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, 2024

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, 2024, 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 $4.2 million, based on the closing price of the registrant's common stock.

As of March 19, 2025, there were 8,873,932 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, 2024 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, 2024 (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 Biofrontera Discovery GmbH ("Discovery"). 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.

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;
- 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;
- changes in our relationship with our Licensors;
- our Licensors' ability to manufacture our licensed products;
- our Licensors' ability to adequately protect their intellectual property and operate their business without infringing upon the intellectual property rights of others;
- 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 and group purchasing organizations ("GPO") 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 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 maintain 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 research, development and preclinical studies and clinical trials for our licensed products;
- our Licensors' ability to obtain and maintain the regulatory approvals necessary for the marketing of our licensed products in the United States, 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 United States based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's primary licensed products, which include Ameluz® as well as the BF-RhodoLED® and RhodoLED®XL lamps (together, the "RhodoLED® Lamps"), are used for the treatment of actinic keratoses ("AKs"), which are pre-cancerous skin lesions. With our national commercial team, we generate revenue by selling our licensed products directly to dermatology offices and groups.

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. We consummated our initial public offering in November 2021. Discovery was formed on February 9, 2022, as a German presence that manages our clinical trial work and facilitates our relationship with the Ameluz Licensor. We consider the Biofrontera Group to be a related party. The Biofrontera Group held more than 5% of the outstanding shares of our common stock until December 10, 2024, and we continue to rely on the Biofrontera Group as the sole supplier of Ameluz® and the RhodoLED® Lamps.

Effective June 1, 2024, we assumed control of all clinical trials relating to Ameluz® in the United States, allowing for more effective cost management and direct oversight of trial efficiency. Our research and development ("R&D") programs are focused on label expansion for Ameluz® as well as supporting PDT growth by improving the capabilities of the RhodoLED® Lamps to better fulfill the needs of dermatologists.

In the third quarter of 2024, the Company reached the decision to divest its Xepi product line and the related intangible asset is currently held for sale. Xepi® (ozenoxacin cream, 1%), is 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 Federal Drug Administration (the "FDA") for the treatment of impetigo, a common skin infection, due to Staphylococcus aureus or Streptococcus pyogenes. The Company did not have any sales of Xepi® during 2024 and generated limited revenue during 2023 from sales of Xepi due to third-party manufacturing delays that have impacted our commercialization of the product. Ferrer is in the process of qualifying a new contract manufacturer. If the new contract manufacturer is qualified, we believe that it will be able to supply enough of the Xepi® product line to meet market demand for as long as we maintain it. However, the Company is working with a potential purchaser and expects to complete a sale of the asset within the next three to six months. The related intangible asset is presented as held for sale under current assets in the Consolidated Balance Sheets. See *Note 9. Assets Held for Sale*, for additional information.

Our Strategy

Our principal objective is to improve patient outcomes through adoption and use of our licensed products. The key elements of our strategy include the following:

- expand our sales in the United States of Ameluz® in combination with the RhodoLED® Lamps for the treatment of minimally to moderately thick AKs of the face and scalp and positioning Ameluz® to be the standard of care in the United States by leveraging new label indications and focusing on acquisition of new customers and growth of the therapy in our current customer base;

- leverage the potential for future approvals and label extensions of our licensed portfolio products that are in the pipeline for the United States market with respect to Ameluz and furthering the clinical development of Ameluz® after taking over responsibility for certain ongoing clinical trials since June 1, 2024, pursuant to the Second A&R Ameluz LSA; and

- strategically manage our licensed portfolio, including opportunistically adding complementary products or services to our portfolio by acquiring or licensing intellectual property to further leverage our commercial infrastructure and customer relationships.

By executing these strategic objectives and continually evaluating our product portfolio with strategic options to improve our business, we will fuel growth, deepen our trusted relationships in the dermatology community, and above all, help patients live healthier, more fulfilling lives.

Employees

As of December 31, 2024, the Company had 93 employees, consisting of 92 full-time employees and one part-time employee. 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, 2024, no customer represented more than 10% of the net accounts receivable balance. For the year ended December 31, 2024, no customer represented more than 10 % of net revenues.

Ameluz® and RhodoLED® Lamps

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® Lamps, 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 keratosis ("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 United States under an exclusive license and supply agreement between Biofrontera Inc. and the Ameluz Licensor, (the "Second A&R Ameluz LSA").

AKs, the number one indication at a dermatologist visit for those 40 and older, 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 as well.

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, and 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 AKs.[4]

Market and competitive landscape

AK is the most common precancer; it affects more than 58 million Americans.[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 and focus on converting cryotherapy treatments of more than 14 lesions to Ameluz® PDT as the switch or even combination of cryotherapy and 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.

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[1] Fuchs, A., & Marmur, E. The kinetics of skin cancer: Progression of actinic keratosis to squamous cell carcinoma. *Dermatologic Surgery*. 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] https://www.skincancer.org/skin-cancer-information/skin-cancer-facts

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

Sales, marketing and distribution

We are currently selling our 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 $262.68 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 R&D programs

We are a sales organization with a focus on commercializing our portfolio of licensed products that are already FDA-approved. Under the Second A&R Ameluz LSA, we hold the exclusive license to sell Ameluz® and the RhodoLED® Lamps in the United States for all indications currently approved by the FDA as well as all future FDA-approved indications identified under the Second A&R Ameluz LSA.

Effective June 1, 2024, in accordance with the Second A&R Ameluz LSA, the Company assumed control of all clinical trials relating to Ameluz® in the US, allowing for more effective cost management and direct oversight of trial efficiency. The increase to R&D spending will be partially offset by the reduced price we pay per unit for Ameluz®, based on certain percentages of the anticipated net selling price, (the "Transfer Price") that covers the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance, and patent administration. This will allow the Company to finance such R&D activities and continue our commercial growth trajectory. Our R&D programs are focused on label expansion for Ameluz® as well as supporting PDT growth by improving the capabilities of our RhodoLED® Lamps to better fulfill the needs of dermatologists.

A summary of our clinical trials is below:

			Clinical Phase				
Product	**Indication**	**Pre-clinical**	I	II	III	Approval Process	**Status**
Ameluz®	Superficial basal cell carcinoma					●	Last-patient-out for 1 year follow up completed in December 2024; Clinical Study Report ("CSR") expected Q2 – 2025.
Ameluz®	Moderate to severe acne			●			Last-patient-out of treatment phase expected Q3 2025. CSR for treatment expected in Q2 2026.
Ameluz®	Actinic keratosis				●		Trunk & extremities applying 1-3 tubes of Ameluz®; last patient-in was March 2025. Last-patient-out of treatment phase expected Q3-2025. CSR expected in Q2-2026.
Ameluz®	Actinic keratosis				●		Combination daylight and conventional PDT, plan to start enrollment in 2026
Ameluz®	Squamous cell carcinoma in situ				●		Plan to start enrollment in 2026

The new, larger RhodoLED® XL was approved by the FDA in 2021 for use 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®. We launched the RhodoLED® XL in June 2024. 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 United States market.

In October 2024, the FDA approved the Company's Supplemental New Drug Application to increase the maximally approved dosage of Ameluz® from one to three tubes per treatment. This approval allows healthcare professionals greater flexibility in

addressing larger or multiple treatment areas for patients undergoing PDT for AK on the face and scalp, leading to greater convenience for both healthcare providers and their patients. In combination with the RhodoLED® XL Lamp, providers can now treat a patient's face more efficiently. Additionally, the change to the label and the RhodoLED® XL are both foundational to support trunk and extremities which we expect to add to the label in the next couple of years.

Also in October 2024, the Company received results in its Phase III trial evaluating Ameluz PDT as a treatment for superficial basal cell carcinoma ("sBCC"). The primary endpoint was a composite of complete clinical and histological clearance of one preselected "main target" BCC lesion per patient 12 weeks after the start of the last PDT cycle. According to the phase III ALA-BCC-CT013 study, Ameluz®-PDT achieved 65.5% success, compared to 4.8% success achieved with placebo-PDT. Complete histological clearance was seen in 75.9% of these lesions in the Ameluz® arm, compared to 19.0% with placebo. Complete clinical clearance was achieved in 83.4% of patients treated with Ameluz® compared to 21.4% with placebo.

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, in 2023, the FDA approved a new formulation of Ameluz® that lacks propylene glycol and reduces the accumulation of certain contaminants over time. The new formulation was implemented in all US productions of Ameluz® starting in 2024. A corresponding patent application has been filed with the United States 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® Lamps is our Licensor, Biofrontera Pharma, who 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 is in the process of qualifying 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.

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® Lamps 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 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 2024, if granted, extends protection to 2043.

Commercial Partners and Agreements

Ameluz® and RhodoLED® Lamps License Service Agreement

On February 19, 2024, the Company entered into the Second A&R Ameluz LSA with the Ameluz Licensor, effective February 13, 2024. The Second A&R Ameluz LSA amended and restated the Ameluz License and Supply Agreement, originally dated as of October 1, 2016, which was subsequently amended on July 1, 2019, June 16, 2021, October 8, 2021, December 5, 2023, and January 26, 2024.

Under the terms of the Second A&R Ameluz LSA, we have an exclusive, non-transferable license from the Ameluz Licensor technology to use, import, export, distribute, market, offer for sale and sell Ameluz® and the RhodoLED® Lamps for its approved indications within the United States and certain of its territories. The Second A&R Ameluz LSA will remain in effect for 15 years from its effective date and automatically renew for a period of five years, in perpetuity as long as certain minimum revenues are achieved. See Note *19. Commitments and Contingencies.*

Among other things, the Second A&R Ameluz LSA reduced 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 indications. 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 assumed 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.

The Ameluz Licensor sell us the RhodoLED® Lamps 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 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® Lamps and/or for Biofrontera to sell Ameluz® and/or the RhodoLED® Lamps 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.

Conversely, Biofrontera is responsible for obtaining all state licenses or any other similar approvals required to market Ameluz® and/or the RhodoLED® Lamps 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 to use commercially reasonable efforts and resources to exploit the license and market Ameluz® and the RhodoLED® Lamps in the United States.

If product or lamps are not delivered in conformance with certain specifications of this Agreement and the Quality Agreement dated November 1, 2016, between the Company and Biofrontera Pharma, 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, 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.

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.

Cost containment efforts by governmental authorities and health care reform continue to exert pressure on product pricing and market access. Pricing pressure continues to be influenced by the power exerted through entities negotiating on behalf of federal health care programs such as Medicare and Medicaid, as well as managed care programs, and commercial insurance plans. We are also seeing government-mandated pricing restrictions aimed at reducing prices and promoting generic drugs adding increased competition and pricing pressure in the market. The U.S. Congress continues to consider and discuss legislation aimed at reducing health care costs, including lowering the price of drugs and biologics.

United States Drug Development and Review

Drug Development Process

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

The United States 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 related to our products.

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/condition 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/condition. 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, without limitations, 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 and clinicians. 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 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

The FDA's post-market surveillance programs monitor the safety of drugs once they are approved. 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. Under the Second A&R Ameluz LSA, these requirements are handled by both us and our Licensor. 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.

Safe Medical Devices Act

The Safe Medical Devices Act of 1990, as amended ("SMDA"), amended the Federal Food, Drug, and Cosmetic Act to require medical device manufacturers and user facilities such as hospitals and ambulatory surgical centers to report any adverse events

associated with a medical device to the FDA. It provides that FDA with two additional post-market activities including monitoring of products after market clearance and device tracking for maintaining traceability of certain devices to the user level. The SMDA makes it mandatory for facilities, manufacturers, and importers to submit medical device reporting forms to the FDA after becoming aware of a serious event associated with a device. Manufacturers are required to submit baseline reports and reports of deaths, serious injuries, and malfunctions associated with the device to the FDA.

Fraud and Abuse Laws

We are subject to healthcare anti-fraud and abuse regulations that are enforced by the United States federal government and the states in which we conduct our business. The laws that may affect our ability to operate include, without limitation:

- 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, (commonly referred to as treble damages), 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.

Physician Payments Sunshine Act

The Physician Payments Sunshine Act is a national disclosure program created by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 that aims to increase transparency in payments from medical device manufacturers and pharmaceutical companies to physicians and teaching hospitals. In 2018, the Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act expanded these covered recipients to include physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, anesthesiologist assistants and certified nurse midwives. Common payments in the industry to physicians and other "covered recipients" can include consulting fees, honoraria, fees for training and education, research fees, gifts, vacations, food and beverage, travel and lodging, charitable contributions, grants, ownership and investment interests, royalty or license fees, and compensation for serving as faculty or a speaker.

Inflation Reduction Act ("IRA")

The IRA, passed by Congress in 2022, makes significant changes to how drugs are covered and paid for under the Medicare Program. Creates financial penalties for drugs whose prices rise faster than the rate of inflation, makes changes to the Medicare Part D program to require manufacturers to bear more liability for certain drug benefits, which has taken effect in 2025, and includes government price setting for certain Medicare Part D drugs starting in 2026 and Medicare Part B drugs starting in 2028.

340B Drug Discount Program and legislative changes

The 340B drug discount program (part of the Public Health Service Act) requires pharmaceutical manufacturers to sell certain outpatient drugs at significantly reduced prices to eligible healthcare providers known as "covered entities" that serve a large number of low-income patients. Participation in this program by manufacturers is often required in exchange for access to the Medicaid market.

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. Among other things, the HITECH 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, together with other information in this Form 10-K, and our other filings with the SEC, including our financial statements and the related notes and the sections entitled "Management's Discussion and Analysis of Financial Condition and Results of Operations" in such filings, 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.

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:

Summary of Material Risk Factors

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

- Currently, our revenue derives solely from sales of products we license from other companies. If the license agreements are terminated, we could lose license rights that are important to our business.
- Certain important patents for Ameluz® expired in 2019. If generic versions of Ameluz® enter the market, we may need to reduce the price of Ameluz® significantly, which would reduce revenues, and may lose significant market share.
- Our business depends substantially on the success of Ameluz®. If we or the Ameluz Licensor are unable to successfully obtain and maintain regulatory approvals or reimbursement for Ameluz® for existing and additional indications, our business may be materially harmed.
- If the Ameluz Licensor fails to maintain its relationships with the manufacturers of Ameluz, or if those manufacturers are unable to produce Ameluz, our business could be materially harmed.
- If our Licensors or our Licensors' manufacturing partners, as applicable, fail to manufacture our licensed products in sufficient quantities and at acceptable quality and cost levels, we may face a bar to, or delays in, the commercialization of those products 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, similar suits may arise 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.
- The Company may be unable to effectuate a sale of Xepi® in a timely manner or receive consideration in excess of the carrying value of the asset that is currently held for sale.

