition of a clinical hold; or
- adverse medical events or side effects experienced by patients during the clinical trials as a result of or resulting from the clinical trial treatments;

Delays can also occur if a clinical trial is suspended or terminated by the IRBs of the clinical trial sites in which such trials are being conducted, or by the FDA or other regulatory authorities. Such authorities may impose a suspension or termination of the clinical trial due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or clinical protocols, inspection of the clinical trial operations or trial site by the FDA or other regulatory authorities resulting in the imposition of a clinical hold, unforeseen safety issues or adverse side effects, or failure to demonstrate a benefit from using a drug.

Post-Approval Requirements for Approved Drugs

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

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

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

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

Investing in our common stock involves a high degree of risk. You should carefully consider the risks described below, as well as the other information in this Form 10-K, including our financial statements and the related notes and the section "Management's Discussion and Analysis of Financial Condition and Results of Operations," before deciding whether to invest in our common stock. The occurrence of any of the events or developments described below could materially and adversely affect our business, financial condition, results of operations and growth prospects. In such an event, the market price of our common stock could decline, and you may lose all or part of your investment. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also impair our business operations.

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, including a related party. If we fail to comply with our obligations in the agreements under which we license rights from such 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.
- 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.
- 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
- 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.
- The trade secrets of our Licensors are difficult to protect.
- Our subsidiary and certain third-party employees and our licensed patents are subject to foreign laws.
- Our international dealings with our Licensors may pose currency risks, which may adversely affect our operating results and net income.

Risks Related to Our Business and Strategy

- We are fully dependent on our collaboration with the Ameluz Licensor for our supply of Ameluz® and RhodoLED® lamps and future development of the Ameluz® product line, on our collaboration with Ferrer for our supply of Xepi® and future development of Xepi® and may depend on the Ameluz Licensor, Ferrer or additional third parties for the supply, development and commercialization of future licensed products or product candidates. Although we have the authority under the Ameluz LSA with respect to the indications that the Ameluz Licensor is currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA) in certain circumstances to take over clinical development, regulatory work and manufacturing from the Ameluz Licensor if they are unable or unwilling to perform these functions appropriately, the sourcing and manufacture of our licensed products as well as the regulatory approvals and clinical trials related to our licensed products are currently controlled, and will likely continue to be controlled for the foreseeable future, by our existing and future collaborators. Our lack of control over some of these functions could adversely affect our ability to implement our strategy for the commercialization of our licensed products.
- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products.
- Healthcare legislative changes may have a material adverse effect on our business and results of operations.
- To date, we have a relatively short history of sales of our licensed products in the United States.
- Competing products and future emerging products may erode sales of our licensed products.
- 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.
- 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.
- 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.
- 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.
- 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.
- 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 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 employees may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.
- We will need to grow the size of our organization and we may experience difficulties in managing this growth.

- Our business and operations would suffer in the event of system failures or, cyber-attacks.
- If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization of our licensed products.
- 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.
- Our licensed products will be subject to ongoing regulatory requirements and we may face future development, manufacturing and regulatory difficulties.
- Generic manufacturers may launch products at risk of patent infringement.
- The results of our R&D efforts are uncertain and there can be no assurance they will enhance the commercial success of our products.

Risks Related to Our Financial Position and Capital Requirements

- There is substantial doubt about our ability to continue as a "going concern."
- Failure to achieve the conditions relating to the additional $7.2 million of proceeds to be provided under the equity financing agreement entered into on February 19, 2024 could adversely affect our financial condition and liquidity over the next twelve months
- 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.

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

- Provisions of our outstanding warrants could discourage an acquisition of us by a third party.
- Our share price may be volatile, and you may be unable to sell your shares and/or warrants at or above the offering price.
- If we fail to regain compliance with applicable listing standards, our common stock and/or our publicly-traded warrants could be delisted from Nasdaq.
- Future sales of our common stock in the public market could cause our share price to fall.
- If the Preferred Warrants are not exercised, we will not receive up to $8 million in aggregate gross proceeds from the exercise of the Warrants which could have a material adverse effect on our financial condition.
- 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.
- If securities or industry analysts do not publish research or publish unfavorable research about our business, our stock price and trading volume could decline.
- Our quarterly operating results may fluctuate significantly.
- 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.
- 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
- 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.
- 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 for our common stock increases.
- 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

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, GmbH and Biofrontera Bioscience, GmbH (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, 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 PDT 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 PDT 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 efforts to commercialize a new lamp (the "RhodoLED® XL") that was approved by the FDA on October 21, 2021 have been delayed due to supply chain matters. We have currently placed an order and issued a PO for 300 units and manufacturing has

commenced on the units. While we anticipate that we will be able to commercialize the RhodoLED® XL in or around the second quarter of 2024, slower than anticipated shipments or other delays are possible.

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.

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.

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, 2023, we have recorded a legal settlement liability in the amount of $0.4 million for the remaining payments due under the settlement agreement for the cost of the forensic expert and a related receivable from related party of $2.8 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. The $2.8 million receivable is presented net of accounts payable, related party on the balance sheet.

On September 13, 2023, Biofrontera was served with a complaint filed in United Stated District Court for the District of Massachusetts by DUSA, Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries LTD in which DUSA alleges breach of contract, violation of the Lanham Act, and unfair trade practices. All claims stem from allegations that Biofrontera has promoted its Ameluz product in a manner that is inconsistent with its approved FDA labeling. Though this complaint was originally filed in the U.S. District Court for the District of Massachusetts, this matter has been transferred by agreement of the parties to the U.S. District Court for the District of New Jersey.

The Company denies the Plaintiffs' claims and intends to defend these matters vigorously. Based on the Company's assessment of the facts underlying the above claims, the uncertainty of litigation and the preliminary stage of the case, the Company cannot estimate the possibility of a material loss, nor the potential range of loss that may result from this action. If the final resolution of the matter is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

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

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, 2023, Biofrontera AG beneficially owns 26.4% 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 the 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. 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 R&D 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 maintaining our marketing and sales infrastructure, we may not be able to successfully grow the market of 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 PDT 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. In February 2024, our Ameluz Licensor initiated a voluntary recall of a limited number of lots of Ameluz® due to a manufacturing defect in the impacted product's packaging, which is provided by an unaffiliated supplier. The Ameluz Licensor confirmed that the recalled product is not likely to cause adverse health consequences. We promptly notified all impacted physician customers of this recall and arranged for the prompt replacement of the recalled products. Refer to *Note 25. Subsequent Events - Voluntary Product Recall of Limited Lots of Ameluz®* for more information.

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 PDT 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 Prof. Dr. Hermann Lübbert, our Chief Executive Officer and 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, 2023, we had 85 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 or cyber-attacks.

Despite the implementation of security measures, our internal computer systems and those of our current and future contract and research organizations, or CROs, licensors, and other contractors and consultants are vulnerable to damage from breaches of information systems, attempts to access information, including customer and company information, malicious code, theft, misuse, loss, release, or destruction of data (including confidential customer information), account takeovers, unavailability of service, 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 or cyber-related incident, if such an event were to occur and cause interruptions in our operations, it could (i) materially disrupt our development programs. The proper functioning of our networks and systems and therefore our business operations and those of our customers; (ii) result in the unauthorized access to, and destruction, loss, theft, misappropriation, or release of confidential, sensitive, or otherwise valuable information of ours or our customers; (iii) result in a violation of applicable privacy, data protection, and other laws, subjecting us to additional regulatory scrutiny and exposing us to civil litigation, enforcement actions, governmental fines, and possible financial liability; (iv) require significant management attention and resources to remedy the damages that result; or (v) harm our reputation or cause a decrease in the number of customers that choose to do business with us. The occurrence of any of the foregoing could have a material adverse effect on our business, financial condition, and results of operations. Furthermore, in the event of a cyber-related incident, we may be delayed in identifying or responding to the incident, which could increase the negative impact of the incident on our business, financial condition,

and results of operations. To the extent that any disruption or cyberrelated incident 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.

The results of our R&D efforts are uncertain and there can be no assurance they will enhance the commercial success of our products.

We believe that we will need to incur additional R&D expenditures to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists and may also incur R&D expenditures to develop new products. The products we are developing and may develop in the future may not be technologically successful. At this time, we have limited internal R&D personnel, which makes us dependent on consulting relationships.

In addition, the length of our product development cycle may be greater than we originally expected, and we may experience delays in product development. If our resulting products are not technologically successful, they may not achieve market acceptance or compete effectively with our competitors' products and services.

Risks Related to Our Financial Position and Capital Requirements

There is substantial doubt about our ability to continue as a "going concern", which has been alleviated through managements plans to mitigate these conditions and obtain additional liquidity.

In connection with our assessment of going concern considerations under applicable accounting standards, the Company's management has determined that substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed consolidated financial statements were issued, which management believes has been alleviated through its plans to mitigate these conditions and obtain additional liquidity. The future viability of the Company is dependent on its ability to continue to execute its growth plan and raise additional capital or find alternative methods of financing to fund its operations during the first half of 2024, and until cash flow from operations is sufficient, if ever. As of March 11, 2024 our unaudited cash was approximately $4.1 million. There can be no guarantee that the Company will be successful in raising additional capital or finding alternative methods of financing. If the Company is not successful in these endeavors, it would likely have a material adverse effect on the Company's business, results of operations and financial condition. See *Note 1. Organization and Business Overview - Liquidity and Going Concern* for additional information.

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, 2023 and December 31, 2022 was $20.1 million and $0.6 million, respectively. As of December 31, 2023, we had an accumulated deficit of $99.7 million.

Our ability to become profitable depends on our ability to further commercialize our principal licensed product Ameluz® and to further commercialize and obtain a larger market share for Xepi. 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 PDT 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 will likely 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, 2023, we received an aggregate of $4.1 million, net of issuance costs, from a registered public offering. On February 19, 2024, we entered into an equity financing agreement which provided net proceeds of $7.2 million with an additional $7.2 million to be provided upon the satisfaction of certain conditions. For additional details, see *Note 25. Subsequent Events - Securities Purchase Agreement for Series B Convertible Preferred.* We believe that the funds available from these transactions and under our working capital line of credit, 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 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® PDT 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.

On December 21, 2023, we entered into credit facilities with two different lenders, each pursuant to a Business Loan and Security Agreement for a term loan in the principal amount of $2,000,000 evidenced by a Secured Promissory Note, effective as of December 21, 2023 (collectively, the "Loan Agreements").

Each loan under the Loan Agreements (the "Loans") requires the Company to make weekly payments of principal and interest in the amount of approximately $102,857 through July 5, 2024, the maturity date. Each Loan is secured by a security interest in substantially all of the Company's assets (the "Collateral"). The default interest rate for each of the Loans is 5.0%.

Each Loan Agreement includes limitations on the Company's ability to sell, lease, transfer, or otherwise dispose of its assets outside the ordinary course of its business; or to create, incur, allow or suffer to exist any lien on any of its assets other than liens in favor of the applicable lender and certain other permitted liens. Each Loan Agreement also contains customary representations and warranties and customary events of default, upon the occurrence of which, after any applicable grace period, the applicable lender would have the ability to accelerate its loan and exercise remedies with respect to the Collateral.

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 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.

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, 2023. 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 is 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 the comparison of our financial statements with other public companies difficult or impossible.

Risks Related to Our Securities and Ownership of Our Common Stock

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

In addition to the discussion of the provisions of our certificate of incorporation 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 November 22, 2023, we received a letter (the "Notice") from the Listing Qualifications staff of Nasdaq notifying the Company that, because the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended September 30, 2023 was $1,038,000, the Company is no longer in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1), which requires that a listed company's stockholders' equity be at least $2,500,000. Additionally, as of the date of the Notice, the Company did not meet either of the alternative requirements of maintaining a market value of listed securities of $35 million or achieving a net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years. As a result, as of the date of this Report, the Company does not satisfy Nasdaq Marketplace Rule 5550(b).

We submitted a compliance plan to Nasdaq on January 8, 2024. The compliance plan was accepted and we were granted 180 calendar days from November 22, 2023 to evidence compliance.

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 5,089,413 shares of common stock outstanding as of March 11, 2024, of which 2,172,628 shares are freely tradable without restrictions or further registration required under the Securities Act. 2,516,785 shares were issued in a private placement that closed on February 22, 2024 (the "Offering") and are currently unregistered, but are subject to registration rights. We have filed a registration statement to register the resale of the shares issued in the Offering and once it is declared effective by the SEC (which we expect to occur soon after the date of this Annual Report on Form 10-K) those 2,516,785 shares will be freely tradable without restriction. The remaining 400,000 shares are currently unregistered and held by Biofrontera AG.

In addition, we have issued warrants to purchase our common stock that, if such warrants are exercised, could be sold in the public market. See *"We have issued several warrants that are exercisable for our common stock and issued Series B Convertible Preferred*

Stock, which, if exercised or converted, could substantially increase the number of shares eligible for future resale in the public market and result in dilution to our stockholders" for more information regarding the potential impact of such warrants.

If the Preferred Warrants are not exercised, we will not receive up to $8 million in aggregate gross proceeds from the exercise of the Warrants which could have a material adverse effect on our financial condition.

We issued warrants (the "Preferred Warrants") to purchase up to 8,000 shares of Series B-3 Convertible Preferred Stock (the "Series B-3 Preferred Stock") at an exercise price of $1,000 per share of Series B-3 Preferred Stock. If the Preferred Warrants are exercised, we will receive up to $8.0 million in gross proceeds as a result of such exercise.

The Preferred Warrants will expire within 5 days of meeting certain milestones, which we expect to occur in the second quarter of 2024. Although we anticipate that the holders of the Preferred Warrants will exercise the Preferred Warrants prior to their expiration, the holders of the Preferred Warrants are not required to do so. In addition, if those milestones are not met the Preferred Warrants will not expire until February 22, 2027 and the Preferred Warrants, if they are exercised at all, will not be exercised within the currently anticipated timeframe.

In addition, while the Company has reserved sufficient shares of Common Stock to cover the number of shares issuable upon conversion of the remaining shares of Series B-1 Convertible Preferred Stock, the Company does not currently have enough authorized shares of Common Stock to cover the shares of Common Stock that would be issuable upon conversion of the Series B-3 Preferred Stock if the investors exercised all of their Warrants. Based on the current conversion price of $0.7074 per share, an additional 11,309,019 shares of Common Stock would need to be reserved and, unless the stockholders approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares of common stock, we only have 7,354,059 shares of common stock available to reserve for the issuance of common stock upon conversion of the Series B-3 Preferred Stock. If we are unable to obtain the stockholder approval necessary to reserve sufficient shares to cover the conversion of the Series B-3 Preferred Stock, then the investors will not be able to exercise any of their Warrants. If the Preferred Warrants are not exercised or are not exercised within the currently anticipated timeline for any of the reasons described above or if the Preferred Warrants are not exercised in full, we would not receive the anticipated proceeds from the exercise of the Preferred Warrants which could have a material adverse effect on our financial condition since our current plans for ensuring sufficient liquidity to continue as a going concern depend on receiving the anticipated proceeds. Even if there were alternate sources of financing available to us, there is no guarantee that they would be sufficient to offset the loss of such proceeds.

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

As of March 10, 2024, we have a total of 2,269,356 outstanding warrants which may each be exercised for one share of our common stock. All of the shares issuable upon exercise of these warrants have been registered on effective registration statements and therefore, when issued, will be freely tradable without restriction or further registration required under the Securities Act. Any shares of our common stock issued upon exercise of outstanding warrants will result in dilution to the then existing holders of our common stock and increase the number of shares eligible for resale in the public market. In addition, in the Offering we issued shares of Series B-1 Convertible Preferred Stock ("Series B-1 Preferred Stock"). Each share of Series B-1 Preferred Stock may be converted into approximately 1,413 shares of our common stock (based on the conversion price of $0.7074 per share and a liquidation preference of $1,000 per share of Series B-1 Preferred Stock). At the time of issuance, the holders of the Series B-1 Preferred Stock converted some of their shares resulting in the issuance of 2,516,785 shares of common stock. However, 4,806 shares of Series B-1 Preferred Stock remain outstanding, which could be converted into up to 6,793,893 shares of common stock.

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

Although the Series B-1 Preferred Stock and Series B-3 Preferred Stock each have a beneficial ownership limitation that prevents the holder from converting if it would result in the holder's beneficial ownership exceeding 9.99% of the then outstanding common stock and although the initial conversion into 2,516,785 shares is close to the beneficial ownership limitation for all current holders of the Series B-1 Stock and the Preferred Warrants, the remaining Series B-1 Preferred Stock and any Series B-3 Preferred Stock issued upon exercise of the Preferred Warrants could be converted into common stock at a future date if the total number of outstanding shares of our common stock increases, if the beneficial ownership limitation is removed or if the holders of the Series B-1 Preferred Stock and Series B-3 Preferred Stock sell any of the common stock they currently hold. Under the terms of the Certificate of Designation for the Series B Convertible Preferred Stock, if our stockholders approve an amendment to our Amended and Restated Certificate of Incorporation to increase the number of authorized shares, the Series B-1 Preferred Stock will automatically be converted into common

stock (to the extent such conversion does not exceed the beneficial ownership limitation described above) or Series B-2 Convertible Preferred Stock with the same terms as the Series B-3 Preferred Stock. Sales of substantial numbers of any such shares described above in the public market could adversely affect the market price of our common stock.

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

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

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, as amended by Amendment No.1 to the Stockholder Rights Agreement, dated as of April 26, 2023.

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

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

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

As of the date of this Form 10-K, 2,192,736 liability classified Warrants remain outstanding. See Note 18. Stockholders' Equity in our audited financial statements for the fiscal year ended December 31, 2023 and 2022 included in this Form 10-K for more information on the Warrants.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 1C. Cybersecurity

Risk Management and Strategy

We have developed and implemented a cybersecurity risk management program intended to protect the confidentiality, integrity, and availability of our critical systems and information. Our cybersecurity program is based on the National Institute of Standards and Technology Cybersecurity Framework (NIST CSF). This does not imply that we meet any particular technical standards, specifications, or requirements, but rather that we use the NIST CSF as a guide to help us identify, assess, and manage cybersecurity risks relevant to our business.

Key elements of our cybersecurity risk management program include:

- risk assessments designed to help identify material cybersecurity risks to our critical systems, information, and our broader enterprise information technology environment;
- leveraging our external service providers, where appropriate, to assess, test, monitor or otherwise assist with aspects of our security controls;
- training and awareness programs for employees to drive adoption and awareness of cybersecurity processes and controls;
- a cybersecurity incident response plan that includes procedures for responding to cybersecurity incidents.

In the last two fiscal years, the Company has not experienced any material cybersecurity incidents, and expenses incurred from cybersecurity incidents were immaterial. For a discussion of whether and how any risks from cybersecurity threats are reasonably likely to materially affect us, including our business, results of operations or financial condition, refer to Item 1A. Risk Factors - "Our business and operations would suffer in the event of system failures or, cyber-attacks or a deficiency in our cyber-security," which is incorporated by reference into this Item 1C.

Governance (Role of Management/Role of the Board)

Our cybersecurity program and function is overseen by the Director of Information Technology ("Director of IT"), who has over 15 years of experience leading information technology divisions in various industries. The Director of IT collaborates with all business units to identify and assess cybersecurity risks and compliance with company policy. The Director of IT stays aware of emerging threats and trends in cybersecurity through attendance at cyber security conferences, subscription to the CISA.gov mailing list, various tech focused news outlets, and other sources.

The Audit Committee is responsible for the oversight of risks associated with cybersecurity threats. The Audit Committee charter provides that the Committee is responsible for considering the effectiveness of the Company's internal control system, including information technology security and control. The Director of IT reports significant cybersecurity events to our Vice President of Administration or Chief Financial Officer, who then reports such events to our Audit Committee.

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 23, *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, 2023, there were two 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.

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, 2023.

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 guarantees 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 a discussion of the factors that could cause such differences. However, other factors besides those listed in Part I, Item 1A, "Risk Factors" or otherwise discussed in this Annual Report also could adversely affect our results, and you should not consider any such list of factors to be a complete set of all potential risks or uncertainties.

Any forward-looking statements made by us or on our behalf speak only as of the date they are made. 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" or "Biofrontera") 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 Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH, our Ameluz Licensor and related parties.

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.

In May 2023, we began research and development ("R&D") activities to support PDT growth and will continue to opportunistically invest in these activities going forward. Our R&D program currently aims to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists. Our goal is to improve the effectiveness of our commercial team by allowing sales representatives to carry approved devices with them allowing for easier product demonstrations and evaluations.

On February 19, 2024, we entered into the Second Amended and Restated License and Supply Agreement with the Ameluz Licensor under which, with immediate effect, the transfer price of Ameluz® will be reduced from 50% to 25% for all purchases in 2024 and 2025. Starting on January 1, 2026, until 2032 there will be stepwise increases in the transfer price from 25% to 35% for sales related to actinic keratosis and, if approved by the FDA, basal cell carcinoma and squamous cell carcinoma. The transfer price for sales related to acne, another indication currently in development, will remain at 25% indefinitely. The transfer price covers the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance, and patent administration.

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

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the BF-RhodoLED® lamp series, for PDT, 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 PDT as the "gold standard" for treating AK, especially multiple AKs and the surrounding photodamaged skin.[1] 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. Our exclusive license and supply agreement, as amended ("Xepi LSA"), with Ferrer Internacional S.A. ("Ferrer") that was assumed by Biofrontera on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. ("Cutanea") enables us to market and sell this product in the United Sates.

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;

- 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, our line of credit, short term debt 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.

[1]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.

Seasonality

Because traditional PDT 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.

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. As previously disclosed in 2021, the Xepi product has experienced manufacturing delays at Ferrer's third-party manufacturer, which have not yet been resolved. We expect a delay in further shipments for an additional five to eight months. We are expecting to launch the RhodoLED® XL in the second quarter 2024 and have begun production activities. However, there have been historical delays due to supply chain issues, and there is a possibility that there are additional supply chain challenges, or our orders are fulfilled at a slower rate than expected. Despite these historic and possible future delays, we expect total revenues will not be significantly impacted (i.e., we experience less growth than expected vs. declining sales) since the majority of our revenues are from sales of Ameluz® and we have RhodeLED lamps on hand and on order. 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® lamp series.

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 to a much lesser extent Xepi® covered by our exclusive LSAs with our Licensors. 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 GmbH to provide BF-RhodoLED® lamps and associated services for the clinical trials performed by Biofrontera Bioscience GmbH.

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.

Under the Ameluz LSA the price we pay per unit will be based upon our sales history. 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.

On February 19, 2024, we entered into the Second Amended and Restated License and Supply Agreement (the "Second A&R Ameluz LSA"), effective as of February 13, 2024, by and among the Company, Pharma, and Bioscience.

Among other things, the Second A&R Ameluz LSA has been amended to (i) change the Transfer Price to 25% through 2025 and then increasing over time pursuant to the schedule set forth in the Second A&R Ameluz LSA to a maximum of 35% starting in 2032, subject to a minimum dollar amount per unit, from the previous Transfer Price of 50% of annual revenue up to $30 million, and then decreasing on further sales until reaching 30% of annual revenue at and above $50 million, (ii) provide for the transfer of responsibilities for Ongoing Trials (as defined in the Second A&R Ameluz LSA) on or before June 1, 2024, including the Company assuming related contracts and transferring key personnel from Pharma and Bioscience to the Company, and (iii) make the failure to achieve the applicable Annual Minimum Sales (as defined in the Second A&R Ameluz LSA) a termination event in certain circumstances, unless waived by Pharma and Bioscience.

In connection with the Second A&R Ameluz LSA, we entered into a Release of Claims dated as of February 13, 2024, by and among the Company, Biofrontera Pharma and Biofrontera Bioscience, pursuant to which the Company agreed to release Biofrontera Pharma and Biofrontera Bioscience from all claims and liabilities arising out of or relating to any failure by Biofrontera Pharma and Biofrontera Bioscience to perform certain obligations under the Second A&R Ameluz LSA with respect to clinical trials that the Company will assume responsibility for under the Second A&R Ameluz LSA.

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, and inventory adjustment due to expiring Xepi® products.

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, relate to the services provided by our significant stockholder, Biofrontera AG, primarily for regulatory support and pharmacovigilance. These expenses are charged to us based on costs incurred plus 6% in accordance with the Amended and Restated Master Contact Services Agreement, (the "2021 Services Agreement"), entered into in December 2021. The 2021 Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us, including regulatory and pharmacovigilance support for as long as we deem necessary. We currently have statements of work in place regarding information technology, 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. As of December 31, 2023, we have migrated most of our significant information technology services from Biofrontera AG to third-party providers.

Research and Development

Our current R&D programs aim to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists and improve the effectiveness of our commercial team by letting sales representatives carry approved devices with them allowing for easier product demonstrations and evaluations.

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 was re-measured at each reporting date until the contingency was resolved. Under the Release, our obligation relating to contingent consideration was relieved as of December 31, 2023.

Change in Fair Value of Warrant Liabilities

For warrants that are classified as liabilities, the Company records the fair value of the warrants at each balance sheet date and records changes in the estimated fair value as a non-cash gain or loss in the consolidated statements of operations until the warrants are exercised, expire or other facts and circumstances lead the warrant liabilities to be reclassified to stockholders' equity or deficit.

Warrant Inducement Expense

In connection with the Securities Purchase Agreement ("Purchase Agreement"), dated as of October 30, 2023, entered into with an institutional investor, the Company entered into the Amendment to Common Stock Purchase Warrants, dated as of October 30, 2023 to amend the common stock purchase warrant dated May 16, 2022 and the common stock purchase warrant dated July 26, 2022 ("Existing Warrants") to (i) revise the exercise price to $3.55 and (ii) extend the date until which the warrants can be exercised until November 2, 2028. As a result of the amendment to the existing warrants, the Company recognized inducement expense which was determined using the Black-Scholes option pricing model before and after the warrant amendment (see *Note 18 Stockholders' Equity* within our consolidated financial statements for details).

The 2022 warrant inducement expense represents the accounting fair value of consideration issued to induce conversion of the common stock purchase warrant dated December 1, 2021 ("2021 Purchase Warrant"). On July 26, 2022, the Company entered into a warrant exercise inducement offer letter (the "Inducement Letter"), in which the Company agreed to lower the exercise price of the 2021 Purchase Warrant and issue a new warrant (the "2022 Inducement Warrant") to purchase up to 4,285,715 shares of common stock in exchange for $4.6 million in proceeds (see *Note 18 Stockholders' Equity* within our consolidated financial statements for details).

The warrant inducement expense was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the 2021 Purchase Warrant prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the 2022 Inducement Warrant issued.

Excess of Warrant Fair Value Over Offering Proceeds

On November 2, 2023, the Company issued common shares and warrants for common shares for net proceeds of $4.1 million (see *Note 18 Stockholders' Equity* within our consolidated financial statements for details). The excess of the fair value of the warrants at the issuance date over the proceeds received was recognized as a loss on the statement of operations.

Change in Fair Value of Investment, Related Party

Our investments are comprised of equity securities in shares of Biofrontera AG, 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.

Under the Release, the Company agreed to transfer 5,451,016 shares of Biofrontera AG to Maruho in exchange for the release of our obligations relating to the Cutanea acquisition.

Gain on Legal Settlement

Under a Confidential Settlement Agreement and Mutual Release (the "Release") dated as of December 27, 2023, entered into with Maruho, the Company was released from its obligations to 1) repay $7.3 million in start-up cost financing to Maruho for Cutanea's redesigned business activities ("start-up cost financing"), and 2) make certain profit-sharing payments pursuant to the Share Purchase and Transfer Agreement dated March 25, 2019 entered into with Maruho (as amended, the "Share Purchase Agreement" or "SPA"). In exchange, the Company agreed to transfer 5,451,016 shares of Biofrontera AG to Maruho. The exchange of the shares of Biofrontera AG for the release of the obligations mentioned above, resulted in a gain.

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 Agreement, as well as interest on our debt instruments, 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 return 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, 2023 and December 31, 2022

The following table summarizes our results of operations for the years ended December 31, 2023 and December 31, 2022:

	For the Year Ended December 31,			
(*in thousands*)	**2023**	**2022**	**Change**	**% Change**
Product revenues, net	$ 34,005	$ 28,541	$ 5,464	19.1%
Related party revenues	66	133	(67)	-50.4%
Revenues, net	**34,071**	**28,674**	**5,397**	**18.8%**
Operating expenses:				
Cost of revenues, related party	16,789	14,618	2,171	14.9%
Cost of revenues, other	655	567	88	15.5%
Selling, general and administrative	38,975	35,137	3,838	10.9%
Selling, general and administrative, related party	152	733	(581)	-79.3%
Research and development	77	-	77	N/A
Change in fair value of contingent consideration	100	(3,800)	3,900	-102.6%
Total operating expenses	56,748	47,255	9,493	20.1%
Loss from operations	**(22,677)**	**(18,581)**	**(4,096)**	**22.0%**
Change in fair value of warrant liabilities	6,456	19,017	(12,561)	-66.1%
Warrant inducement expense	(1,045)	(2,629)	1,584	-60.3%
Excess of warrant fair value over offering proceeds	(2,272)	-	(2,272)	N/A
Change in fair value of investment, related party	(7,421)	1,747	(9,168)	-524.8%
Gain on legal settlement	7,385	-	7,385	N/A
Interest expense, net	(468)	(195)	(273)	-140.0%
Other income, net	(75)	33	(108)	-327.3%
Loss before income taxes	**(20,117)**	**(608)**	**(19,509)**	**-3208.7%**
Income tax expenses	14	32	(18)	-56.3%
Net loss	**$ (20,131)**	**$ (640)**	**$ (19,491)**	**-3045.5%**

Revenues, net

Net product revenue for 2023 increased $5.5 million, or 19.1% compared to 2022. The increase was primarily driven by the expansion of our salesforce in 2023, which resulted in a higher volume of Ameluz® orders and, therefore, an increase in Ameluz® revenue of $5.2 million. The remaining increase was attributed to an increase in the price of Ameluz® .