Risks Related to Our Business and Strategy

- The sourcing and manufacture of our licensed products as well as, in part, the regulatory approvals and clinical trials related to our licensed products are currently controlled by our existing collaborators. Our lack of control 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, and our operating results will suffer if we fail to compete effectively.
- 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 United States market size for Ameluz® for the treatment of AK may be smaller than we have estimated.
- If our Licensors are subjected to sanctions due to noncompliance with law, our licensed products could be subject to restrictions or withdrawal from the market.
- Our licensed products may not gain market acceptance among members of the medical community.
- Our failure to comply with healthcare laws and regulations and could have a material adverse effect on our results of operations and financial condition.
- A recall of our licensed drug or medical products, or the discovery of serious safety issues with our licensed drug or medical products, could have a significant negative impact on us.
- Our products subject to extensive governmental regulation, and failure to comply with applicable requirements could cause our business to suffer.
- Our actual or perceived failure to comply with data and data security regulations 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.
- We will need to grow 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
- Failure to comply with applicable anti-corruption legislation could result in fines and criminal penalties.
- Our licensed products will be subject to ongoing regulatory requirements.
- Generic manufacturers may launch products at risk of patent infringement.
- The results of our R&D efforts are uncertain.

Risks Related to Our Financial Position and Capital Requirements

- There is substantial doubt about our ability to continue as a "going concern."
- We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never achieve profitability.
- If we fail to obtain additional financing, we may be unable to pursue our plans for strategic growth.
- Our existing and any future indebtedness could adversely affect our ability to operate our business.

Risks Related to Clinical Trials and Regulatory Approvals of Indication Expansion

- Delay or termination of planned clinical trials would result in unplanned expenses and significantly and adversely impact our remaining developmental activities and potential commercial prospects.
- If third parties conducting some of our clinical trials do not carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval to extend the indications of our licensed products.
- Our licensed products may pose safety and other issues that could delay or prevent the regulatory approval of additional indications and result in significant negative consequences.
- If we are ultimately unable to obtain regulatory approval for additional indications of our licensed products on a timely basis or at all, our business will be substantially harmed.

Risks Related to Corporate Governance, Including Being a Public Company

- If we fail to maintain an effective system of internal controls, our ability to produce timely and accurate financial statements may be impaired, investors may lose confidence in our financial reporting, and the price of our common stock may decline.
- We have incurred, and will continue to incur, increased costs as a result of operating as a public company, and our management devotes substantial time to compliance with our public company responsibilities.
- We cannot be certain if the reduced disclosure requirements applicable to us as an emerging growth company or smaller reporting company 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.
- If we fail to maintain compliance with applicable listing standards, our common stock and publicly-traded warrants could be delisted from Nasdaq.
- Future sales of our common stock in the public market could cause our share price to fall.
- Warrants are exercisable for our common stock, which, if exercised, would 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 could result in dilution and could cause the stock price of our common stock to decline.
- Any gain on an investment in our common stock likely depends on increases in the price of our common stock.
- Our stockholder rights plan could discourage a takeover or other transaction that stockholders may favor.
- 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 certificate of incorporation could limit our stockholders' ability to obtain a judicial forum other than the Court of Chancery of the State of Delaware 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 our warrants are accounted for as a liability and recorded at fair value with changes in fair value each period, 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® Lamps) 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*" in this Form 10-K.

Disputes have arisen and may continue to 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 United States Patent No. 6,559,183, which, prior to its expiration, served as a material, significant and possibly the only barrier to entry into the United States 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 United States 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 United States 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 United States patent application has been filed by the Ameluz Licensor but is still pending. We cannot guarantee that this United States 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 we or the Ameluz Licensor are 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® Lamps, 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;
- receipt 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 we or the Ameluz Licensor do not achieve one or more of these factors in a timely manner, or at all, we could experience significant delays or an inability to successfully commercialize our 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.

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 United States 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, 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.

Our Licensors supply us with the licensed product that we sell in the United States 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.

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' 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 the clinical trials for our licensed products are related, 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 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 United States 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 United States 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. 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 September 13, 2023, Biofrontera was served with a complaint 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. Separately, on June 26, 2024 and June 27, 2024, Sun filed two complaints against Biofrontera, Biofrontera AG, Biofrontera Pharma, and Biofrontera Bioscience with the United States District Court for the District of Massachusetts and the International Trade Commission, both alleging infringement of two patents held by Sun. See Note *19. Commitments and Contingencies – Legal Claims* for more information regarding these cases.

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 and, the uncertainty of litigation, the Company cannot estimate the possibility of a material loss, nor the potential range of loss that may result from either 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, Biofrontera Discovery 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.

The Company may be unable to effectuate a sale of Xepi® in a timely manner or receive consideration in excess of the carrying value of the asset that is currently held for sale.

In the third quarter of 2024, the Company committed to a plan to sell its Xepi® product line. Although the Company expects a sale to be completed during 2025, it cannot provide any assurance that it will be successful in selling the asset for a price in excess of the carrying value of the asset, which is currently classified as "held for sale." The carrying amount of the asset at the time of classification was $2.3 million, which was the lower of its carrying value or estimated fair value less cost to sell. In the event that the Company is unable to sell its Xepi® product line for a price at least equal to the remaining carrying value of the assets, then it will have to record additional charges, which could have an adverse effect on the Company's financial position. See Note 9, *Assets Held for Sales* in our consolidated financial statements included within this Form 10-K.

Risks Related to Our Business and Strategy

The sourcing and manufacturing of our licensed products as well as the regulatory approvals 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 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 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 we are entitled to enter into a direct agreement with the Ameluz Licensor's supplier under certain circumstances, 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.

Under the Second A&R Ameluz 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, as a result of its control of the manufacturing 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.

Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, including with respect to future indications of our licensed products, which could make it difficult for us to sell our licensed products.

Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. As such, patients are unlikely to use our products unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost of our products. Therefore, adequate coverage and reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and third-party payors, such as private health insurers and health maintenance organizations, is critical to product acceptance. Government authorities and third-party payors, decide which products they will cover and the amount of reimbursement. Such reimbursement 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.

Coverage decisions may depend on clinical and economic standards that disfavor new products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Third-party payors may refuse to include a particular branded product in their formularies or lists of medications for which third-party payors provide coverage and reimbursement, or otherwise restrict patient access through formulary controls or otherwise to a branded product when a less costly generic equivalent or alternative is available. Coverage may be more limited than the purposes for which a product is approved by the FDA or similar regulatory authorities outside the United States.

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.

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. 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, including with respect to future indications of 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, 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 United States 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 United States 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 we or 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. 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 United States federal government and by authorities in the United States. Such United States 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.

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.

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 United States 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.

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 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, 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 these laws and regulations could result in regulatory investigations, enforcement notices and significant fines. 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.

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 Luebbert, 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, 2024, we had 93 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 licensors, and other contractors and consultants are vulnerable to damage from breaches of information systems, attempts to access information, including customer and company information, information relating to our clinical trials, 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. Further, these risks may be exacerbated by recent developments in artificial intelligence and its increased use to produce sophisticated malware, phishing schemes, and other fraudulent activities. 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;
- decreased enrollment rates of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- 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 United States 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 United States 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 United States Office of Foreign Assets Control and the United States 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 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 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".

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 consolidated financial statements were issued. 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 second half of 2025, and until cash flow from operations is sufficient, if ever. As of March 12, 2025 our unaudited cash was approximately $2.2 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, 2024 and December 31, 2023 was $17.8 million and $20.1 million, respectively. As of December 31, 2024, we had an accumulated deficit of $117.4 million.

Our ability to become profitable depends on our ability to further commercialize our principal licensed product Ameluz®. Even if we are successful in increasing our licensed product sales, we may never achieve or sustain profitability. In the long term, we anticipate increasing our sales and marketing expense as we attempt to exploit the regulatory approvals to market Ameluz® in the United States for the 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.

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,

On February 19, 2024, we entered into an equity financing agreement which provided net proceeds of $14.6 million. On November 21, 2024, the Company entered into a Securities Purchase Agreement with its principal stockholders providing for the private placement of $4.2 million in aggregate principal amount of the Company's 10.0% Senior Secured Convertible Notes (the "Notes"). However, we will still need to raise additional capital through debt or equity financing in order to support our operating, investing and financing activities of the Company 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
- 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.

The Company funds its operations, in part, with borrowed funds. Our existing and future 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; and
- placing us at a competitive disadvantage to competitors that are better capitalized than we are.

The Notes contain restrictive covenants that, among other things, generally limit the ability of the Company and its subsidiaries to (i) create liens, (ii) pay dividends, acquire shares of capital stock and make payments on subordinated debt, (iii) incur indebtedness, or (iv) enter into transactions with affiliates. The foregoing restrictive covenants are subject to a number of important exceptions and qualifications, as set forth in the Notes. The Notes are secured by substantially all property of the Company, including but not limited to the Company's assets, inventory, intellectual property and accounts. See *Note 11. Debt*, for additional information regarding our existing indebtedness.

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 Clinical Trials and Regulatory Approvals Regulatory Approvals of Indication Expansion

Delay or termination of planned clinical trials for expanding the indications of Ameluz® would result in unplanned expenses and significantly and adversely impact our remaining developmental activities and potential commercial prospects with respect to, and ability to generate revenues from, such indications.

We may experience delays in completing ongoing trials and initiating planned trials, and we cannot be certain whether these trials or any other future clinical trials for expanding the indications of Ameluz® will be completed on schedule, if at all. Clinical trials can be delayed or terminated for a variety of reasons, including delays or failures related to:

- disagreements with regulators as to the design or implementation of our clinical trials;
- agreeing on acceptable terms with prospective CROs, clinical trial sites, and prospective strategic partners, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, trial sites and partners;
- obtaining institutional review board ("IRB") approval at each site;
- adverse events occurring in clinical studies;
- our ability to enroll a sufficient number of suitable patients who remain in the trial until its conclusion;
- having patients complete a trial or return for post-treatment follow-up;
- clinical sites deviating from trial protocols;
- how we address patient safety concerns that arise during the course of a trial;
- adding a sufficient number of clinical trial sites;
- manufacturing sufficient quantities of products for use in clinical trials;
- utilizing an adequate container and delivery device for the product;
- changes to our financial priorities or insufficient capital available to fund clinical trials; or
- suspension of trials by us, by the IRBs of the institutions in which such trials are being conducted, by the Data Safety Monitoring Board ("DSMB"), for such trial, or by regulatory authorities.

If we experience delays in the completion of, or the termination of, our clinical trials, we may experience increased costs and/or have difficulty raising capital, either of which would cause us to have to delay our product development and regulatory approval process timelines. Further, the commercial prospects of the expanded indications of our licensed products may be harmed, and our ability to generate product revenues from any of these indications could be delayed or not realized at all. Any of these occurrences may significantly harm our business, financial condition and prospects.

We rely on third parties to conduct some of our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may be unable to obtain regulatory approval to extend the indications of our licensed products.

The FDA requires us to comply with regulations and standards, commonly referred to as good clinical practice, or GCP, requirements for conducting, monitoring, recording and reporting the results of clinical trials, in order to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. We rely on medical institutions, independent clinical investigators, contract laboratories and other third parties, such as CROs, to conduct GCP-compliant clinical trials on our licensed products properly and on time. Although we rely on these third parties to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GCP clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations.

These third parties play a significant role in the conduct of these trials and the subsequent collection and analysis of data. While we have agreements governing their activities, we control only certain aspects of their activities and have limited influence over their actual performance or control over the amount or timing of resources that they devote to our programs. If the third parties conducting our GCP clinical trials do not perform their contractual duties or obligations, experience work stoppages, do not meet expected deadlines, terminate their agreements with us or otherwise need to be replaced, or if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical trial protocols or for any other reason, we may need to enter into new arrangements with alternative third parties. This could be difficult, costly or impossible, and our clinical trials may need to be extended, delayed, terminated or repeated. As a result, we may not be able to obtain regulatory approval in a timely fashion, or at all, for the applicable indication, our financial results and the commercial prospects for our licensed products would be harmed, our costs could increase, and our ability to generate additional revenues could be delayed.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and may receive compensation in connection with such services. If these relationships and any related compensation result in perceived or actual conflicts of interest, or the FDA concludes that the financial relationships may have affected the interpretation of the trial, the integrity of the data generated at the applicable clinical trial site may be questioned and the utility of the clinical trial itself may be jeopardized, which could result in the delay or rejection by the FDA of regulatory approval of additional indications. Any such delay or rejection could prevent us from commercializing expanded indications of our licensed products.

Our licensed products may pose safety issues, cause adverse events, have side effects or have other properties that could delay or prevent the regulatory approval of additional indications, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if any.

Results of our clinical trials could reveal a high and unacceptable severity and prevalence of adverse events or unexpected characteristics. We, any partner with whom we may collaborate, or the FDA may suspend, delay, require modifications to or terminate our clinical trials at any time, for various reasons, including the discovery of serious or unexpected toxicities or other safety issues experienced by trial participants. In addition, adverse events caused by our licensed products could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of regulatory approvals by the FDA. Treatment-related adverse events could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims. In addition, these adverse events may not be appropriately recognized or managed by the treating medical staff. Any of the foregoing events could prevent us from obtaining regulatory approval for expanded indications of our licensed products and from achieving or maintaining market acceptance of our licensed products for some or all indications, and may result in the failure to realize significant revenues, which would materially and adversely affect our results of operations and business.

The regulatory approval processes of the FDA are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain regulatory approval for additional indications of our licensed products on a timely basis or at all, our business could be substantially harmed.

We are not permitted to market any indication of our product in the United States for which we have not received applicable regulatory approval. The time required to obtain approval by the FDA is unpredictable, lengthy, and depends upon numerous factors, including the substantial discretion of the regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of clinical testing for expanded indications.

Prior to obtaining marketing approval for additional indications of a product in the United States, we must demonstrate, with substantial evidence from well-controlled clinical trials, and to the satisfaction of the FDA, that the product is safe and effective for the target indication. The FDA can delay, limit or deny approval of additional indications of our licensed products or require us to conduct costly additional clinical testing or abandon a program for many reasons, including:

● disagreements with regulators as to the design or implementation of our clinical trials;
● unfavorable or ambiguous results from our clinical trials;
● results that may not meet the level of statistical significance required by the FDA for approval;
● serious and unexpected drug-related adverse events experienced by participants in our clinical trials or by individuals using drugs similar to our licensed products;
● our inability to demonstrate to the satisfaction of the FDA that our licensed products are safe and effective for the proposed indication;
● the FDA's disagreement with the interpretation of data from clinical trials;
● our inability to demonstrate that the clinical and other benefits of our licensed products outweigh any safety or other perceived risks;
● the FDA's disagreement regarding the formulation, container, dosing delivery device, labeling or the specifications of our licensed products;
● the FDA's failure to approve the manufacturing processes or facilities of third-party manufacturers with which we contract; or

- the potential for approval policies or regulations of the FDA to significantly change in a manner rendering our clinical data insufficient for approval.

Of the large number of drugs in development, only a small percentage successfully complete the FDA approval process and become commercialized. The lengthy approval process as well as the unpredictability of outcomes from future clinical trials may result in our failing to obtain regulatory approval to market our licensed products for additional indications. The FDA also may approve a more limited indication than we target, and the FDA may not approve the labeling that we believe is necessary or desirable for the successful commercialization of our licensed products. Any delay in obtaining, or inability to obtain, in whole or in part, applicable regulatory approval for additional indications we are targeting would hinder the commercialization of our licensed products, which would limit our ability to increase our revenues, materially and adversely affecting our results of operations and business.

Risks Related to Corporate Governance, Including Being a Public Company

If we fail to maintain an effective system of internal controls, our ability to produce timely and accurate financial statements may be impaired, investors may lose confidence in our financial reporting, and the price of our common stock may decline.

We are subject to the reporting requirements of the Exchange Act and other laws and regulations applicable to public companies. These laws and regulations require, among other things, that we maintain effective procedures and internal control over financial reporting and disclosure controls. We engage in continuous improvement of our internal control over financial reporting, disclosure controls, and other procedures designed to provide assurance that information we disclose in our consolidated financial statements and in the reports that we file with the SEC is recorded, processed, summarized, and reported within the time periods specified in SEC rules and forms, and information required to be disclosed in reports under the Exchange Act is accumulated and communicated to our principal executive and financial officers. Our current controls and any new controls we develop may become inadequate because of changes in conditions in our business.

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. 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. We have since enhanced our internal control environment and remediated this material weakness. However, we cannot guarantee that we will not identify different material weaknesses in the future.

If we identify 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. Any failure to develop or maintain effective internal control over financial reporting and disclosure controls, or any difficulties encountered in their implementation or improvement, could result in a restatement of our consolidated financial statements for prior periods, cause us to fail to meet our financial and other reporting obligations, result in an adverse opinion regarding our internal control over financial reporting from our independent registered public accounting firm, and lead to investigations or sanctions by regulatory authorities. Any of the foregoing could have a material adverse effect on our business, results of operations, and financial condition, and could cause our investors to lose confidence in the accuracy and completeness of our financial reports and the price of our common stock to decline.

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.

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.

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 our periodic reports and proxy statements.

To the extent we take advantage of the exemptions described above, comparison of our financial statements with other public companies may be difficult or impossible. If some investors find our common stock less attractive as a result of our taking advantage of such exemptions, investors may find our common stock less attractive and there may be a less active trading market for our common stock, causing the price of our common stock to be more volatile.

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 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);
- 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 maintain 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.

In addition, if we fail to maintain 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 8,873,932 shares of common stock outstanding as of March 19, 2025, of which 8,473,932 shares are freely tradable without restrictions or further registration required under the Securities Act. 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.

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 19, 2025, we have a total of 2,269,356 outstanding warrants which may each be exercised for one share of our common stock In addition, we have shares of Series B-2 and Series B-3 Convertible Preferred Stock ("Series B Preferred Stock"). Each share of Series B 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 Preferred Stock). As of March 19, 2025 we have 10,129 shares of Series B Preferred Stock outstanding, which could be converted into up to 14,318,632 shares of common stock.

Although the Series B Preferred Stock has 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, the remaining Series B Preferred Stock 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 Preferred Stock sell any of the common stock they currently hold.

All of the shares issuable upon exercise of these warrants or the conversion of the Series B Preferred Stock 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 or conversion of the Series B convertible preferred stock 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.

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);
- our execution of any licensing or similar arrangements, and the timing of payments we may make or receive under these arrangements;
- seasonality in the demand for traditional PDT treatment using a lamp;
- delays in the delivery of our products due to supply chain issues;
- the timing of milestone payments under our existing license agreements; and
- the level of underlying demand for Ameluz® 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, our 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 is 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.

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 United States 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 3. Fair Value Measurements.*

As of the date of this Form 10-K, 2,269,356 liability classified Warrants remain outstanding. See Note 14. Stockholders' Equity in our audited financial statements for the fiscal year ended December 31, 2024 and 2023 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 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 November 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 19. *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**."

As of December 31, 2024, there were three holders of record of our common stock. Holders of record are defined as those stockholders whose shares are registered in their names in our stock records and do not include beneficial owners of common stock whose shares are held in the names of brokers, dealers or clearing agencies.

Dividend Policy

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

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, 2024.

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") is a United States based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's primary licensed products, which include Ameluz® as well as the BF-RhodoLED® and RhodoLED®XL lamps (the "RhodoLED® Lamps"), are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions. With our national commercial team, we generate revenue by selling our licensed products directly to dermatology offices and groups.

We are currently selling Ameluz® in the United States under an exclusive license and supply agreement, the Second Amended and Restated License and Supply Agreement, effective as of February 13, 2024 with the Ameluz Licensor (the "Second A&R Ameluz LSA"). The Second A&R Ameluz LSA reduced the Transfer Price of Ameluz® from 50% to 25% which covers the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance and patent administration 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.

Effective June 1, 2024, we assumed control of all clinical trials relating to Ameluz® in the United States, allowing for more effective cost management and direct oversight of trial efficiency. Our research and development ("R&D") program is focused on label expansion for Ameluz® as well as supporting PDT growth by improving the capabilities of our RhodoLED® Lamps to better fulfill the needs of dermatologists. The reduced LSA transfer price will allow the Company to finance such R&D activities and continue our commercial growth trajectory.

In October 2024, the FDA approved the Company's Supplemental New Drug Application to increase the maximally approved dosage of Ameluz® from one to three tubes per treatment. This approval allows healthcare professionals greater flexibility in addressing larger or multiple treatment areas for patients undergoing PDT for AK on the face and scalp, leading to greater convenience for both healthcare providers and their patients. In combination with the RhodoLED® XL Lamp, providers can now treat a patient's face more efficiently. Additionally, the change to the label and the RhodoLED® XL are both foundational to support trunk and extremities which we expect to add to the label in the next couple years.

Also, in October 2024, the Company received results in its Phase III trial evaluating its drug-device therapy, Ameluz® with the BF-RhodoLED lamp, as a treatment for superficial basal cell carcinoma ("sBCC"). The primary endpoint was a composite of complete clinical and histological clearance of one preselected "main target" BCC lesion per patient 12 weeks after the start of the last PDT cycle. According to the phase III ALA-BCC-CT013 study, Ameluz®-PDT achieved 65.5% success, compared to 4.8% success achieved with placebo-PDT. Complete histological clearance was seen in 75.9% of these lesions in the Ameluz® arm, compared to 19.0% with placebo. Complete clinical clearance was achieved in 83.4% of patients treated with Ameluz® compared to 21.4% with placebo.

In the third quarter of 2024, the Company reached the decision to divest its Xepi product line and the related intangible asset is currently held for sale. Xepi® (ozenoxacin cream, 1%), is 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. Our exclusive license and supply agreement, as amended ("Xepi LSA"), with Ferrer Internacional S.A. ("Ferrer") enables us to market and sell this product in the United Sates. However, the Company did not have any sales of Xepi® during 2024 and generated limited revenue during 2023 from sales of Xepi due to third-party manufacturing delays that have impacted our commercialization of the product. Ferrer is now in the process of qualifying a new contract manufacturer. If the new contract manufacturer is qualified, we believe that it will be able to supply enough of the Xepi® product line to meet market demand for as long as we maintain it. Nevertheless, the Company is working with a potential purchaser and expects to complete a sale of the asset within the next three to six months. The related intangible asset is presented as held for sale under current assets in the Consolidated Balance Sheets. See *Note 9. Assets Held for Sale*, for additional information.

Our principal objective is to improve patient outcomes through adoption and use 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 RhodoLED® Lamps 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 focusing on acquisition of new customers and growth of the therapy in our current customer base;

- leveraging the potential for future approvals and label extensions of our licensed portfolio products that are in the pipeline for the United States market with respect to Ameluz® and furthering the clinical development of this product after taking over responsibility for certain ongoing clinical trials since June 1, 2024, pursuant to the Second A&R Ameluz LSA; and

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

By executing these 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.

We devote a substantial portion of our cash resources to the commercialization of our licensed products, Ameluz® and the BF-RhodoLED® Lamps. We have financed our operating and capital expenditures through cash proceeds generated from our product sales, short term debt and proceeds received from convertible notes and 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.

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[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.

Components of Our Results of Operations

Product Revenues, net

We generate product revenues through the third-party sales of our licensed products Ameluz® and RhodoLED® Lamps. Revenues from product sales are recorded net of trade discounts and allowances and government rebates.

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.

Revenues, Related Party

Prior to June 1, 2024, the date on which we took over clinical trials, we generated insignificant related party revenue in connection with an agreement with Biofrontera Bioscience to provide RhodoLED® Lamps and associated services for the clinical trials performed by Biofrontera Bioscience. In the future, we do not expect to receive related party revenue regarding RhodoLED® Lamps and associated services for clinical trials.

Cost of Revenues, Related Party

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

Effective February 12, 2024, the Second A&R Ameluz LSA, among other things, was amended to change the Transfer Price from 50% to 25% of the anticipated net selling price per unit 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% of the anticipated net selling price starting in 2032, subject to a minimum dollar amount per unit.

Cost of Revenues, Other

Cost of revenues, other, is comprised of third-party logistics and distribution costs including packaging, freight, transportation, shipping and handling costs.

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 assets 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 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 regulatory affairs, medical affairs, and pharmacovigilance, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine (i) if they will be needed, and (ii) whether they can or should be obtained from other third-party providers.

Research and Development

Effective June 1, 2024, we took control of all clinical trials for Ameluz® in the Unites States, allowing for more effective cost management and direct oversight of trial efficiency. Our R&D expenses include costs directly attributable to the clinical development of Ameluz®, including personnel-related expenses, the cost of services provided by outside contractors, including services related to the Company's clinical trials, facilities, depreciation, and other direct and allocated expenses. Along with our Ameluz® clinical trials, our R&D program also aims to improve the capabilities of our 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. All costs associated with research and development are expensed as incurred.

Change in Fair Value of Contingent Consideration

In connection with our acquisition of Cutanea Life Sciences, Inc ("Cutanea") from Maruho Co., Ltd ("Maruho") on March 25, 2019, 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 and was re-measured at each reporting date until the contingency was resolved. Our obligation relating to contingent consideration was relieved under a Confidential Settlement Agreement and Mutual Release (the "Release") dated December 27, 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.

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. 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 the Release, the Company was released from its obligations to (i) repay $7.3 million in start-up cost financing to Maruho for Cutanea's redesigned business activities ("start-up cost financing"), and (ii) 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.

Loss on Debt Extinguishment

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. Effective as of January 4, 2024, we voluntarily terminated the Loan Agreement and recognized a $0.3 million loss on debt extinguishment upon the early termination related to prepayment fees and the write-off of deferred financing costs.

Interest Income (Expense), net

Interest expense, net, primarily consists of interest on our convertible notes, and short-term debt including amortization of deferred costs.

Other Income (Expense), 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, 2024 and December 31, 2023

The following table summarizes our results of operations for the years ended December 31, 2024 and December 31, 2023:

(in thousands)	**2024**	**2023**	**Change**
Product revenues, net	$ 37,303	$ 34,005	3,298
Revenues, related party	18	66	(48)
Revenues, net	**37,321**	**34,071**	**(3,250)**
Operating expenses:			
Cost of revenues, related party	17,855	16,789	1,066
Cost of revenues, other	752	655	97
Selling, general and administrative	33,793	38,975	(5,182)
Selling, general and administrative, related party	42	152	(110)
Research and development	2,089	77	2,012
Change in fair value of contingent consideration	-	100	(100)
Total operating expenses	54,531	56,748	(2,217)
Loss from operations	**(17,210)**	**(22,677)**	**5,467**
Change in fair value of warrant liabilities	1,680	6,456	(4,776)
Warrant inducement expense	-	(1,045)	1,045
Excess of warrant fair value over offering proceeds	-	(2,272)	2,272
Change in fair value of investment, related party	(14)	(7,421)	7,407
Loss on debt extinguishment	(316)	-	(316)
Gain on legal settlement	-	7,385	(7,385)
Interest expense, net	(2,035)	(468)	(1,567)
Other income (expense), net	158	(75)	233
Loss before income taxes	**(17,737)**	**(20,117)**	**2,380**
Income tax expenses	22	14	8
Net loss	**$ (17,759)**	**$ (20,131)**	**$ 2,372**

Product Revenues, net

Net product revenue for 2024 increased $3.3 million, or 9.7% compared to 2023. The increase was primarily driven by organic growth of Ameluz® sales volume of $0.5 million, a $1.7 million increase due to an increased Ameluz® unit price, and the launch of our RhodoLED® XL Lamp, which resulted in sales of RhodoLED®XL Lamps of $1.1 million.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party increased $1.1 million, or 6.3% compared to 2023, driven by the increase in revenue. Cost of revenues, increased at a slower pace as compared to the sales increase of 9.7% due to cost savings under the Second A&R Ameluz LSA and volume discounts under the original license and supply agreement with the Ameluz Licensors.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for 2024 decreased $5.2 million, or 13.3% compared to 2023. This decrease was primarily driven by a $3.0 million decrease in general and administrative expenses, primarily attributable to a decrease in external legal expenses and expenses relating to financing activities. The decrease was further driven by a decrease in general sales and marketing expenses of $1.8 million, primarily attributable to more targeted trade shows and conference spending and close management of promotional spend, including a $0.8 million reduction in direct sales personnel expenses due to reduction in sales force and a $0.3 million reduction in direct sales travel and lodging.