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party increased $2.2 million, or 14.9% compared to 2022. The increase was primarily driven by the increase in Ameluz® product revenue. For the revenues in 2023 exceeding $30 million, the related cost of revenues decreased from 50% to 40% of net selling price tier pursuant to the Ameluz LSA, which offset the increase of cost due to the increase of sales volume.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for 2023 increased $3.8 million, or 10.9% compared to 2022. This increase was primarily driven by an increase in personnel-related expenses of $2.4 million, reflecting a realignment of our workforce strategy to reduce general and administrative costs and deploy some of these costs to revenue generating related functions. The increase was further driven by sales-related travel of $0.3 million, auto lease expense of $0.2 million, clinical grant expenses of $0.5 million, franchise fee and sales tax of $0.2 million and external legal expenses related to a legal settlement of $1.2 million and other legal costs of $0.8 million related to a variety of non-routine matters including legal claims as disclosed in Note *23. Commitments and Contingencies – Legal Proceedings*. These increases are partially offset by a decrease in issuance costs of $0.6 million related to liability classified equity financings, a decrease of $0.5 million in business insurance, and a decrease in stock compensation of $0.8 million in 2023 due to a decline in the Company's award of executive's restricted stock units.

Gain on Legal Settlement

Under the Release, the Company was released from its obligations to repay $7.3 million in start-up cost financing to Maruho for Cutanea's redesigned business activities and released from having to make certain profit-sharing payments pursuant to the SPA. In exchange, the Company agreed to transfer 5,451,016 shares of Biofrontera AG to Maruho. The exchange pursuant to the Release resulted in a gain of $7.4 million, recorded in December 2023.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was an increase of $0.1 million and a decrease of $3.8 million for 2023 and 2022, respectively. The change in contingent consideration was driven by the estimated profit share the Company is required to pay under the Share Purchase Agreement. There weren't any material changes in 2023. However, during 2022, the estimated profit share was reduced by approximately $3.8 million after receiving notification of third-party manufacturing delays that impacted the timing of sales expansion and improved market positioning of the Xepi® product.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a decrease of $12.6 million from 2022, driven primarily by changes in the underlying value of the Company's common stock.

Warrant Inducement Expense

The warrant inducement expense was $1.0 million and $2.6 million for the years ended December 31, 2023 and 2022, respectively. The 2023 inducement expense was driven by a lower exercise price and extended term to exercise for the 2022 Purchase Warrant and 2022 Inducement Warrant, pursuant to the Amendment to Common Stock Purchase Warrants entered into on October 30, 2023. The 2022 inducement expense was driven by changes in fair value due to the repricing of the 2021 Purchase Warrant, pursuant to the Inducement Letter.

Excess of Warrant Fair Value Over Offering Proceeds

The excess of the fair value of the November 2023 warrants at the issuance date over the proceeds received was recognized as a loss on the statement of operations.

Change in Fair Value of Investment, Related Party

The change in fair value of investment, related party was a decrease of $7.4million and an increase of $1.7 million for the years ended December31, 2023 and 2022, driven by changes in the quoted market price of the common stock of Biofrontera AG and losses on securities we sold during the period.

Net Income to Adjusted EBITDA Reconciliation for years ended December 31, 2023 and 2022

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 were to 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 was re-measured at each reporting date. We exclude the impact of the change in fair value of contingent consideration as this is non-cash. Further, we were relieved of our obligations relating to the contingent consideration under the Release. As such, our future results of operations will not be impacted by the change in fair value.

Gain on legal settlement: Under the Release, we were relieved of our obligations relating to the start-up cost financing and profit sharing under the Share Purchase Agreement in exchange for 5,451,016 shares of Biofrontera AG. The exchange of the shares of Biofrontera AG for the release of the liabilities mentioned above, both of which were recorded at their respective fair values at the exchange date, resulted in a gain. We exclude the impact of the gain on legal settlement as this is non-cash and non-recurring.

Change in fair value of warrant liabilities: The Warrants issued in conjunction with our private placement offerings and registered public offering 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.

Warrant inducement expense: The warrant inducement expense was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the applicable warrants prior to, and immediately after, the reduction in the exercise price on the date of repricing and is presented within the statement of operations. We exclude the impact of the change in fair value of the warrant inducement expense as this is non-cash.

Excess of warrant fair value over offering proceeds: The excess of warrant fair value over offering proceeds was determined by the difference between the fair value of the warrants upon issuance on November 2, 2023 and the proceeds received. We exclude the impact of the variance between the warrant fair value and the proceeds as this is non-cash.

Change in fair value of investment, related party: The Company accounts for its investment, related party 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 realized and unrealized 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 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, 2023 and 2022:

	Years ended December 31,	
	2023	**2022**
Net loss	**$ (20,131)**	**$ (640)**
Interest expense, net	468	195
Income tax expenses	14	32
Depreciation and amortization	504	519
EBITDA	**(19,145)**	**106**
Gain on legal settlement	(7,385)	-
Change in fair value of contingent consideration	100	(3,800)
Change in fair value of warrant liabilities	(6,456)	(19,017)
Warrant inducement expense	1,045	2,629
Excess of warrant fair value over offering proceeds	2,272	-
Change in fair value of investment, related party	7,421	(1,747)
Legal settlement expenses	1,225	870
Stock based compensation	1,045	1,852
Expensed issuance costs	422	1,045
Adjusted EBITDA	**$ (19,456)**	**$ (18,062)**
Adjusted EBITDA margin	-57.1%	-63.0%

Adjusted EBITDA

Adjusted EBITDA decreased from ($18.1) million for the year ended December 31, 2022 to ($19.5) million for the year ended December 31, 2023. The decrease was primarily driven by an increase in selling, general, and administrative expenses (excluding legal settlement expenses) ("SG&A expenses") due to increased headcount. Our Adjusted EBITDA margin increased from (63.0%) for the year ended December 31, 2022 to (57.1%) for the year ended December 31, 2023, as the increase in revenue outpaced the decline in our Adjusted EBITDA.

Liquidity and Capital Resources

Since we commenced operations in 2015, we have generated significant losses and have incurred net cash outflows from operations of $24.9 million and $16.2 million for the years ended December 31, 2023 and 2022, respectively. The Company had an accumulated deficit as of December 31, 2023 of $99.7 million. The Company's primary sources of liquidity are its cash collected from the sales of its products, and cash flows from financing transactions. During the year ended December 31, 2023, we received proceeds of $4.1 million from the issuance of common stock and warrants, net of issuance costs (See *Note 18. Stockholders' Equity*). As of December

31, 2023, we had cash and cash equivalents of $1.3 million, compared to $17.2 million as of December 31, 2022. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months from the issuance date of this report, which management believes has been alleviated through its plans to mitigate these conditions and obtain additional liquidity.

Pursuant to the requirements of the Financial Accounting Standards Board's Accounting Standards Codification ("ASC") Topic 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year from the date the consolidated financial statements included in this Annual Report on Form 10-K are issued. This evaluation does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented or are not within control of the Company as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

In an effort to alleviate these conditions, management plans include execution on the 2024 budget approved by the Board, which includes significant discretionary sales and marketing, medical affairs, and dermatology community outreach efforts as we seek to expand the commercialization of Ameluz® in the United States, however, discretionary expenses are about $5.5 million less than what was spent in 2023. We have reduced spending at both the commercial and general and administrative level but do not expect these reductions to impact our ability to grow and achieve our revenue targets. We also expect to incur additional expenses in support of our product commercialization efforts. In addition, we expect to continue to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company in the U.S.

Also, on February 20, 2024, the Company entered into the 2024 LSA with Biofrontera AG which will significantly reduce our cost of inventory in the future. The Company will begin to see gross margins of its primary product, Ameluz®, of approximately 75% as opposed to the prior 50% beginning with inventory purchases after the execution date. This will reduce our cash needs for inventory which will be partially offset by R&D costs, resulting in expected net savings of $0.7 million by March 2025 and continuing in subsequent years.

In addition, on February 19, 2024, the Company entered into a securities and purchase agreement with healthcare-focused institutional investors resulting in net proceeds of $7.2 million, which were received on February 22, 2024. Under the agreement, we also issued warrants to purchase 8,000 shares of Series B-3 Convertible Preferred Stock at an exercise price of $1,000 per share. If these warrants are exercised in full, we will receive additional net proceeds of $7.2 million. To encourage the investors to exercise the warrants, they will expire within 21 days upon the satisfaction of certain conditions (but if such conditions are not met, they will expire three years after issuance). Even though we anticipate that we will satisfy the conditions to trigger the expiration of the warrants and receive additional financing as a result of the exercise of the warrants, there can be no assurance that such conditions will be met or that the investors will choose to exercise the warrants prior to expiration. See *Note 25. Subsequent Events- Securities Purchase Agreement for Series B Convertible Preferred*.

The Company believes that, as a result of these plans, it has sufficient liquidity and probable financing to meet its funding requirements for at least one year from the date the financial statements are issued. However, the Company's plans will depend on many factors, including executing on our sales plan over one year from issuance, reaching at least 5% in year to date revenue growth over 2023 by June 2024, receiving shareholder approval to increase the number of authorized shares to enable the warrant exercise, controlling our selling, general and administrative costs, and the investors electing to exercise their warrants within the anticipated timeframe, among other possible challenges and unforeseen circumstances. A lack of execution or unforeseen circumstances may require the Company to raise additional capital or debt which may not be available on acceptable terms, or at all which could result in a material adverse effect on the Company and its financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

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)	**2023**	**2022**
Net cash used in operating activities	$ (24,895)	$ (16,199)
Net cash provided by (used in) investing activities	619	(5,156)
Net cash provided by financing activities	8,411	14,021
Net increase (decrease) in cash and restricted cash	$ (15,865)	$ (7,334)

Operating Activities

During the year ended December 31, 2023, operating activities used $24.9 million of cash, primarily resulting from our net loss of $20.1 million, adjusted for the add back of non-cash income of $0.4 million and offset by net cash used by changes in our operating assets and liabilities of $4.4 million. Non-cash income includes a gain on legal settlement of $7.4 million and a change in fair value of warrant liabilities of $6.5 million offset by a change in fair value of equity securities of $7.4 million, loss on warrant fair value over offering proceeds of $2.3 million, warrant inducement expense of $1.1 million, stock-based compensation of $1.1 million, non-cash interest expense of $0.4 million, change in fair value of contingent consideration of $0.1 million, provision for doubtful accounts of $0.1 million and depreciation and amortization in the aggregate of $1.1 million.

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 $19.0 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, 2023, investing activities provided $0.6 million, primarily resulting from the sale of shares of Biofrontera AG.

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, related party* within our consolidated financial statements*)*

Financing Activities

During the year ended December 31, 2023, net cash provided by financing activities was $8.4 million which consisted of net proceeds received from our loan and line of credit of $3.9 million and net proceeds of $4.5 million from the issuance of common stock and warrants in a public offering.

During the year ended December 31, 2022, net cash provided by financing activities was $14.0 million which 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.

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.

Critical Accounting Estimates

We believe that the following are the most critical estimates which required significant judgments 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 and until settlement, we revalue the remaining obligations and record increases or decreases in their fair value as an adjustment to operating 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, 2023 and 2022 as included in this Form 10-K. 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 and if the carrying value is also determined to be greater than its fair value. 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, and again in December 2023, when we implemented a marketing hold in response to continued manufacturing delays experienced by our Licensor and also entered the Release, relieving us of obligations that had previously reduced the carrying value of the asset group, we deemed it necessary to assess the recoverability of our Xepi® asset group. As of the date of notification in 2022 and the Release in 2023, future undiscounted cash flows were estimated over the expected remaining useful life using revenue and operating expense growth rates. The expected cash flows were based on the assumption that sales levels would grow considerably after resolution of the manufacturing delays as a result of expanding the sales force and marketing efforts related to relaunching the asset group. Further, in 2023, due to the uncertainty relating to the timing of resolution of the previously identified supply chain issues, the Company used a probability-weighted approach to estimate the future cash flows under several scenarios. 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 in 2023, we determined that, on an undiscounted basis, expected cash flows did not exceed the carrying amount of the asset group, which had increased significantly as a result of the relief of obligations under the Release agreement. As such, we determined that the carrying value was not recoverable as of December 29, 2023 and proceeded to determine whether the carrying value exceeded the asset group's fair value, indicating an impairment loss. The valuation of the asset group required that management use valuation techniques such as the income approach. The income approach includes the use of a discounted cash flow model, which includes discounted cash flow scenarios and requires significant estimates such as future expected revenue, expenses and other costs, and discount rates. The fair value calculated was in excess of the carrying value, indicating that no impairment loss had been incurred. 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 including warrants issued to induce conversion 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. Due to the relatively limited period during which our stock has been publicly traded, volatility is based on a weighted average of our historical volatility and of a selected peer group of publicly traded companies within a similar industry. 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.

Contingencies and Litigation

In the ordinary course of our business, we are subject to various legal proceedings, claims and other regulatory matters, the outcomes of which are subject to significant uncertainty. In determining whether a loss should be accrued, we evaluate, among other factors, the probability of an unfavorable outcome and the ability to make a reasonable estimate of the amount of loss. As additional information becomes available, we reassess the potential liability related to our pending litigation and other contingencies and revise our estimates as applicable. Revisions of our estimates of the potential liability could materially impact our results of operations. Additionally, if the final outcome of such litigation and contingencies differs adversely from that currently expected, it would result in a charge to operating results when determined.

Going Concern Estimates

We assume that the Company will continue as a going concern, which contemplates continuity of operations, realization of assets, and liquidation of liabilities in the normal course of business. This estimate requires us to consider various factors such as historical performance, expected performance, liquidity, debt obligations, and potential sources of additional funding. A different outcome in any of these assumptions could adversely affect our financial condition and liquidity over the next twelve months.

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*.

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

To the Shareholders and Board of Directors of Biofrontera, Inc.

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Biofrontera, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2023, 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, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

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 audits 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/ Marcum LLP

Marcum LLP

We have served as the Company's auditor since 2023.

East Hanover, New Jersey
March 15, 2024

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

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,343	$ 17,208
Investment, related party	78	10,548
Accounts receivable, net	5,162	3,748
Other receivables, related party	-	3,658
Inventories, net	10,908	7,168
Prepaid expenses and other current assets	425	810
Other assets, related party	5,159	-
Total current assets	**23,075**	**43,140**
Other receivables long term, related party	-	2,813
Property and equipment, net	134	204
Operating lease right-of-use assets	1,612	1,375
Intangible asset, net	2,629	3,032
Other assets	482	320
Total assets	**$ 27,932**	**$ 50,884**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,308	1,278
Accounts payable, related parties, net	5,698	1,312
Acquisition contract liabilities, net	-	6,942
Operating lease liabilities	691	498
Accrued expenses and other current liabilities	4,487	10,864
Short term debt	3,904	-
Total current liabilities	**18,088**	**20,894**
Long-term liabilities:		
Acquisition contract liabilities, net	-	2,400
Warrant liabilities	4,210	2,843
Operating lease liabilities, non-current	804	848
Other liabilities	37	21
Total liabilities	**23,139**	**27,006**
Commitments and contingencies (see Note 23)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2023 and 2022	-	-
Common Stock, $0.001 par value, 15,000,000 shares authorized; 1,517,628 and 1,334,950 shares issued and outstanding as of December 31, 2023 and 2022	2	1
Additional paid-in capital	104,441	103,396
Accumulated deficit	(99,650)	(79,519)

Total stockholders' equity	**4,793**	**23,878**
Total liabilities and stockholders' equity	**$ 27,932**	**$ 50,884**

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,	
	2023	**2022**
Products revenues, net	$ 34,005	$ 28,541
Revenues, related party	66	133
Total revenues, net	**34,071**	**28,674**
Operating expenses		
Cost of revenues, related party	16,789	14,618
Cost of revenues, other	655	567
Selling, general and administrative	38,975	35,137
Selling, general and administrative, related party	152	733
Research and development	77	-
Change in fair value of contingent consideration	100	(3,800)
Total operating expenses	**56,748**	**47,255**
Loss from operations	**(22,677)**	**(18,581)**
Other income (expense)		
Change in fair value of warrant liabilities	6,456	19,017
Warrant inducement expense	(1,045)	(2,629)
Excess of warrant fair value over offering proceeds	(2,272)	-
Change in fair value of investment, related party	(7,421)	1,747
Gain on legal settlement	7,385	-
Interest expense, net	(468)	(195)
Other income (expense), net	(75)	33
Total other income (expense)	**2,560**	**17,973**
Loss before income taxes	**(20,117)**	**(608)**
Income tax expense	14	32
Net loss	**$ (20,131)**	**$ (640)**
Loss per common share:		
Basic and diluted	$ (13.02)	$ (0.61)
Weighted-average common shares outstanding:		
Basic and diluted	1,546,297	1,056,988

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	Accumulated	
	Shares	Amount	Capital	Deficit	Total
Balance at December 31, 2021	855,237	$ 1	$ 90,216	$ (78,879)	$ 11,338
Issuance of common stock in exchange for investment, related party	157,402	0	3,683	-	3,683
Issuance of common stock and warrants under private placement, net of negligible issuance costs	92,500	0	117	-	117
Exercise of pre-funded warrants	78,450	0	2,842		2,842
Exercise of PIPE warrants	142,857	0	4,686	-	4,686
Issuance of shares for vested restricted stock units	8,504	-	-	-	-
Stock-based compensation	-	-	1,852	-	1,852
Net loss	-	-	-	(640)	(640)
Balance at December 31, 2022	1,334,950	$ 1	$ 103,396	$ (79,519)	$ 23,878
Issuance of shares for vested restricted stock units	8,588	0	-	-	0
Issuance of shares in reverse stock split (for fractional shares)	24,090	0	-	-	0
Issuance of common stock and warrants, under registered public offering	150,000	1	-	-	1
Stock based compensation	-	-	1,045		1,045
Net loss	-	-	-	(20,131)	(20,131)
Balance at December 31, 2023	1,517,628	$ 2	$ 104,441	$ (99,650)	$ 4,793

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,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net loss	$ (20,131)	$ (640)
Adjustments to reconcile net loss to cash flows used in operations		
Gain on legal settlement	(7,385)	-
Depreciation	86	101
Amortization of right-of-use assets	560	653
Amortization of acquired intangible assets	418	418
Change in fair value of investment, related party	7,421	(1,747)
Change in fair value of contingent consideration	100	(3,800)
Change in fair value of warrant liabilities	(6,456)	(19,017)
Warrant inducement expense	1,045	2,629
Excess of warrant fair value over offering proceeds	2,272	-
Stock-based compensation	1,045	1,852
Provision for inventory obsolescence	-	100
Provision for doubtful accounts	122	106
Non-cash interest expense	402	358
Changes in operating assets and liabilities:		
Accounts receivable	(1,536)	(70)
Other receivables, related party	6,470	4,990
Prepaid expenses and other assets	174	4,154
Other assets, related party	(5,159)	-
Inventories	(3,750)	(2,810)
Accounts payable and related party payables	6,415	912
Operating lease liabilities	(657)	(781)
Accrued expenses and other liabilities	(6,351)	(3,607)
Cash flows used in operating activities	**(24,895)**	**(16,199)**
Cash flows from investing activities		
Purchases of investment, related party	-	(5,118)
Sales of investment, related party	624	-
Purchases of property and equipment	(5)	(38)
Cash flows provided by (used in) investing activities	**619**	**(5,156)**
Cash flows from financing activities		
Proceeds from line of credit	21,448	-
Proceeds from short term debt	3,800	-
Principal payments short term debt, net	(21,344)	
Proceeds from issuance of common stock and warrants	4,507	9,391
Proceeds from exercise of warrants	-	4,630
Cash flows provided by financing activities	**8,411**	**14,021**
Net decrease in cash and cash equivalents	**(15,865)**	**(7,334)**

Cash, cash equivalents and restricted cash, at the beginning of the year		**17,408**		**24,742**
Cash, cash equivalents and restricted cash, at the end of the year	**$**	**1,543**	**$**	**17,408**
Supplemental disclosure of cash flow information				
Interest paid	$	125	$	1
Interest paid, related party	$	22	$	-
Income tax paid, net	$	15	$	32
Supplemental non-cash investing and financing activities				
Release of start-up cost financing obligation as part of legal settlement	$	(7,300)	$	-
Release of contingent consideration obligation as part of legal settlement	$	(2,500)	$	-
Transfer of investment as part of legal settlement	$	2,415	$	-
Addition of right-of-use assets in exchange for operating lease liabilities	$	800	$	234
Conversion of warrant liability to equity in connection with exercise of warrants	$	-	$	6,840
Issuance of common shares in exchange for investment, related party	$	-	$	3,683

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

Notes to the Audited Consolidated Financial Statements as of and for the Years Ended December 31, 2023 and 2022

1. Organization and Business Overview

Biofrontera Inc., a Delaware Corporation, (the "Company" or "Biofrontera") is 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.

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

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 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") with Biofrontera Pharma ("Pharma") GmbH and Biofrontera Bioscience GmbH ("Biofrontera Bioscience," and, together with Pharma, the "Ameluz Licensor"), both of which are related parties.

Our second prescription drug licensed 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, 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. Our exclusive license and supply agreement, as amended ("Xepi LSA") with Ferrer Internacional S.A. ("Ferrer") and assumed by the Company on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. ("Cutanea") enables the Company to market and sell this product in the United States. The Company has generated limited revenue from sales of Xepi during the current reporting periods and recent developments with the third-party manufacturer that was providing our supply of Xepi® have resulted in further delays of our commercialization of the product. However, Ferrer is qualifying a new contract manufacturer, Cambrex, which is expected to begin production in the second half of 2024. Once the new third-party manufacturer is qualified, we expect the supply of Xepi® will meet our future market demand.

Liquidity and Going Concern

Since we commenced operations in 2015, we have generated significant losses and have incurred net cash outflows from operations of $24.9 million and $16.2 million for the years ended December 31, 2023 and 2022, respectively . The Company had an accumulated deficit as of December 31, 2023 of $ 99.7 million. The Company's primary sources of liquidity are its cash collected from the sales of its products, and cash flows from financing transactions. During the year ended December 31, 2023, we received proceeds of $4.1 million from the issuance of common stock and warrants, net of issuance costs (See *Note 18. Stockholders' Equity*). As of December 31, 2023, we had cash and cash equivalents of $1.3 million, compared to $17.2 million as of December 31, 2022. These conditions raise substantial doubt about our ability to continue as a going concern for at least twelve months from the issuance date of this report, which management believes has been alleviated through its plans to mitigate these conditions and obtain additional liquidity.

Pursuant to the requirements of the Financial Accounting Standards Board's Accounting Standards Codification ("ASC") Topic 205-40, Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern, management must evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the Company's ability to continue as a going concern for one year from the date the consolidated financial statements included in this Annual Report on Form 10-K are issued. This evaluation does not take into consideration the potential mitigating effect of management's plans that have not been fully implemented or are not within control of the Company as of the date the financial statements are issued. When substantial doubt exists under this methodology, management evaluates whether the mitigating effect of its plans sufficiently alleviates substantial doubt about the Company's ability to continue as a going concern. The mitigating effect of management's plans, however, is only considered if both (1) it is probable that the plans will be effectively implemented within one year after the date that the financial statements are issued, and (2) it is probable that the plans, when implemented, will mitigate the relevant conditions or events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the consolidated financial statements are issued.

In an effort to alleviate these conditions, management plans include execution on the 2024 budget approved by the Board, which includes significant discretionary sales and marketing, medical affairs, and dermatology community outreach efforts as we seek to expand the commercialization of Ameluz® in the United States, however, discretionary expenses are about $5.5 million less than what was spent in 2023. We have reduced spending at both the commercial and general and administrative level but do not expect these reductions to impact our ability to grow and achieve our revenue targets. We also expect to incur additional expenses in support of our

product commercialization efforts. In addition, we expect to continue to incur significant costs to comply with corporate governance, internal controls and similar requirements applicable to us as a public company in the U.S.

Also, on February 20, 2024, the Company entered into the 2024 LSA with Biofrontera AG which will significantly reduce our cost of inventory in the future. The Company will begin to see gross margins of its primary product, Ameluz®, of approximately 75% as opposed to the prior 50% beginning with inventory purchases after the execution date. This will reduce our cash needs for inventory which will be partially offset by R&D costs, resulting in expected net savings of $0.7 million by March 2025 and continuing in subsequent years.

In addition, on February 19, 2024, the Company entered into a securities and purchase agreement with healthcare-focused institutional investors resulting in net proceeds of $7.2 million, which were received on February 22, 2024. Under the agreement, we also issued warrants to purchase 8,000 shares of Series B-3 Convertible Preferred Stock at an exercise price of $1,000 per share. If these warrants are exercised in full, we will receive additional net proceeds of $7.2 million. To encourage the investors to exercise the warrants, they will expire within 21 days upon the satisfaction of certain conditions (but if such conditions are not met, they will expire three years after issuance). Even though we anticipate that we will satisfy the conditions to trigger the expiration of the warrants and receive additional financing as a result of the exercise of the warrants, there can be no assurance that such conditions will be met or that the investors will choose to exercise the warrants prior to expiration. See *Note 25. Subsequent Events- Securities Purchase Agreement for Series B Convertible Preferred*.

The Company believes that, as a result of these plans, it has sufficient liquidity and probable financing to meet its funding requirements for at least one year from the date the financial statements are issued. However, the Company's plans will depend on many factors, including executing on our sales plan over one year from issuance, reaching at least 5% in year to date revenue growth over 2023 by June 2024, receiving shareholder approval to increase the number of authorized shares to enable the warrant exercise, controlling our selling, general and administrative costs, and the investors electing to exercise their warrants within the anticipated timeframe, among other possible challenges and unforeseen circumstances. A lack of execution or unforeseen circumstances may require the Company to raise additional capital or debt which may not be available on acceptable terms, or at all which could result in a material adverse effect on the Company and its financial statements.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above.

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-makers in deciding how to allocate resources and assess performance. The Company's chief operating decision makers (determined to be the Chief Executive Officer and the Chief Financial Officer) do 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.

Reverse Stock Split

On July 3, 2023, the Company effected a 1-for-20 reverse stock split (the "Reverse Stock Split") of the issued and outstanding shares of the Company's common stock, $0.001 par value (the "Common Stock"). The Common Stock began trading on the Nasdaq Capital Market on a post-split basis on July 5, 2023.

All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Stock Split as if it had been effective from the beginning of the earliest period presented, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

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 realization and valuation of receivables and inventory, valuation of contingent consideration and warrant liabilities, impairment assessment of intangibles and other long-lived assets, share-based payments, income taxes including deferred tax assets and liabilities and contingent liability recognition. 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.

The Company maintains its cash balances at financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). At December 31, 2023, approximately $1.0 million of the Company's cash balances were in excess of FDIC limits. The Company has not experienced any losses on these accounts and management does not believe that the Company is exposed to any significant risks with respect to these accounts.

Restricted Cash

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards *(see Note 13. Cash Balances and Statement of Cash Flows Reconciliation)*. Long-term restricted cash was recorded in other assets in the consolidated balance sheet.

Investment, Related Party

The Company accounts for its investment, related party 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 receivable 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. The allowance for estimated credit losses represents management's best estimate of probable credit losses. The allowance is based upon a number of factors, including the length of time accounts receivable are past due, the Company's previous loss history, the specific customer's ability to pay its obligation and any other forward-looking data regarding customers' ability to pay which may be available. In addition, management considered other qualitative factors, particularly in relation to the greater actinic keratosis and dermatological market. Receivables are written off against the allowance when management believes that the amount receivable will not be recovered. 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.

The Company has 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®). The Addendum to Amended and Restated License

and Supply Agreement, effective December 5, 2023, and as amended on January 29, 2024, allows for the Company to set off the amounts due to Biofrontera AG and Ameluz Licensor, with the amounts due from Biofrontera AG and Ameluz Licensor. As such, in accordance with ASC 210-20-45-1 the other receivables, related party have been offset against accounts payable, related parties for the year ended December 31, 2023.

We are dependent on two licensors, Biofrontera Pharma and Ferrer, 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. These licensors may have risks associated with limited source suppliers and contract manufacturers. If our licensors fail to maintain relationships with these suppliers and manufacturers or they are unable to produce product, our business could be materially harmed.

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. 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. The IBR for the twelve months ended December 31, 2023 was 9.5%. Given the absence of an outstanding debt agreement for the twelve months ended December 31, 2022, 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 lease liabilities at inception and 8.5% for 2022 lease 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 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 of 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. Refer to *Note 12. Intangible Asset, Net.*

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 is 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 subsequent 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 is also 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 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 on November 2, 2023, the Pre-Funded Warrants ("2023 Pre-Funded Warrants") (see Note 18. Stockholders' Equity) were accounted for as equity as these instruments met all of the requirements for equity classification under ASC 815-40.