Research and Development Expense

R&D expenses for the year ended December 31, 2024 increased $2.0 million as compared to the year ended December 31, 2023. The increase was attributed to our assumption of all clinical trial activities for Ameluz® in the United States effective June 1, 2024, allowing for more effective cost management and direct oversight of trial efficiency. This increase in R&D expense was and will continue to be offset in 2024 and 2025 by a reduction in the Transfer Price of Ameluz® from 50% to 25% for inventory purchases. As of December 31, 2024, we generated savings of approximately $0.8 million from inventory purchased in 2024 due to the reduced Transfer Price.

The following table summarizes the major categories of our R&D expenses for the years ended December 31, 2024 and 2023:

	2024	2023
Actinic keratosis	$ 682	$ -
Moderate to severe acne	267	-
Superficial basal cell carcinoma	148	-
Portable devices	94	-
Personnel-related costs	756	-
Other research and development	142	77
	$ 2,089	$ 77

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was driven primarily by a greater decrease in the underlying value of the Company's common stock during 2023 as compared to 2024.

Change in Fair Value of Investment, Related Party

As of December 31, 2023, the Company had transferred substantially all of its investment in Biofrontera AG to Maruho in exchange for the release of certain obligations, in accordance with the Release. As a result, for the year ended December 31, 2024, the net balance of our investment in Biofrontera AG and the related change in fair value was minimal.

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. There were no legal settlements that occurred in 2024.

Interest Expense, net

The increase of interest expense of $1.6 million was driven by the interest and debt discount recognized on the loans issued on December 21, 2023, for an aggregate principal balance of $4.0 million. The loans required the Company to make weekly payments of principal and interest in the amount of approximately $0.2 million through July 5, 2024, the maturity date.

Net Income to Adjusted EBITDA Reconciliation for years ended December 31, 2024 and 2023

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.

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 Accounting Standards Codification ("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.

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.

Loss on debt extinguishment: Effective as of January 4, 2024, we voluntarily terminated the Loan Agreement and recognized a $0.3 million loss on debt extinguishment upon the early termination of the loan. We exclude the impact of this loss as it is attributed to the prepayment fee, which is considered non-recurring and the write-off of deferred financing costs, which is considered 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.

Our management uses adjusted EBITDA to measure our performance from period to period and to compare our results to those of our competitors. We believe that adjusted EBITDA 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, 2024 and 2023:

	Years ended December 31,	
	2024	**2023**
Net loss	**$ (17,759)**	**$ (20,131)**
Interest expense, net	2,035	468
Income tax expenses	22	14
Depreciation and amortization	421	504
EBITDA	**(15,281)**	**(19,145)**
Change in fair value of contingent consideration	-	100
Change in fair value of warrant liabilities	(1,680)	(6,456)
Warrant inducement expense	-	1,045
Excess of warrant fair value over offering proceeds	-	2,272
Change in fair value of investment, related party	14	7,421
Gain on legal settlement	-	(7,385)
Loss on debt extinguishment	316	-
Legal settlement expenses	-	1,225
Stock based compensation	1,019	1,045
Expensed issuance costs	354	422
Adjusted EBITDA	**$ (15,258)**	**$ (19,456)**
Adjusted EBITDA margin	-40.9%	-57.1%

Adjusted EBITDA

Adjusted EBITDA increased from ($19.5) million for the year ended December 31, 2023 to ($15.3) million for the year ended December 31, 2024. The increase was primarily driven by an increase in gross profit due to the increase in sales and a reduction in purchase price for sales of inventory purchased under the Second A&R Ameluz LSA, and a decrease in selling, general and administrative expenses due to a reduction in financing related activities and legal expenses. These decreases were partially offset by an increase in R&D expenses. Our Adjusted EBITDA margin increased from (57.1%) for the year ended December 31, 2023 to (40.9%) for the year ended December 31, 2024, as the impact of the decrease in cost of revenue and the decrease in selling, general and administrative expenses outweighed the impact of the increase in revenue.

Liquidity and Capital Resources

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. Since we commenced operations in 2015, we have generated significant losses. The Company incurred net cash outflows from operations of $10.3 million and $24.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company's accumulated deficit was $117.4 million. The Company's primary sources of liquidity are its cash collected from the sales of its products and cash flows from financing transactions. As of December 31, 2024, we had cash and cash equivalents of $5.9 million. The Company cannot provide assurance that it will ultimately achieve profitable operations and become operating cash flow positive or raise additional debt or equity capital. Additionally, the current capital resources are not adequate to continue operating and maintaining the business strategy for a period of twelve months from the issuance date of this report. Management believes that these conditions raise substantial doubt about the Company's ability to continue as a going concern for at least twelve months from the date of this Annual Report on Form 10-K.

Management's plans that are intended to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern include expanding the commercialization of Ameluz® in the United States while controlling expenses and limiting capital expenditures, as well as capitalizing on the reduced cost of inventory in line with the terms of the Second A&R Ameluz LSA. The Company also plans to secure additional capital through equity or debt financings, or the sale of assets to carry out the Company's planned commercial and development activities. However, there can be no assurance that the Company will be successful in executing the aforementioned commercial strategies and/or obtaining sufficient funding on acceptable terms, if at all, and that the substantial doubt will be alleviated. If the Company is unable to raise capital when needed, the Company will not have sufficient cash resources and liquidity to fund its business operations and the Company may be forced to delay or reduce continued commercialization efforts or R&D programs which could have a material adverse effect on the Company and its financial statements.

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, that might be necessary should the Company be unable to continue as a going concern.

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)	**2024**	**2023**
Net cash used in operating activities	$ (10,270)	$ (24,895)
Net cash provided by (used in) investing activities	(3)	619
Net cash provided by financing activities	14,835	8,411
Net increase (decrease) in cash and restricted cash	$ 4,562	$ (15,865)

Operating Activities

During the year ended December 31, 2024, operating activities used $10.3 million of cash, primarily resulting from our net loss of $17.8 million, adjusted for the add back of non-cash income of $1.3 million and offset by net cash used by changes in our operating assets and liabilities of $6.2 million. Non-cash income includes a change in fair value of warrant liabilities of $1.7 million offset by stock-based compensation of $1.0 million, non-cash interest expense of $0.3 million, loss on debt extinguishment of $0.3 million, provision for doubtful accounts of $0.2 million and depreciation and amortization in the aggregate of $1.1 million.

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.

Investing Activities

During the year ended December 31, 2024, the Company had minimal investing activities which consisted of proceeds from the sales of equity investments which were partially offset by capitalized software and computer purchases.

During the year ended December 31, 2023, investing activities provided $0.6 million, primarily resulting from the sale of shares of Biofrontera AG.

Financing Activities

During the year ended December 31, 2024, net cash provided by financing activities was $14.8 million which consisted of proceeds of $7.7 million, net of capitalized issuance costs, from the issuance of preferred stock and warrants, $7.4 million from the exercise of warrants for preferred stock, plus $4 million, net of issuance costs received from the issuance of convertible notes, offset by repayments of $4.2 million on our short-term debt, and prepayment fees of $0.2 million to extinguish our line of credit. See *Note 11. Debt, for additional information.*

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.

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.

Fair Value – Warrant Liabilities

The warrants issued in conjunction with our private placement offerings, including warrants for common stock, preferred stock and 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-Merton ("BSM") option pricing model to estimate the fair value of the warrants for common stock which is considered a Level 3 fair value measurement. Due to the uncertainty of the how the convertible preferred warrants would ultimately settle, the Company used a probability-weighted approach along with a BSM model equation to estimate the fair value of the preferred warrants under different scenarios. While we believe these assumptions were reasonable, the manner or timeframe in which the warrants ultimately settle may differ. The BSM 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 BSM pricing model may fluctuate in future periods based upon factors which are outside of the Company's control. Most significantly, 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 the aforementioned 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. At least quarterly, we review the status of each significant matter and assess its potential financial exposure considering all available information including, but not limited to, the impact of negotiations, settlements, rulings, advice of internal and external legal counsel and other updated information and events pertaining to a particular matter. If the potential loss from any claim or legal proceeding is considered probable and the amount can be reasonably estimated, we accrue a liability for the estimated loss. Significant judgment is required in assessing the likelihood of a loss being incurred and in estimating the loss or range of loss in each matter. Due to the uncertainty of litigation and the preliminary stage of the claims, we cannot estimate the possibility of a material loss, nor the potential range of loss that may result from the actions discussed in Note *19. Commitments and Contingencies – Legal Claims*. 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. See Note *19. Commitments and Contingencies – Legal Claims* for more details.

Impairment Assessment-Intangible Assets and Asset Held for Sale

In the third quarter of 2024, the Xepi intangible asset was classified as held for sale. Subsequent to the major asset being classified as held for sale, impairment assessment is no longer considered a critical estimate, and the Company does not consider the accounting under ASC 360-10-35-37 to 43 for assets held for sale to be a critical accounting estimate because of the simplistic nature of the basis of the fair value measurement. See Note *9. Assets Held for Sale.*

Prior to the classification as held for sale, the Company regularly reviewed the carrying amount of its long-lived assets to determine whether indicators of impairment may have existed that warranted adjustments to carrying values or estimated useful lives. In connection with this review, assets were grouped at the lowest level at which identifiable cash flows were largely independent of other asset groupings. If indications of impairment existed, projected future undiscounted cash flows associated with the asset grouping were compared to the carrying amount to determine whether the asset's value was recoverable. An impairment loss would be recognized when estimated undiscounted future cash flows expected to result from the use of an asset group were less than its carrying amount and if the carrying value was 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, various factors were taken 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 included changes in our strategic, operational, and financial decisions, economic conditions, demand for our product, and other corporate initiatives that may have eliminated or significantly decreased 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.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is included in *Note 2, Summary of Significant Accounting Policies—Recently Issued Accounting Pronouncements*.

Off-balance Sheet Arrangements

Besides the contractual obligations and commitments discussed in the section entitled "Liquidity and Capital Resources" above, 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, 2024 and 2023, the related consolidated statements of operations, stockholders' equity and cash flows for each of the two years in the period ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audits, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024 and 2023, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2024, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As more fully described in Note 1, the Company has incurred significant losses and needs to raise additional funds to meet its obligations and sustain its operations. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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.

Morristown, New Jersey
March 20, 2025

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

	December 31,	
	2024	**2023**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 5,905	$ 1,343
Investment, related party	7	78
Accounts receivable, net	5,315	5,162
Inventories, net	6,646	10,908
Prepaid expenses and other current assets	527	425
Asset held for sale	2,300	-
Other assets, related party	-	5,159
Total current assets	**20,700**	**23,075**
Property and equipment, net	80	134
Operating lease right-of-use assets	903	1,612
Intangible assets, net	35	2,629
Other assets	383	482
Total assets	**$ 22,101**	**$ 27,932**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,856	3,308
Accounts payable, related parties, net	5,344	5,698
Operating lease liabilities	548	691
Accrued expenses and other current liabilities	4,273	4,487
Short term debt	-	3,904
Total current liabilities	**12,021**	**18,088**
Long-term liabilities:		
Convertible notes payable	4,098	-
Warrant liabilities	1,250	4,210
Operating lease liabilities, non-current	276	804
Other liabilities	23	37
Total liabilities	**17,668**	**23,139**
Commitments and contingencies (see Note 19)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, no Series B-1, 3,366 Series B-2 and 6,763 Series B-3 shares issued and outstanding as of December 31, 2024 and no shares issued and outstanding as of December 31, 2023	-	-
Common Stock, $0.001 par value, 35,000,000 shares authorized; 8,873,932 and 1,517,628 shares issued and outstanding as of December 31, 2024 and 2023	9	2
Additional paid-in capital	121,833	104,441
Accumulated deficit	(117,409)	(99,650)
Total stockholders' equity	**4,433**	**4,793**

Total liabilities and stockholders' equity	**$ 22,101**	**$ 27,932**

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,	
	2024	**2023**
Product revenues, net	$ 37,303	$ 34,005
Revenues, related party	18	66
Total revenues, net	**37,321**	**34,071**
Operating expenses		
Cost of revenues, related party	17,855	16,789
Cost of revenues, other	752	655
Selling, general and administrative	33,793	38,975
Selling, general and administrative, related party	42	152
Research and development	2,089	77
Change in fair value of contingent consideration	-	100
Total operating expenses	**54,531**	**56,748**
Loss from operations	**(17,210)**	**(22,677)**
Other income (expense)		
Change in fair value of warrant liabilities	1,680	6,456
Warrant inducement expense	-	(1,045)
Excess of warrant fair value over offering proceeds	-	(2,272)
Change in fair value of investment, related party	(14)	(7,421)
Gain on legal settlement	-	7,385
Loss on debt extinguishment	(316)	-
Interest expense, net	(2,035)	(468)
Other income (expense), net	158	(75)
Total other income (expense)	**(527)**	**2,560**
Loss before income taxes	**(17,737)**	**(20,117)**
Income tax expense	22	14
Net loss	**$ (17,759)**	**$ (20,131)**
Loss per common share:		
Basic and diluted	$ (3.22)	$ (13.02)
Weighted-average common shares outstanding:		
Basic and diluted	5,516,334	1,546,297

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)