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, 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 Ameluz® product, which 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, (ii) rental agreements, or (iii) 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 or rental 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 has historically maintained 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. During 2023, due to the continued delays with the supply of Xepi®, the co-pay assistance program was discontinued.

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).

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 were $0.1 million and negligible for the years ended December 31, 2023 and 2022, respectively, 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 for each of the years ended December 31, 2023 and 2022, 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 option pricing model to calculate the 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 Black-Scholes-Merton 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, the warrant implied volatility and the historical equity volatility of the Company. The peer group was developed based on companies in the biopharma 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 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, 2023 and 2022, advertising costs totaled $0.2 million and $0.1 million, respectively.

R&D Costs

R&D costs are expensed as incurred. R&D costs include external costs of outside vendors engaged to conduct R&D activities, and other operational costs related to the Company's R&D activities.

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 loss per common share is computed by dividing net 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 Accounting Standards Update ("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 was effective for us on January 1, 2023, and did not have a material effect on our consolidated financial statements.

In November 2023, FASB issued ASU 2023-07, Segment Reporting (Topic 280), *Improvements to Reportable Segment Disclosures* to improve reportable segment disclosure requirements through enhanced disclosures about significant segment expenses on an interim and annual basis. All disclosure requirements of ASU 2023-07 are required for entities with a single reportable segment. ASU 2023-07 is effective for fiscal years beginning after December 15, 2023, and interim periods for the fiscal years beginning after December 15, 2024, and should be applied on a retrospective basis to all periods presented. Early adoption is permitted. We are currently evaluating the effect of adopting the ASU on our disclosures.

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740) – *Improvements to Income Tax Disclosures*. The ASU requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. The amendments in this ASU are required to be adopted for fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments should be applied on a prospective basis. We are currently evaluating the effect of adopting the ASU on our disclosures.

3. Acquisition Contract Liabilities

On March 25, 2019, we entered into an agreement (as amended, the "Share Purchase Agreement" or "SPA") 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 owned approximately 29.9% of Biofrontera AG through its wholly-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 were 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 was be shared equally between Maruho and Biofrontera until 2030 ("contingent consideration").

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-measured contingent consideration and re-assessed the underlying assumptions and estimates at each reporting period utilizing a scenario-based method.

On December 29, 2023, we entered into a Confidential Settlement Agreement and Mutual Release (the "Release"), with Maruho, and a Share Transfer Agreement (together with the Release, the "Settlement Agreement"). The Settlement Agreement resolves the arbitration proceeding initiated by the Company against Maruho in the International Chamber of Commerce (the "Arbitration") in which the Company alleged certain claims against Maruho concerning the Share Purchase Agreement. In the Arbitration, the Company sought, in part, a declaration that it is not obligated to repay $7.3 million of "start-up costs" to Maruho.

The Settlement Agreement contains a mutual release whereby each of the Company and Maruho agreed to release and discharge the other party from any and all claims, actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, controversies, agreements, promises, variances, trespasses, damages, judgments, extents, executions, claims, and demands whatsoever, in law, admiralty, equity, arbitration or otherwise, which against the other arising from or in

connection with or in any manner relating to the Share Purchase Agreement, including but not limited to any claims that were or could have been asserted in the Arbitration.

Under the Settlement Agreement, the obligations of the Company to repay the $7.3 million of start-up costs to Maruho, and to make the contingent consideration payments, were released. In exchange the Company agreed to transfer to Maruho 5,451,016 shares of Biofrontera AG. The exchange of the shares of Biofrontera AG for the release of the liabilities mentioned above, both of which were recorded at their respective fair values at the exchange date, resulted in a gain.

The following table provides a summary of the transaction under the settlement Agreement:

(in thousands)		
Release of contingent consideration	$	(2,500)
Release of start-up cost financing		(7,300)
Transfer of Investment in Biofrontera AG	$	2,415
Gain on settlement	$	(7,385)

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, 2023	December 31, 2022
Assets:			
Investment, related party	1	$ 78	$ 10,548
Liabilities:			
Contingent Consideration	3	$ -	$ 2,400
Warrant liability – 2023 Purchase Warrants	3	$ 3,470	$ -
Warrant liability – 2022 Purchase Warrants	3	$ 328	$ 1,129
Warrant liability – 2022 Inducement Warrants	3	$ 412	$ 1,714

Investment, related party

As of December 31, 2023 and 2022, the Company has an investment in 177,465 and 6,466,946, respectively, of common shares of Biofrontera AG, a company traded on the Frankfurt Stock Exchange and a significant shareholder of Biofrontera. The fair value of this investment was determined with Level 1 inputs through references to quoted market prices. See *Note 6. Investment Related Party* and *Note 17. Related Party Transactions*.

Contingent Consideration

Contingent consideration, which relates to the estimated profits from the sale of Cutanea products to be shared equally with Maruho under the Share Purchase Agreement, 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.

Under the Settlement Agreement (see Note 3), the obligations of the Company to make the profit-sharing payments related to the products acquired by the Company pursuant to the Share Purchase Agreement were released.

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

(in thousands)	
Balance at December 31, 2021	**$ 6,200**
Change in fair value of contingent consideration	(3,800)
Balance at December 31, 2022	**$ 2,400**
Change in fair value of contingent consideration	100
Release of contingent consideration	(2,500)
Balance at December 31, 2023	$ -

The increase/(decrease) in fair value of the contingent consideration in the amount of $0.1 million and $(3.8) million during the years ended December 31, 2023 and 2022 was recorded in operating expenses in the statements of operations.

Warrant Liabilities

The warrant liabilities are comprised of (i) outstanding warrants to purchase 170,950 shares of Common Stock originally issued in a private placement on May 16, 2022, as amended on November 2, 2023 to extend the expiration date until November 2, 2028 and revise the exercise price to $3.55 per share (the "2022 Purchase Warrants") (ii) warrants to purchase 214,286 shares of Common Stock issued on July 26, 2022, as amended on November 2, 2023 to extend the expiration date until November 2, 2028 and revise the exercise price to $3.55 per share (the "2022 Inducement Warrants") and (iii) warrants to purchase 1,807,500 shares of Common Stock issued on November 2, 2023 expiring five years following the date of issuance and with an exercise price of $3.55 per share (the "2023 Purchase Warrants"). See Note *18. Stockholders' Equity - Registered Public Offering and Warrant Amendment* for additional details.

The 2022 Purchase Warrants, the 2022 Inducement Warrants and the 2023 Purchase Warrants were accounted for as liabilities as these warrants provide for a redemption right in the case of a fundamental transaction which fails the requirement of the indexation guidance under ASC 815-40. The resulting warrant liabilities are re-measured at each balance sheet date until their exercise or expiration, and any change in fair value is recognized in the Company's consolidated statement of operations. 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 warrant liabilities 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 for the Level 3 warrants was estimated using a Black-Scholes pricing model based on the following assumptions at May 16, 2022 for the 2022 Purchase Warrants, July 26, 2022 for the 2022 Inducement Warrants, and November 2, 2023 for the 2023 Purchase Warrants:

	2023 Purchase	**2022 Purchase**	**2022 Inducement**
Stock price	$ 4.90	$ 52.40	$ 32.80
Expiration term (in years)	5.00	5.50	4.34
Volatility	90%	65.0%	70.0%
Risk-free Rate	4.6%	2.83%	2.84%
Dividend yield	0.0%	0.0%	0.0%

The fair value for the Level 3 warrants at December 31, 2023 was estimated using Black-Scholes pricing model based on the following assumptions:

	2023 Purchase 2022 Purchase 2022 Inducement
Stock price	$ 2.77
Expiration term (in years)	4.84

Volatility	95%
Risk-free Rate	3.82%
Dividend yield	0.0%

The fair value for the Level 3 warrants at December 31, 2022 was estimated using Black-Scholes pricing model based on the following assumptions:

	2022 Purchase	2022 Inducement
Stock price	$ 18.40	$ 18.40
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, 2023	December 31, 2022
Fair value at beginning of year	$ 2,843	$ 12,854
Issuance of new warrants	6,778	13,217
Exercise of warrants	-	(6,840)
Change in fair value of warrant liability	(6,456)	(19,017)
Warrant inducement expense (See Note *18. Stockholders' Equity - Exercise of 2021 Purchase Warrant and Issuance of 2022 Inducement Warrant)*	1,045	2,629
Fair value at end of year	$ 4,210	2,843

5. Revenue

We generate revenue primarily through the sales of our licensed 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 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, 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**
Provision related to current period sales	4	156	3	344	507
Credit or payments made during the period	-	(165)	(2)	(310)	(477)
Balance at December 31, 2023	**$ 52**	**-**	**6**	**54**	**112**

6. Investment, Related Party

As of December 31, 2023 and December 31, 2022, our investment in equity securities consisted solely of 177,465 and 6,466,946, respectively of common shares of Biofrontera AG, a significant shareholder. (See *Note 17. Related Party Transactions*). Equity securities gains and losses include unrealized gains and losses from changes in fair values during the period on equity securities we still own, as well as gains and losses on securities we sold or transferred during the period. As reflected in the consolidated statements of cash flows, we received proceeds from sales of equity securities of approximately $0.6 million during the twelve months ended December 31, 2023. There were no proceeds from sales of equity securities during the twelve months ended December 31, 2022.

(in thousands):	December 31, 2023	December 31, 2022
Net losses recognized during the period on equity securities	$ (7,421)	$ (1,747)
Less: Net realized losses on equity securities sold or transferred	7,219	-
Unrealized losses recognized during the reporting period on equity securities still held at the reporting date	(202)	(1,747)

7. Accounts Receivable, net

Accounts receivable are mainly attributable to the sale of Ameluz®. products. It is expected that all trade receivables will be settled within twelve months of the balance sheet date. Trade accounts receivable are stated at their net realizable value. The allowance for credit losses reflects our best estimate of expected credit losses of the receivables determined on the basis of historical experience and

current information. In developing the estimate for expected credit losses, trade accounts receivable are segmented into pools of assets depending primarily on delinquency status, and fixed reserve percentages are established for each pool of trade accounts receivable.

In determining the reserve percentages for each pool of trade accounts receivable, we considered our historical experience with certain customers, regulatory and legal environments and other relevant current and future forecasted macroeconomic factors. If we become aware of any customer-specific factors that impact credit risk, specific allowances for these known troubled accounts will be recorded.

The allowance for doubtful accounts was $0.2 million and $0.1 million as of December 31, 2023 and 2022, respectively.

8. Other Receivables, Related Party

As of December 31, 2023 and 2022 the Company had a receivable, related party of $2.8 million (presented net in accounts payable, related party) and $6.5 million ($3.7 million short term and $2.8 million long term), respectively, primarily due from Biofrontera AG for its 50% share of the balance of a legal settlement (See *Note 23. Commitments and Contingencies – Legal proceedings*) 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 ("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 Allocation Agreement, as amended, 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®). See *Note 17. Related Party.*

The Addendum to Amended and Restated License and Supply Agreement, effective December 5, 2023, and as amended on January 29, 2024, allows for us to set off the amounts due to Biofrontera AG and the Ameluz Licensor, with the amounts due from Biofrontera AG, and the Ameluz Licensor. As such, in accordance with ASC 210-20-45-1 the other receivables, related party have been offset against accounts payable, related parties for the year ended December 31, 2023. No reserve for the receivable was deemed necessary as of December 31, 2023 or December 31, 2022.

9. Inventories

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

The provision related to BF-RhodoLED® devices was negligible and $0.1 million for the years ended December 31, 2023 and 2022, respectively. The provision for Xepi® inventory obsolescence was $0.1 million and negligible for the years ended December 31, 2022 and 2023, respectively. There was no provision relating to Ameluz® at December 31, 2022. As of December 31, 2023, in connection with the voluntary recall by the Ameluz Licensor, we recorded an inventory write-off of $5.2 million with a corresponding asset for the anticipated replacement from the licensor to other assets, related party, as the recalled lots of Ameluz products will be replaced by the Ameluz Licensor at no additional cost in accordance with the Ameluz LSA. See Note *25. Subsequent Events*, *Voluntary Product Recall of Limited Lots of Ameluz®* for further discussion of the voluntary recall.

10. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	December 31, 2023	December 31, 2022
Prepaid expenses	$ 305	$ 439
Security deposits	-	85
Other	120	286
Total	$ 425	$ 810

11. Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	December 31, 2023	December 31, 2022
Computer equipment	$ 94	$ 89
Computer software	27	27
Furniture & fixtures	81	81
Leasehold improvement	368	368
Machinery & equipment	121	146
Property and equipment, gross	691	711

Less: Accumulated depreciation	(557)	(507)
Property and equipment, net	$ 134	$ 204

Depreciation expense was $0.1 million for each of the years ended December 31, 2023 and 2022, 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, 2023	December 31, 2022
Capitalized software costs	$ 15	$ -
Xepi® license	4,600	$ 4,600
Less: Accumulated amortization	(1,986)	(1,568)
Intangible asset, net	$ 2,629	$ 3,032

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 of the years ended December 31, 2023 and 2022.

We review the Xepi® license intangible asset for impairment whenever events or changes in circumstances indicate that the carrying amount of the asset group may not be fully recoverable. The Company has generated limited revenue from the sales of Xepi® during the current reporting periods and recent developments with the third-party manufacturer that was providing our supply of Xepi® have resulted in further constraints on the commercialization of the product. However, Ferrer is qualifying a new Contract manufacturer, Cambrex, which is expected to begin production in the second half of 2024.

The Company performed an impairment analysis because of this situation, coupled with the relief from the start-up cost and contingent consideration payment obligations under the Release, which significantly increased the carrying value of the asset group, and determined no impairment charges were deemed necessary during the twelve months ended December 31, 2023.

Capitalized Software Costs. The Company capitalizes the application development phase costs of internal use software in accordance with ASC 350-40, "*Intangibles-Goodwill and Other-Internal Use Software".* Capitalized costs will be amortized on a straight-line basis over the estimated useful life of the asset upon completion. There was no amortization expense as of December 31, 2023.

13. Cash Balances and Statement of Cash Flows Reconciliation

The Company maintains its cash balances at financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). At December 31, 2023, approximately $1.0 million of the Company's cash balances were in excess of FDIC limits. The Company has not experienced any losses on these accounts and management does not believe that the Company is exposed to any significant risks with respect to these accounts.

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards. Long-term restricted cash was recorded in other assets in the consolidated balance sheet.

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, 2023	December 31, 2022
Cash and cash equivalents	$ 1,343	$ 17,208
Long-term restricted cash	200	200
Total cash and cash equivalent, and restricted cash shown on the statements of cash flows	$ 1,543	$ 17,408

Long-term restricted cash was recorded in other assets in the consolidated balance sheet.

14. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	December 31, 2023	December 31, 2022

Legal settlement (See Note 24)	$ 403	$ 6,207
Employee compensation and benefits	2,185	2,850
Professional fees	1,064	1,353
Distribution and Storage	118	40
Product revenue allowances and reserves	149	82
Other	568	332
Total	$ 4,487	$ 10,864

15. 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, 2023 and December 31, 2022. Income tax expense incurred in 2023 and 2022 relates to state income taxes. At December 31, 2023 and December 31, 2022, 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,	
	2023	**2022**
Income tax computed at federal statutory tax rate	21.00%	21.00%
State taxes	5.21%	(5.85)%
Permanent differences – non-deductible expenses	(0.48)%	(37.93)%
Change in fair value of contingent consideration	(0.10)%	133.62%
Change in fair value of warrant liabilities	3.27%	576.27%
Gain on legal settlement	2.61%	-
True-ups	(0.08)%	(7.42)%
Federal R&D Credits	0.04%	-
Change in valuation allowance	(31.61)%	(685.54)%
Effective income tax rate	(0.14)%	(5.85)%

The principal components of the Company's deferred tax assets and liabilities consist of the following at December 31, 2023 and 2022:

(in thousands)	December 31, 2023	December 31, 2022
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 36,964	$ 30,450
Credit Carryforward	8	-
Intangible assets	4,270	4,824
Acquisition contract liabilities	-	(96)
Property and equipment	129	123
Accrued expenses and reserves	393	890
Stock based compensation	711	449
Lease liability	391	361
Other	40	-
ROU asset	(422)	(369)
Investment revaluation	43	(469)
Total deferred tax assets	42,527	36,163
Less valuation allowance	(42,527)	(36,163)
Net deferred taxes	$ -	$ -

The Company has had no federal 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 2023, the valuation allowance increased by $6.4 million, primarily due to the increase in the Company's net operating loss carryforwards during the period.

As of December 31, 2023, the Company had approximately $148.6 million and $111.5 million of Federal and state net operating loss carryforwards, respectively. $139.0 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, 2023, 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, 2023 the Company had no reserves for uncertain tax positions. For the year ended December 31, 2023 no estimated interest or penalties were recognized on uncertain tax positions.

The Company's tax returns for 2019 through 2023 remain open and subject to examination by the Internal Revenue Service and state taxing authorities. Under the provisions of the Internal Revenue Code, the net operating loss and tax credit carryforwards are subject to review and possible adjustment by the Internal Revenue Service and state tax authorities. Net operating loss and tax credit carryforwards may become subject to an annual limitation in the event of certain cumulative changes in the ownership interest of significant shareholders over a three-year period in excess of 50 percentage points, as defined under Sections 382 and 383 of the Internal Revenue Code, respectively, as well as similar state provisions. This could limit the amount of tax attributes that can be utilized annually to offset future tax liabilities. The amount of the annual limitation is determined based on the value of the Company immediately prior to an ownership change. Subsequent ownership changes may further affect the limitation in future years. The Company has completed numerous financings since its inception, which may have resulted in a change in control as defined by Sections 382 and 383 of the Internal Revenue Code. As of December 31, 2023, we have not completed a formal Internal Revenue Code Section 382 analysis of our equity changes.

16. Debt

Line of Credit

On May 8, 2023, the Company entered into a Loan and Security Agreement (the "Loan Agreement") with MidCap Business Credit LLC, providing us with a revolving line of credit in the aggregate principal amount of up to $6.5 million, subject to a borrowing base and an availability block, with a maturity date of May 8, 2026. The Loan Agreement is secured by a lien on substantially all of the assets of the Company, subject to customary exceptions.

Advances under the Loan Agreement bear interest at the 30-Day Adjusted Term Secured Overnight Financing Rate ("SOFR"), set monthly on the first day of the month based on 30-Day Term SOFR plus a spread adjustment of 15 basis points and subject to a floor of 2.25%, plus 4.00% calculated and charged monthly in arrears. 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 Loan Agreement, amounts available for advances would be subject to a borrowing base, which is a formula based on certain eligible receivables and inventory, and a block on such availability in the amount of $650,000. Our borrowing capacity is based on our eligible receivables with an additional $1.0 million borrowing capacity based on inventory. The borrowing base is up to 85% of accounts receivable, plus the least of (a) $1.0 million for inventory and (b) 85% of accounts receivable, less borrowing base reserve, if any, as defined in the Loan Agreement. The Loan Agreement also includes an Unused Line Fee Rate of 0.375% of the credit limit less all outstanding advances, which shall be paid on a monthly basis.

The interest rate as of December 31, 2023 was 5.5% and interest expense for the twelve months ended December 31, 2023 was $0.1 million. The Company recorded approximately $0.2 million of costs related to the line of credit as an asset to be amortized on a straight-line basis over the term of the line of credit. The Company recognized minimal amortization expense in connection with this line of credit for the twelve months ended December 31, 2023, which is recorded as interest expense on the accompanying consolidated statement of operations. The line of credit balance as of December 31, 2023 was $0.2 million.

Effective as of January 4, 2024, we voluntarily terminated the Loan Agreement and paid the outstanding principal balance on the revolving line of credit of approximately $194,000. We also paid a termination fee of $150,000 in connection with the early termination of the revolving line of credit.

Loan Facilities

On December 21, 2023, we entered into credit facilities with two different lenders, each pursuant to a Business Loan and Security Agreement for a term loan in the principal amount of $2,000,000, evidenced by a Secured Promissory Note, effective as of December 21, 2023.

Each of the Loans requires the Company to make weekly payments of principal and interest in the amount of approximately $102,857 through July 5, 2024, the maturity date. Each of the Loans is secured by a security interest in substantially all of the Company's assets (the "Collateral"). The default interest rate for each of the Loans is 5.0%.

Each of the Business Loan and Security Agreements includes limitations on the Company's ability to sell, lease, transfer, or otherwise dispose of its assets outside the ordinary course of its business; or to create, incur, allow or suffer to exist any lien on any of its assets other than liens in favor of either lender and certain other permitted liens. Each of the Business Loan and Security Agreements also contains customary representations and warranties and customary events of default, upon the occurrence of which, after any applicable grace period, the applicable lender would have the ability to accelerate its loan and exercise remedies with respect to the Collateral.

The interest rate as of December 31, 2023 was 44% and interest expense for the twelve months ended December 31, 2023 was negligible. The loan balance as of December 31, 2023 was $3.7 million.

17. Related Party Transactions

License and Supply Agreement

On October 8, 2021, we entered into an amendment to the Ameluz LSA under which the price we pay per unit is based upon our sales history. Under the Ameluz LSA, 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 such products exclusively from Pharma. 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.

Purchases of the licensed products from Pharma, inclusive of estimated and actual purchase price adjustments during the years ended December 31, 2023 and 2022 were $23.4 million and $17.9 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, 2023 and 2022 were $8.5 million and $1.3 million, respectively, which were recorded in accounts payable, related parties in the consolidated balance sheets.

On December 12, 2023, we entered into an addendum (the "Addendum"), effective as of December 5, 2023, to the Ameluz LSA. The Addendum provides, among other things, for a schedule of payments in relation to various financial obligations among the Company, Biofrontera Pharma, Biofrontera Bioscience, and Biofrontera AG, including updated terms relating to payments by the Company to Pharma for purchases of Licensed Products (as that term is defined in the Amulez LSA) under the Amulez LSA through the end of 2024. As of December 31, 2023 any receivable amounts from related parties were offset against accounts payable, related parties in accordance with the Addendum.

On February 19, 2024, we entered into the Second Amended and Restated License and Supply Agreement (the "Second A&R Amezuz LSA"), effective as of February 13, 2024, by and among the Company, Biofrontera Pharma, and Biofrontera Bioscience. See Note *24. Subsequent Events - Ameluz LSA Amendment,* for new terms effective February 13, 2024.

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, by and among the Company, Biofrontera AG, Biofrontera Pharma and Biofrontera Bioscience, primarily for regulatory support and pharmacovigilance. The Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us for as long as we deem necessary. We currently have statements of work in place regarding pharmacovigilance, regulatory affairs, medical affairs, information technology, 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.

As of December 31, 2023, we have migrated away from Biofrontera AG to third party providers for most of our significant information technology services. Expenses related to the Services Agreement were $0.2 million and $0.7 million for the years ended December 31, 2023 and 2022, which were recorded in selling, general and administrative, related party. Amounts due to Biofrontera AG related to the Services Agreement were $0.1 million and $0.2 million as of December 31, 2023 and 2022, respectively which were recorded in accounts payable, related parties in the consolidated balance sheets.

As of December 31, 2023, any receivable amounts from related parties were offset against accounts payable, related parties in accordance with the Addendum.

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 agreement was approximately $0.1 million for each of the years ended December 31, 2023 and 2022 and recorded as revenues, related party. Amounts due from Biofrontera Bioscience for clinical lamp and other reimbursements were approximately $0.2 million for each of the years ended December 31, 2023 and 2022, which were offset against accounts payable, related parties in accordance with the Addendum.

Others

The Company has recorded a receivable of $2.8 million and $6.4 million as of December 31, 2023 and December 31, 2022, respectively, due from Biofrontera AG for its 50% share of the balance of a legal settlement for which both parties are jointly and severally liable. See *Note 8. Other Receivables, Related Party*. The Company recognized $0 and $0.1 million of interest income in connection with this receivable for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023 and December 31, 2022, our investment, related party consisted solely of 177,465 and 6,466,946, respectively, of common shares of Biofrontera AG. In accordance with a Share Purchase and Transfer Agreement dated, November 3, 2022, the Company had purchased approximately 1,674,996 shares (of the total 6,466,946 shares) for $1.7 million from Maruho. The total investment was valued at $0.1 million and $10.5 million, as of December 31, 2023 and 2022, respectively. See *Note 6. Investment, Related Party*. In 2023, under the Release, the Company transferred 5,451,016 shares of our shares in Biofrontera AG to Maruho in exchange for the extinguishment of the total acquisition costs due to Maruho.

As of December 31, 2023, any receivable amounts for related party transactions among the Company, Pharma, Bioscience and Biofrontera AG were offset against accounts payable, related parties in accordance with the Addendum.

18. Stockholders' Equity

Under the Company's Certificate of Amendment to the Amended and Restated Certificate of Incorporation, effective July 3, 2023, the Company is authorized to issue 15,000,000 shares of common stock, par value $0.001 per share and 20,000,000 shares of preferred stock, par value $0.001 per share. See *Note 2. Summary of Significant Accounting Policies* for information relating to the Reverse Stock Split.

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.

Registered Public Offering - On October 30, 2023, the Company entered into a securities purchase agreement ("2023 Purchase Agreement") with an institutional investor for the purchase and sale, in a registered public offering (the "Public Offering") by the Company of: (i) 150,000 shares of Common Stock at a combined offering price of $3.74, (ii) 1,055,000 pre-funded warrants to purchase up to 1,055,000 shares of Common Stock (the "Pre-Funded Warrants") at a combined offering price of $3.7399 and (iii) 1,205,000 warrants to purchase up to 1,807,500 shares of Common Stock (the "Common Warrants"), resulting in gross proceeds of approximately $4.5 million. The Public Offering closed on November 2, 2023.

The Common Warrants are exercisable upon issuance, will expire five years following the date of issuance and have an exercise price of $3.55 per share. The Pre-Funded Warrants are exercisable upon issuance, will expire five years following the date of issuance and have an exercise price of $0.0001 per share.

Warrant Amendment

On October 30, 2023, in connection with the 2023 Purchase Agreement, the Company entered into an amendment to amend the 2022 Purchase Warrant and the 2022 Inducement Warrant (the "Existing Warrants Amendment") pursuant to which the Company agreed, effective November 2, 2023, to (i) revise the exercise price of the Existing Warrants to $3.55 and (ii) extend the date until which the Existing Warrants can be exercised until November 2, 2028. No other terms of the Existing Warrants were revised or changed.

As a result of this amendment to the Existing Warrants, the Company recorded an inducement expense on modification of common stock warrants in the amount of $1.0 million. The loss represents the increase in fair value of the Existing Warrants, as amended. The increase in fair value was calculated as the difference in value immediately before and after modification using the Black-Scholes option pricing model. The fair value of the Existing Warrants was determined to be $0.4 million immediately prior to the modification in accordance with the following key assumptions:

	2022 Purchase	2022 Inducement
Stock price	$ 4.90	$ 4.90
Expiration term (in years)	4.04	3.08
Volatility	90.0%	90.0%
Risk-free Rate	4.66%	4.72%
Dividend yield	0.0%	0.0%

The fair value of the Existing Warrants was determined to be $1.4 million immediately after the modification in accordance with the following key assumptions:

	2022 Purchase	2022 Inducement
Stock price	$ 4.90	$ 4.90
Expiration term (in years)	5.00	5.00
Volatility	90.0%	90.0%
Risk-free Rate	4.60%	4.60%
Dividend yield	0.0%	0.0%

Warrants – The details of all outstanding warrants as of December 31, 2023 were as follows:

	Warrant Shares	Weighted Average Exercise Price
Balance, December 31, 2021	**219,477**	**$ 99.69**

Issued	463,686	35.77
Exercised	(221,307)	20.92
Balance, December 31, 2022	**461,856**	**52.29**
Issued	2,862,500	2.24
Exercised	-	
Balance, December 31, 2023	**3,324,356**	**$ 2.46**

Reverse Stock Split - On July 3, 2023 Biofrontera Inc. effected a 1-for-20 reverse stock split (the "Reverse Stock Split") of the issued and outstanding shares of the Company's common stock, $0.001 par value (the "Common Stock"). The Common Stock began trading on the Nasdaq Capital Market on a post-split basis on July 5, 2023.

All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Stock Split as if it had been effective from the beginning of the earliest period presented, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split, as required by the terms of those securities.

Exercise of 2021 Purchase Warrant and Issuance of 2022 Inducement Warrant – On July 26, 2022, the Company entered into the Reprice and Reload Offer of Common Stock Purchase Warrants (the "Inducement Letter") with the holder of the Company's 2021 Purchase Warrant (the "Investor"). The Investor agreed to exercise for cash, the 2021 Purchase Warrant, in exchange for the Company's agreement to (i) lower the exercise price of the 2021 Purchase Warrant from $105.00 to $32.40 per share and (ii) issue the 2022 Inducement Warrant to purchase up to 214,286 shares of common stock. The Company received proceeds of $4.6 million, from the exercise of the 2021 Purchase Warrant and expensed the related issuance costs of $0.3 million. The 2021 Purchase Warrant modification along with the fair value of the 2022 Inducement Warrant of $2.6 million was expensed as warrant modification expense in the accompanying consolidated statement of operations for the year ended December 31, 2022.

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) 92,500 shares of the common stock, (ii) a warrant to purchase up to 170,950 shares of the common stock ("2022 Purchase Warrant") and (iii) a warrant to purchase up to 78,450 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 $55.00. In connection with the 2023 Purchase Agreement, the Company entered into the Amendment to Common Stock Purchase Warrants effective November 2, 2023, to (i) revise the exercise price from $55.40 to $3.55 and (ii) extend the date which the warrant can be exercised from November 18, 2027 until November 2, 2028 for the 2022 Purchase Warrant. Because the warrants are accounted for as liabilities, the May 2022 PIPE proceeds were allocated the first to the warrants based on their fair value with the remaining proceeds allocated to common stock and additional paid in capital.