	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
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	-	-	-	-
Issuance of shares in reverse stock split (for fractional shares)	-	-	24,090	-	-	-	-
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
Exercise of pre-funded warrants	-	-	1,055,000	1	(1)	-	-
Conversion of Series B-1 Preferred (mezzanine) into Series B-2 Preferred and common stock	3,790	-	3,952,393	4	3,566	-	3,570
Issuance of Series B-3 Preferred upon exercise of warrants	7,998	-	-	-	12,810	-	12,810
Conversion of Series B-2 and B-3 Preferred into common stock	(1,659)	-	2,344,140	2	(2)	-	-
Issuance of shares for restricted stock units	-	-	4,771	-	-	-	-
Stock based compensation	-	-	-	-	1,019	-	1,019
Net Loss	-	-	-	-	-	(17,759)	(17,759)
Balance, December 31, 2024	10,129	$ -	8,873,932	$ 9	$ 121,833	$ (117,409)	$ 4,433

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,	
	2024	**2023**
Cash flows from operating activities:		
Net loss	$ (17,759)	$ (20,131)
Adjustments to reconcile net loss to cash flows used in operations		
Gain on legal settlement	-	(7,385)
Depreciation	92	86
Amortization of right-of-use assets	728	560
Amortization of acquired intangible assets	329	418
Realized/unrealized loss in investment, related party	14	7,421
Change in fair value of contingent consideration	-	100
Change in fair value of warrant liabilities	(1,680)	(6,456)
Warrant inducement expense	-	1,045
Excess of warrant fair value over offering proceeds	-	2,272
Stock-based compensation	1,019	1,045
Provision for inventory obsolescence	-	-
Provision for doubtful accounts	162	122
Loss on debt extinguishment	316	-
Non-cash interest expense	297	402
Changes in operating assets and liabilities:		
Accounts receivable	(315)	(1,536)
Other receivables, related party	2	6,470
Prepaid expenses and other assets	(141)	174
Other assets, related party	5,159	(5,159)
Inventories	4,233	(3,750)
Accounts payable	(1,452)	2,029
Accounts payable, related parties, net	(355)	4,386
Operating lease liabilities	(689)	(657)
Accrued expenses and other liabilities	(230)	(6,351)
Cash flows used in operating activities	**(10,270)**	**(24,895)**
Cash flows from investing activities		
Sales of investment, related party	57	624
Purchase of intangible assets	(50)	-
Purchases of property and equipment	(10)	(5)
Cash flows provided by (used in) investing activities	**(3)**	**619**
Cash flows from financing activities		
Proceeds from issuance of Series B-1 preferred stock and warrants to purchase series B-3 preferred stock, net of issuance costs	7,662	-
Proceeds from issuance of Series B-3 preferred stock from exercise of warrants	7,438	-
Proceeds from issuance of convertible notes, net of issuance costs	4,050	-
Proceeds from line of credit	-	21,448
Proceeds from issuance of common stock and warrants	-	4,507
Proceeds from short term debt	-	3,800
Payment of short-term debt	(4,315)	(21,344)

Cash flows provided by financing activities		**14,835**		**8,411**
Net decrease in cash and cash equivalents		**4,562**		**(15,865)**
Cash, cash equivalents and restricted cash, at the beginning of the year		**1,543**		**17,408**
Cash, cash equivalents and restricted cash, at the end of the year	**$**	**6,105**	**$**	**1,543**
Supplemental disclosure of cash flow information				
Interest paid	$	1,728	$	125
Interest paid, related party	$	-	$	22
Income tax paid, net	$	24	$	15
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	$	55	$	800

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, 2024 and 2023

1. Organization and Business Overview

Biofrontera Inc., a Delaware Corporation, (the "Company," "we," "us," "our," or "Biofrontera") is a United States based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's primary licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions.

The Company includes its wholly owned subsidiary Biofrontera Discovery GmbH ("Discovery"), 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 and manage our clinical trial work.

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® Lamps, 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 United States under an exclusive license and supply agreement (as amended, the "Second A&R 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.

Liquidity and Going Concern

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. Since we commenced operations in 2015, we have generated significant losses. The Company incurred net cash outflows from operations of $10.3 million and $24.9 million for the years ended December 31, 2024 and 2023, respectively. As of December 31, 2024, the Company's accumulated deficit was $117.4 million. The Company's primary sources of liquidity are its cash collected from the sales of its products, and cash flows from financing transactions. As of December 31, 2024, we had cash and cash equivalents of $5.9 million. The Company cannot provide assurance that it will ultimately achieve profitable operations and become operating cash flow positive or raise additional debt or equity capital. Additionally, the current capital resources are not adequate to continue operating and maintaining the business strategy for a period of twelve months from the issuance date of this report. Management believes that these conditions raise substantial doubt about the Company's ability to continue as a going concern for at least twelve months from the date of this Annual Report on Form 10-K.

Management's plans that are intended to mitigate the conditions that raise substantial doubt about the Company's ability to continue as a going concern, include expanding the commercialization of Ameluz® in the United States while controlling expenses and limiting capital expenditures, as well as capitalizing on the reduced cost of inventory in line with the terms of the Second A&R Ameluz LSA. The Company also plans to secure additional capital through equity or debt financings, or the sale of assets to carry out the Company's planned commercial and development activities. However, there can be no assurance that the Company will be successful in executing the aforementioned commercial strategies and/or obtaining sufficient funding on acceptable terms, if at all, and that the substantial doubt will be alleviated. If the Company is unable to raise capital when needed, it will not have sufficient cash resources and liquidity to fund its business operations and may be forced to delay or reduce continued commercialization efforts or R&D programs which could have a material adverse effect on the Company and its financial statements.

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, that might be necessary should the Company be unable to continue as a going concern.

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

The Company evaluates segment reporting in accordance with ASU 2023-07, Segment Reporting (Accounting Standards Codification ("ASC") Topic 280), *Improvements to Reportable Segment Disclosures,* each reporting period, including by evaluating the reporting package reviewed by the Company's chief operating decision maker ("CODM"). In accordance with ASU 2023-07, the Company has determined that the Chief Executive Officer functions as the CODM. The CODM manages the Company's business activities as a single operating segment at the consolidated level. Accordingly, the CODM uses consolidated net (loss) to measure segment profit or loss, allocate resources and assess performance. Further, the CODM reviews and utilizes functional expenses (cost of revenues, sales and marketing, research and development ("R&D"), and general and administrative) at the consolidated level to manage the Company's operations. All of the Company's revenues are derived from within the United States and, therefore, no geographical segments are presented.

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 ("Nasdaq") 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 United States 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 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").

Restricted Cash

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards *(see Note 8. Cash Balances and Statement of Cash Flows Reconciliation)*. Long-term restricted cash was recorded in other assets in the consolidated balance sheet.

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. The provision for credit losses is 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.

We are dependent on Biofrontera Pharma 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. This licensor may have risks associated with limited source suppliers and contract manufacturers. If our licensor fails to maintain relationships with 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, based on shipping location. 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. Accumulated depreciation was $0.6 million for each of the years ended December 31, 2024 and 2023.

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, 2023. 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, 2023.

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, 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. 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 contracts and leases that existed prior to the commencement date (i) to determine whether any expired or existing contracts are or contain leases, (ii) for lease classification, or (iii) for 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.

Assets Held for Sale

The Company generally considers assets to be held for sale when the following criteria are met: (i) management commits to a plan to sell the assets, (ii) the assets are available for sale immediately, (iii) management has initiated an active program to locate a buyer or buyers and other actions required to complete the plan to sell the assets, (iv) the sale of the assets within one year is considered probable, (v) the assets are actively being marketed for sale at a price that is reasonable in relation to their current fair value and (vi) significant changes to the plan to sell are not expected. Assets classified as held for sale are no longer depreciated and are

reported at the lower of their carrying value or fair value less estimated costs to sell in accordance with *ASC 360, Property, Plant and Equipment-Impairment or Disposal of Long-Lived Assets.* See *Note 9. Assets Held for Sale.*

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. See Note *19. Commitments and Contingencies.*

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

The Company evaluates its convertible instruments to determine if those contracts or embedded components of those contracts qualify as derivative financial instruments to be separately accounted for in accordance with ASC Topic 815: *Derivatives and Hedging*. The accounting treatment of derivative financial instruments requires that the Company record qualifying embedded conversion options and any related freestanding instruments at their fair values as of the inception date of the agreement and at fair value as of each subsequent balance sheet date. Any change in fair value is recorded as non-operating, non-cash income or expense for each reporting period at each balance sheet date. The Company reassesses the classification of its derivative instruments at each balance sheet date. If the classification changes as a result of events during the period, the contract is reclassified as of the date of the event that caused the reclassification. Embedded conversion options classified as derivative liabilities and any related equity classified freestanding instruments are recorded as a discount to the host instrument. The fair value for the warrants issued on February 22, 2024, to purchase shares of Series B-3 Convertible Preferred Stock, was estimated utilizing a probability weighted average approach, involving two scenarios; one based on the underlying value of the convertible preferred stock and the other based on the underlying value of the publicly traded common equity value. See Note *3. Fair Value Measurements* for additional information.

Debt Issuance Costs

Debt issuance costs on debt financings are deferred and amortized over the term of the debt using the interest method or the straight-line method, (if results are not materially different than the interest method). If a conversion of the underlying debt occurs prior to maturity a proportionate share of the unamortized amount is expensed. Any unamortized debt issuance costs are presented net of the related debt on the consolidated balance sheets

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. See additional information in Note *3. Fair Value Measurements.*

Fair Value of Financial Instruments

The carrying amounts reflected in the consolidated balance sheets for accounts receivable, other receivables, and accounts payable 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.

RhodoLED® Lamps are 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 and government rebates. 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 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.

Product Warranty

The Company generally provides a 36-month warranty for sales of RhodoLED® Lamps 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 negligible and $0.1 million for the years ended December 31, 2024 and 2023, 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 $0.6 million and $0.5 million for the years ended December 31, 2024 and 2023, 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 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 No. 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 and were negligible for the year ended December 31, 2024 and totaled $0.2 million for the year ended December31, 2023.

R&D Costs

R&D expenses include costs directly attributable to the clinical development of Ameluz®, including personnel-related expenses, the cost of services provided by outside contractors, including services related to the Company's clinical trials, facilities, depreciation, and other direct and allocated expenses. All costs associated with research and development are expensed as incurred.

Clinical trial costs are a significant component of our research and development expenses and include costs associated with third-party contractors. The Company outsources a substantial portion of its clinical trial activities, utilizing external entities such as Clinical Research Organizations, independent clinical investigators, and other third-party service providers to assist the Company with the execution of its clinical trials. We record accruals for estimated costs under these contracts. When evaluating the adequacy of the accrued liabilities, we analyze the progress of the studies or clinical trials, including the phase or completion of events, invoices received, contracted costs and purchase orders. Significant judgments and estimates are made in determining the accrued balances at the end of any reporting period based on the facts and circumstances known at that time. Although we do not expect the estimates to be materially different from the amounts actually incurred, actual results could differ from our 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. Payments made under these arrangements in advance of the receipt of the

related services are recorded as prepaid expenses until the services are rendered.

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.

Reclassification of Prior Year Presentation

Certain prior period amounts have been reclassified for consistency with the current period presentation. The reclassification was limited to the condensed consolidated statements of cash flow and had no impact on the reported results of operations. Specifically, accounts payable-related parties of $4.4 million was reclassed from accounts payable and related party payables for prior year presentation.

Recently Issued or Adopted Accounting Pronouncements

In November 2023, FASB issued Accounting Standards Update ("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. We adopted this ASU retrospectively on December 31, 2024. See *Note 21. Segment Reporting*.

In August 2020, FASB issued ASU 2020-06 - *Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging and Contracts in Entity's Own Equity (Subtopic 815-40)*, aimed at simplifying the accounting for certain financial instruments. ASU 2020-06 eliminates the current models that require separation of beneficial conversion and cash conversion features from convertible instruments and simplifies the derivative scope exception guidance pertaining to equity classification of contracts in an entity's own equity. Additionally, the new standard introduces enhanced disclosures for convertible debt and freestanding instruments indexed to and settled in an entity's own equity. It also amends the diluted earnings per share guidance, mandating the use of the if-converted method for all convertible instruments. ASU 2020-06 is effective for fiscal years beginning after December 15, 2023, and must be applied on a full or modified retrospective basis. We adopted the ASU effective January 1, 2024, which did not have a material impact on the Company's financial statements.

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 evaluating the effect that this guidance will have on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expense*. The new guidance requires disaggregated information about certain income statement expense line items on an annual and interim basis. This ASU is effective for public business entities for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027. The new standard permits early adoption and can be applied prospectively or retrospectively. We are evaluating the effect that this guidance will have on our consolidated financial statements and related disclosures.

In November 2024, the FASB issued ASU 2024-04, *Debt with Conversion and Other Options (Subtopic 470-20); Induced Conversions of Convertible Debt.* This ASU clarifies requirements for determining whether certain settlements of convertible debt instruments, including convertible debt instruments with cash conversion features or convertible debt instruments that are not currently convertible, should be accounted for as an induced conversion. It is effective for all entities for annual reporting periods beginning after December 15, 2025, and interim reporting periods within those annual reporting periods. Early adoption is permitted. We are currently evaluating the effect that this guidance will have on our consolidated financial statements and related disclosures.

3. 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, 2024	December 31, 2023
Assets:			
Investment, related party	1	$ 7	$ 78
Liabilities:			
Warrant liability – 2023 Purchase Warrants	3	$ 1,030	$ 3,470
Warrant liability – 2022 Purchase Warrants	3	$ 98	$ 328
Warrant liability – 2022 Inducement Warrants	3	$ 122	$ 412
Total Liabilities		$ 1,250	$ 4,210

Investment, related party

As of December 31, 2024 and 2023, the Company owned 3,019 and 8,450 common shares of Biofrontera AG, respectively. 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 13. Related Party Transactions*.

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 *14. Stockholders' Equity* for additional details.