The 2022 Pre-Funded Warrant had a term of exercise equal to five (5) years with a nominal exercise price of $0.02 per share and was exercised on July 14, 2022, for a total of 78,450 shares of common stock, resulting in negligible net proceeds. As of December 31, 2023, there were no 2022 Pre-Funded Warrants outstanding.

Adoption of a stockholder rights plan. On October 13, 2022 the Company's 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, as amended by Amendment No. 1 to the Stockholder Rights Agreement, dated as of April 26, 2023, between the Company and Computershare Trust Company, N.A, as Rights agent.

While the stockholder rights plan described above (the "Rights Plan") became 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 Board. The Rights Plan will expire on June 30, 2026.

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 pursuant to which the parties agreed to a negotiated private exchange, and closed on a series of private exchanges of 3,148,042 shares of the Company's common stock in exchange for the AG Options.

19. Equity Incentive Plans and Share-Based Payments

2021 Omnibus Incentive Plan

In 2021, the Board adopted, and our shareholders approved, the 2021 Omnibus Incentive Plan ("2021 Plan). On December 12, 2022, the 2021 Plan was amended by our stockholders and the number of shares reserved and authorized for awards under the 2021 Plan was increased from 137,500 shares to 266,990 shares. The maximum contractual term for stock options issued under the 2021 Plan is ten years. As of December 31, 2023, there were 141,824 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 Black-Scholes option pricing model with the following assumptions:

	2023	2022
Expected volatility	70% - 95%	55% -70%
Expected term (in years)	6.0	5.24 - 6.0
Risk-free interest rate	3.54%- 4.66%	1.34% - 4.10%
Expected dividend yield	0.0%	0.0%

The weighted average grant-date fair value of options granted during the years ended December 31, 2023 and 2022 was $6.40 and $29.28, respectively.

Share-based compensation expense related to stock options of approximately $0.7 million and $0.8 million was recorded in selling, general and administrative expenses on the accompanying consolidated statement of operations for the years ended December 31, 2023 and 2022, respectively.

Options outstanding and exercisable under the employee share option plan as of December 31, 2023 and 2022, 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, 2021	30,737	$ 95.40	9.94	$ 1,691
Granted	64,572	$ 48.20		
Exercised	-	$ -		
Canceled or forfeited	(8,358)	$ 76.11		
Outstanding at December 31, 2022	86,951	$ 62.16	9.27	$ 1
Granted	49,730	$ 9.35		
Exercised	-	$ -		
Canceled or forfeited	37,195	$ 52.55		
Outstanding at December 31, 2023	99,486	$ 39.36	8.79	$ -
Exercisable at December 31, 2023	27,815	$ 67.54	8.14	$ -

(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, 2023 and December 31, 2022.

As of December 31, 2023, there was $0.9 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 2.0 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 related to RSUs of $0.3 million and $1.0 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, 2023 and 2022.

As of December 31, 2023, there was $0.1 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 0.4 years.

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, 2021	8,504	$ 95.40
Granted	17,176	52.20
Issued	(8,504)	95.40
Forfeited	-	-
Outstanding balance at December 31, 2022	17,176	$ 52.20
Awarded	-	-
Issued	(8,588)	52.20

Forfeited	(3,817)	52.20
Outstanding balance at December 31, 2023	4,771	$ 52.20

20. Interest Expense, net

Interest expense, net consists of the following:

	For years ended December 31,	
(in thousands)	2023	2022
Interest expense	(220)	(12)
Interest expense, related party	(22)	-
Contract asset interest expense	(358)	(358)
Interest income- related party	-	165
Interest income – other	132	10
Interest expense, net	$ (468)	$ (195)

Interest expense is comprised primarily of interest on our Loan and Security Agreements.

Interest expense, related party relates to interest incurred on late payments to the Biofrontera Group.

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 was amortized on a straight-line basis using a 6% interest rate over the financing arrangement contract term, which ended on December 31, 2023.

Interest income - related party, relates to default interest on the recorded receivable of $6.1 million as of September 30, 2022 from Biofrontera AG for its 50% share of the balance of a legal settlement.

Interest income – other, relates primarily to interest earned on funds deposited in our bank accounts.

21. Other Income, net

Other income, net consists of the following:

	For years ended December 31,	
(in thousands)	2023	2022
Gain/Loss on termination of operating leases	134	93
Foreign currency transactions	(114)	(28)
Bank service charges	(92)	(8)
Other, net	(3)	(24)
Interest expense, net	$ (75)	$ 33

22. Net Loss per Share

Basic net earnings (loss) per common share are calculated by dividing net income by the weighted average number of common shares outstanding during the period. As noted in ASC 260-10-45-13, shares issuable for little to no consideration should be included in the number of outstanding shares used for basic EPS. As such, the 2022 Pre-Funded Warrants are included in the outstanding shares for EPS purposes. Diluted net earnings per common share are calculated by dividing net income (loss) by the diluted weighted average number of common shares outstanding during the period. The diluted shares include the dilutive effect of stock-based awards based on the treasury stock method. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive.

The following table sets forth the computation of the Company's basic and diluted net earnings (loss) per share attributable to common stockholders (in thousands, except share and per share data):

	For years ended December 31,	
	2023	2022
Net loss	$ (20,131)	$ (640)
Weighted average common shares outstanding, basic and diluted	1,546,297	1,056,988
Net loss per share, basic and diluted	$ (13.02)	$ (0.61)

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,	2023	2022
Common stock warrants	2,269,356	459,856
Common stock options and RSUs	104,257	104,127
Unit Purchase Options	20,182	20,182
Total	2,393,795	584,165

23. 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 varying expiration dates through March 2027.

The components of lease expense for the year ended December 31, 2023 were as follows (in thousands except lease term and discount rate):

Operating Lease expense	**December 31, 2023**	**December 31, 2022**
Amortization of ROU assets (operating lease cost)	$ 560	$ 653
Interest on lease liabilities	84	99
Total lease expense	$ 644	$ 752
Other Information		
Operational cash flow used for operating leases	$ 733	$ 781
ROU assets obtained in exchange for lease liabilities	800	234
Weighted -average remaining lease term (in years)	2.22	2.54
Weighted -average discount rate	7.76%	6.31%

Future lease payments under non-cancelable leases as of December 31, 2023 were as follows (in thousands):

Years ending December 31,	**Future lease commitments**
2024	779
2025	587
2026	238
2027	31
Thereafter	-
Total future minimum lease payments	$ 1,635
Less imputed interest	$ (140)
Total lease liability	$ 1,495

Reported as:	**December 31, 2023**
Operating lease liability, current	$ 691
Operating lease liability, non-current	804
Total	1,495

Ameluz LSA Sales Commitment

If we fail to earn $150 million in revenues from Ameluz® and the RhodoLED® lamp series over the preceding five (5) year period leading to the Ameluz LSA's termination date (either fifteen (15) years from the date of the Amended and Restated License and Supply Agreement, dated June 16, 2021 or any later termination date following the automatic renewal of this Agreement), Biofrontera Pharma has the right to terminate the Ameluz LSA by providing one (1) year written notice. See Note 25, *Subsequent Events, Amendments to the Ameluz LSA.*

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 2023 or 2022 related to Xepi® milestones.

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.

Settlement Agreement with DUSA Pharmaceuticals Inc.

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. On September 13, 2023, we were served with a new complaint filed by DUSA Pharmaceuticals Inc. See *DUSA – 2023 Legal Claim* section below for details.

As of December 31, 2023, we have reflected a legal settlement liability in the amount of $0.4 million for the remaining payments due under the settlement for the estimated remaining cost of the forensic expert and a related receivable from related party of $2.8 million (presented net in accounts payable, related party) 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.

Settlement Agreement with Biofrontera AG

Pursuant to the terms of that certain Settlement Agreement, dated as of April 11, 2023, among the Company, Biofrontera AG and certain current and former directors of the Company (the "AG Settlement Agreement"), the Company has taken or committed, among other things, to take the following actions:

- On July 7, 2023, in connection with the AG Settlement Agreement, Board appointed Heikki Lanckriet to the Board. Mr. Lanckriet will serve as a Class I Director to hold office for a term expiring at the annual meeting of the Company's stockholders for fiscal year 2025. Mr. Lanckriet's term as director began upon his appointment at the July 7, 2023 meeting.
- The Company will begin a search, pursuant to the conditions set forth in the AG Settlement Agreement including a strike right granted to the aforementioned director nominated by Biofrontera AG, for an additional director candidate, who is fully independent from Biofrontera AG, Deutsche Balaton Aktiengesellschaft and any of their respective affiliates, to be nominated for election as a Class II Director at the Company's 2024 annual meeting of stockholders.
- The Board will increase its size to seven members, including the two directors appointed and elected pursuant to the AG Settlement Agreement as noted above.

In addition, the AG Settlement Agreement contains provisions to maintain Biofrontera AG's representation on the Board as long as it holds at least 20% of the Company's outstanding common stock and to limit further increases in the size of the Board or changes to the Company's stockholder rights plan. Under the AG Settlement Agreement, Biofrontera AG also agrees, subject to certain conditions, to vote in support of the directors nominated by, and the proposals recommended by, the Board. With the closing of the Securities Purchase Agreement, dated February 19, 2024 (see Note *25. Subsequent Events),* Biofrontera AG ceased to own at least 20% of our common stock outstanding. Accordingly, if Biofrontera AG does not acquire sufficient shares of our common stock to own at least 20% within 30 days from the date of notice, February 26, 2024, the Board representation provisions, and the standstill/voting provisions noted above shall terminate. Our Related Party Transaction Committee has elected to waive the requirement that AG must cause its sitting non-independent director, Heikki Lanckriet, to resign from his position of director.

DUSA – 2023 Legal Claim

On September 13, 2023, Biofrontera was served with a complaint filed in United Stated District Court for the District of Massachusetts by DUSA Pharmaceuticals, Inc., Sun Pharmaceutical Industries, Inc., and Sun Pharmaceutical Industries LTD (collectively "DUSA" or "Plaintiffs") in which DUSA alleges breach of contract, violation of the Lanham Act, and unfair trade practices. All claims stem from allegations that Biofrontera has promoted its Ameluz product in a manner that is inconsistent with its approved FDA labeling. Though this complaint was originally filed in the U.S. District Court for the District of Massachusetts, this matter has been transferred by agreement of the parties to the U.S. District Court for the District of New Jersey.

The Company denies the Plaintiffs' claims and intends to defend these matters vigorously. Based on the Company's assessment of the facts underlying the above claims, the uncertainty of litigation and the preliminary stage of the case, the Company cannot estimate the possibility of a material loss, nor the potential range of loss that may result from this action. If the final resolution of the matter is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

24. 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.

Matching contribution costs paid by the Company were $0.3 million and $0.2 million for the years ended December 31, 2023 and 2022, respectively.

25. Subsequent Events

We have completed an evaluation of subsequent events after the balance sheet date of December 31, 2023 through the date this Annual Report on Form 10-K was filed with the SEC.

Termination of Loan Agreement

Effective as of January 4, 2024, we voluntarily terminated the Loan Agreement (See *Note 16. Debt)*. We repaid the outstanding principal balance on the revolving line of credit of approximately $194,000 and paid a termination fee of $150,000 in connection with the early termination of the revolving line of credit.

Exercise of 2023 Pre-Funded Warrants

On January 8, 2024 and February 2, 2024, an investor exercised 167,000 and 888,000 the 2023 Pre-Funded Warrants, respectively and purchased a total of 1,055,000 shares of common stock at an exercise price of $.0001 per share, resulting in negligible net proceeds,

Notice from Nasdaq

On November 22, 2023, we received a letter (the "Notice") from the Listing Qualifications Staff of Nasdaq notifying us that, because our stockholders' equity as reported in our Quarterly Report on Form 10-Q for the period ended September 30, 2023 was $1,038,000, we are no longer in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1), which requires that a listed company's stockholders' equity be at least $2,500,000. Additionally, as of the date of the Notice, the Company did not meet either of the alternative requirements of maintaining a market value of listed securities of $35 million or achieving a net income from continuing operations of $500,000 in the most recently completed fiscal year or in two of the last three most recently completed fiscal years. As a result, as of the date of this Form 10-K, we do not satisfy Nasdaq Marketplace Rule 5550(b).

We submitted a compliance plan to Nasdaq on January 8, 2024. The compliance plan was accepted and we were granted 180 calendar days from November 22, 2023 to evidence compliance.

Amendments to the Ameluz LSA

On January 29, 2024, we entered into an amendment and restatement (the "Amendment"), effective January 26, 2024*,* of the Ameluz LSA. The Amendment modifies a schedule of payments in relation to various financial obligations among the Company, Biofrontera Pharma, Biofrontera Bioscience, and Biofrontera AG, including terms relating to payments by the Company to Biofrontera Pharma for purchases of Licensed Products (as that term is defined in the Ameluz LSA) under the Ameluz LSA. Among other things, the Addendum provides that payment that was due from the Company on January 31, 2024 be deferred to February 29, 2024.

On February 19, 2024, we entered into the Second A&R Ameluz LSA, effective as of February 13, 2024, by and among the Company, Biofrontera Pharma, and Biofrontera Bioscience. The Second A&R Ameluz LSA amends and restates the Ameluz LSA, originally dated as of October 1, 2016 which was previously amended on July 1, 2019, June 16, 2021, October 8, 2021, December 5, 2023 and January 26, 2024.

Among other things, the Second A&R Ameluz LSA has been amended to (i) change the Transfer Price (as defined in the Second A&R Ameluz LSA) to 25% through 2025 and then increasing over time pursuant to the schedule set forth in the Second A&R Ameluz LSA to a maximum of 35% starting in 2032, subject to a minimum dollar amount per unit, from the previous Transfer Price of 50% of annual revenue up to $30 million, and then decreasing on further sales until reaching 30% of annual revenue at and above $50 million, (ii) provide for the transfer of responsibilities for Ongoing Trials (as defined in the Second A&R Ameluz LSA) on or before June 1, 2024, including the Company assuming related contracts and transferring key personnel from Pharma and Bioscience to the Company, and (iii) make the failure to achieve the applicable Annual Minimum Sales (as defined in the Second A&R Ameluz LSA) a termination event in certain circumstances, unless waived by Biofrontera Pharma and Biofrontera Bioscience. The Second A&R Ameluz LSA also includes an Addendum to the Second A&R Ameluz LSA which modifies a schedule of payments in relation to various financial obligations among the Company, Biofrontera Pharma, Biofrontera Bioscience, and Biofrontera AG, including terms relating to payments by the Company to Biofrontera Pharma for purchases of Licensed Products (as that term is defined in the Second A&R Ameluz LSA) under the Second A&R Ameluz LSA. Based on the most current budget projections, we expect to order Ameluz to be delivered in Q4 2024, and therefore, the positive effects of the Second A&R Ameluz LSA amendment will not be realized until then.

In connection with the Second A&R Ameluz LSA, the Company entered into a Release of Claims, dated February 13, 2024, by and among the Company, Biofrontera Pharma and Biofrontera Bioscience, pursuant to which the Company agreed to release Biofrontera Pharma and Biofrontera Bioscience from all claims and liabilities arising out of or relating to any failure by Biofrontera Pharma and Biofrontera Bioscience to perform certain obligations under the Second A&R Ameluz LSA with respect to clinical trials that the Company will assume responsibility for under the Second A&R Ameluz LSA.

Voluntary Product Recall of Limited Lots of Ameluz®

On February 9, 2024, we were notified that our Ameluz Licensor, had initiated a voluntary recall of a limited number of lots of Ameluz® due to a manufacturing defect in the impacted product's packaging, which is provided by an unaffiliated supplier. In its communication, the Ameluz Licensor confirmed that the recalled product is not likely to cause adverse health consequences. We have notified all impacted physician customers of this recall and have arranged for the prompt replacement of the recalled products. There were no sales of recalled product for the year ended December 31, 2023. See Note *9. Inventories* for impact to inventory as of December 31, 2023.

Pursuant to the Ameluz LSA, the Company will not bear any financial responsibility for the costs associated with this recall. As such, the Company does not anticipate a material financial impact on its business as a result of the recall.

Securities Purchase Agreement for Series B Convertible Preferred

On February 19, 2024, we entered into a securities purchase agreement (the "Preferred Purchase Agreement") with certain accredited investors (the "Preferred Investors"), pursuant to which the Company agreed to issue and sell, in a private placement (the "Offering"), (i) 6,586 shares of Series B-1 Convertible Preferred Stock, par value $0.001 per share (the "Series B-1 Preferred Stock"), and (ii) warrants (the "Preferred Warrants") to purchase shares of Series B-3 Convertible Preferred Stock, par value $0.001 per share (the "Series B-3 Preferred Stock") for an aggregate offering price of $8.0 million. Each share of Series B-1 Preferred Stock was sold for $1,000 per share and the consideration for each Preferred Warrant was $0.125 per share of common stock that each share of Series B-3 Preferred Stock may be converted into. The net proceeds of the Offering were approximately $7.2 million, after deducting fees paid to the placement agent and other estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Offering for working capital purposes and other general corporate purposes and ongoing activities related to expediting the development and approval of additional indications for Ameluz®.

The aggregate exercise price of the Preferred Warrants is approximately $8.0 million, exercisable for an aggregate of 8,000 shares of Series B-3 Preferred Stock commencing on the Exercisability Date (as defined in the Form of Preferred Warrant) until the earlier of (i) 5 days following the date of completion of (A) the Company's public announcement of (I) at least 95% of the Company's territory managers, medical science liaisons, and reimbursement employees are using the Company's customer relationship management system routinely or on a performance improvement plan and (II) the Company's revenue for the period starting on January 1, 2024 and ending no earlier than April 30, 2024 excluding revenue from related parties (including Biofrontera AG) is at least 5% higher than the Company's revenue excluding revenue from related parties (including Biofrontera AG) for the corresponding period of the same length, starting on January 1, 2023, which announcement shall be made promptly after certification by the Company's board of directors that

such targets have been completed, and (B) the Stockholder Approval (as defined below) and (C) the effectiveness of a registration statement with the U.S. Securities and Exchange Commission covering the resale of the Common Stock underlying all shares of Series B-3 Preferred Stock (as defined below) and (ii) February 22, 2027.

Subject to the terms and limitations contained in the Certificate of Designation, the shares of the Series B-1 Preferred Stock issued in the Offering are immediately convertible and the Series B-3 Preferred Stock issuable upon exercise of the Warrants issued in the Offering will not become convertible until the Company's stockholders approve (i) the issuance of all Common Stock issuable upon conversion of the Issued Preferred Stock and the Series B-3 Preferred Stock or the Series B-3 Preferred Stock upon exercise of the Preferred Warrants to the extent required under the Nasdaq listing rules, (iii) an increase to the Company's authorized share capital (collectively, the "Stockholder Approval").

Pursuant to the Preferred Purchase Agreement and as soon as practicable following the date of the Stockholder Approval, the Company shall appoint two independent directors to the Company's Board who are designated by Rosalind Advisors, Inc.

On February 22, 2024, concurrent with the closing of the Offering, each purchaser delivered a notice of initial conversion requesting that the Company convert the Series B-1 Preferred Stock they had acquired in the Offering up to the Cap (as defined in the Certificate of Designation) for each purchaser. As a result of this conversion, the Company issued 2,516,785 shares of the Company's common stock to the purchasers, and as of February 22, 2024, the total number of the Company's outstanding shares of common stock is 5,089,413 and the total number of the Company's outstanding shares of Series B-1 Convertible Preferred Stock is 4,806, with 6,793,893 shares of common stock issuable upon conversion of the Series B-1 Preferred. Upon obtaining the Stockholder Approval, there will be 11,309,019 shares of common stock issuable upon conversion of all of the Series B-3 Convertible Preferred Stock, that may be acquired upon exercise of the Warrants.

Amendment to Articles of Incorporation - Series B Preferred Stock

Pursuant to the terms of the Preferred Purchase Agreement, on February 20, 2024, the Company filed the Certificate of Designation with the Delaware Secretary of State designating 6,586 shares of its authorized and unissued preferred stock as Series B-1 Preferred Stock, 6,586 shares as Series B-2 Preferred Stock and 8,000 shares as Series B-3 Convertible Preferred Stock, each with a stated value of $1,000 per share. The Certificate of Designation sets forth the rights, preferences and limitations of the shares of Series B Preferred Stock. The company will need to increase the number of authorized shares from the current 15,000,000 in order to have enough common shares available to allow for the conversion of the B-2 and B-3 Preferred Stock. The Board of Directors has approved an increase of authorized shares up to 35,000,000 on March 4, 2024, subject to shareholder approval.

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

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

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

Conversion. Prior to the Stockholder Approval, the Series B Preferred Stock is not convertible in excess of the Cap. Following the Stockholder Approval, each share of Series B-1 Preferred Stock will automatically convert into either Common Stock or, to the extent the conversion would cause a holder to exceed their beneficial ownership limitation, shares of Series B-2 Preferred Stock.

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

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

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

defined in the Certificate of Designation) shall not be redeemed and shall be excluded from the calculations set forth in this sentence. If, on the Redemption Date, Delaware law governing distributions to stockholders prevents the Company from redeeming all shares of Series B-1 Preferred Stock to be redeemed, the Company shall ratably redeem the maximum number of shares that it may redeem consistent with such law, and shall redeem the remaining shares as soon as it may lawfully do so under such law.

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

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, including 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 management, including our Chief Executive Officer and Chief Financial Officer, concluded that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

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 Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of our internal control over financial reporting as of December 31, 2023 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, our management, including our Chief Executive Officer and Chief Financial Officer, concluded that our internal control over financial reporting was effective as of December 31, 2023.

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, 2023.

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, 2023 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).

Item 9B. Other Information

None

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Information required by this Item is incorporated by reference to our Proxy Statement for our Annual Meeting of Stockholders for the fiscal year ended December 31, 2023, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2023 fiscal year covered by this Form 10-K,or alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 11. Executive Compensation

Information required by this Item is incorporated by reference to our Proxy Statement for our Annual Meeting of Stockholders for the fiscal year ended December 31, 2023, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2023 fiscal year covered by this Form 10-K,or alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

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

Information required by this Item is incorporated by reference to our Proxy Statement for our Annual Meeting of Stockholders for the fiscal year ended December 31, 2023, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2023 fiscal year covered by this Form 10-K,or alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

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

Information required by this Item is incorporated by reference to our Proxy Statement for our Annual Meeting of Stockholders for the fiscal year ended December 31, 2023, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2023 fiscal year covered by this Form 10-K,or alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

Item 14. Principal Accountant Fees and Services

Information required by this Item is incorporated by reference to our Proxy Statement for our Annual Meeting of Stockholders for the fiscal year ended December 31, 2023, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2023 fiscal year covered by this Form 10-K,or alternatively, by amendment to this Form 10-K under cover of Form 10-K/A no later than the end of such 120 day period.

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).
3.4	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Biofrontera Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023
3.5	Certificate of Designation of Preferences, Rights and Limitations of the Series B Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024).
4.1*	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)
4.11	Amendment No. 1 to the Stockholder Rights Agreement, dated as of April 26, 2023, between Biofrontera Inc. and Computershare Trust Company, N.A., as Rights Agent (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K, filed on April 28, 2023).
4.12	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
4.13	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
4.14	Form of Series B-3 Convertible Preferred Stock Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024)
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 Lübbert (incorporated by reference to Exhibit 10.11 to Amendment No. 5 to the Company's Form S-1 filed with the SEC on October 1, 2021).
10.12†	2021 Omnibus Incentive Plan (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 10.2 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 Lübbert (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on March 8, 2022).
10.21	Amended Settlement Allocation Agreement dated March 31,2022 between the Company and Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on April 5, 2022).
10.22†	Amendment to Employment Agreement effective as April 1, 2022 — Erica Monaco (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on April 5, 2022).
10.23	Form of Securities Purchase Agreement for 2022 Private Placement (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022)
10.24	Form of Registration Rights Agreement for 2022 Private Placement (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed with the SEC on May 20, 2022)
10.25	Form of Inducement Letter (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on July 27, 2022)
10.26†	Employment Agreement —Fred Leffler (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on October 24, 2022)
10.27	Form of Exchange Agreement (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on October 31, 2022)
10.28#	Settlement Agreement dated April 11, 2023 between Biofrontera Inc., Hermann Luebbert, John J. Borer, Loretta M. Wedge, Beth J. Hoffman, Kevin D. Weber and Biofrontera AG (incorporated by reference to Exhibit 10.1 to the Company's Form 10-Q filed with the SEC on May 12, 2023)
10.29	Securities Purchase Agreement, dated October 30, 2023, by and between Biofrontera Inc. and an institutional investor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
10.30	Placement Agency Agreement, dated October 30, 2023, by and between Biofrontera Inc. and Roth Capital Partner, LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on November 2, 2023)
10.31	Amendment to Common Stock Purchase Warrants, dated October 30, 2023, by and between Biofrontera Inc. and institutional investor (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the SEC on November 2, 2023)

10.32	Amendment No. 1 to Settlement Agreement dated as of October 12, 2023, between Biofrontera Inc., Hermann Luebbert, John J. Borer, Loretta M. Wedge, Beth J. Hoffman, Kevin D. Weber and Biofrontera AG (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 13, 2023)
10.33	Addendum to Amended and Restated License and Supply Agreement, dated as of December 12, 2023 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on December 15, 2023)
10.34*	Amended and Restated Business Loan and Security Agreement between Biofrontera Inc. and Agile Capital Funding, LLC and Agile Lending, LLC, dated as of December 21, 2023
10.35*	Business Loan and Security Agreement between Biofrontera Inc. and Cedar Advance, LLC, dated as of December 21, 2023
10.36	Confidential Settlement Agreement and Mutual Release, dated as of December 27, 2023 and effective as of December 22, 2023, by and between the Company and Maruho (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on January 3, 2024)
10.37	Amended and Restated Addendum to Amended and Restated License and Supply Agreement, dated January 29, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 2, 2024)
10.38	Second Amended and Restated License and Supply Agreement, dated February 19, 2024, between the Company, Pharma and Bioscience. (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 20, 2024)
10.39	Release of Claims, dated February 13, 2024, between the Company, Pharma and Bioscience. (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on February 20, 2024)
10.40	Form of Securities Purchase Agreement, dated February 19, 2024, by and amount Biofrontera Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024)
10.41	Placement Agency Agreement, dated February 19, 2024, by and between Biofrontera Inc. and Roth Capital Partners, LLC (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on February 23, 2024)
21.1*	List of Subsidiaries of the Company
23.1*	Consent of Marcum 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
97*	Compensation Clawback Policy, as approved by the Board of Directors on November 29, 2023
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 15, 2024.

BIOFRONTERA INC.

By: */s/ Hermann Lübbert*
Name: Hermann Lübbert
Title: Chief Executive Officer and Chairman

Signature	Title	Date
/s/ Hermann Lübbert Hermann Lübbert	Chief Executive Officer and Chairman (*Principal Executive Officer)*	March 15, 2024
/s/ E. Fred Leffler E. Fred Leffler	Chief Financial Officer (*Principal Financial Officer)* *(Principal Accounting Officer)*	March 15, 2024
/s/ John J. Borer John J. Borer	Director	March 15, 2024
/s/ Beth J. Hoffman Beth J. Hoffman	Director	March 15, 2024
/s/ Heikki Lanckriet Heikki Lanckriet	Director	March 15, 2024
/s/ Kevin D. Weber Kevin D. Weber	Director	March 15, 2024

Exhibit 4.1

DESCRIPTION OF REGISTERED SECURITIES

(For information about securities we issued subsequent to December 31, 2023, please refer to our Current Report on Form 8-K filed with the Securities and Exchange Commission on February 23, 2024)

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, 2023 of which this exhibit is a part. There are currently 76,620 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 $100.00 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, as amended on April 26, 2023 (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, 2023.

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 June 30, 2026; 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 2025 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 10.34

AMENDED AND RESTATED BUSINESS LOAN AND SECURITY AGREEMENT

THIS AMENDED AND RESTATED BUSINESS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of December 21, 2023 (the "**Effective Date**") among Agile Capital Funding, LLC as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and Agile Lending, LLC, a Virginia limited liability company ("**Lead Lender**") and each assignee that becomes a party to this Agreement pursuant to Section 12.1 (each individually with the Lead Lender, a "Lender" and collectively with the Lead Lender, the "Lenders"), and BIOFRONTERA INC. ("**BFRIW**" or "**Parent**"), a Domestic Delaware Corporation, and the other entities that are joined hereto from time to time as a Borrower, individually and collectively, jointly and severally, ("**Borrower**"), and provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders the loans described herein. This Agreement amends and restates the Business Loan and Security Agreement, dated as of December 18, 2023, entered into by and among the Parties (as defined below) (the "**Prior Agreement**") in its entirety, and supersedes the Prior Agreement in all respects. The Collateral Agent, Lenders, and Borrower, each a "Party" and collectively the "Parties", intending to be legally bound, hereby agree as follows:

1. DEFINITIONS, ACCOUNTING AND OTHER TERMS

1.1 Capitalized terms used herein shall have the meanings set forth in Section 13 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules thereto. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loan advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. The Lenders, relying upon each of the representations and warranties set out in this Agreement, as well as each of the representations, covenants and warranties set out in the other Loan Documents, hereby severally and not jointly agree with the Borrower that, subject to and upon the terms and conditions of this Agreement, shall advance the term loan in the principal amount set forth in Exhibit B-5 hereto (the "**Term Loan**") to the Borrower on the Effective Date, but in any event no later than two (2) Business Days after the date hereof, by wiring the funds to the Borrower's Account.

(b) Repayment. Borrower agrees to pay all amounts owing pursuant to the terms of this Agreement, including any financing charge, specified fees, interest and any other charges that may be assessed as provided in this Agreement or as documented in the Business Loan and Security Agreement Supplement (the "**Supplement**") or the Secured Promissory Note (as defined below). The Term Loan shall be repaid by Borrower on the dates specified on Exhibit B-4 of this Agreement (each a "**Scheduled Repayment Date**") by the amount set out opposite each Scheduled Repayment Date (each a "**Scheduled Repayment Amount**") and in accordance with the Term Loan Amortization Schedule. If any payment on the Secured Promissory Note is due on a day which is not a Business Day, such payment shall be due on the next succeeding Business Day, and such extension of time shall be taken into account in calculating the amount of interest payable under this Note. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d). Once repaid, no portion of the Term Loan may be reborrowed.

(c) Mandatory Prepayments. If the Term Loan is accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon accrued through the prepayment date, (ii) the Prepayment Fee (as defined in Section 2.2(d) below), plus (iii) all other Obligations that are due and payable, including, without limitation, interest at the Default Rate with respect to any past due amounts.

(d) Permissive Prepayments and Make-Whole Premium. Borrower shall have the right to make a full prepayment or partial prepayment of any or all of the Obligations in accordance with the prepayment amendment in Exhibit E of this Agreement. The foregoing notwithstanding, upon the prepayment of any principal amount, Borrower shall be obligated to pay a make-whole premium payment on account of such principal so paid, which shall be equal to the aggregate and actual amount of interest (at the contract rate of interest) that would be paid through the Maturity Date ("**Prepayment Fee**").

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate. Borrower agrees to pay in full the interest as set forth in the Supplement found in Exhibit B-5 of this Agreement. Interest shall accrue on the Term Loan commencing on, and including, the Effective Date of such Term Loan, and shall accrue on the principal amount outstanding under the Term Loan through and including the day on which the Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360 Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year and the actual number of days elapsed.

(d) Debit of Accounts; Payments. All payments on the Secured Promissory Note shall be made via automated clearing house transfers of immediately available funds to be initiated by Lender in accordance with the authorization and direction of Borrower to Lead Lender provided in Exhibit B-6 of this Agreement.

(e) Usury Savings Clause. This Agreement and the other Loan Documents are subject to the express condition that at no time shall Borrower be required to pay interest on the principal balance of the Term Loan at a rate which could subject Lenders to either civil or criminal liability as a result of being in excess of the Maximum Legal Rate. If by the terms of this Agreement or the other Loan Documents, Borrower is at any time required or obligated to pay interest on the principal balance due hereunder at a rate in excess of the Maximum Legal Rate, the Interest Rate or the Default Rate, as the case may be, shall be deemed to be immediately reduced to the Maximum Legal Rate and all previous payments in excess of the Maximum Legal Rate shall be deemed to have been payments in reduction of principal and not on account of the interest due hereunder. All sums paid or agreed to be paid to the Collateral Agent or Lenders for the use, forbearance, or detention of the sums due under the Loan, shall, to the extent permitted by applicable law, be amortized, prorated, allocated, and spread throughout the full stated term of the Loan until payment in full.

2.4 Fees. Borrower shall pay to Collateral Agent and/or Lenders:

(a) Administrative Agent Fee. The Administrative Agent Fee of ONE-HUNDRED THOUSAND DOLLARS ($100,000.00), which shall be paid at closing out of proceeds of the Term Loan for the account of Collateral Agent.

2.5 Secured Promissory Notes. The Term Loan shall be evidenced by a Secured Promissory Note in the form attached as Exhibit D hereto ("**Secured Promissory Note**") and shall be repayable as set forth in this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Term Loan. Each Lender's obligation to make the Term Loan is subject to the condition precedent that each Lender shall consent to or shall have received, in form and substance satisfactory to each Lender, such documents, and completion of such other matters, as each Lender may reasonably deem necessary or appropriate.

3.2 Discharge of Prior Indebtedness.

(a) Prior to the Effective Date, Borrower shall provide Lender with documentation of Borrower's notice of termination, together with any corresponding payoff letter from MidCap (as defined below), regarding the MidCap Agreement (as defined below).

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Effective from and after the Effective Date of the Term Loan, Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower shall grant to Collateral Agent, for the ratable benefit of the Lenders, a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent. If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations), Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower, and this Agreement and all obligations (other than inchoate indemnity obligations) of the parties hereto shall terminate, all without delivery of any instrument or any further action by any party, and all rights to the Collateral shall revert to Borrower. At the request of Borrower following any such termination, Collateral Agent and/or Lenders shall deliver to Borrower any Collateral held by Collateral Agent or Lenders hereunder and execute and deliver to Borrower such documents as Borrower shall reasonable request to evidence such termination.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file such financing statements and/or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights in the Collateral and under the Loan Documents.

4.3 Guaranty. (Intentionally omitted).

5. REPRESENTATIONS AND WARRANTIES

Each Borrower, jointly and severally, represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Each Borrower and each of its respective Subsidiaries is duly formed, validly existing and in good standing as under the laws of its jurisdiction of organization or formation and each Borrower and each of its respective Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.2 Collateral. Borrower and Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any deposit accounts, securities accounts, commodity accounts or other investment accounts other than the collateral accounts or other investment accounts (the "**Collateral Accounts**"), if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect to which Borrower has given Collateral Agent notice and taken, subject to Section 6.6 (a), such actions as are necessary to give Collateral Agent a perfected security interest therein. The security interests granted herein are and shall at all times continue to be a first priority senior perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. All Inventory and Equipment that is part of the Collateral is in all material respects of good and marketable quality, free from material defects, ordinary wear and tear excepted with respect to Equipment.

5.3 Litigation. Except as disclosed on the Perfection Certificate, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of any of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Five Hundred Thousand Dollars ($500,000.00).

5.4 No Material Adverse Change; Financial Statements. All consolidated financial statements for Parent and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Parent and its Subsidiaries, and the consolidated results of operations of Parent and its Subsidiaries. Since the date of the most recent financial statements submitted to any Lender, there has not been a Material Adverse Change.

5.5 Solvency. Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to result in a Material Adverse Change. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary to continue their respective businesses as currently conducted.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Each Borrower and each of its respective Subsidiaries has timely filed all required tax returns and reports, and, except as disclosed, each Borrower and each of its respective Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by such Borrower and such Subsidiaries, in all jurisdictions in which such Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in good faith.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Term Loan i) to effectuate termination of a pre-existing Loan and Security Agreement (the "MidCap Agreement") with MidCap Business Credit LLC ("MidCap") and ii) to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of any Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contained, as of the date such statement was so furnished, any untrue statement of a material fact or omitted to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 Shares. Each Borrower has full power and authority to create a lien on its Shares and no disability or contractual obligation exists that would prohibit such Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. With respect to each Subsidiary which is a corporation, the Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.12 Guarantee. (Intentionally omitted)

5.13 UCC Filings. Further to Section 5.2, each Borrower represents, warrants and covenants that (i) there are no UCC filings, in any jurisdiction in which any of its assets that constitute the Collateral are based, that supersede or are senior to or are prior or priority over those of MidCap, (ii) promptly following the full satisfaction of Borrower's obligations under the MidCap Agreement, Borrower shall deliver confirmation of termination of such obligations, which would include delivering copy(ies) of file-stamped UCC-3 Financing Statement(s) evidencing the termination of the lien of MidCap in Borrower's Collateral, in any and all relevant and applicable jurisdictions, which will thereby mean that as of the date of filing of such UCC-3 Financing Statement(s), there shall be no existing security interest, perfected or otherwise, in the Collateral other than Borrower's security interest thereon as provided herein and Permitted Liens, and (iii) Borrower will ensure that on or promptly following the Actual Satisfaction Date (as defined below), Borrower shall fully facilitate Collateral Agent's filing of a UCC-1 Financing Statement on behalf of Lead Lender, with respect to the Collateral, and Collateral Agent's UCC filing and placement shall constitute a first priority senior perfected security interest in the Collateral subject to Permitted Liens.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance. Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change.

6.2 Financial Statements, Reports, Certificates, Notices.

(a) Deliver to Collateral Agent and each Lender: (i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent; (ii) prompt notice of any material amendments of or other changes to the capitalization table of Borrower (other than Parent) and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto; (iii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); (iv) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the Borrower's Intellectual Property and (B) could reasonably be expected to result in a Material Adverse Change; (v) written notice at least (10) days' prior to Borrower's creation of a new Subsidiary; (vi) written notice at least (30) days' prior to Borrower's (A) changing its jurisdiction of organization, (B) changing its organizational structure or type, (C) changing its legal name, (D) changing any organizational number (if any) assigned by its jurisdiction of organization, or (E) registering or filing any Intellectual Property; (vii) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default; (viii) notice of any commercial tort claim of Borrower or any Guarantor and of the general details thereof; (ix) other information as reasonably requested by Collateral Agent or any Lender. (x) written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of more than Five Hundred Thousand Dollars ($500,000.00); and (xi) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Five Hundred Thousand Dollars ($500,000.00) individually or in the aggregate in any calendar year.

(b) Keep proper, complete and true books of record and account in accordance with GAAP and in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once during the term of this Agreement unless (and more frequently if) an Event of Default has occurred and is continuing. Notwithstanding the foregoing, upon request of any Lender, Borrower agrees to permit such Lender to communicate with Borrower's accounting firm, in the presence of a Responsible Officer of the Borrower or the Parent, with respect to the consolidated financial statements delivered pursuant to this Section 6.2.

6.3 Inventory and Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective account debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date.

6.4 Taxes. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request (including customary lender's loss payable endorsements and naming the Collateral Agent as an additional insured), and give the Collateral Agent thirty (30) days' prior written notice before any such policy or policies shall be materially altered or canceled (other than cancellation for non-payment of premiums, for which ten (10) days' prior written notice shall be required). At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments to Collateral Agent. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's books and records, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.7 Landlord Waivers; Bailee Waivers. In the event that Borrower, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2 then Borrower must first receive the written consent of Collateral Agent to do so.

6.8 Further Assurances. Execute any further instruments and take any and all further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement, including without limitation, permit Collateral Agent or any Lender to discuss Borrower's financial condition with Borrower's accountants in the presence of a Responsible Officer of the Borrower or the Parent.

6.9 Discharge of Prior Indebtedness.

(a) As soon reasonably possible following the Effective Date, but in any event no more than three (3) Business Days following the Effective Date, provide evidence of Borrower's transfer of funds to MidCap necessary to terminate the MidCap Agreement in a form satisfactory to Lender.

(b) As soon as reasonably possible following the Effective Date, but in any event no more than ten (10) Business Days following the Effective Date, provide confirmation of Borrower's full satisfaction of its obligations under the MidCap Agreement and the effective termination thereof in a form satisfactory to Lender; *provided, however*, Borrower must (i) provide a payoff letter from MidCap, (ii) ensure that promptly following the date of actual full satisfaction of its obligations under the MidCap Agreement (the "**Actual Satisfaction Date**"), Borrower shall deliver to Lender copy(ies) of file-stamped UCC-3 Financing Statement(s) evidencing the termination of MidCap's lien in Borrower's Collateral, in any and all relevant and applicable jurisdictions, and (iii) ensure that on or promptly following the Actual Satisfaction Date, Borrower fully facilitates Collateral Agent's filing of a UCC-1 Financing Statement on behalf of Lead Lender, with respect to the Collateral, and that Collateral Agent's UCC filing and placement shall constitute a first priority senior perfected security interest in the Collateral subject to Permitted Liens.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property (including Intellectual Property), except for Transfers (a) of (i) Inventory in the ordinary course of business and (ii) Inventory, that, prior to the Effective Date, has been written down or written off, together with related tangible assets and non-material Intellectual Property; (b) of worn out or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments, Permitted Indebtedness and Permitted Licenses; (d) of any non-material Intellectual Property; (e) from (i) Borrower to another Borrower, (ii) a non-Borrower Subsidiary to a Borrower, and (iii) a non-Borrower Subsidiary to another non-Borrower ; or (f) permitted under Section 7.3 below.

7.2 Changes in Business or Management, Ownership. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve; or (c) cause or permit, voluntarily or involuntarily, any Key Person to cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent and each Lender within ten (10) days of such Key Person ceasing to be actively engaged in the management of Borrower.

7.3 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority senior security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property.

7.4 Maintenance of Collateral Accounts. Maintain any Collateral Account [except pursuant to the terms of Section 6.6 hereof.

7.5 Restricted Payments. Following the occurrence and during the continuance of an Event of Default, pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock.

7.6 Transactions with Affiliates. Directly or indirectly enter into any material transaction with any Affiliate of Borrower or any of its Subsidiaries (other than among Borrower), except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, and (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on the Term Loan on its due date, or (b) pay any other Obligation within three (3) Business Days after such Obligation is due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1(i) hereof.

8.2 Covenant Default. Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes) or 6.5 (Insurance) or violates Section 7.2 (Change in Business, Management or Ownership), or Borrower violates any other provision in Section 7 and such violation is not cured within thirty (30) days after Borrower becomes aware of failure.

8.3 Material Adverse Change. A Material Adverse Change has occurred and is continuing.

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Parent is or becomes Insolvent; (b) Parent and its Subsidiaries, taken as a whole, are or become Insolvent; (c) Borrower or any Subsidiary begins an Insolvency Proceeding; or (d) an Insolvency Proceeding is begun against Borrower or any Subsidiary and is not dismissed or stayed within forty five (45) days (but no Term Loan shall be extended while Parent or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Judgments. (a) One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars ($500,000.00) (not covered by independent third party insurance) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of thirty (30) days after the entry thereof or (b) any judgments, orders or decrees rendered against Borrower that could reasonably be expected to result in a Material Adverse Change;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made.

8.9 Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected first Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens or liens arising as a matter of applicable law.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies. Upon the occurrence of an Event of Default hereunder (unless all Events of Default have been cured by Borrower, as applicable, or waived by Lenders in writing), Lenders may, at their option: (i) by written notice to Borrower, declare the entire unpaid principal balance of the Term Loan, together with all accrued interest thereon and any other charges or fees payable hereunder, immediately due and payable regardless of any prior forbearance and (ii) exercise any and all rights and remedies available to it hereunder, under the Secured Promissory Note and/or under applicable law, including, without limitation, the right to collect from Borrower all sums due under this Agreement and the Secured Promissory Note and repossess any Collateral at Borrower's expense. Borrower shall pay all reasonable costs and expenses incurred by or on behalf of Lenders or Collateral Agent in connection with Lenders' exercise of any or all of its rights and remedies under this Agreement or the Secured Promissory Note, including, without

limitation, reasonable attorneys' fees. Borrower waives the right to any stay of execution and the benefit of all exemption laws now or hereafter in effect.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney in fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney in fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in, and lien on, the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed.

9.3 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.4 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission or e-mail; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, any Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

BIOFRONTERA INC.
Address:
120 Presidential Way, Suite 330
Woburn, MA 01864

E-Mail Address: h.luebbert@bfinc.com

If to Collateral Agent:

Agile Capital Funding, LLC
104 E. 25th Street 10th Floor
New York, NY 10010
E-Mail Address: aaron@agilecapitalfunding.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

11.1 Waiver of Jury Trial. EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

11.2 Governing Law and Jurisdiction.

(a) THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE COMMONWEALTH OF VIRGINIA (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE COMMONWEALTH OF VIRGINIA), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN VIRGINIA SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

(b) Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the Commonwealth of Virginia, including, without limitation the Circuit Court of Arlington County in the Commonwealth of Virginia and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

(c) Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(d) Non-exclusive Jurisdiction. Nothing contained in this Section 11.2 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each Party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, any one or more Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents. In the event of such a Lender Transfer, Collateral Agent or Lead Lender shall have the right to, at its respective sole and absolute option, (a) notify Borrower of such Lender Transfer, in accordance with Section 10 hereof, and direct Borrower to make payments directly to such other Lender or Lenders, indicating such other Lenders' Pro Rata share of the Term Loan and the amount of the payment to be made in connection therewith, or (b) continue to collect payments hereunder and under the other Loan Documents and pay such other Lenders their Pro Rata Share of the Term Loan, in accordance with, and on such terms, as are determined by and between the Lenders.

12.2 Indemnification. Borrower, jointly and severally, agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective members, managers, directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses (i) directly caused by such Indemnified Person's gross negligence or willful misconduct or (ii) resulting from a Claim brought by Borrower against any Indemnified Person for breach in bad faith of such Indemnified Person's obligations under the Loan Documents. Borrower hereby further, jointly and severally, indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements (x) directly caused by such Indemnified Person's gross negligence or willful misconduct or (y) resulting from a Claim brought by Borrower against any Indemnified Person for breach in bad faith of such Indemnified Person's obligations under the Loan Documents.

12.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.4 Correction of Loan Documents. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the Parties.

12.5 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, and no consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Pro Rata Share of the Term Loan shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to the Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to the Term Loan (B) postpone the date fixed for, or waive, any payment of principal of the Term Loan or of interest on the Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i) (iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.6 Counterparts; Electronic Signatures. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Any and all electronic signatures, whether by scan, e-mail, PDF, Docusign or similar means, and any electronic delivery of signature pages hereto, shall be treated as originals.

12.7 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loan (provided, however, the Lenders and Collateral Agent shall obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent at no fault of the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

12.9 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising, upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

12.10 Borrower Liability. Each Borrower may, acting singly, request credit extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting credit extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all credit extensions made hereunder, regardless of which Borrower actually receives said credit extension, as if each Borrower hereunder directly received all credit extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and/or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section 12.10 shall be null and void. If any payment is made to a Borrower in contravention of this Section 12.10, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

12.11. Change of Law. If, due to any change in applicable law or regulations, or the interpretation thereof by any court of law or other governing body having jurisdiction subsequent to the date of this Agreement, the performance of any provision of this Agreement, the loans granted pursuant hereto or any transaction contemplated hereby shall become unlawful, impracticable or impossible, the Lender shall have the right, with the consent of the Borrower not to be unreasonably withheld, conditioned or delayed, to amend the terms hereof in good faith so as to comply with the then current laws, rules and/or regulations in the way that, in its reasonable judgment, best and most closely reflects the terms and conditions negotiated herein and intended hereby.

13. DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

"Accounts" shall mean accounts receivable of Parent.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners if such Person is a partnership and, for any Person that is a limited liability company, that Person's managers and members.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which banks are closed in the Commonwealth of Virginia.

"**Code**" is the Uniform Commercial Code, as enacted in the Commonwealth of Virginia.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Disbursement Instruction Form**" is that certain form attached hereto as Exhibit B-2.

"Drawdown" means any principal amount borrowed or to be borrowed (by any means) under the provisions hereof.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**German Subsidiary**" means Bio-FRI GmbH, a German entity.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, (d) merchant cash advances; and (e) Contingent Obligations in respect of any of the foregoing.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"Intellectual Property" shall mean, all (a) trademarks, trademark rights, trade names, trade name rights, service marks, service mark rights, logos, trade dress, domain names, web sites, and all other indicia of origin or quality, and goodwill associated therewith and arising therefrom; (b) patents and patent rights; and (c) works of authorship and copyrights therein, and all common law rights in all of the foregoing, and registration and applications for all of the foregoing issued by or filed with the US Patent and Trademark Office, any State of the US, the US Copyright Office, or any foreign equivalent thereof, and all of the foregoing (a)-(c) used in, at, or in connection with and/or necessary for the (i) conduct of any Borrower's business and/or (ii) use and/or operation of the Collateral.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**Key Person**" is EUGENE FREDERICK LEFFLER III

"**Lien**" is a mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, each Secured Promissory Note, each Disbursement Instruction Form, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future document, certificate, form or agreement entered into by Borrower or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified or supplemented from time to time.

"**Material Adverse Change**" is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Parent, or Parent and each Subsidiary, taken as a whole; (b) a material impairment of the prospect of repayment of the Obligations in full in accordance with the terms hereof, or (c) a material adverse effect on a material portion of the Collateral.

"**Maturity Date**" is 28 weeks from the Effective Date.

"Maximum Legal Rate" shall mean the maximum nonusurious interest rate, if any, that at any time or from time to time may be contracted for, taken, reserved, charged or received on the indebtedness evidenced by the Note and as provided for herein or the other Loan Documents, under the laws of such state or states whose laws are held by any court of competent jurisdiction to govern the interest rate provisions of the Term Loan.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, the Prepayment Fee, the Final Fee, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Perfection Certificate**" is that certain form attached hereto as Exhibit B-1.

"**Permitted Indebtedness**" is: (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents; (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s); (c) unsecured Indebtedness to trade creditors and Indebtedness in connection with credit cards incurred in the ordinary course of business; (d) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (c) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be;

"**Permitted Investments**" are: (a) investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business; (b) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (b) shall not apply to Investments of Borrower in any Subsidiary; and (c) investments set forth in Section 7 of the Perfection Certificate.

"**Permitted Licenses**" are licenses of over-the-counter software that is commercially available to the public.

"**Permitted Liens**" are (a) landlords', carriers', warehouseman's, mechanic's and other similar Liens arising by operation of law in the ordinary course of Borrower's business; (b) Liens arising out of pledge or deposits under worker's compensation, unemployment insurance, old age pension, social security, retirement benefits or other similar legislation; (c) purchase money Liens arising in the ordinary course of business for the purchase of equipment so long as the Indebtedness secured thereby does not exceed the lesser of the cost or fair market value of the property subject thereto, and such Lien extends to no other property, and the amount of the Indebtedness secured thereby does not exceed $50,000 in the aggregate outstanding at any time; (d) Liens for unpaid taxes that are (x) not yet due and payable or (y) are subject to protest that is diligently instituted and prosecuted by Borrower in good faith; (e) Liens which have been subordinated to the Liens of the Collateral Agent on terms and conditions satisfactory to the Lenders; (f) rights of setoff or bankers' liens upon deposits of cash in favor of banks or other depository institutions, solely to the extent incurred in connection with the maintenance of such deposit accounts in the ordinary course of business; (g) Liens existing on the Effective Date and disclosed on the Perfection Certificates; (h) Liens in favor of [Cedar Advance, LLC] pursuant to that certain [Loan and Security Agreement, dated as of the date hereof, between Borrower and Cedar Advance, LLC] and (i) Liens arising under this Agreement and the other Loan Documents in favor of the Collateral Agent, for the benefit of the Collateral Agent and the Lenders, and Liens securing payment of the Obligations;

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Property**" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of the Term Loan held by such Lender by the aggregate outstanding principal amount of the Term Loan.

"**Required Lenders**" means (i) for so long as the Lead Lender has not assigned or transferred any of its interests in the Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after the Lead Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least fifty one percent (51%) of the aggregate outstanding principal balance of the Term Loan.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower or Parent.

"**Shares**" means one hundred percent (100.0%) of the stock, units or other evidence of equity ownership held by Borrower or its Subsidiaries of any Subsidiary which is organized under the laws of the United States.

"**Solvent**" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"**Secured Promissory Note**" is defined in Section 2.5.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries. Unless otherwise specified, references herein to a Subsidiary means a Subsidiary of Borrower.

"**Term Loan**" is defined in Section 2.2(a) hereof.

"**Term Loan Amortization Schedule**" means the amortization schedule set forth in Exhibit B-4 of this Agreement.

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IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:
BIOFRONTERA INC.

By: */s/ Hermann Luebbert*
Name: Hermann Luebbert
Title: Chief Executive Officer

LEAD LENDER:
Agile Lending, LLC

/s/ Aaron Greenblott
By: Aaron Greenblott
Its: Member

COLLATERAL AGENT:
Agile Capital Funding, LLC

/s/ Aaron Greenblott
By: Aaron Greenblott
Its: Member

EXHIBITS TO FOLLOW

APPENDIX 1

BORROWER LIST

Biofrontera Inc.

EXHIBIT A
DESCRIPTION OF COLLATERAL

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All of Borrower's assets wherever located and whether now owned or hereafter owned, existing, acquired or arising, whether tangible or intangible, wherever now or hereafter located, and whether or not eligible or qualified for lending purposes, including, without limitation, the following: all Accounts, chattel paper (whether tangible or electronic), cash, documents, software, general intangibles (including without limitation all Intellectual Property, goodwill, registrations, licenses, software, franchises, customer lists, tax refund claims, claims against carriers and shippers, guarantee claims, contracts rights or rights to payment of money, leases, license agreements, franchise agreements, payment intangibles, security interests, security deposits and rights to indemnification), intellectual property, payment intangibles, instruments (including any promissory notes), deposit accounts and other Collateral Accounts, bank accounts, deposits, money, letters of credit and letter of credit rights (whether or not the letter of credit is evidenced by a writing), supporting obligations, financial assets commercial tort claims, all investment property (including, without limitation, any equity interests in its Subsidiaries (including its German Subsidiary), and all economic rights, all control rights, authority and powers), all securities, certificates of deposit, Inventory, Equipment, farm products, health-care-insurance receivables, vehicles, fixtures, books and records (relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing), and other goods (as those terms are defined in the Code), any other property of Borrower now or hereafter in the possession, custody or control of Lender or any agent or any parent, Affiliate or Subsidiary of Lender or any Participant with Lender in the Loans, for any purpose (whether for safekeeping, deposit, collection, custody, pledge, transmission or otherwise), and all additions, accessions, replacements, substitutions, proceeds and products of all of the foregoing in any form, including, without limitation, all proceeds of credit, fire or other insurance, and also including, without limitation, rents and profits resulting from the temporary use of any of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral." For the avoidance of doubt, the term "Collateral" shall not include Borrowers assets related to the Xepi product, as described in a License and Supply Agreement with Ferrer Internacional, S.A.

EXHIBIT B-1

PERFECTION CERTIFICATE

The undersigned, the President of BIOFRONTERA INC. ("**BFRIW**" or "**Parent**") a Domestic Delaware Corporation (the "Company"), hereby certifies, with reference to (i) the Business Loan and Security Agreement, dated as of December 18, 2023 (the "Loan Agreement"), among Agile Capital Funding, LLC as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and Agile Lending, LLC, a Virginia limited liability company ("**Lead Lender**"), and each assignee that becomes a party to this Agreement pursuant to Section 12.1 (each individually with the Lead Lender, a "**Lender**" and collectively with the Lead Lender, the "**Lenders**"), and BFRIW and the other entities that are joined from time to time as a Borrower, individually and collectively, jointly and severally, "**Borrower**") to the Lender as follows:

1. Name, Tax ID, and State of Formation. The exact legal name of the Borrower as that name appears on its Certificate of Organization, as amended, is as follows:

Name	Tax ID
BIOFRONTERA INC.	**47-3765675**

2. Other Identifying Factors.

(a) The following is the mailing address of the Borrower:

120 PRESIDENTIAL WAY STE 330 WOBURN MA 01801

(b) The following are any DBAs of the Borrower: N/A

3. Other Current Locations.

(a) The following are all other locations in the in which the Borrower maintains any books or records relating to any of the Collateral consisting of accounts, instruments, chattel paper, general intangibles or mobile goods:

(b) The following are all other places of business of the Company in the United States of America:

(c) The following are all other locations where any of the Collateral consisting of inventory or equipment is located:

(d) The following are the names and addresses of all persons or entities other than the Company, such as lessees, consignees, warehousemen or purchasers of chattel paper, which have possession or are intended to have possession of any of the Collateral consisting of instruments, chattel paper, inventory or equipment:

4. Prior Locations.

(a) Set forth below is the information required by §4(a) or (b) with respect to each location or place of business previously maintained by the Company at any time during the past five years in a state in which the Company has previously maintained a location or place of business at any time during the past four months:

(b) Set forth below is the information required by §4(c) or (d) with respect to each other location at which, or other person or entity with which, any of the Collateral consisting of inventory or equipment has been previously held at any time during the past twelve months:

5. Fixtures. Set forth below is the information required by UCC §9-502(b) or former UCC §9-402(5) of each state in which any of the Collateral consisting of fixtures are or are to be located and the name and address of each real estate recording office where a mortgage on the real estate on which such fixtures are or are to be located would be recorded.

6. Intellectual Property.

Set forth below is a complete list of all United States and foreign patents, copyrights, trademarks, trade names and service marks registered or for which applications are pending in the name of the Company.

7. Securities; Instruments. Set forth below is a complete list of all stocks, bonds, debentures, notes and other securities and investment property owned by the Company *(provide name of issuer, a description of security and value)*.

8. Motor Vehicles. The following is a complete list of all motor vehicles owned by the Borrower *(describe each vehicle by make, model and year and indicate for each the state in which registered and the state in which based)*:

Vehicle	State of Registration	State in Which Based

Truck	Plate	VIN	Make

9. **Permitted Indebtedness.**

Lender	Balance	Total Payment (indicate daily, weekly, or monthly)
Cedar Advance, LLC	**$ 2,000,000**	$102,857.14 weekly

10. Permitted Liens:

Liens in connection with Permitted Indebtedness.