The 2023 Purchase Warrants, the 2022 Inducement Warrants and the 2022 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 for the Level 3 warrants at December 31, 2024 and December 31, 2023 was estimated using Black-Scholes pricing model based on the following assumptions:

	December 31, 2024	December 31, 2023
Stock price	$ 1.09	$ 2.77
Expiration term (in years)	3.84	4.84
Volatility	105%	95%
Risk-free Rate	4.27%	3.82%
Dividend yield	0.0%	0.0%

The warrants issued on February 22, 2024 to purchase 8,000 shares of Series B-3 Convertible Preferred Stock, par value $0.001 per share (the "2024 Preferred Warrants"), were also accounted for as liabilities, as they were redeemable in the event of a change in control, which was not solely within the control of the Company (see Note 14. Stockholders' Equity). The 2024 Preferred Warrants were issued in the first quarter of 2024 and exercised prior to the end of the second quarter of 2024. The fair value for the Level 3 2024 Preferred Warrants was estimated utilizing a probability weighted average approach, which incorporated two scenarios. In scenario one, the warrant value was based on the underlying value of the convertible preferred stock, using an option-pricing model backsolve that solved for the value of our publicly traded equity on the valuation date to obtain the valuation date fair value of the Series B-3 Convertible Preferred Stock, then applied the Series B-3 Convertible Preferred Stock value into the BSM model equation to determine the value of the Series B-3 convertible warrants. In scenario two, the warrant value was based on the underlying value of the publicly traded common equity value. Scenario two assumes the preferred stock will be converted into Common Stock prior to a liquidity event. A simple BSM model was utilized to value the warrant under scenario two, using the closing price of our Common Stock as an input to the model. The BSM model used the following range of inputs and assumptions for the 2024 Preferred Warrants at the issuance date of February 22, 2024, for the three months ended March 31, 2024 and at the exercise date of May 13, 2024: (i) expected stock price volatility of 79.3% to 105%; (ii) risk-free interest rate of 5.39%; to 5.54%; (iii) expected life of the warrants of 0.003 to 0.21 years; and (iv) dividend yield of 0.0%. The fair value of the 2024 Preferred Warrants was $4.1 million at issuance and $5.4 million at the exercise date. See Note *14. Stockholders' Equity* for additional details.

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

	December 31, 2024	December 31, 2023
Fair value at beginning of year	$ 4,210	$ 2,843
Issuance of new warrants	4,092	6,778
Exercise of warrants	(5,372)	-
Change in fair value of warrant liability	(1,680)	(6,456)
Warrant inducement expense	-	1,045
Fair value at end of year	$ 1,250	4,210

4. Revenue

We generate revenue primarily through the sales of our licensed products, Ameluz® and BF-RhodoLED® lamps.

Related party revenue relates to an arrangement with Biofrontera Bioscience for BF-RhodoLED® leasing and installation service associated with the clinical lamps. This arrangement is no longer effective as of December 31, 2024. Refer to *Note 13, Related Party Transactions*.

5. 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, 2024, approximately $5.7 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, 2024	December 31, 2023
Cash and cash equivalents	$ 5,905	$ 1,343
Long-term restricted cash	200	200
Total cash and cash equivalent, and restricted cash shown on the statements of cash flows	$ 6,105	$ 1,543

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

6. Investment, Related Party

As of December 31, 2024 and December 31, 2023, our investment in equity securities consisted solely of 3,019 and 8,450, common shares of Biofrontera AG, respectively (See *Note 13. 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 $0.1 million and $0.6 million during the year ended December 31, 2024 and 2023, respectively.

(in thousands):	**December 31, 2024**	**December 31, 2023**
Net losses recognized during the period on equity securities	$ (14)	$ (7,421)
Less: Net realized losses on equity securities sold or transferred	98	7,219
Unrealized losses recognized during the reporting period on equity securities still held at the reporting date	(84)	(202)

7. Accounts Receivable, net

Accounts receivables are mainly attributable to the sale of Ameluz®. 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 reserve percentages are established for each pool of trade accounts receivables.

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 are recorded.

The allowance for credit losses was $0.2 million as of December 31, 2024 and 2023.

8. Inventories

Inventories are comprised of Ameluz® and RhodoLED® Lamps.

There was a negligible adjustment to realizable value recorded for the years ended December 31, 2024 and 2023. As of December 31, 2023, in connection with a 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 were to be replaced by the Ameluz Licensor at no additional cost in accordance with the Second A&R Ameluz LSA. As of July 23, 2024, we received the full amount of the replacement inventory for the recalled Ameluz®.

9. Assets Held for Sale

Assets held for sale consists of the following:

(in thousands)	December 31, 2024	December 31, 2023
Xepi® license	$ 4,600	$ -
Less: Accumulated amortization	$ (2,300)	$ -
Assets held for sale	$ 2,300	$ -

During the third quarter of 2024, the Company adopted a plan to sell its Xepi product line and determined that the intangible asset meets the criteria to be classified as held for sale in accordance with ASC 360-10-45-9. The Company is working with a potential purchaser and expects to complete a sale within the next three to six months and, as such, has classified the asset as held for sale under current assets in the Consolidated Balance Sheets. The carrying amount of the asset at the time of classification was $2.3 million, which was the lower of its carrying value or estimated fair value less cost to sell. No gain or loss was recognized in the Statement of Operations upon classification as an asset held for sale and the related revenue and expenses associated with the asset were de-minimus. This divestiture does not represent a strategic shift that will have a major effect on our consolidated results of operations and therefore is not being reported as discontinued operations.

The Xepi® license intangible asset was recorded at acquisition-date fair value of $4.6 million and was amortized on a straight-line basis over the useful life of 11 years. Prior to recording it as held for sale, amortization expense was $0.3 million and $0.4 million for the years ended December 31, 2024 and 2023, respectively.

10. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	December 31, 2024	December 31, 2023
Employee compensation and benefits	$ 2,428	$ 2,185
Professional fees	632	1,064
Research and Development	542	-
Product revenue allowances and reserves	58	149
Legal settlement	-	403
Distribution and Storage	-	118
Other	613	568
Total	$ 4,273	$ 4,487

11. Debt

Line of Credit

Effective as of January 4, 2024, we voluntarily terminated the Loan and Security Agreement with Midcap Business Credit LLC (the "Loan Agreement"), paying a total of approximately $0.4 million, consisting of (1) the outstanding principal of and interest balance due under the Loan Agreement, aggregating approximately $0.2 million, and (2) early termination fees of approximately $0.2 million.

As a result of the termination of the Loan Agreement, the Company recognized a $0.3 million loss related to prepayment fees and the write-off of deferred financing costs in the accompanying consolidated statement of operations for the year ended December 31, 2024.

Loan Facilities

On December 21, 2023, we entered into credit facilities with two different lenders (the "Loans"), each pursuant to a Business Loan and Security Agreement providing for a term loan in the principal amount of $2,000,000. Each of the Loans was evidenced by a Secured Promissory Note, effective as of December 21, 2023, and required the Company to make weekly payments of principal and interest in the amount of approximately $102,857 through July 5, 2024, the maturity date. Interest expense was recognized using the effective interest method, such that a constant effective interest rate was applied to the carrying amount of the debt at the beginning of each period until maturity. There were approximately $0.3 million of related issuance costs, recognized as a debt discount (contra liability against the debt balance), that were amortized as interest expense over the life of the loan using the effective interest method, The Company recognized discount amortization and interest expense of $0.3 million and $1.7 million for the year ended December 31, 2024 and negligible amounts for the year ended December 31, 2023. As of December 31, 2024, the Company had repaid both Loans.

Convertible Notes Payable

On November 22, 2024, the Company issued $4.2 million in an aggregate principal amount of the Company's 10.0% Senior Secured Convertible Notes (the "Notes") pursuant to a Securities Purchase Agreement entered into on November 21, 2024 with its principal stockholders.

The Notes bear interest at 10.0% per annum, payable in-kind ("PIK interest") through the issuance of additional principal on a quarterly basis. In the Event of Default (as defined in the Notes), the interest will increase to 15% per annum from the date of written notice from the holder. The Notes may be converted at any time into shares of the Company's Common Stock at a conversion price of $0.78 per share subject to customary adjustments for stock splits, stock dividends and recapitalizations, as described in the Notes.

The Notes mature on November 22, 2027, unless earlier converted or repurchased. The Company may not redeem the Notes at its option prior to maturity. Upon maturity, the Company will pay to the holders of the Notes an amount in cash representing all of the outstanding aggregate principal amount of the Notes, together with any accrued and unpaid interest. Alternatively, the entire amount of the note will be automatically converted to shares of Common Stock if the 10-day volume weighted average price of a share of the Company's Common Stock on Nasdaq is greater than 250% of the conversion price, and certain other conditions are met.

The Notes provide for customary events of default and contain conversion limitations, providing that no conversion may be made if the aggregate number of shares of Common Stock beneficially owned by the holder would exceed 9.99% immediately after conversion. There were no events of default at December 31, 2024.

The Notes are secured by substantially all property of the Company, including but not limited to the Company's assets, inventory, intellectual property and accounts.

The Notes were accounted for as a liability under ASC 470 and the embedded conversion option has been assessed under ASC 815. Based on the Company's evaluation, there were no embedded features that required bifurcation as a derivative liability.

As of December 31, 2024, the outstanding balance of the Notes was $4.1 million including PIK interest and net of unamortized issuance costs of $0.1 million.

12. Income Taxes

The components of (loss) before income taxes are as follows (dollars in thousands):

	Year ended December 31,	
	2024	2023
Domestic	$ (17,228)	$ (20,117)
Foreign	(509)	-
(Loss) before income taxes	$ (17,737)	$ (20,117)

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, 2024 and December 31, 2023. Income tax expense incurred in 2024 and 2023 relates to state income taxes. At December 31, 2024 and December 31, 2023, 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,	
	2024	2023
Income tax computed at federal statutory tax rate	21.0%	21.0%
State taxes	4.3%	5.2%
Permanent differences – non-deductible expenses	(1.0)%	(0.5)%
Change in fair value of contingent consideration	-	(0.1)%
Change in fair value of warrant liabilities	2.0%	3.3%
Gain on legal settlement	-	2.6%
True-ups	(0.6)%	(0.1)%
Federal R&D Credits	(0.0)%	0.1%
Foreign rate differential	0.1%	-
Change in valuation allowance	(25.9)%	(31.6)%
Effective income tax rate	(0.1)%	(0.1)%

The principal components of the Company's deferred tax assets and liabilities consist of the following at December 31, 2024 and 2023:

(in thousands)	December 31, 2024	December 31, 2023
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 41,154	$ 36,964
Credit Carryforward	-	8
Intangible assets	3,794	4,270
Property and equipment	140	129
Accrued expenses and reserves	404	393
Stock based compensation	937	711
Lease liability	215	391
Other	705	40
ROU asset	(235)	(422)
Investment revaluation	-	43
Total deferred tax assets	47,114	42,527
Less valuation allowance	(47,114)	(42,527)
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 2024, the valuation allowance increased by $4.5 million, primarily due to the increase in the Company's net operating loss carryforwards during the period.

As of December 31, 2024, the Company had approximately $164.5 million and $126.3 million of Federal and state net operating loss ("NOL") carryforwards, respectively. $154.9 million of the federal NOLs are not subject to expiration and the remaining NOLs

begin to expire in 2035. 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, 2024, 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, 2024, the Company had no reserves for uncertain tax positions. For the year ended December 31, 2024 no estimated interest or penalties were recognized on uncertain tax positions.

The Company's tax returns for 2021 through 2024 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, 2024, we have not completed a formal Internal Revenue Code Section 382 analysis of our equity changes.

13. Related Party Transactions

We consider Biofrontera AG and its consolidated subsidiaries, ("the Biofrontera Group") to be a related party. The Biofrontera Group held more than 5% of the outstanding shares of our common stock until December 10, 2024, and we continue to rely on the Biofrontera Group as the sole supplier of Ameluz® and the RhodoLED® Lamps.

License and Supply Agreement

Under the Second A&R Ameluz LSA, the Company has an exclusive, non-transferable license to market and sell the licensed products, Ameluz® and RhodoLED® Lamps, in the United States and must purchase the licensed products exclusively from Biofrontera Pharma. The Second A&R Ameluz LSA, among other things, amended the Ameluz LSA to:

(i) updated the price we pay per unit, based on certain percentages of the anticipated net selling price, (the "Transfer Price") that covers the cost of goods, royalties on sales, and services, including all regulatory efforts, agency fees, pharmacovigilance, and patent administration, as follows:

- Twenty-five percent of the anticipated net selling price per unit through 2025;
- Thirty percent of the anticipated net selling price per unit for 2026 to 2028;
- Thirty-two percent of the anticipated net selling price per unit for 2029 to 2031;
- Thirty-five percent of the anticipated net selling price per unit for 2032 and beyond, subject to a minimum dollar amount per unit; and
- The Transfer Price for sales related to acne, another indication currently in development, will remain at twenty-five percent of the anticipated net selling price per unit indefinitely.

(ii) provided for the transfer of responsibilities for clinical trials relating to Ameluz® in the US on June 1, 2024, including the Company assuming related contracts and transferring key personnel from the Ameluz Licensor to the Company.

The Company entered into a Release of Claims with the Ameluz Licensor, dated February 13, 2024, pursuant to which the Company agreed to release the Ameluz Licensor from all claims and liabilities arising out of or relating to any failure by the Ameluz Licensor to perform certain obligations under the Second A&R Ameluz LSA with respect to clinical trials for which the Company assumed responsibility.

On February 9, 2024, Biofrontera was notified that the 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 communications, the Ameluz Licensor confirmed that the recalled product is not likely to cause adverse health consequences. The Company did not bear any financial responsibility for the costs associated with this recall and it did not have a material financial impact on its business as a result of the recall. As of December 31, 2023, in connection with the voluntary recall by the Ameluz Licensor, the Company 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 of July 23, 2024, we received the full amount of the replacement inventory for the recalled Ameluz®.

Purchases of licensed products, inclusive of estimated and actual purchase price adjustments during the years ended December 31, 2024 and 2023 were $8.3 million and $23.4 million, respectively and recorded in inventories in the consolidated balance sheets, and, when sold, in cost of revenues, related party in the consolidated statements of operations. Amounts due and payable to Biofrontera Pharma as of December 31, 2024 and December 31, 2023 were $5.3 million and $8.5 million, respectively, and were recorded in accounts payable, related parties net of applicable accounts receivable in the consolidated balance sheets.