11. Bank Accounts. The following is a complete list of all bank accounts (including securities and commodities accounts) maintained by the Borrower (*provide name and address of depository bank, type of account and account number*):

Bank Account	Account Number	Account Routing

12. Unusual Transactions. All of the Collateral has been originated by the Borrower in the ordinary course of the Borrower's business or consists of goods which have been acquired by the Borrower in the ordinary course from a person in the business of selling goods of that kind.

13. Litigation

a. The following is a complete list of pending and threatened litigation or claims involving amounts claimed against the Borrower in an indefinite amount or in excess of $500,000 in each case:

b. The following are the only claims which the Borrower has against others (other than claims on accounts receivable), which the Borrower is asserting or intends to assert, and in which the potential recovery exceeds $500,000:

14. Insurance Broker. The following broker handles the Borrower's property insurance**:**

Broker	Contact	Telephone	Email
Arthur J. Gallagher & Co	Sarah E. Palmer	617-646-0223	Sarah_Palmer@ajg.com

The Borrower agrees to advise you of any change or modification to any of the foregoing information or any supplemental information provided on any continuation pages attached hereto, and, until such notice is received by you, you shall be entitled to rely upon such information and presume it is correct. The Borrower acknowledges that your acceptance of this Perfection Certificate and any continuation pages does not imply any commitment on your part to enter into a loan transaction with the Borrower, and that any such commitment may only be made by an express written loan commitment, signed by one of your authorized officers.

Date: Jan 9, 2024

BIOFRONTERA INC.

By: */s/ Hermann Luebbert*

Name: Hermann Luebbert

Its: Chief Executive Officer

Email: h.luebbert@bfinc.com

EXHIBIT B-2

DISBURSEMENT INSTRUCTION FORM

The proceeds of the first advance of Term Loan shall be disbursed as follows:

Term Loan	$	2,000,000.00
Less:		
Administrative Agent Fee to be remitted to Agile Capital Funding, LLC	$	(100,000.00)
TOTAL TERM LOAN NET PROCEEDS TO BORROWER	$	1,900,000.00

The aggregate net proceeds of the Term Loan shall be transferred to the Designated Deposit Account as follows:

BORROWER: BIOFRONTERA INC.

Account Name: _____ _____

Bank Name: _____

ABA Number: _____

Account Number: _____ _____

The proceeds of the subsequent advances of the Term Loan shall be disbursed as follows:

EXHIBIT B-3

DRAWDOWN SCHEDULE

Within 2 Business Days of Closing Date.

EXHIBIT B-4
REPAYMENT AND AMORTIZATION SCHEDULE

Projected Payment Schedule

	Weekly Payment
1/5/2023	$ 102,857.14
1/12/2024	$ 102,857.14
1/19/2024	$ 102,857.14
1/26/2024	$ 102,857.14
2/2/2024	$ 102,857.14
2/9/2024	$ 102,857.14
2/16/2024	$ 102,857.14
2/23/2024	$ 102,857.14
3/1/2024	$ 102,857.14
3/8/2024	$ 102,857.14
3/15/2024	$ 102,857.14
3/22/2024	$ 102,857.14
3/29/2024	$ 102,857.14
4/5/2024	$ 102,857.14
4/12/2024	$ 102,857.14
4/19/2024	$ 102,857.14
4/26/2024	$ 102,857.14
5/3/2024	$ 102,857.14
5/10/2024	$ 102,857.14
5/17/2024	$ 102,857.14
5/24/2024	$ 102,857.14
5/31/2024	$ 102,857.14
6/7/2024	$ 102,857.14
6/14/2024	$ 102,857.14
6/21/2024	$ 102,857.14
6/28/2024	$ 102,857.14
7/5/2024	$ 102,857.14
7/12/2024	$ 102,857.22
Total	$ 2,880,000.00

EXHIBIT B-5

Business Loan and Security Agreement Supplement

Principal Amount of Loan:	**$2,000,000.00, including the Administrative Agent Fee,** available as set forth in the Drawdown Schedule found in Exhibit B-3 of this Agreement.
Total Repayment Amount:	The total repayment amount of the Term Loan, including all interest, lender fees, and third-party fees, assuming all payments are made on time is **$2,880,000.00**
Payment Schedule:	As set forth in the Repayment and Amortization Schedule found in Exhibit B-4 of the Agreement.
Payment Multiplier: (The per dollar cost of the loan inclusive of all interest and fees).	**1.44**
Interest Charge:	**$880,000.00,** assuming all payments are made on time.
Fees payable to Collateral Agent and its designees:	**Administrative Agent Fee: $100,000.00,** payable at closing out of proceeds of the Term Loan

EXHIBIT B-6

AUTHORIZATION AGREEMENT
FOR AUTOMATED CLEARING HOUSE TRANSACTIONS

Borrower hereby authorizes Lender and / or Servicer (or its representatives) to present automated clearing house (ACH) debits to the following checking account in the amount of fees and other obligations due to Lender from Borrower under the terms of the Business Loan and Security Agreement (the "**Agreement**") and Secured Promissory Note (the "**Note**"), in each case entered into between Lender and Borrower, as it may be amended, supplemented or replaced from time to time. In addition, if an Event of Default (as defined in the Agreement or the Note) occurs, Borrower authorizes Lender and / or Servicer (or its representatives) to debit any and all accounts controlled by Borrower or controlled by any entity with the same Federal Tax Identification Number as Borrower up to the total amount, including but not limited to, all fees and charges, due to Lender from Borrower under the terms of the Agreement.

Transfer Funds To/From:	Agile/Biofrontera
Account Name:	Biofrontera Operating Account
Bank Name:	
ABA Number:	
Account Number:	

This authorization is to remain in full force and effect until all obligations due to Borrower under the Agreement have been fulfilled.

Borrower Information:	
Borrower's Name:	Biofrontera Inc
Signature of Authorized Representative:	
Print Name:	Hermann Luebbert
Title:	CEO and Chairman
Borrower's Tax ID:	473765675
Date:	12/21/2023

EXHIBIT D

SECURED PROMISSORY NOTE

SECURED PROMISSORY NOTE

$2,000,000.00 Dated: December 21, 2023

FOR VALUE RECEIVED, the undersigned, BIOFRONTERA INC. ("**BFRIW**") A Domestic Delaware Corporation (**"Parent"**), and the other entities shown as signatories hereto or that are joined from time to time as a Borrower, individually and collectively, jointly and severally, "**Borrower**"), HEREBY JOINTLY AND SEVERALLY PROMISE TO PAY to the order of Agile Lending, LLC, or its designees or assigns ("**Lead Lender**") the principal amount of TWO MILLION DOLLARS) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Business Loan and Security Agreement dated December 21, 2023, by and among Borrower, Lead Lender, Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**").

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured as provided under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the Commonwealth of Virginia.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

BORROWER HEREBY KNOWINGLY, VOLUNTARILY AND INTELLIGENTLY WAIVES ANY AND ALL RIGHTS THAT EACH PARTY TO THIS NOTE MAY NOW OR HEREAFTER HAVE UNDER THE LAWS OF THE UNITED STATES OF AMERICA OR THE COMMONWEALTH OF VIRGINIA, TO A TRIAL BY JURY OF ANY AND ALL ISSUES ARISING DIRECTLY OR INDIRECTLY IN ANY ACTION OR PROCEEDING RELATING TO THIS NOTE, THE OTHER LOAN DOCUMENTS OR ANY TRANSACTIONS CONTEMPLATED THEREBY OR RELATED THERETO. IT IS INTENDED THAT THIS WAIVER SHALL APPLY TO ANY AND ALL DEFENSES, RIGHTS, CLAIMS AND/OR COUNTERCLAIMS IN ANY SUCH ACTION OR PROCEEDING.

[Signature Page to Follow]

IN WITNESS WHEREOF, Borrower caused this Note to be duly executed under seal by one of its officers thereunto duly authorized on the date hereof.

/s/ *Hermann Luebbert*

Hermann Luebbert

Exhibit 10.35

BUSINESS LOAN AND SECURITY AGREEMENT

THIS BUSINESS LOAN AND SECURITY AGREEMENT (as the same may be amended, restated, modified, or supplemented from time to time, this "**Agreement**") dated as of December 21, 2023 (the "**Effective Date**") among Cedar Advance, LLC as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and Cedar Advance, LLC, a Delaware limited liability company ("**Lead Lender**") and each assignee that becomes a party to this Agreement pursuant to Section 12.1 (each individually with the Lead Lender, a "Lender" and collectively with the Lead Lender, the "Lenders"), and BIOFRONTERA INC. ("**BFRIW**" or "**Parent**"), a Domestic Delaware Corporation, and the other entities that are joined hereto from time to time as a Borrower, individually and collectively, jointly and severally, ("**Borrower**"), and provides the terms on which the Lenders shall lend to Borrower and Borrower shall repay the Lenders the loans described herein. The Collateral Agent, Lenders, and Borrower, each a "Party" and collectively the "Parties", intending to be legally bound, hereby agree as follows:

1. DEFINITIONS, ACCOUNTING AND OTHER TERMS

1.1 Capitalized terms used herein shall have the meanings set forth in Section 13 to the extent defined therein. All other capitalized terms used but not defined herein shall have the meaning given to such terms in the Code. Any accounting term used but not defined herein shall be construed in accordance with GAAP and all calculations shall be made in accordance with GAAP. The term "financial statements" shall include the accompanying notes and schedules thereto. Any section, subsection, schedule or exhibit references are to this Agreement unless otherwise specified.

2. LOANS AND TERMS OF PAYMENT

2.1 Promise to Pay. Borrower hereby unconditionally promises to pay each Lender the outstanding principal amount of the Term Loan advanced to Borrower by such Lender and accrued and unpaid interest thereon and any other amounts due hereunder as and when due in accordance with this Agreement.

2.2 Term Loans.

(a) Availability. The Lenders, relying upon each of the representations and warranties set out in this Agreement, as well as each of the representations, covenants and warranties set out in the other Loan Documents, hereby severally and not jointly agree with the Borrower that, subject to and upon the terms and conditions of this Agreement, shall advance the term loan in the principal amount set forth in Exhibit B-5 hereto (the "**Term Loan**") to the Borrower on the Effective Date, but in any event no later than two (2) Business Days after the date hereof, by wiring the funds to the Borrower's Account.

(b) Repayment. Borrower agrees to pay all amounts owing pursuant to the terms of this Agreement, including any financing charge, specified fees, interest and any other charges that may be assessed as provided in this Agreement or as documented in the Business Loan and Security Agreement Supplement (the "**Supplement**") or the Secured Promissory Note (as defined below). The Term Loan shall be repaid by Borrower on the dates specified on Exhibit B-4 of this Agreement (each a "**Scheduled Repayment Date**") by the amount set out opposite each Scheduled Repayment Date (each a "**Scheduled Repayment Amount**") and in accordance with the Term Loan Amortization Schedule. If any payment on the Secured Promissory Note is due on a day which is not a Business Day, such payment shall be due on the next succeeding Business Day, and such extension of time shall be taken into account in calculating the amount of interest payable under this Note. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on the Maturity Date. The Term Loan may only be prepaid in accordance with Sections 2.2(c) and 2.2(d). Once repaid, no portion of the Term Loan may be reborrowed.

(c) Mandatory Prepayments. If the Term Loan is accelerated following the occurrence of an Event of Default, Borrower shall immediately pay to Lenders, payable to each Lender in accordance with its respective Pro Rata Share, an amount equal to the sum of: (i) all outstanding principal of the Term Loans plus accrued and unpaid interest thereon accrued through the prepayment date, (ii) the Prepayment Fee (as defined in Section 2.2(d) below), plus (iii) all other Obligations that are due and payable, including, without limitation, interest at the Default Rate with respect to any past due amounts.

(d) Permissive Prepayments and Make-Whole Premium. Borrower shall have the right to make a full prepayment or partial prepayment of any or all of the Obligations in accordance with the prepayment amendment in Exhibit E of this Agreement. The foregoing notwithstanding, upon the prepayment of any principal amount, Borrower shall be obligated to pay a make-whole premium payment on account of such principal so paid, which shall be equal to the aggregate and actual amount of interest (at the contract rate of interest) that would be paid through the Maturity Date ("**Prepayment Fee**").

2.3 Payment of Interest on the Term Loans.

(a) Interest Rate. Borrower agrees to pay in full the interest as set forth in the Supplement found in Exhibit B-5 of this Agreement. Interest shall accrue on the Term Loan commencing on, and including, the Effective Date of such Term Loan, and shall accrue on the principal amount outstanding under the Term Loan through and including the day on which the Term Loan is paid in full.

(b) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, Obligations shall accrue interest at a fixed per annum rate equal to the rate that is otherwise applicable thereto plus five percentage points (5.00%) (the "**Default Rate**"). Payment or acceptance of the increased interest rate provided in this Section 2.3(b) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Collateral Agent.

(c) 360 Day Year. Interest shall be computed on the basis of a three hundred sixty (360) day year and the actual number of days elapsed.

(d) Debit of Accounts; Payments. All payments on the Secured Promissory Note shall be made via automated clearing house transfers of immediately available funds to be initiated by Lender in accordance with the authorization and direction of Borrower to Lead Lender provided in Exhibit B-6 of this Agreement.

(e) Usury Savings Clause. This Agreement and the other Loan Documents are subject to the express condition that at no time shall Borrower be required to pay interest on the principal balance of the Term Loan at a rate which could subject Lenders to either civil or criminal liability as a result of being in excess of the Maximum Legal Rate. If by the terms of this Agreement or the other Loan Documents, Borrower is at any time required or obligated to pay interest on the principal balance due hereunder at a rate in excess of the Maximum Legal Rate, the Interest Rate or the Default Rate, as the case may be, shall be deemed to be immediately reduced to the Maximum Legal Rate and all previous payments in excess of the Maximum Legal Rate shall be deemed to have been payments in reduction of principal and not on account of the interest due hereunder. All sums paid or agreed to be paid to the Collateral Agent or Lenders for the use, forbearance, or detention of the sums due under the Loan, shall, to the extent permitted by applicable law, be amortized, prorated, allocated, and spread throughout the full stated term of the Loan until payment in full.

2.4 Fees. Borrower shall pay to Collateral Agent and/or Lenders:

(a) Administrative Agent Fee. The Administrative Agent Fee of ONE-HUNDRED THOUSAND DOLLARS ($100,000.00), which shall be paid at closing out of proceeds of the Term Loan for the account of Collateral Agent.

2.5 Secured Promissory Notes. The Term Loan shall be evidenced by a Secured Promissory Note in the form attached as Exhibit D hereto ("**Secured Promissory Note**") and shall be repayable as set forth in this Agreement.

3. CONDITIONS OF LOANS

3.1 Conditions Precedent to Term Loan. Each Lender's obligation to make the Term Loan is subject to the condition precedent that each Lender shall consent to or shall have received, in form and substance satisfactory to each Lender, such documents, and completion of such other matters, as each Lender may reasonably deem necessary or appropriate.

3.2 Discharge of Prior Indebtedness.

(a) Prior to the Effective Date, Borrower shall provide Lender with documentation of Borrower's notice of termination, together with any corresponding payoff letter from MidCap (as defined below), regarding the MidCap Agreement (as defined below).

4. CREATION OF SECURITY INTEREST

4.1 Grant of Security Interest. Effective from and after the Effective Date of the Term Loan, Borrower hereby grants Collateral Agent, for the ratable benefit of the Lenders, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Collateral Agent, for the ratable benefit of the Lenders, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof. If Borrower shall acquire a commercial tort claim (as defined in the Code), Borrower shall grant to Collateral Agent, for the ratable benefit of the Lenders, a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Collateral Agent. If this Agreement is terminated, Collateral Agent's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations), Collateral Agent shall, at the sole cost and expense of Borrower, release its Liens in the Collateral and all rights therein shall revert to Borrower, and this Agreement and all obligations (other than inchoate indemnity obligations) of the parties hereto shall terminate, all without delivery of any instrument or any further action by any party, and all rights to the Collateral shall revert to Borrower. At the request of Borrower following any such termination, Collateral Agent and/or Lenders shall deliver to Borrower any Collateral held by Collateral Agent or Lenders hereunder and execute and deliver to Borrower such documents as Borrower shall reasonable request to evidence such termination.

4.2 Authorization to File Financing Statements. Borrower hereby authorizes Collateral Agent to file such financing statements and/or take any other action required to perfect Collateral Agent's security interests in the Collateral, without notice to Borrower, with all appropriate jurisdictions to perfect or protect Collateral Agent's interest or rights in the Collateral and under the Loan Documents.

4.3 Guaranty. (Intentionally omitted).

5. REPRESENTATIONS AND WARRANTIES

Each Borrower, jointly and severally, represents and warrants to Collateral Agent and the Lenders as follows:

5.1 Due Organization, Authorization: Power and Authority. Each Borrower and each of its respective Subsidiaries is duly formed, validly existing and in good standing as under the laws of its jurisdiction of organization or formation and each Borrower and each of its respective Subsidiaries is qualified and licensed to do business and is in good standing in any jurisdiction in which the conduct of its businesses or its ownership of property requires that it be qualified except where the failure to do so could not reasonably be expected to result in a Material Adverse Change.

5.2 Collateral. Borrower and Subsidiaries have good title to, have rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien under the Loan Documents, free and clear of any and all Liens except Permitted Liens, and neither Borrower nor any of its Subsidiaries have any deposit accounts, securities accounts, commodity accounts or other investment accounts other than the collateral accounts or other investment accounts (the "**Collateral Accounts**"), if any, described in the Perfection Certificates delivered to Collateral Agent in connection herewith with respect to which Borrower has given Collateral Agent notice and taken, subject to Section 6.6 (a), such actions as are necessary to give Collateral Agent a perfected security interest therein. The security interests granted herein are and shall at all times continue to be a first priority senior perfected security interest in the Collateral, subject only to Permitted Liens that are permitted by the terms of this Agreement to have priority to Collateral Agent's Lien. All Inventory and Equipment that is part of the Collateral is in all material respects of good and marketable quality, free from material defects, ordinary wear and tear excepted with respect to Equipment.

5.3 Litigation. Except as disclosed on the Perfection Certificate, there are no actions, suits, investigations, or proceedings pending or, to the knowledge of any of the Responsible Officers, threatened in writing by or against Borrower or any of its Subsidiaries involving more than Five Hundred Thousand Dollars ($500,000.00).

5.4 No Material Adverse Change; Financial Statements. All consolidated financial statements for Parent and its Subsidiaries, delivered to Collateral Agent fairly present, in conformity with GAAP, in all material respects the consolidated financial condition of Parent and its Subsidiaries, and the consolidated results of operations of Parent and its Subsidiaries. Since the date of the most recent financial statements submitted to any Lender, there has not been a Material Adverse Change.

5.5 Solvency. Borrower and each of its Subsidiaries, when taken as a whole, is Solvent.

5.6 Regulatory Compliance. Neither Borrower nor any of its Subsidiaries has violated any laws, ordinances or rules, the violation of which could reasonably be expected to result in a Material Adverse Change. Borrower and each of its Subsidiaries has obtained all consents, approvals and authorizations of, made all declarations or filings with, and given all notices to, all governmental authorities that are necessary to continue their respective businesses as currently conducted.

5.7 Investments. Neither Borrower nor any of its Subsidiaries owns any stock, shares, partnership interests or other equity securities except for Permitted Investments.

5.8 Tax Returns and Payments; Pension Contributions. Each Borrower and each of its respective Subsidiaries has timely filed all required tax returns and reports, and, except as disclosed, each Borrower and each of its respective Subsidiaries, has timely paid all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by such Borrower and such Subsidiaries, in all jurisdictions in which such Borrower or any such Subsidiary is subject to taxes, including the United States, unless such taxes are being contested in good faith.

5.9 Use of Proceeds. Borrower shall use the proceeds of the Term Loan i) to effectuate termination of a pre-existing Loan and Security Agreement (the "MidCap Agreement") with MidCap Business Credit LLC ("MidCap") and ii) to fund its general business requirements in accordance with the provisions of this Agreement, and not for personal, family, household or agricultural purposes.

5.10 Full Disclosure. No written representation, warranty or other statement of any Borrower or any of its Subsidiaries in any certificate or written statement given to Collateral Agent or any Lender, as of the date such representation, warranty, or other statement was made, taken together with all such written certificates and written statements given to Collateral Agent or any Lender, contained, as of the date such statement was so furnished, any untrue statement of a material fact or omitted to state a material fact necessary to make the statements contained in the certificates or statements not misleading (it being recognized that projections and forecasts provided by Borrower in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

5.11 Shares. Each Borrower has full power and authority to create a lien on its Shares and no disability or contractual obligation exists that would prohibit such Borrower from pledging the Shares pursuant to this Agreement. To Borrower's knowledge, there are no subscriptions, warrants, rights of first refusal or other restrictions on transfer relative to, or options exercisable with respect to the Shares. With respect to each Subsidiary which is a corporation, the Shares have been and will be duly authorized and validly issued, and are fully paid and non-assessable. To Borrower's knowledge, the Shares are not the subject of any present or threatened suit, action, arbitration, administrative or other proceeding, and Borrower knows of no reasonable grounds for the institution of any such proceedings.

5.12 Guarantee. (Intentionally omitted)

5.13 UCC Filings. Further to Section 5.2, each Borrower represents, warrants and covenants that (i) there are no UCC filings, in any jurisdiction in which any of its assets that constitute the Collateral are based, that supersede or are senior to or are prior or priority over those of MidCap, (ii) promptly following the full satisfaction of Borrower's obligations under the MidCap Agreement, Borrower shall deliver confirmation of termination of such obligations, which would include delivering copy(ies) of file-stamped UCC-3 Financing Statement(s) evidencing the termination of the lien of MidCap in Borrower's Collateral, in any and all relevant and applicable jurisdictions, which will thereby mean that as of the date of filing of such UCC-3 Financing Statement(s), there shall be no existing security interest, perfected or otherwise, in the Collateral other than Borrower's security interest thereon as provided herein and Permitted Liens, and (iii) Borrower will ensure that on or promptly following the Actual Satisfaction Date (as defined below), Borrower shall fully facilitate Collateral Agent's filing of a UCC-1 Financing Statement on behalf of Lead Lender, with respect to the Collateral, and Collateral Agent's UCC filing and placement shall constitute a first priority senior perfected security interest in the Collateral subject to Permitted Liens.

6. AFFIRMATIVE COVENANTS

Borrower shall, and shall cause each of its Subsidiaries to, do all of the following:

6.1 Government Compliance. Maintain its and all its Subsidiaries' legal existence and good standing in their respective jurisdictions of organization and maintain qualification in each jurisdiction in which the failure to so qualify could reasonably be expected to have a Material Adverse Change.

6.2 Financial Statements, Reports, Certificates, Notices.

(a) Deliver to Collateral Agent and each Lender: (i) as soon as available, but no later than thirty (30) days after the last day of each month, a company prepared consolidated and consolidating balance sheet, income statement and cash flow statement covering the consolidated operations of Parent and its Subsidiaries for such month certified by a Responsible Officer and in a form reasonably acceptable to Collateral Agent; (ii) prompt notice of any material amendments of or other changes to the capitalization table of Borrower (other than Parent) and to the Operating Documents of Borrower or any of its Subsidiaries, together with any copies reflecting such amendments or changes with respect thereto; (iii) as soon as available, but no later than thirty (30) days after the last day of each month, copies of the month end account statements for each Collateral Account maintained by Borrower or its Subsidiaries, which statements may be provided to Collateral Agent and each Lender by Borrower or directly from the applicable institution(s); (iv) prompt notice of any event that (A) could reasonably be expected to materially and adversely affect the Borrower's Intellectual Property and (B) could reasonably be expected to result in a Material Adverse Change; (v) written notice at least (10) days' prior to Borrower's creation of a new Subsidiary; (vi) written notice at least (30) days' prior to Borrower's (A) changing its jurisdiction of organization, (B) changing its organizational structure or type, (C) changing its legal name, (D) changing any organizational number (if any) assigned by its jurisdiction of organization, or (E) registering or filing any Intellectual Property; (vii) upon Borrower becoming aware of the existence of any Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default, prompt (and in any event within three (3) Business Days) written notice of such occurrence, which such notice shall include a reasonably detailed description of such Event of Default or event which, with the giving of notice or passage of time, or both, would constitute an Event of Default; (viii) notice of any commercial tort claim of Borrower or any Guarantor and of the general details thereof; (ix) other information as reasonably requested by Collateral Agent or any Lender. (x) written notice of any litigation or governmental proceedings pending or threatened (in writing) against Borrower or any of its Subsidiaries, which could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of more than Five Hundred Thousand Dollars ($500,000.00); and (xi) written notice of all returns, recoveries, disputes and claims regarding Inventory that involve more than Five Hundred Thousand Dollars ($500,000.00) individually or in the aggregate in any calendar year.

(b) Keep proper, complete and true books of record and account in accordance with GAAP and in all material respects. Borrower shall, and shall cause each of its Subsidiaries to, allow, at the sole cost of Borrower, Collateral Agent or any Lender, during regular business hours upon reasonable prior notice (provided that no notice shall be required when an Event of Default has occurred and is continuing), to visit and inspect any of its properties, to examine and make abstracts or copies from any of its books and records, and to conduct a collateral audit and analysis of its operations and the Collateral. Such audits shall be conducted no more often than once during the term of this Agreement unless (and more frequently if) an Event of Default has occurred and is continuing. Notwithstanding the foregoing, upon request of any Lender, Borrower agrees to permit such Lender to communicate with Borrower's accounting firm, in the presence of a Responsible Officer of the Borrower or the Parent, with respect to the consolidated financial statements delivered pursuant to this Section 6.2.

6.3 Inventory and Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower, or any of its Subsidiaries, and their respective account debtors shall follow Borrower's, or such Subsidiary's, customary practices as they exist at the Effective Date.

6.4 Taxes. Timely file and require each of its Subsidiaries to timely file, all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local taxes, assessments, deposits and contributions owed by Borrower or its Subsidiaries, except as otherwise permitted pursuant to the terms of Section 5.8 hereof.

6.5 Insurance. Keep Borrower's and its Subsidiaries' business and the Collateral insured for risks and in amounts standard for companies in Borrower's and its Subsidiaries' industry and location and as Collateral Agent may reasonably request (including customary lender's loss payable endorsements and naming the Collateral Agent as an additional insured), and give the Collateral Agent thirty (30) days' prior written notice before any such policy or policies shall be materially altered or canceled (other than cancellation for non-payment of premiums, for which ten (10) days' prior written notice shall be required). At Collateral Agent's request, Borrower shall deliver certified copies of policies and evidence of all premium payments to Collateral Agent. If Borrower or any of its Subsidiaries fails to obtain insurance as required under this Section 6.5 or to pay any amount or furnish any required proof of payment to third persons, Collateral Agent and/or any Lender may make (but has no obligation to do so), at Borrower's expense, all or part of such payment or obtain such insurance policies required in this Section 6.5, and take any action under the policies Collateral Agent or such Lender deems prudent.

6.6 Litigation Cooperation. Commencing on the Effective Date and continuing through the termination of this Agreement, make available to Collateral Agent and the Lenders, without expense to Collateral Agent or the Lenders, Borrower and each of Borrower's officers, employees and agents and Borrower's books and records, to the extent that Collateral Agent or any Lender may reasonably deem them necessary to prosecute or defend any third party suit or proceeding instituted by or against Collateral Agent or any Lender with respect to any Collateral or relating to Borrower.

6.7 Landlord Waivers; Bailee Waivers. In the event that Borrower, after the Effective Date, intends to add any new offices or business locations, including warehouses, or otherwise store any portion of the Collateral with, or deliver any portion of the Collateral to, a bailee, in each case pursuant to Section 7.2 then Borrower must first receive the written consent of Collateral Agent to do so.

6.8 Further Assurances. Execute any further instruments and take any and all further action as Collateral Agent or any Lender reasonably requests to perfect or continue Collateral Agent's Lien in the Collateral or to effect the purposes of this Agreement, including without limitation, permit Collateral Agent or any Lender to discuss Borrower's financial condition with Borrower's accountants in the presence of a Responsible Officer of the Borrower or the Parent.

6.9 Discharge of Prior Indebtedness.

(a) As soon reasonably possible following the Effective Date, but in any event no more than three (3) Business Days following the Effective Date, provide evidence of Borrower's transfer of funds to MidCap necessary to terminate the MidCap Agreement in a form satisfactory to Lender.

(b) As soon as reasonably possible following the Effective Date, but in any event no more than ten (10) Business Days following the Effective Date, provide confirmation of Borrower's full satisfaction of its obligations under the MidCap Agreement and the effective termination thereof in a form satisfactory to Lender; *provided, however*, Borrower must (i) provide a payoff letter from MidCap, (ii) ensure that promptly following the date of actual full satisfaction of its obligations under the MidCap Agreement (the "**Actual Satisfaction Date**"), Borrower shall deliver to Lender copy(ies) of file-stamped UCC-3 Financing Statement(s) evidencing the termination of MidCap's lien in Borrower's Collateral, in any and all relevant and applicable jurisdictions, and (iii) ensure that on or promptly following the Actual Satisfaction Date, Borrower fully facilitates Collateral Agent's filing of a UCC-1 Financing Statement on behalf of Lead Lender, with respect to the Collateral, and that Collateral Agent's UCC filing and placement shall constitute a first priority senior perfected security interest in the Collateral subject to Permitted Liens.