Service Agreements

In December 2021, we entered into an Amended and Restated Master Contract Services Agreement (the "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, and medical affairs, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine (i) if they will be needed, and (ii) whether they can or should be obtained from other third-party providers. Expenses related to the Services Agreement were negligible and $0.2 million for the years ended December 31, 2024 and 2023, respectively, and were recorded in selling, general and administrative, related party. Amounts due to Biofrontera AG related to the Services Agreement were negligible and $0.1 million as of as of December 31, 2024 and 2023, respectively, and were recorded in accounts payable, related parties in the consolidated balance sheets.

Clinical Lamp Lease Agreement

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

Total revenue related to the clinical lamp lease agreement was negligible and $0.1 million for the years ended December 31, 2024 and 2023 and recorded as revenues, related party. Amounts due from Biofrontera Bioscience for clinical lamp and other reimbursements were negligible and $0.2 million for the years ended December 31, 2024 and 2023, which were offset against accounts payable, related parties.

Other

The Company recorded a receivable of $2.8 million as of December 31, 2023, due from Biofrontera AG (presented net in accounts payable, related party) for its 50% share of the balance of a legal settlement for which both parties were jointly and severally liable. There was no interest income recognized for the years ended December 31, 2024 and 2023, in connection with this receivable and the $2.8 million balance was net settled against payments for inventory in February 2024.

The Company received expense reimbursement from Biofrontera AG and Biofrontera Bioscience on a quarterly basis for costs incurred on behalf of these entities, which are netted against expenses incurred within selling, general and administrative expenses. Total expense reimbursements were $0.3 million and $0.7 million for the years ended December 31, 2024 and 2023 respectively.

As of December 31, 2024 and December 31, 2023, our investment, related party consisted solely of 3,019 and 8,450 common shares of Biofrontera AG, respectively. The total investment had minimal value as of December 31, 2024 and $0.1 million as of December 31, 2023. See *Note 6. Investment, Related Party*.

14. Stockholders' Equity

Under the Company's Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation ("Certificate"), effective April 25, 2024, the Company is authorized to issue 35,000,000 shares of common stock, par value $0.001 per share ("Common Stock"), and 20,000,000 shares of preferred stock, par value $0.001 per share ("Preferred Stock").

Common Stock:

The holders of Common Stock are entitled to one vote for each share held. Holders of Common Stock are not entitled to receive dividends, unless declared by the Company's board of directors ("Board"). 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. As of December 31, 2024, there were 8,873,932 shares of Common Stock outstanding.

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.

In connection with the 2023 Purchase Agreement, the Company amended the 2022 Purchase Warrant and the 2022 Inducement Warrant (together, the "Existing Warrants") 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.

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

As of December 31, 2024, we had outstanding warrants to purchase an aggregate of 2,269,356 shares of Common Stock with an exercise price range of $3.55 to $100.00 per share. These warrants have expiration dates ranging from November 2026 to November 2028. A summary of the warrants outstanding as of December 31, 2024 is presented below.

Warrants	Number of Shares	Exercise Price	Expiration Date
Liability classified (See *Note 3. Fair Value Measurements*)	2,192,736	$ 3.55	11/02/2028
Equity classified	76,620	100.00	11/02/2026

Series B Preferred Stock:

On February 19, 2024, the Company entered into a securities purchase agreement (the "Preferred Purchase Agreement"), with certain accredited 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) the 2024 Preferred Warrants to purchase 8,000 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 2024 Preferred Warrant was $0.125 per share of Common Stock that each share of Series B-3 Preferred Stock may be converted into (or 11,309,019 Common Stock shares). The conversion price of Series B Preferred Stock is $0.7074 per share of Common Stock, such that each Series B share is convertible into 1,413.6 shares of the Common Stock. The net proceeds received were approximately $7.3 million, after deducting fees paid to the placement agent and other offering expenses payable by the Company. Pursuant to the Preferred Purchase Agreement, the Company may be compelled to appoint two independent directors designated by Rosalind Advisors, Inc to the Company's Board. No such appointment has

been made as of December 31, 2024.

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, with a par value of $0.001 per share (collectively the "Series B Preferred Stock").

On February 22, 2024, concurrent with the closing of the Offering, in exchange for the conversion of 1,780 shares of Series B-1 Preferred Stock, the Company issued 2,516,785 shares of Common Stock. Pursuant to the Certificate, upon the Company's stockholders' May 2024 approval of an increase in the authorized shares of Common Stock ("Stockholder Approval"), the remaining 4,806 shares of Series B-1 Preferred Stock automatically converted into Series B-2 Preferred Stock (as a conversion to Common Stock would have caused the holders to exceed their respective beneficial ownership limitations). During the third quarter of 2024, an additional 1,016 shares of Series B Preferred Stock were converted into Common Stock. As of December 31, 2024, there were 10,129 shares of Series B Preferred Stock issued and outstanding (convertible into 14,318,632 shares of Common Stock) and all of the 2024 Preferred Warrants had been exercised for Series B-3 Preferred Stock.

On May 13 and 14, 2024, 7,998 of the 2024 Preferred Warrants were exercised to purchase 7,998 shares of Series B-3 Convertible Preferred stock, par value $0.001 per share for net proceeds of $7.4 million, net of fees paid to the placement agent, while two warrants expired due to non-issuance of fractional shares. As of the exercise date, $12.8 million was applied to additional paid-in-capital, comprised of the $7.4 million of net proceeds and $5.4 of million warrant liability fair value. As of December 31, 2024, the 2024 Preferred Warrants issued in the Offering have been exercised or expired.

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.

Conversion. Subject to certain beneficial ownership limitations, at the option of the holder, each share of Series B Preferred Stock is convertible into shares of Common Stock at the applicable conversion price, rounded down to the nearest whole share. The conversion price for the Series B Preferred Stock is $0.7074 per share of Common Stock, subject to adjustment in the event of any stock dividend, stock split, combination or other similar recapitalization. Following the Stockholder Approval, each share of Series B-1 Preferred Stock was automatically converted into either Common Stock or, to the extent the conversion would cause a holder to exceed its beneficial ownership limitation, shares of Series B-2 Preferred Stock.

Liquidation. Following 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, as defined in the Certificate of Designation (any such event, a "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.

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

Mezzanine Classification

Prior to the Stockholder Approval, Series B-1 Preferred Stock was redeemable at the option of the holder and Series B-2 and B-3 Preferred Stock were redeemable in the event of a change in control. ASC 480-10-S99-3A(2) of the SEC's Accounting Series Release No. 268 ("ASR 268") requires preferred securities that are redeemable for cash or other assets to be classified outside of permanent equity if they are redeemable (i) at a fixed or determinable price on a fixed or determinable date, (ii) at the option of the holder, or (iii) upon the occurrence of an event that is not solely within the control of the issuer. Preferred securities that are mandatorily redeemable are required to be classified by the issuer as liabilities whereas under ASR 268, an issuer should classify a preferred security whose redemption is contingent on an event not entirely in control of the issuer as mezzanine equity. The Series B-1 Preferred Stock was redeemable at the option of the holder, Series B-2 Preferred Stock and Series B-3 Preferred Stock were redeemable, upon a change in control that was not solely within control of the Company. Prior to the Stockholder Approval, the Series B Preferred Stock was considered senior to the Common Stock and all other series of the Company's capital stock with respect to dividend rights and rights on the distribution of assets on any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Company. As such, the Company determined that mezzanine treatment was appropriate for the Series B Preferred Stock at issuance in February 2024 and as of March 31, 2024, and the Series B Preferred Stock was presented as such in our consolidated balance sheets and consolidated statements of changes in stockholders' equity and mezzanine equity for periods prior to the Stockholder Approval. The Series B Preferred Stock was not considered mandatorily redeemable.

Upon the Stockholder Approval, each share of Series B-1 Preferred Stock automatically converted into either Common Stock or, to the extent the conversion would cause a holder to exceed its beneficial ownership limitation, shares of Series B-2 Preferred Stock, thereby removing the redemption feature at the option of the holder (which was only present for Series B-1) and eliminating one of the requirements for classification as mezzanine equity.

Following the Stockholder Approval, upon any liquidation, the assets of the Corporation available for distribution to its stockholders will 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 filed on February 20, 2024. Accordingly, the Series B Preferred stock is classified as permanent equity on our consolidated balance sheets and consolidated statements of change in stockholders' equity as of December 31, 2024, due to the limited exception under ASC 480-10-S99-3A(3)(f).

Adoption of a stockholder rights plan. On October 13, 2022 the 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 (the "Rights Plan"). 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 (the "Rights Agreement"), 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 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.

Convertible Debt

On November 22, 2024, the Company issued $4.2 million in an aggregate principal amount of the Notes. The Notes allow for up to 5,384,615 shares of Common Stock to be issued upon conversion for principal plus additional shares for PIK interest. *See Note 11.*

Debt - Convertible Notes Payable, for additional details.

15. 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"), under which the maximum contractual term is 10 years for stock options issued. On June 12, 2024, the stockholders of the Company approved an amendment to the 2021 Plan to increase the number of shares authorized for issuance by 3,483,010 shares, from 266,990 shares to 3,750,000 shares. As of December 31, 2024, there were 1,915,602 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:

	2024	2023
Expected volatility	100%	70% - 95%
Expected term (in years)	5.24 - 6	6.0
Risk-free interest rate	4.2% - 4.3%	3.54% - 4.66%
Expected dividend yield	0%	0.0%

The total grant-date fair value of options granted during the year ended December 31, 2024 was $1.1 million. The weighted average grant-date fair value of options granted during the years ended December 31, 2024 and 2023 was $0.82 and $6.40, respectively.

Share-based compensation expense related to stock options of approximately $0.8 million and $0.7 million was recorded in selling, general and administrative expenses on the accompanying consolidated statement of operations for the years ended December 31, 2024 and 2023, respectively.

Options outstanding and exercisable under the employee share option plan as of December 31, 2024 and 2023, 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, 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	$ -
Granted	1,289,954	$ 1.37		
Exercised	-	$ -		
Canceled or forfeited	(30,722)	$ 11.77		
Outstanding at December 31, 2024	1,358,718	$ 3.88	9.36	$ 5
Exercisable at December 31, 2024	83,382	$ 34.45	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, 2024 and December 31, 2023.

As of December 31, 2024, there was $1.0 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 2.4 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 $0.2 million and $0.3 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, 2024 and 2023.

As of December 31, 2024, there was $0.4 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 1.5 years.

The following table summarizes the activity for RSUs during the year ended December 31, 2024 and December 31, 2023:

	Shares	Weighted Average Grant Date Fair Value
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
Awarded	450,000	$ 1.06
Issued	(4,771)	$ 52.20
Forfeited	-	$ -
Outstanding balance at December 31, 2024	450,000	$ 1.06

16. Interest Expense, net

Interest expense, net consists of the following:

	For years ended December 31,	
(in thousands)	2024	2023
Interest expense	(2,106)	(220)
Interest expense, related party	-	(22)
Contract asset interest expense	-	(358)
Interest income	71	132
Interest expense, net	$ (2,035)	$ (468)

Interest expense is comprised primarily of interest on our convertible notes, short-term loans and line of credit, including amortization of deferred costs.

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

17. Other Income, net

Other income, net consists of the following:

	For years ended December 31,	
(in thousands)	2024	2023
Gain on termination of operating leases	168	134
Foreign currency transactions	32	(114)
Bank service charges	(41)	(92)
Other expense	(1)	(3)
Other income (expense), net	$ 158	$ (75)

18. Net Loss per Share

Basic net loss per common share is 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 earnings per share ("EPS"). As such, the Pre-Funded Warrants were included in the outstanding shares for EPS purposes, until exercised in January 2024. Diluted net loss per common share is calculated by dividing net 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,	
	2024	2023
Net loss	$ (17,759)	$ (20,131)
Weighted average common shares outstanding, basic and diluted	5,516,334	1,546,297
Net loss per share, basic and diluted	$ (3.22)	$ (13.02)

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,	2024	2023
Common stock warrants	2,269,356	2,269,356
Common stock options and RSUs	1,808,718	104,257
Unit Purchase Options	20,182	20,182
Series B convertible preferred stock	14,318,632	-
Convertible notes	5,384,615	-
Total	23,801,503	2,393,795

19. Commitments and Contingencies

Facility Leases

The Company leases its corporate headquarters under an operating lease that expires in November 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 January 2028.

The components of lease expense for the year ended December 31, 2024 were as follows (in thousands except lease term and discount rate):

Operating Lease expense	**December 31, 2024**	**December 31, 2023**
Amortization of ROU assets (operating lease cost)	$ 728	$ 560
Interest on lease liabilities	88	84
Total lease expense	$ 816	$ 644
Other Information		
Operational cash flow used for operating leases	$ 778	$ 733
ROU assets obtained in exchange for lease liabilities	55	800
Weighted -average remaining lease term (in years)	1.55	2.22
Weighted -average discount rate	8.22%	7.76%

Future lease payments under non-cancelable leases as of December 31, 2024 were as follows (in thousands):

Years ending December 31,	**Future lease commitments**
2025	589
2026	246
2027	44
2028	1
Thereafter	-
Total future minimum lease payments	$ 880
Less imputed interest	$ (56)
Total lease liability	$ 824

Reported as:	**December 31, 2024**
Operating lease liability, current	$ 548
Operating lease liability, non-current	276
Total	824

Second A&R Ameluz LSA Sales Commitment

The Second A&R Ameluz LSA will remain in effect for 15 years from its effective date and shall renew automatically for a period of five years, in perpetuity, so long as we have earned revenues from Ameluz product and lamps equal to or greater than $150 million over the preceding five years. If we fail to earn $150 million in revenues from Ameluz® and the RhodoLED® Lamps over the preceding five (5) year period prior to the Second A&R Ameluz LSA's termination date, Biofrontera Pharma has the right to terminate the Second A&R Ameluz LSA by providing one (1) year written notice.