7. NEGATIVE COVENANTS

Borrower shall not, and shall not permit any of its Subsidiaries to, do any of the following without the prior written consent of the Required Lenders:

7.1 Dispositions. Convey, sell, lease, transfer, assign, dispose of (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property (including Intellectual Property), except for Transfers (a) of (i) Inventory in the ordinary course of business and (ii) Inventory, that, prior to the Effective Date, has been written down or written off, together with related tangible assets and non-material Intellectual Property; (b) of worn out or obsolete Equipment; (c) in connection with Permitted Liens, Permitted Investments, Permitted Indebtedness and Permitted Licenses; (d) of any non-material Intellectual Property; (e) from (i) Borrower to another Borrower, (ii) a non-Borrower Subsidiary to a Borrower, and (iii) a non-Borrower Subsidiary to another non-Borrower ; or (f) permitted under Section 7.3 below.

7.2 Changes in Business or Management, Ownership. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses engaged in by Borrower as of the Effective Date or reasonably related thereto; (b) liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve; or (c) cause or permit, voluntarily or involuntarily, any Key Person to cease to be actively engaged in the management of Borrower unless written notice thereof is provided to Collateral Agent and each Lender within ten (10) days of such Key Person ceasing to be actively engaged in the management of Borrower.

7.3 Encumbrance. Create, incur, allow, or suffer any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, or permit any Collateral not to be subject to the first priority senior security interest granted herein (except for Permitted Liens), or enter into any agreement, document, instrument or other arrangement (except with or in favor of Collateral Agent, for the ratable benefit of the Lenders) with any Person which directly or indirectly prohibits or has the effect of prohibiting Borrower, or any of its Subsidiaries, from assigning, mortgaging, pledging, granting a security interest in or upon, or encumbering any of Borrower's or such Subsidiary's Intellectual Property.

7.4 Maintenance of Collateral Accounts. Maintain any Collateral Account [except pursuant to the terms of Section 6.6 hereof.

7.5 Restricted Payments. Following the occurrence and during the continuance of an Event of Default, pay any dividends (other than dividends payable solely in capital stock) or make any distribution or payment in respect of or redeem, retire or purchase any capital stock.

7.6 Transactions with Affiliates. Directly or indirectly enter into any material transaction with any Affiliate of Borrower or any of its Subsidiaries (other than among Borrower), except for (a) transactions that are in the ordinary course of Borrower's or such Subsidiary's business, upon fair and reasonable terms that are no less favorable to Borrower or such Subsidiary than would be obtained in an arm's length transaction with a non-affiliated Person, and (b) Subordinated Debt or equity investments by Borrower's investors in Borrower or its Subsidiaries.

8. EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

8.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on the Term Loan on its due date, or (b) pay any other Obligation within three (3) Business Days after such Obligation is due and payable (which three (3) Business Day grace period shall not apply to payments due on the Maturity Date or the date of acceleration pursuant to Section 9.1(i) hereof.

8.2 Covenant Default. Borrower or any of its Subsidiaries fails or neglects to perform any obligation in Sections 6.2 (Financial Statements, Reports, Certificates), 6.4 (Taxes) or 6.5 (Insurance) or violates Section 7.2 (Change in Business, Management or Ownership), or Borrower violates any other provision in Section 7 and such violation is not cured within thirty (30) days after Borrower becomes aware of failure.

8.3 Material Adverse Change. A Material Adverse Change has occurred and is continuing.

8.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any of its Subsidiaries or of any entity under control of Borrower or its Subsidiaries on deposit with any institution at which Borrower or any of its Subsidiaries maintains a Collateral Account, or (ii) a notice of lien, levy, or assessment is filed against Borrower or any of its Subsidiaries or their respective assets by any government agency, and the same under subclauses (i) and (ii) hereof are not, within ten (10) days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); and

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting any part of its business;

8.5 Insolvency. (a) Parent is or becomes Insolvent; (b) Parent and its Subsidiaries, taken as a whole, are or become Insolvent; (c) Borrower or any Subsidiary begins an Insolvency Proceeding; or (d) an Insolvency Proceeding is begun against Borrower or any Subsidiary and is not dismissed or stayed within forty five (45) days (but no Term Loan shall be extended while Parent or any Subsidiary is Insolvent and/or until any Insolvency Proceeding is dismissed);

8.6 Judgments. (a) One or more judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least Five Hundred Thousand Dollars ($500,000.00) (not covered by independent third party insurance) shall be rendered against Borrower or any of its Subsidiaries and shall remain unsatisfied, unvacated, or unstayed for a period of thirty (30) days after the entry thereof or (b) any judgments, orders or decrees rendered against Borrower that could reasonably be expected to result in a Material Adverse Change;

8.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document or in any writing delivered to Collateral Agent and/or Lenders or to induce Collateral Agent and/or the Lenders to enter this Agreement or any Loan Document, and such representation, warranty, or other statement, when taken as a whole, is incorrect in any material respect when made.

8.9 Lien Priority. Any Lien created hereunder or by any other Loan Document shall at any time fail to constitute a valid and perfected first Lien on any of the Collateral purported to be secured thereby, subject to no prior or equal Lien, other than Permitted Liens or liens arising as a matter of applicable law.

9. RIGHTS AND REMEDIES

9.1 Rights and Remedies. Upon the occurrence of an Event of Default hereunder (unless all Events of Default have been cured by Borrower, as applicable, or waived by Lenders in writing), Lenders may, at their option: (i) by written notice to Borrower, declare the entire unpaid principal balance of the Term Loan, together with all accrued interest thereon and any other charges or fees payable hereunder, immediately due and payable regardless of any prior forbearance and (ii) exercise any and all rights and remedies available to it hereunder, under the Secured Promissory Note and/or under applicable law, including, without limitation, the right to collect from Borrower all sums due under this Agreement and the Secured Promissory Note and repossess any Collateral at Borrower's expense. Borrower shall pay all reasonable costs and expenses incurred by or on behalf of Lenders or Collateral Agent in connection with Lenders' exercise of any or all of its rights and remedies under this Agreement or the Secured Promissory Note, including, without limitation, reasonable attorneys' fees. Borrower waives the right to any stay of execution and the benefit of all exemption laws now or hereafter in effect.

9.2 Power of Attorney. Borrower hereby irrevocably appoints Collateral Agent as its lawful attorney in fact, exercisable upon the occurrence and during the continuance of an Event of Default, to: (a) endorse Borrower's or any of its Subsidiaries' name on any checks or other forms of payment or security; (b) sign Borrower's or any of its Subsidiaries' name on any invoice or bill of lading for any Account or drafts against Account Debtors; (c) settle and adjust disputes and claims about the Accounts directly with Account Debtors, for amounts and on terms Collateral Agent determines reasonable; (d) make, settle, and adjust all claims under Borrower's insurance policies; (e) pay, contest or settle any Lien, charge, encumbrance, security interest, and adverse claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (f) transfer the Collateral into the name of Collateral Agent or a third party as the Code or any applicable law permits. Borrower hereby appoints Collateral Agent as its lawful attorney in fact to sign Borrower's or any of its Subsidiaries' name on any documents necessary to perfect or continue the perfection of Collateral Agent's security interest in, and lien on, the Collateral regardless of whether an Event of Default has occurred until all Obligations (other than inchoate indemnity obligations) have been satisfied in full. Collateral Agent's foregoing appointment as Borrower's or any of its Subsidiaries' attorney in fact, and all of Collateral Agent's rights and powers, coupled with an interest, are irrevocable until all Obligations (other than inchoate indemnity obligations) have been fully repaid and performed.

9.3 No Waiver; Remedies Cumulative. Failure by Collateral Agent or any Lender, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Collateral Agent or any Lender thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by Collateral Agent and the Required Lenders and then is only effective for the specific instance and purpose for which it is given. The rights and remedies of Collateral Agent and the Lenders under this Agreement and the other Loan Documents are cumulative. Collateral Agent and the Lenders have all rights and remedies provided under the Code, any applicable law, by law, or in equity. The exercise by Collateral Agent or any Lender of one right or remedy is not an election, and Collateral Agent's or any Lender's waiver of any Event of Default is not a continuing waiver. Collateral Agent's or any Lender's delay in exercising any remedy is not a waiver, election, or acquiescence.

9.4 Demand Waiver. Borrower waives, to the fullest extent permitted by law, demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Collateral Agent or any Lender on which Borrower or any Subsidiary is liable.

10. NOTICES

All notices, consents, requests, approvals, demands, or other communication (collectively, "**Communication**") by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and three (3) Business Days after deposit in the U.S. mail, first class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by facsimile transmission or e-mail; (c) one (1) Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address, facsimile number, or email address indicated below. Any of Collateral Agent, any Lender or Borrower may change its mailing address or facsimile number by giving the other party written notice thereof in accordance with the terms of this Section 10.

If to Borrower:

BIOFRONTERA INC. Address:
120 Presidential Way, Suite 330
Woburn, MA 01864

E-Mail Address: h.luebbert@bfinc.com

If to Collateral Agent:

Cedar Advance, LLC
simon@cedaradvance.com

11. CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER

11.1 Waiver of Jury Trial. EACH OF BORROWER, COLLATERAL AGENT AND LENDERS UNCONDITIONALLY WAIVES ANY AND ALL RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION BASED UPON OR ARISING OUT OF THIS AGREEMENT, ANY OF THE OTHER LOAN DOCUMENTS, ANY OF THE INDEBTEDNESS SECURED HEREBY, ANY DEALINGS AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS RELATING TO THE SUBJECT MATTER OF THIS TRANSACTION OR ANY RELATED TRANSACTIONS, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED AMONG BORROWER, COLLATERAL AGENT AND/OR LENDERS. THE SCOPE OF THIS WAIVER IS INTENDED TO BE ALL ENCOMPASSING OF ANY AND ALL DISPUTES THAT MAY BE FILED IN ANY COURT. THIS WAIVER IS IRREVOCABLE. THIS WAIVER MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING. THE WAIVER ALSO SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS OR MODIFICATIONS TO THIS AGREEMENT, ANY OTHER LOAN DOCUMENTS, OR TO ANY OTHER DOCUMENTS OR AGREEMENTS RELATING TO THIS TRANSACTION OR ANY RELATED TRANSACTION. THIS AGREEMENT MAY BE FILED AS A WRITTEN CONSENT TO A TRIAL BY THE COURT.

11.2 Governing Law and Jurisdiction.

(a) THIS AGREEMENT, THE OTHER LOAN DOCUMENTS (EXCLUDING THOSE LOAN DOCUMENTS THAT BY THEIR OWN TERMS ARE EXPRESSLY GOVERNED BY THE LAWS OF ANOTHER JURISDICTION) AND THE RIGHTS AND OBLIGATIONS OF THE PARTIES HEREUNDER AND THEREUNDER SHALL IN ALL RESPECTS BE GOVERNED BY AND CONSTRUED IN ACCORDANCE WITH, THE INTERNAL LAWS OF THE COMMONWEALTH OF VIRGINIA (WITHOUT REGARD TO THE CONFLICT OF LAWS PRINCIPLES THAT WOULD RESULT IN THE APPLICATION OF ANY LAWS OTHER THAN THE LAWS OF THE COMMONWEALTH OF VIRGINIA), INCLUDING ALL MATTERS OF CONSTRUCTION, VALIDITY AND PERFORMANCE, REGARDLESS OF THE LOCATION OF THE COLLATERAL, PROVIDED, HOWEVER, THAT IF THE LAWS OF ANY JURISDICTION OTHER THAN VIRGINIA SHALL GOVERN IN REGARD TO THE VALIDITY, PERFECTION OR EFFECT OF PERFECTION OF ANY LIEN OR IN REGARD TO PROCEDURAL MATTERS AFFECTING ENFORCEMENT OF ANY LIENS IN COLLATERAL, SUCH LAWS OF SUCH OTHER JURISDICTIONS SHALL CONTINUE TO APPLY TO THAT EXTENT.

(b) Submission to Jurisdiction. Any legal action or proceeding with respect to the Loan Documents shall be brought exclusively in the courts of the Commonwealth of Virginia, including, without limitation the Circuit Court of Arlington County in the Commonwealth of Virginia and, by execution and delivery of this Agreement, Borrower hereby accepts for itself and in respect of its Property, generally and unconditionally, the jurisdiction of the aforesaid courts. Notwithstanding the foregoing, Collateral Agent and Lenders shall have the right to bring any action or proceeding against Borrower (or any property of Borrower) in the court of any other jurisdiction Collateral Agent or Lenders deem necessary or appropriate in order to realize on the Collateral or other security for the Obligations. The parties hereto hereby irrevocably waive any objection, including any objection to the laying of venue or based on the grounds of forum non conveniens, that any of them may now or hereafter have to the bringing of any such action or proceeding in such jurisdictions.

(c) Service of Process. Borrower irrevocably waives personal service of any and all legal process, summons, notices and other documents and other service of process of any kind and consents to such service in any suit, action or proceeding brought in the United States of America with respect to or otherwise arising out of or in connection with any Loan Document by any means permitted by applicable requirements of law, including by the mailing thereof (by registered or certified mail, postage prepaid) to the address of Borrower specified herein (and shall be effective when such mailing shall be effective, as provided therein). Borrower agrees that a final judgment in any such action or proceeding shall be conclusive and may be enforced in other jurisdictions by suit on the judgment or in any other manner provided by law.

(d) Non-exclusive Jurisdiction. Nothing contained in this Section 11.2 shall affect the right of Collateral Agent or Lenders to serve process in any other manner permitted by applicable requirements of law or commence legal proceedings or otherwise proceed against Borrower in any other jurisdiction.

12. GENERAL PROVISIONS

12.1 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each Party. Borrower may not transfer, pledge or assign this Agreement or any rights or obligations under it without Collateral Agent's prior written consent (which may be granted or withheld in Collateral Agent's discretion, subject to Section 12.5). The Lenders have the right, without the consent of or notice to Borrower, to sell, transfer, assign, pledge, negotiate, or grant participation in (any such sale, transfer, assignment, negotiation, or grant of a participation, a "**Lender Transfer**") all or any part of, or any interest in, any one or more Lenders' obligations, rights, and benefits under this Agreement and the other Loan Documents. In the event of such a Lender Transfer, Collateral Agent or Lead Lender shall have the right to, at its respective sole and absolute option, (a) notify Borrower of such Lender Transfer, in accordance with Section 10 hereof, and direct Borrower to make payments directly to such other Lender or Lenders, indicating such other Lenders' Pro Rata share of the Term Loan and the amount of the payment to be made in connection therewith, or (b) continue to collect payments hereunder and under the other Loan Documents and pay such other Lenders their Pro Rata Share of the Term Loan, in accordance with, and on such terms, as are determined by and between the Lenders.

12.2 Indemnification. Borrower, jointly and severally, agrees to indemnify, defend and hold Collateral Agent and the Lenders and their respective members, managers, directors, officers, employees, consultants, agents, attorneys, or any other Person affiliated with or representing Collateral Agent or the Lenders (each, an "**Indemnified Person**") harmless against: (a) all obligations, demands, claims, and liabilities (collectively, "**Claims**") asserted by any other party in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents; and (b) all losses or expenses incurred, or paid by Indemnified Person in connection with; related to; following; or arising from, out of or under, the transactions contemplated by the Loan Documents between Collateral Agent, and/or the Lenders and Borrower (including reasonable attorneys' fees and expenses), except for Claims and/or losses (i) directly caused by such Indemnified Person's gross negligence or willful misconduct or (ii) resulting from a Claim brought by Borrower against any Indemnified Person for breach in bad faith of such Indemnified Person's obligations under the Loan Documents. Borrower hereby further, jointly and severally, indemnifies, defends and holds each Indemnified Person harmless from and against any and all liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements of any kind or nature whatsoever (including the fees and disbursements of counsel for such Indemnified Person) in connection with any investigative, response, remedial, administrative or judicial matter or proceeding, whether or not such Indemnified Person shall be designated a party thereto and including any such proceeding initiated by or on behalf of Borrower, and the reasonable expenses of investigation by engineers, environmental consultants and similar technical personnel and any commission, fee or compensation claimed by any broker (other than any broker retained by Collateral Agent or Lenders) asserting any right to payment for the transactions contemplated hereby which may be imposed on, incurred by or asserted against such Indemnified Person as a result of or in connection with the transactions contemplated hereby and the use or intended use of the proceeds of the loan proceeds except for liabilities, obligations, losses, damages, penalties, actions, judgments, suits, claims, costs, expenses and disbursements (x) directly caused by such Indemnified Person's gross negligence or willful misconduct or (y) resulting from a Claim brought by Borrower against any Indemnified Person for breach in bad faith of such Indemnified Person's obligations under the Loan Documents.

12.3 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

12.4 Correction of Loan Documents. Collateral Agent may correct patent errors and fill in any blanks in this Agreement and the other Loan Documents consistent with the agreement of the Parties.

12.5 Amendments in Writing; Integration. (a) No amendment, modification, termination or waiver of any provision of this Agreement or any other Loan Document, no approval or consent thereunder, and no consent to any departure by Borrower or any of its Subsidiaries therefrom, shall in any event be effective unless the same shall be in writing and signed by Borrower, Collateral Agent and the Required Lenders provided that:

(i) no such amendment, waiver or other modification that would have the effect of increasing or reducing a Lender's Pro Rata Share of the Term Loan shall be effective as to such Lender without such Lender's written consent;

(ii) no such amendment, waiver or modification that would affect the rights and duties of Collateral Agent shall be effective without Collateral Agent's written consent or signature; and

(iii) no such amendment, waiver or other modification shall, unless signed by all the Lenders directly affected thereby, (A) reduce the principal of, rate of interest on or any fees with respect to the Term Loan or forgive any principal, interest (other than default interest) or fees (other than late charges) with respect to the Term Loan (B) postpone the date fixed for, or waive, any payment of principal of the Term Loan or of interest on the Term Loan (other than default interest) or any fees provided for hereunder (other than late charges or for any termination of any commitment); (C) change the definition of the term "Required Lenders" or the percentage of Lenders which shall be required for the Lenders to take any action hereunder; (D) release all or substantially all of any material portion of the Collateral, authorize Borrower to sell or otherwise dispose of all or substantially all or any material portion of the Collateral, except, in each case with respect to this clause (D), as otherwise may be expressly permitted under this Agreement or the other Loan Documents (including in connection with any disposition permitted hereunder); (E) amend, waive or otherwise modify this Section 12.5 or the definitions of the terms used in this Section 12.5 insofar as the definitions affect the substance of this Section 12.5; (F) consent to the assignment, delegation or other transfer by Borrower of any of its rights and obligations under any Loan Document or release Borrower of its payment obligations under any Loan Document, except, in each case with respect to this clause (F), pursuant to a merger or consolidation permitted pursuant to this Agreement; (G) amend any of the provisions of Section 9.4 or amend any of the definitions of Pro Rata Share, Term Loan Commitment, Commitment Percentage or that provide for the Lenders to receive their Pro Rata Shares of any fees, payments, setoffs or proceeds of Collateral hereunder; (H) subordinate the Liens granted in favor of Collateral Agent securing the Obligations. It is hereby understood and agreed that all Lenders shall be deemed directly affected by an amendment, waiver or other modification of the type described in the preceding clauses (C), (D), (E), (F), (G) and (H) of the immediately preceding sentence.

(b) Other than as expressly provided for in Section 12.5(a)(i) (iii), Collateral Agent may, if requested by the Required Lenders, from time to time designate covenants in this Agreement less restrictive by notification to a representative of Borrower.

(c) This Agreement and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements with respect to such subject matter. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of this Agreement and the Loan Documents merge into this Agreement and the Loan Documents.

12.6 Counterparts; Electronic Signatures. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Any and all electronic signatures, whether by scan, e-mail, PDF, Docusign or similar means, and any electronic delivery of signature pages hereto, shall be treated as originals.

12.7 Survival. All covenants, representations and warranties made in this Agreement continue in full force and effect until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations and any other obligations which, by their terms, are to survive the termination of this Agreement) have been satisfied. The obligation of Borrower in Section 12.2 to indemnify each Lender and Collateral Agent, as well as the confidentiality provisions in Section 12.8 below, shall survive until the statute of limitations with respect to such claim or cause of action shall have run.

12.8 Confidentiality. In handling any confidential information of Borrower, the Lenders and Collateral Agent shall exercise the same degree of care that it exercises for their own proprietary information, but disclosure of information may be made: (a) subject to the terms and conditions of this Agreement, to the Lenders' and Collateral Agent's Subsidiaries or Affiliates; (b) to prospective transferees (other than those identified in (a) above) or purchasers of any interest in the Term Loan (provided, however, the Lenders and Collateral Agent shall obtain such prospective transferee's or purchaser's agreement to the terms of this provision or to similar confidentiality terms); (c) as required by law, regulation, subpoena, or other order; (d) to Lenders' or Collateral Agent's regulators or as otherwise required in connection with an examination or audit; (e) as Collateral Agent reasonably considers appropriate in exercising remedies under the Loan Documents; and (f) to third party service providers of the Lenders and/or Collateral Agent so long as such service providers have executed a confidentiality agreement or have agreed to similar confidentiality terms with the Lenders and Collateral Agent with terms no less restrictive than those contained herein. Confidential information does not include information that either: (i) is in the public domain or in the Lenders' and/or Collateral Agent's possession when disclosed to the Lenders and/or Collateral Agent, or becomes part of the public domain after disclosure to the Lenders and/or Collateral Agent at no fault of the Lenders or the Collateral Agent; or (ii) is disclosed to the Lenders and/or Collateral Agent by a third party, if the Lenders and/or Collateral Agent does not know that the third party is prohibited from disclosing the information. Collateral Agent and the Lenders may use confidential information for any purpose, including, without limitation, for the development of client databases, reporting purposes, and market analysis. The provisions of the immediately preceding sentence shall survive the termination of this Agreement. The agreements provided under this Section 12.8 supersede all prior agreements, understanding, representations, warranties, and negotiations between the parties about the subject matter of this Section 12.8.

12.9 Right of Set Off. Borrower hereby grants to Collateral Agent and to each Lender, a lien, security interest and right of set off as security for all Obligations to Collateral Agent and each Lender hereunder, whether now existing or hereafter arising, upon and against all deposits, credits, collateral and property, now or hereafter in the possession, custody, safekeeping or control of Collateral Agent or the Lenders or any entity under the control of Collateral Agent or the Lenders (including a Collateral Agent affiliate) or in transit to any of them. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Collateral Agent or the Lenders may set off the same or any part thereof and apply the same to any liability or obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE COLLATERAL AGENT TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS OR OTHER PROPERTY OF BORROWER ARE HEREBY KNOWINGLY, VOLUNTARILY AND IRREVOCABLY WAIVED BY BORROWER.

12.10 Borrower Liability. Each Borrower may, acting singly, request credit extensions hereunder. Each Borrower hereby appoints the other as agent for the other for all purposes hereunder, including with respect to requesting credit extensions hereunder. Each Borrower hereunder shall be jointly and severally obligated to repay all credit extensions made hereunder, regardless of which Borrower actually receives said credit extension, as if each Borrower hereunder directly received all credit extensions. Each Borrower waives (a) any suretyship defenses available to it under the Code or any other applicable law, and (b) any right to require Collateral Agent or any Lender to: (i) proceed against any Borrower or any other person; (ii) proceed against or exhaust any security; or (iii) pursue any other remedy. Collateral Agent and/or any Lender may exercise or not exercise any right or remedy it has against any Borrower or any security it holds (including the right to foreclose by judicial or non-judicial sale) without affecting any Borrower's liability. Notwithstanding any other provision of this Agreement or other related document, each Borrower irrevocably waives all rights that it may have at law or in equity (including, without limitation, any law subrogating Borrower to the rights of Collateral Agent and the Lenders under this Agreement) to seek contribution, indemnification or any other form of reimbursement from any other Borrower, or any other Person now or hereafter primarily or secondarily liable for any of the Obligations, for any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise and all rights that it might have to benefit from, or to participate in, any security for the Obligations as a result of any payment made by Borrower with respect to the Obligations in connection with this Agreement or otherwise. Any agreement providing for indemnification, reimbursement or any other arrangement prohibited under this Section 12.10 shall be null and void. If any payment is made to a Borrower in contravention of this Section 12.10, such Borrower shall hold such payment in trust for Collateral Agent and the Lenders and such payment shall be promptly delivered to Collateral Agent for application to the Obligations, whether matured or unmatured.

12.11. Change of Law. If, due to any change in applicable law or regulations, or the interpretation thereof by any court of law or other governing body having jurisdiction subsequent to the date of this Agreement, the performance of any provision of this Agreement, the loans granted pursuant hereto or any transaction contemplated hereby shall become unlawful, impracticable or impossible, the Lender shall have the right, with the consent of the Borrower not to be unreasonably withheld, conditioned or delayed, to amend the terms hereof in good faith so as to comply with the then current laws, rules and/or regulations in the way that, in its reasonable judgment, best and most closely reflects the terms and conditions negotiated herein and intended hereby.

13. DEFINITIONS

As used in this Agreement, the following terms have the following meanings:

"Accounts" shall mean accounts receivable of Parent.

"**Affiliate**" of any Person is a Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners if such Person is a partnership and, for any Person that is a limited liability company, that Person's managers and members.

"**Business Day**" is any day that is not a Saturday, Sunday or a day on which banks are closed in the Commonwealth of Virginia.

"**Code**" is the Uniform Commercial Code, as enacted in the Commonwealth of Virginia.

"**Collateral**" is any and all properties, rights and assets of Borrower described on Exhibit A.

"**Disbursement Instruction Form**" is that certain form attached hereto as Exhibit B-2.

"Drawdown" means any principal amount borrowed or to be borrowed (by any means) under the provisions hereof.

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**German Subsidiary**" means Bio-FRI GmbH, a German entity.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures or similar instruments, (c) capital lease obligations, (d) merchant cash advances; and (e) Contingent Obligations in respect of any of the foregoing.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions or proceedings seeking reorganization, arrangement, or other relief.

"**Insolvent**" means not Solvent.

"Intellectual Property" shall mean, all (a) trademarks, trademark rights, trade names, trade name rights, service marks, service mark rights, logos, trade dress, domain names, web sites, and all other indicia of origin or quality, and goodwill associated therewith and arising therefrom; (b) patents and patent rights; and (c) works of authorship and copyrights therein, and all common law rights in all of the foregoing, and registration and applications for all of the foregoing issued by or filed with the US Patent and Trademark Office, any State of the US, the US Copyright Office, or any foreign equivalent thereof, and all of the foregoing (a)-(c) used in, at, or in connection with and/or necessary for the (i) conduct of any Borrower's business and/or (ii) use and/or operation of the Collateral.

"**Inventory**" is all "inventory" as defined in the Code in effect on the date hereof with such additions to such term as may hereafter be made under the Code, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process and finished products, including without limitation such inventory as is temporarily out of any Person's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership interest or other securities), and any loan, advance or capital contribution to any Person.

"**Key Person**" is EUGENE FREDERICK LEFFLER III

"**Lien**" is a mortgage, deed of trust, levy, charge, pledge, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement, each Secured Promissory Note, each Disbursement Instruction Form, any subordination agreements, any note, or notes or guaranties executed by Borrower or any other Person, and any other present or future document, certificate, form or agreement entered into by Borrower or any other Person for the benefit of the Lenders and Collateral Agent in connection with this Agreement; all as amended, restated, or otherwise modified or supplemented from time to time.

"**Material Adverse Change**" is (a) a material adverse change in the business, operations or condition (financial or otherwise) of Parent, or Parent and each Subsidiary, taken as a whole; (b) a material impairment of the prospect of repayment of the Obligations in full in accordance with the terms hereof, or (c) a material adverse effect on a material portion of the Collateral.

"**Maturity Date**" is 28 weeks from the Effective Date.

"Maximum Legal Rate" shall mean the maximum nonusurious interest rate, if any, that at any time or from time to time may be contracted for, taken, reserved, charged or received on the indebtedness evidenced by the Note and as provided for herein or the other Loan Documents, under the laws of such state or states whose laws are held by any court of competent jurisdiction to govern the interest rate provisions of the Term Loan.

"**Obligations**" are all of Borrower's obligations to pay when due any debts, principal, interest, the Prepayment Fee, the Final Fee, and other amounts Borrower owes the Lenders now or later, in connection with, related to, following, or arising from, out of or under, this Agreement or, the other Loan Documents, or otherwise, and including interest accruing after Insolvency Proceedings begin (whether or not allowed) and debts, liabilities, or obligations of Borrower assigned to the Lenders and/or Collateral Agent, and the performance of Borrower's duties under the Loan Documents.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than thirty (30) days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership, its partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Perfection Certificate**" is that certain form attached hereto as Exhibit B-1.

"**Permitted Indebtedness**" is: (a) Borrower's Indebtedness to the Lenders and Collateral Agent under this Agreement and the other Loan Documents; (b) Indebtedness existing on the Effective Date and disclosed on the Perfection Certificate(s); (c) unsecured Indebtedness to trade creditors and Indebtedness in connection with credit cards incurred in the ordinary course of business; (d) extensions, refinancings, modifications, amendments and restatements of any items of Permitted Indebtedness (a) through (c) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose materially more burdensome terms upon Borrower, or its Subsidiary, as the case may be;

"**Permitted Investments**" are: (a) investments (including debt obligations) received in connection with the bankruptcy or reorganization of customers or suppliers and in settlement of delinquent obligations of, and other disputes with, customers or suppliers arising in the ordinary course of business; (b) Investments consisting of notes receivable of, or prepaid royalties and other credit extensions, to customers and suppliers who are not Affiliates, in the ordinary course of business; provided that this paragraph (b) shall not apply to Investments of Borrower in any Subsidiary; and (c) investments set forth in Section 7 of the Perfection Certificate.

"**Permitted Licenses**" are licenses of over-the-counter software that is commercially available to the public.

"**Permitted Liens**" are (a) landlords', carriers', warehouseman's, mechanic's and other similar Liens arising by operation of law in the ordinary course of Borrower's business; (b) Liens arising out of pledge or deposits under worker's compensation, unemployment insurance, old age pension, social security, retirement benefits or other similar legislation; (c) purchase money Liens arising in the ordinary course of business for the purchase of equipment so long as the Indebtedness secured thereby does not exceed the lesser of the cost or fair market value of the property subject thereto, and such Lien extends to no other property, and the amount of the Indebtedness secured thereby does not exceed $50,000 in the aggregate outstanding at any time; (d) Liens for unpaid taxes that are (x) not yet due and payable or (y) are subject to protest that is diligently instituted and prosecuted by Borrower in good faith; (e) Liens which have been subordinated to the Liens of the Collateral Agent on terms and conditions satisfactory to the Lenders; (f) rights of setoff or bankers' liens upon deposits of cash in favor of banks or other depository institutions, solely to the extent incurred in connection with the maintenance of such deposit accounts in the ordinary course of business; (g) Liens existing on the Effective Date and disclosed on the Perfection Certificates; (h) Liens in favor of Agile Capital Funding, LLC pursuant to that certain Loan and Security Agreement, dated as of the date hereof, between Borrower and Agile Capital Funding, LLC and (i) Liens arising under this Agreement and the other Loan Documents in favor of the Collateral Agent, for the benefit of the Collateral Agent and the Lenders, and Liens securing payment of the Obligations;

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity or government agency.

"**Property**" means any interest in any kind of property or asset, whether real, personal or mixed, and whether tangible or intangible.

"**Pro Rata Share**" is, as of any date of determination, with respect to each Lender, a percentage (expressed as a decimal, rounded to the ninth decimal place) determined by dividing the outstanding principal amount of the Term Loan held by such Lender by the aggregate outstanding principal amount of the Term Loan.

"**Required Lenders**" means (i) for so long as the Lead Lender has not assigned or transferred any of its interests in the Term Loan, Lenders holding one hundred percent (100%) of the aggregate outstanding principal balance of the Term Loan, or (ii) at any time from and after the Lead Lender has assigned or transferred any interest in its Term Loan, Lenders holding at least fifty one percent (51%) of the aggregate outstanding principal balance of the Term Loan.

"**Responsible Officer**" is any of the President, Chief Executive Officer, or Chief Financial Officer of Borrower or Parent.

"**Shares**" means one hundred percent (100.0%) of the stock, units or other evidence of equity ownership held by Borrower or its Subsidiaries of any Subsidiary which is organized under the laws of the United States.

"**Solvent**" is, with respect to any Person: the fair salable value of such Person's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of such Person's liabilities; such Person is not left with unreasonably small capital after the transactions in this Agreement; and such Person is able to pay its debts (including trade debts) as they mature in the ordinary course (without taking into account any forbearance and extensions related thereto).

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all Indebtedness of Borrower and/or its Subsidiaries to the Lenders (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Collateral Agent and the Lenders entered into between Collateral Agent, Borrower, and/or any of its Subsidiaries, and the other creditor), on terms acceptable to Collateral Agent and the Lenders.

"**Secured Promissory Note**" is defined in Section 2.5.

"**Subsidiary**" is, with respect to any Person, any Person of which more than fifty percent (50%) of the voting stock or other equity interests (in the case of Persons other than corporations) is owned or controlled, directly or indirectly, by such Person or through one or more intermediaries. Unless otherwise specified, references herein to a Subsidiary means a Subsidiary of Borrower.

"**Term Loan**" is defined in Section 2.2(a) hereof.

"**Term Loan Amortization Schedule**" means the amortization schedule set forth in Exhibit B-4 of this Agreement.

[Balance of Page Intentionally Left Blank]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed by one of its officers thereunto duly authorized on the date hereof.

BORROWER:
BIOFRONTERA INC.

By: /s/ *Hermann Luebbert*
Name: Hermann Luebbert
Title: Chief Executive Officer

LEAD LENDER:
Cedar Advance, LLC

/s/ Shimon Schonbrun
By: Shimon Schonbrun
Its: Member

COLLATERAL AGENT:
Cedar Advance, LLC

/s/ Shimon Schonbrun
By: Shimon Schonbrun
Its: Member

EXHIBITS TO FOLLOW

APPENDIX 1

BORROWER LIST

Biofrontera Inc.

EXHIBIT A

DESCRIPTION OF COLLATERAL

The Collateral consists of all of Borrower's right, title and interest in and to the following property:

All of Borrower's assets wherever located and whether now owned or hereafter owned, existing, acquired or arising, whether tangible or intangible, wherever now or hereafter located, and whether or not eligible or qualified for lending purposes, including, without limitation, the following: all Accounts, chattel paper (whether tangible or electronic), cash, documents, software, general intangibles (including without limitation all Intellectual Property, goodwill, registrations, licenses, software, franchises, customer lists, tax refund claims, claims against carriers and shippers, guarantee claims, contracts rights or rights to payment of money, leases, license agreements, franchise agreements, payment intangibles, security interests, security deposits and rights to indemnification), intellectual property, payment intangibles, instruments (including any promissory notes), deposit accounts and other Collateral Accounts, bank accounts, deposits, money, letters of credit and letter of credit rights (whether or not the letter of credit is evidenced by a writing), supporting obligations, financial assets commercial tort claims, all investment property (including, without limitation, any equity interests in its Subsidiaries (including its German Subsidiary), and all economic rights, all control rights, authority and powers), all securities, certificates of deposit, Inventory, Equipment, farm products, health-care-insurance receivables, vehicles, fixtures, books and records (relating to the foregoing, and any and all claims, rights and interests in any of the above and all substitutions for, additions, attachments, accessories, accessions and improvements to and replacements, products, proceeds and insurance proceeds of any or all of the foregoing), and other goods (as those terms are defined in the Code), any other property of Borrower now or hereafter in the possession, custody or control of Lender or any agent or any parent, Affiliate or Subsidiary of Lender or any Participant with Lender in the Loans, for any purpose (whether for safekeeping, deposit, collection, custody, pledge, transmission or otherwise), and all additions, accessions, replacements, substitutions, proceeds and products of all of the foregoing in any form, including, without limitation, all proceeds of credit, fire or other insurance, and also including, without limitation, rents and profits resulting from the temporary use of any of the foregoing.

Notwithstanding the foregoing, the Collateral does not include (i) any license or contract, in each case if the granting of a Lien in such license or contract is prohibited by or would constitute a default under the agreement governing such license or contract (but (A) only to the extent such prohibition is enforceable under applicable law and (B) other than to the extent that any such term would be rendered ineffective pursuant to Sections 9-406, 9-408 or 9-409 (or any other Section) of Division 9 of the Code); provided that upon the termination, lapsing or expiration of any such prohibition, such license or contract, as applicable, shall automatically be subject to the security interest granted in favor of Collateral Agent hereunder and become part of the "Collateral." For the avoidance of doubt, the term "Collateral" shall not include Borrowers assets related to the Xepi product, as described in a License and Supply Agreement with Ferrer Internacional, S.A.

EXHIBIT B-1

PERFECTION CERTIFICATE

The undersigned, the President of BIOFRONTERA INC. ("**BFRIW**" or "**Parent**") a Domestic Delaware Corporation (the "Company"), hereby certifies, with reference to (i) the Business Loan and Security Agreement, dated as of December 18, 2023 (the "Loan Agreement"), among Cedar Advance, LLC as collateral agent (in such capacity, together with its successors and assigns in such capacity, "**Collateral Agent**"), and Cedar Advance, LLC, a Delaware limited liability company ("**Lead Lender**"), and each assignee that becomes a party to this Agreement pursuant to Section 12.1 (each individually with the Lead Lender, a "**Lender**" and collectively with the Lead Lender, the "**Lenders**"), and BFRIW and the other entities that are joined from time to time as a Borrower, individually and collectively, jointly and severally, "**Borrower**") to the Lender as follows:

1. **Name, Tax ID, and State of Formation**. The exact legal name of the Borrower as that name appears on its Certificate of Organization, as amended, is as follows:

Name	Tax ID
BIOFRONTERA INC.	**47-3765675**

2. Other Identifying Factors.

(a) The following is the mailing address of the Borrower:

120 PRESIDENTIAL WAY STE 330 WOBURN MA 01801

(b) The following are any DBAs of the Borrower: N/A

3. Other Current Locations.

(a) The following are all other locations in the in which the Borrower maintains any books or records relating to any of the Collateral consisting of accounts, instruments, chattel paper, general intangibles or mobile goods:

(b) The following are all other places of business of the Company in the United States of America:

(c) The following are all other locations where any of the Collateral consisting of inventory or equipment is located:

(d) The following are the names and addresses of all persons or entities other than the Company, such as lessees, consignees, warehousemen or purchasers of chattel paper, which have possession or are intended to have possession of any of the Collateral consisting of instruments, chattel paper, inventory or equipment:

4. Prior Locations.

(a) Set forth below is the information required by §4(a) or (b) with respect to each location or place of business previously maintained by the Company at any time during the past five years in a state in which the Company has previously maintained a location or place of business at any time during the past four months:

(b) Set forth below is the information required by §4(c) or (d) with respect to each other location at which, or other person or entity with which, any of the Collateral consisting of inventory or equipment has been previously held at any time during the past twelve months:

5. Fixtures. Set forth below is the information required by UCC §9-502(b) or former UCC §9-402(5) of each state in which any of the Collateral consisting of fixtures are or are to be located and the name and address of each real estate recording office where a mortgage on the real estate on which such fixtures are or are to be located would be recorded.

6. Intellectual Property.

Set forth below is a complete list of all United States and foreign patents, copyrights, trademarks, trade names and service marks registered or for which applications are pending in the name of the Company.

7. Securities; Instruments. Set forth below is a complete list of all stocks, bonds, debentures, notes and other securities and investment property owned by the Company *(provide name of issuer, a description of security and value)*.

8. Motor Vehicles. The following is a complete list of all motor vehicles owned by the Borrower *(describe each vehicle by make, model and year and indicate for each the state in which registered and the state in which based)*:

Vehicle	State of Registration	State in Which Based

Truck	Plate	VIN	Make

9. **Permitted Indebtedness.**

Lender	Balance	Total Payment (indicate daily, weekly, or monthly)
Agile Lending, LLC	**$ 2,000,000**	$ 102,857.14 weekly

10. Permitted Liens:

Liens in connection with Permitted Indebtedness.

11. Bank Accounts. The following is a complete list of all bank accounts (including securities and commodities accounts) maintained by the Borrower (*provide name and address of depository bank, type of account and account number*):

Bank Account	Account Number	Account Routing

12. Unusual Transactions. All of the Collateral has been originated by the Borrower in the ordinary course of the Borrower's business or consists of goods which have been acquired by the Borrower in the ordinary course from a person in the business of selling goods of that kind.

13. Litigation

a. The following is a complete list of pending and threatened litigation or claims involving amounts claimed against the Borrower in an indefinite amount or in excess of $500,000 in each case:

b. The following are the only claims which the Borrower has against others (other than claims on accounts receivable), which the Borrower is asserting or intends to assert, and in which the potential recovery exceeds $500,000:

14. Insurance Broker. The following broker handles the Borrower's property insurance**:**

Broker	Contact	Telephone	Email
Arthur J. Gallagher & Co	Sarah E. Palmer	617-646-0223	Sarah_Palmer@ajg.com

The Borrower agrees to advise you of any change or modification to any of the foregoing information or any supplemental information provided on any continuation pages attached hereto, and, until such notice is received by you, you shall be entitled to rely upon such information and presume it is correct. The Borrower acknowledges that your acceptance of this Perfection Certificate and any continuation pages does not imply any commitment on your part to enter into a loan transaction with the Borrower, and that any such commitment may only be made by an express written loan commitment, signed by one of your authorized officers.

Date:

BIOFRONTERA INC.

By: /s/ *Hermann Luebbert*

Name: Hermann Luebbert

Its: Chief Executive Officer
Email: h.luebbert@bfinc.com

EXHIBIT B-2

DISBURSEMENT INSTRUCTION FORM

The proceeds of the first advance of Term Loan shall be disbursed as follows:

Term Loan	$	2,000,000.00
Less:		
Administrative Agent Fee to be remitted to Cedar Advance, LLC	$	(100,000.00)
TOTAL TERM LOAN NET PROCEEDS TO BORROWER	$	1,900,000.00

The aggregate net proceeds of the Term Loan shall be transferred to the Designated Deposit Account as follows:

BORROWER: BIOFRONTERA INC.

Account Name: _____

Bank Name: _____

ABA Number: _____

Account Number: _____ _____

The proceeds of the subsequent advances of the Term Loan shall be disbursed as follows:

EXHIBIT B-3

DRAWDOWN SCHEDULE

Within 2 Business Days of Closing Date.

EXHIBIT B-4
REPAYMENT AND AMORTIZATION SCHEDULE

Projected Payment Schedule

	Weekly Payment
12/29/2023	$ 102,857.14
1/5/2023	$ 102,857.14
1/12/2024	$ 102,857.14
1/19/2024	$ 102,857.14
1/26/2024	$ 102,857.14
2/2/2024	$ 102,857.14
2/9/2024	$ 102,857.14
2/16/2024	$ 102,857.14
2/23/2024	$ 102,857.14
3/1/2024	$ 102,857.14
3/8/2024	$ 102,857.14
3/15/2024	$ 102,857.14
3/22/2024	$ 102,857.14
3/29/2024	$ 102,857.14
4/5/2024	$ 102,857.14
4/12/2024	$ 102,857.14
4/19/2024	$ 102,857.14
4/26/2024	$ 102,857.14
5/3/2024	$ 102,857.14
5/10/2024	$ 102,857.14
5/17/2024	$ 102,857.14
5/24/2024	$ 102,857.14
5/31/2024	$ 102,857.14
6/7/2024	$ 102,857.14
6/14/2024	$ 102,857.14
6/21/2024	$ 102,857.14
6/28/2024	$ 102,857.14
7/5/2024	$ 102,857.22
Total	$ 2,880,000.00

EXHIBIT B-5

Business Loan and Security Agreement Supplement

Principal Amount of Loan:	**$2,000,000.00, including the Administrative Agent Fee,** available as set forth in the Drawdown Schedule found in Exhibit B-3 of this Agreement.
Total Repayment Amount:	The total repayment amount of the Term Loan, including all interest, lender fees, and third-party fees, assuming all payments are made on time is **$2,880,000.00**
Payment Schedule:	As set forth in the Repayment and Amortization Schedule found in Exhibit B-4 of the Agreement.
Payment Multiplier: (The per dollar cost of the loan inclusive of all interest and fees).	**1.44**
Interest Charge:	**$880,000.00,** assuming all payments are made on time.
Fees payable to Collateral Agent and its designees:	**Administrative Agent Fee: $100,000.00,** payable at closing out of proceeds of the Term Loan

EXHIBIT B-6

AUTHORIZATION AGREEMENT
FOR AUTOMATED CLEARING HOUSE TRANSACTIONS

Borrower hereby authorizes Lender and / or Servicer (or its representatives) to present automated clearing house (ACH) debits to the following checking account in the amount of fees and other obligations due to Lender from Borrower under the terms of the Business Loan and Security Agreement (the "**Agreement**") and Secured Promissory Note (the "**Note**"), in each case entered into between Lender and Borrower, as it may be amended, supplemented or replaced from time to time. In addition, if an Event of Default (as defined in the Agreement or the Note) occurs, Borrower authorizes Lender and / or Servicer (or its representatives) to debit any and all accounts controlled by Borrower or controlled by any entity with the same Federal Tax Identification Number as Borrower up to the total amount, including but not limited to, all fees and charges, due to Lender from Borrower under the terms of the Agreement.

Transfer Funds To/From:	Cedar/Biofrontera
Account Name:	
Bank Name:	
ABA Number:	
Account Number:	

This authorization is to remain in full force and effect until all obligations due to Borrower under the Agreement have been fulfilled.

Borrower Information:	
Borrower's Name:	Biofrontera Inc
Signature of Authorized Representative:	
Print Name:	Hermann Luebbert
Title:	CEO and Chairman
Borrower's Tax ID:	473765675
Date:	12/21/2023

EXHIBIT D

SECURED PROMISSORY NOTE

SECURED PROMISSORY NOTE

$2,000,000.00 Dated: December 21,2023

FOR VALUE RECEIVED, the undersigned, BIOFRONTERA INC. ("**BFRIW**") A Domestic Delaware Corporation (**"Parent"**), and the other entities shown as signatories hereto or that are joined from time to time as a Borrower, individually and collectively, jointly and severally, "**Borrower**"), HEREBY JOINTLY AND SEVERALLY PROMISE TO PAY to the order of Cedar Advance, LLC, or its designees or assigns ("**Lead Lender**") the principal amount of TWO MILLION DOLLARS) or such lesser amount as shall equal the outstanding principal balance of the Term Loan made to Borrower by Lender, plus interest on the aggregate unpaid principal amount of such Term Loan, at the rates and in accordance with the terms of the Business Loan and Security Agreement dated December 18, 2023, by and among Borrower, Lead Lender, Collateral Agent, and the other Lenders from time to time party thereto (as amended, restated, supplemented or otherwise modified from time to time, the "**Loan Agreement**"). If not sooner paid, the entire principal amount and all accrued and unpaid interest hereunder shall be due and payable on the Maturity Date as set forth in the Loan Agreement. Any capitalized term not otherwise defined herein shall have the meaning attributed to such term in the Loan Agreement.

Principal, interest and all other amounts due with respect to the Term Loan, are payable in lawful money of the United States of America to Lender as set forth in the Loan Agreement and this Secured Promissory Note (this "**Note**").

The Loan Agreement, among other things, (a) provides for the making of a secured Term Loan by Lender to Borrower, and (b) contains provisions for acceleration of the maturity hereof upon the happening of certain stated events.

This Note may not be prepaid except as set forth in Section 2.2 (c) and Section 2.2(d) of the Loan Agreement.

This Note and the obligation of Borrower to repay the unpaid principal amount of the Term Loan, interest on the Term Loan and all other amounts due Lender under the Loan Agreement is secured as provided under the Loan Agreement.

Presentment for payment, demand, notice of protest and all other demands and notices of any kind in connection with the execution, delivery, performance and enforcement of this Note are hereby waived.

Borrower shall pay all reasonable fees and expenses, including, without limitation, reasonable attorneys' fees and costs, incurred by Lender in the enforcement or attempt to enforce any of Borrower's obligations hereunder not performed when due.

This Note shall be governed by, and construed and interpreted in accordance with, the internal laws of the Commonwealth of Virginia.

The ownership of an interest in this Note shall be registered on a record of ownership maintained by Lender or its agent. Notwithstanding anything else in this Note to the contrary, the right to the principal of, and stated interest on, this Note may be transferred only if the transfer is registered on such record of ownership and the transferee is identified as the owner of an interest in the obligation. Borrower shall be entitled to treat the registered holder of this Note (as recorded on such record of ownership) as the owner in fact thereof for all purposes and shall not be bound to recognize any equitable or other claim to or interest in this Note on the part of any other person or entity.

BORROWER HEREBY KNOWINGLY, VOLUNTARILY AND INTELLIGENTLY WAIVES ANY AND ALL RIGHTS THAT EACH PARTY TO THIS NOTE MAY NOW OR HEREAFTER HAVE UNDER THE LAWS OF THE UNITED STATES OF AMERICA OR THE COMMONWEALTH OF VIRGINIA, TO A TRIAL BY JURY OF ANY AND ALL ISSUES ARISING DIRECTLY OR INDIRECTLY IN ANY ACTION OR PROCEEDING RELATING TO THIS NOTE, THE OTHER LOAN DOCUMENTS OR ANY TRANSACTIONS CONTEMPLATED THEREBY OR RELATED THERETO. IT IS INTENDED THAT THIS WAIVER SHALL APPLY TO ANY AND ALL DEFENSES, RIGHTS, CLAIMS AND/OR COUNTERCLAIMS IN ANY SUCH ACTION OR PROCEEDING.

[Signature Page to Follow}

IN WITNESS WHEREOF, Borrower caused this Note to be duly executed under seal by one of its officers thereunto duly authorized on the date hereof.

/s/ *Hermann Luebbert*

Exhibit 21.1

List of Subsidiaries of the Company

Bio-Fri GmbH	Germany

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statements of Biofrontera Inc. (the "Company") on Forms S-1 (File No. 333-265467, 333-268124, and 333-274871) and S-8 (File No. 333-265463) of our report dated March 15, 2024, with respect to our audits of the consolidated financial statements of the Company as of December 31, 2023 and 2022 and for the years ended December 31, 2023 and 2022, which report is included in this Annual Report on Form 10-K of Biofrontera Inc. for the year ended December 31, 2023.

/s/ Marcum LLP

Marcum LLP
East Hanover, NJ
March 15, 2024

Exhibit 31.1

Certification of Principal Executive Officer Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

I, Hermann Lübbert, 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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: 3/15/2024

By: */s/ Hermann Lübbert*

Hermann Lübbert
Chief Executive Officer and Chairman
(Principal Executive Officer)

Exhibit 31.2

Certification of Principal Financial Officer Pursuant to Exchange Act Rule 13a-14(a)/15d-14(a) as Adopted Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002

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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) 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

d) 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: 3/15/2024

By: */s/ E. Fred Leffler*

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

Exhibit 32.1

Certification of Principal Executive Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 *

In connection with the Annual Report of Biofrontera Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to 18 U.S.C.§ 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Hermann Lübbert, Chief Executive Officer of the Company, do hereby certify, to 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: 3/15/2024

By: */s/ Hermann Lübbert*

Hermann Lübbert
Chief Executive Officer and Chairman
(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 of Principal Financial Officer Pursuant to 18 U.S.C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002*

In connection with the Annual Report of Biofrontera Inc. (the "Company") on Form 10-K for the fiscal year ended December 31, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Annual Report") pursuant to 18 U.S.C.§ 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, E. Fred Leffler, Chief Financial Officer of the Company, do hereby certify, to 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: 3/15/2024

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.

COMPENSATION CLAWBACK POLICY

1. Purpose and Scope. Biofrontera Inc. (the "Company") has adopted this Compensation Clawback Policy (the "Policy") to comply with Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 ("Dodd-Frank"), as codified by Section 10D of the Securities Exchange Act of 1934 (the "Exchange Act"), which requires the recovery of certain forms of executive compensation in the case of accounting restatements resulting from a material error in an issuer's financial statements. This Policy shall be administered by the Board of Directors of the Company (the "Board") or, if so designated by the Board, the Compensation Committee.

2. Effective Date. This Policy shall be effective as of October 2, 2023 (the "Effective Date") and shall apply to Incentive-Based Compensation (as defined below) that is approved, awarded, or granted to Covered Executives on or after the Effective Date.

3. Covered Executives. This Policy applies to all of the Company's current and former executive officers, and such other employees who may from time to time be deemed subject to this Policy by the Board (each, a "Covered Executive"). For purposes of this Policy, an executive officer means an officer as defined in Rule 10D-1(d) under the Exchange Act. Each Covered Executive shall be required to sign and return to the Company an acknowledgment of this Policy in the form attached hereto as Exhibit A, pursuant to which such Covered Executive will agree to be bound by the terms of, and comply with, this Policy.

4. Incentive-Based Compensation. For purposes of this Policy, the term "Incentive-Based Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a financial reporting measure. "Financial reporting measures" are measures that are determined and presented in accordance with the accounting principles used in preparing the issuer's financial statements, and any measures that are derived wholly or in part from such measures, including stock price and total shareholder return. A financial reporting measure need not be presented within the Company's financial statements or included in a filing with the Securities and Exchange Commission. For the avoidance of doubt, Incentive-Based Compensation does not include annual salary and/or compensation awarded based on subjective standards, strategic measures, or operational measures.

Biofrontera

5. Recovery; Accounting Restatement.

(a) In the event the Company is required to prepare an accounting restatement of its financial statements due to material noncompliance with any financial reporting requirement under the federal securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "Restatement"), the Company shall, as promptly as it reasonably can, recover any excess Incentive-Based Compensation received by a Covered Executive (a) after beginning service as an executive officer; (b) who served as an executive officer at any time during the performance period for that Incentive-Based Compensation; (c) while the Company has a class of securities listed on a national securities exchange or a national securities association; and (d) during the three completed fiscal years immediately preceding the date on which the Company is required to prepare such Restatement (the "Restatement Date"). Each Covered Executive shall surrender any such excess Incentive-Based Compensation to the Company, at such time or times, and via such method or methods, as determined by the Committee in accordance with this Policy. Notwithstanding the foregoing, this Policy will not (a) require the recovery of Incentive-Based Compensation received by an individual before beginning service as an executive officer, or (b) apply to an individual who is an executive officer at the time recovery is required if that individual was not an executive officer at any time during the period for which the Incentive-Based Compensation is subject to recovery.

(b) The Restatement Date shall be the earlier of (i) the date the Board or a committee of the Board, or the Company's officer(s) authorized to take such action if Board action is not required, concludes, or reasonably should have concluded, that the issuer is required to prepare an accounting restatement due to the material noncompliance of the issuer with any financial reporting requirement under the securities laws as described in Rule 10D-1(b)(1) under the Exchange Act or (ii) the date a court, regulator, or other legally authorized body directs the issuer to prepare an accounting restatement.

(c) The amount to be recovered will be the excess of the Incentive-Based Compensation paid to the Covered Executive based on the erroneous data in the original financial statements over the Incentive-Based Compensation that would have been paid to the Covered Executive had it been based on the restated results (as determined by the Board), without respect to any taxes paid. If the Committee cannot determine the amount of excess Incentive-Based Compensation received by the Covered Executive directly from the information in the accounting restatement, then it will make its determination based on a reasonable estimate of the effect of the accounting restatement.

(d) Subsequent changes in a Covered Executive's employment status, including retirement or termination of employment, do not affect the Company's rights to recover Incentive-Based Compensation pursuant to this Policy. For purposes of this Policy, Incentive-Based Compensation shall be deemed to have been received during the fiscal period in which the financial reporting measure specified in the award is attained, even if such Incentive-Based Compensation is paid or granted after the end of such fiscal period.

(e) The Board shall determine, in its sole discretion, the method of recovering any Incentive-Based Compensation pursuant to this Policy.

(f) Limited Exclusion: No recovery shall be required in the case of a Board determination that such recovery would be impracticable in accordance with Rule 10D-1 of the Exchange Act and the listing standards of a national securities exchange on which the Company's securities are then listed. Such determination shall be made only after a reasonable and well-documented attempt to recover the Incentive-Based Compensation, which documentation shall be provided to the relevant listing exchange or association.

6. No Indemnification. The Company shall not indemnify any current or former Covered Executive against the loss of erroneously awarded Incentive-Based Compensation, and shall not pay, or reimburse any Covered Executives for premiums, for any insurance policy to fund such executive's potential losses.

7. Amendment and Interpretation. The Board may amend this Policy from time to time in its discretion, and shall amend this Policy as it deems necessary to reflect the regulations adopted by the SEC and to comply with any rules or standards adopted by a national securities exchange on which the Company's securities are then listed. It is intended that this Policy be interpreted in a manner that is consistent with the requirements of Section 10D of the Exchange Act and any applicable rules or standards adopted by the SEC and any national securities exchange on which the Company's securities are then listed.

8. Other Recoupment Rights. The Board intends that this Policy will be applied to the fullest extent of the law. The Board may require that any employment agreement, equity award agreement, or similar agreement entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, require a Covered Executive to agree to abide by the terms of this Policy. Any right of recoupment under this Policy is in addition to, and not in lieu of, any other remedies or rights of recoupment or offset that may be available to the Company pursuant to (a) the terms of any similar policy in any employment agreement, equity award agreement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), or similar agreement and any other legal remedies available to the Company; (b) any other legal requirements, including, but not limited to, Section 304 of Sarbanes-Oxley Act of 2002 ("SOX"); and (c) any other legal rights or remedies available to the Company. Any amounts paid to the Company pursuant to Section 304 of SOX shall be considered in determining any amounts recovered under this Policy.

9. Successors. This Policy shall be binding and enforceable against all Covered Executives and their beneficiaries, heirs, executors, administrators, or other legal representatives.

10. Supersedure. This Policy will supersede any provisions in any agreement, plan or other arrangement applicable to any Covered Executive that (a) exempt any Incentive-Based Compensation from the application of this Policy, (b) waive or otherwise prohibit or restricts the Company's right to recover any erroneously awarded Incentive-Based Compensation, including, without limitation, in connection with exercising any right of setoff as provided herein, or (c) require or provide for indemnification to the extent that such indemnification is prohibited under the section entitled "No Indemnification" above.

11. Severability. If any provision of this Policy or the application of such provision to any Covered Executive shall be adjudicated to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal, or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision (or the application of such provision) valid, legal, or enforceable.

EXHIBIT A

COMPENSATION CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Biofrontera, Inc. (the "Company") Compensation Clawback Policy (the "Policy").

By signing this Acknowledgement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any erroneously awarded Incentive-Based Compensation (as defined in the Policy) to the Company to the extent required by, and in a manner consistent with, the Policy.

COVERED EXECUTIVE

_____

Signature

_____

Print Name

_____

Date