In addition, starting in 2025, under the Second A&R Ameluz LSA, we are to purchase the higher of (i) a minimum quantity of tubes of Ameluz® per year as set forth in the Second A&R Ameluz LSA or (ii) 75% of the annual average of audited Ameluz® tubes sold during the preceding four (4) full calendar years ("Annual Minimum Sales"). If we fail to achieve the respective Annual Minimum Sales for any calendar year, such failure will constitute a termination event, unless waived by the Ameluz Licensor.

Ameluz® Minimum Research and Development Costs

During the years 2025 through 2030, we will be required to fund minimum R&D costs in an amount that is at least 85% of the difference between (i) the Transfer Price for product, effective February 13, 2024 and (ii) the Transfer Price for product as it would have been determined under the previous version of the license and supply agreement with the Ameluz Licensor, dated October 8, 2021. If we fail to meet the minimum requirement, the difference shall be paid to Biofrontera Pharma on February 15, 2031, in either cash or our Common Stock, at our discretion.

Licensing Agreement with Optical Tools

On December 2, 2022, the Company entered into the technology transfer agreement with Optical Tools LLC ("Optical Tools"), Stephen Tobin and Paul Sowyrda (the "Agreement"). The Agreement allowed for the transfer of the assigned patents and trademarks, and upon notification by the Company to Optical Tools, the research and development of certain prototypes. The Company paid a licensing fee of $0.2 million which was expensed during the year ended December 31, 2022.

On May 28, 2023, the Company authorized Optical Tools to design, develop, manufacture, and deliver at least two portable photodynamic therapy lamp prototypes ("PDT Device") using the technology in the assigned patents. The PDT Device provides illumination, based on different light profiles, to the external skin surface of the human body. The Company is to reimburse Optical Tools for all reasonable out-of-pocket, material and labor costs per the Agreement.

As part of the Agreement, Optical Tools will be eligible to receive regulatory and sales milestone payments totaling up to $1.0 million, and royalties of up to 3% of net revenue of certain products developed under this Agreement.

The Company did not make any milestone or royalty payments or accruals for such payments during the years ended December 31, 2024 or 2023.

Milestone payments with Ferrer Internacional S.A.

Under the Xepi license and supply agreement 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 or accruals for such payments were made during the years ended December 31, 2024 or 2023 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.

Legal Claims

On September 13, 2023, Biofrontera was served with a complaint filed by DUSA Pharmaceuticals, Inc., Sun Pharmaceutical Industries, Inc. ("Sun"), and Sun Pharmaceutical Industries LTD in which DUSA alleges i) breach of contract, ii) violation of the Lanham Act, and iii) unfair trade practices under Massachusetts law. 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 United States District Court for the District of Massachusetts, this matter has been transferred by agreement of the parties to the United States District Court for the District of New Jersey. In March of 2024, Biofrontera Company filed a partial motion to dismiss the Lanham Act and Massachusetts statutory claims, which was denied on October 15, 2024. Biofrontera subsequently answered Sun's complaint and filed counterclaims on October 30, 2024 alleging i) violation of the Lanham Act, ii) deceptive trade practices under Georgia law, and iii) trade libel/product disparagement, which Sun answered on December 17, 2024. On March 11, 2025, Biofrontera received an additional notice alleging breach of contract through unlawful marketing practices which makes reference to similar previous communications sent by Sun to Biofrontera on February 4, 2022 and September 9, 2022.

Discovery is ongoing in the above-referenced matters. The Company denies the claims brought by Sun and intends to defend them 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.

Separately, on June 26, 2024 and June 27, 2024, Sun filed two complaints against Biofrontera, Biofrontera AG, Biofrontera Pharma, and Biofrontera Bioscience with the United States District Court for the District of Massachusetts and the International Trade Commission ("ITC"), both alleging infringement of two patents held by Sun (the "Sun Patents"). The complaint filed in the United States District Court for the District of Massachusetts has been held in abeyance pending the completion of the case before the ITC. A hearing is scheduled to be held in front of an administrative law judge on June 30, 2025, with an Initial Determination expected by October 1, 2025. The Commission's Final Determination is expected by February 2, 2026.

The Company denies Sun's patent claims and intends to defend them vigorously in the above-referenced matters. In addition, Biofrontera has challenged the validity of the Sun Patents by filing separate petitions for inter partes review at the United States Patent Trial and Appeal Board ("PTAB") for each of the Sun Patents. One such petition was instituted by the PTAB on February 24, 2025, and an institution decision on the other petition is anticipated to be received from the PTAB in June, 2025.

Based on the Company's assessment of the facts underlying the above-referenced patent matters, as well as the uncertainty of litigation, the Company cannot estimate the possibility of a material loss, nor the potential range of loss that may result from either action. Money damages are not available to Sun through the case before the ITC, and an adverse ruling could result in an exclusion order being imposed on the allegedly infringing product. If the final resolution of the case before the United States District Court for the District of Massachusetts is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

20. 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 $0.2 million and $0.3 million for the years ended December 31, 2024 and 2023, respectively.

21. Segment Reporting

The Company operates as one operating segment, that derives revenue primarily from our principal licensed product, Ameluz®, which is a prescription drug approved for use in PDT using our RhodoLED® Lamps, for the treatment of actinic keratoses. We are currently selling Ameluz® for this indication in the United States under an exclusive license and supply agreement. Ameluz® (including the RhodoLED® Lamps) accounts for approximately 100% of our revenue.

The Company's CODM is its Chief Executive Officer, who reviews financial information presented on a consolidated basis. The CODM uses consolidated net income to allocate resources and assesses financial performance by comparing actual results to historical results and previously forecasted financial information.

The following table presents selected financial information with respect to the Company's single operating segment for the years ended December 31, 2024, and 2023**:**

(*in thousands)*	**December 31, 2024**	**December 31, 2023**
Revenues, net	**37,321**	**34,071**
Operating expenses:		
Cost of revenues	18,607	17,444
Direct sales	9,058	10,940
Sales support	8,498	9,698
General and administrative	16,279	18,489
Research and development	2,089	77
Other operating expenses	-	100
Total operating expenses	54,531	56,748
Loss from operations	**(17,210)**	**(22,677)**
Other income (expense), net	(527)	2,560
Loss before income taxes	**(17,737)**	**(20,117)**
Income tax expenses	22	14
Net loss	**$ (17,759)**	**$ (20,131)**

22. Subsequent Events

We have completed an evaluation of subsequent events after the balance sheet date of December 31, 2024 through the date this Annual Report on Form 10-K was filed with the SEC. There have been no subsequent events that occurred during such period that would require disclosure in or would be required to be recognized in the financial statements as of December 31, 2024.

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, 2024, 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, 2024 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, 2024.

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, 2024.

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, 2024 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, 2024, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2024 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, 2024, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2024 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, 2024, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2024 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, 2024, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2024 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, 2024, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2024 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).
3.6	Certificate of Second Amendment to the Amended and Restated Certificate of Incorporation of Biofrontera Inc. filed April 25, 2024 (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed with the SEC on April 30, 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 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)
4.6	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)
4.7	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).
4.8	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)
4.9	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).
4.10	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)
4.11	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)
4.12	Form of Senior Secured Convertible Note dated November 22, 2024 (incorporated by reference to Exhibit 4.1 of the Company's Current Report on Form 8-K filed with the SEC on November 27, 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	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).
10.7	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).
10.8	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).
10.9†	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).

10.10†	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).
10.11†	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).

10.12†	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).
10.13†	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).
10.14†	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 filed with the SEC on October 12, 2021).
10.15#	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).
10.16	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).
10.17	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).
10.18†	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).
10.19	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).
10.20	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)
10.21	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)
10.22	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)
10.23†	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)
10.24	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)
10.25#	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)
10.26	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)
10.27	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)

10.28	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)
10.29	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)
10.30	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)
10.31	Amended and Restated Business Loan and Security Agreement between Biofrontera Inc. and Agile Capital Funding, LLC and Agile Lending, LLC, dated as of December 21, 2023 (incorporated by reference to Exhibit 10.34 of the Company's Form 10-K filed with the SEC on March 15, 2024)
10.32	Business Loan and Security Agreement between Biofrontera Inc. and Cedar Advance, LLC, dated as of December 21, 2023 (incorporated by reference to Exhibit 10.35 of the Company's Form 10-k filed with the SEC on March 15, 2024)
10.33	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)
10.34	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)
10.35	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)
10.36	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)
10.37	Form of Securities Purchase Agreement, dated February 19, 2024, by and among 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)
10.38	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)
10.39	Form of Securities Purchase Agreement dated November 21, 2024 (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on November 27, 2024)
10.40	Security Agreement dated as of November 21, 2024 between the Company and the Collateral Agent (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on November 27, 2024)
10.41†	2021 Omnibus Incentive Plan (as amended and restated (as amended and restated on June 12, 2024) (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on June 14, 2024)
19.1*	Insider Trading Policy
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 (incorporated by reference to Exhibit 97.1 in the Company's Form 10-K filed with the SEC on March 15, 2024)
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 20, 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 20, 2025
/s/ E. Fred Leffler E. Fred Leffler	Chief Financial Officer (*Principal Financial Officer)* *(Principal Accounting Officer)*	March 20, 2025
/s/ John J. Borer John J. Borer	Director	March 20, 2025
/s/ Beth J. Hoffman Beth J. Hoffman	Director	March 20, 2025
/s/ Heikki Lanckriet Heikki Lanckriet	Director	March 20, 2025
/s/ Kevin D. Weber Kevin D. Weber	Director	March 20, 2025

Exhibit 4.1

DESCRIPTION OF REGISTERED SECURITIES

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

Common Stock

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

In the event of our liquidation, dissolution or winding up, holders of our common stock will be entitled to share ratably in all assets remaining after payment of all debts and other liabilities and any liquidation preference of any outstanding preferred stock. The shares as part of the units to be issued by us in this offering will be, when issued and paid for, validly issued, fully paid and non-assessable.

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

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

Warrants

The following summary of certain terms and provisions of the warrants to purchase one share of our common stock issued in connection with our initial public offering is not complete and is subject to, and qualified in its entirety by, the provisions of the warrant agent agreement between us and Computershare Trust Company, N.A., as warrant agent, and the form of warrant, both of which are filed as exhibits to our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 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, 2024.

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 19.1

BIOFRONTERA INC

INSIDER TRADING POLICY

This Insider Trading Policy (the "Policy") describes the standards of Biofrontera, Inc and its subsidiaries (the "Company") on trading, and causing the trading of, the Company's securities or securities of certain other publicly traded companies by directors, officers, and employees of the Company while in possession of confidential information ("Insider Trading"). The prohibition of Insider Trading also applies to Biofrontera shares acquired in connection with the Company's employee stock option plans.

The purpose of this document is to ensure the persons referred to above, as well as persons connected with them such as immediate family members, do not abuse inside information they may have or may be thought to have. Failure to comply with this Policy is a serious disciplinary matter. Insider Trading and market manipulation are crimes.

In general, Insider Trading occurs when a person uses material, nonpublic information obtained through involvement with the Company to make decisions to purchase, sell, give away or otherwise trade the Company's securities or to provide that information to others outside the Company. The prohibitions against Insider Trading apply to trades, tips, and recommendations by virtually any person, including all persons associated with the Company, if the information involved is "material" and "nonpublic." These terms are defined in this Policy under Part I, Section 3 below. The prohibitions would apply to any director, officer or employee who buys or sells Company securities based on material, nonpublic information that he or she obtained about the Company, its customers, suppliers, or others with which the Company has contractual relationships or may be negotiating transactions.

This Policy is divided into two parts: Part I prohibits trading in certain circumstances and applies to all directors, officers and employees of the Company and their respective immediate family members. Part II imposes special additional trading restrictions and applies to all (i) directors of the Company, (ii) officers of the Company at the level of Vice President and above and (iii) all other employees who are informed by the Compliance Officer that they have been deemed by the Company as a "Section 16 Person" (collectively, "Covered Persons"). For purposes of this Policy, the term "directors" means and includes any member of the board of directors or other governing body of Biofrontera Inc.

Biofrontera Inc Insider Trading Policy
Rev: August 2023

PART I

Part I of this policy applies to all directors, officers and employees of the Company and their respective immediate family members. It prohibits trading of the Company's securities under certain circumstances, provides definitions and explains the consequences in case of violation of this Policy.

1. Applicability

This Policy applies to all trading or other transactions in the Company's securities, including ordinary shares, options, and any other securities that the Company may issue, such as preferred shares, notes, warrant bonds, convertible bonds, other bonds, and convertible securities, as well as to derivative securities relating to any of the Company's securities, whether or not issued by the Company.

This Policy applies to all directors, officers, and employees of the Company, as well as any employee family members or casual acquaintances who may come into possession of insider information.

2. General Policy: No Trading or Disclosure of Information Which May Then Lead To Trading While in Possession of Material, Nonpublic Information

a) No director, officer, or employee or any of their immediate family members may purchase or sell, or offer to purchase or sell, any Company security, whether or not issued by the Company, while in possession of material, nonpublic information about the Company. (The terms "material" and "nonpublic" are defined in Part I, Section 3(a) and (b) below.)

b) No director, officer, or employee or any of their immediate family members in possession of any material, nonpublic information about the Company may communicate that information to (a "tip") any other person, including family members, friends, or casual acquaintances, or otherwise disclose such information without the Company's authorization.

c) No director, officer, or employee, or any of their immediate family members or acquaintances may purchase or sell any security of any other company, whether or not issued by the Company, while in possession of material, nonpublic information about that company that was obtained during his or her involvement with the Company. No director, officer, employee or any of their immediate family members or acquaintances who knows of any such material, nonpublic information may communicate that information to, or tip, any other person, including family members and friends, or otherwise disclose such information without the Company's authorization.

d) For compliance purposes, you should never trade, tip, or recommend securities (or otherwise cause the purchase or sale of securities) while in possession of information that you have reason to believe is material and nonpublic. If you are unsure if certain information is material and/or nonpublic, you should first consult with, and obtain the advance approval of the Compliance Officer (which is defined in Part I, Section 3(c) below) prior to making a trade, tip, or recommending securities.

e) These restrictions continue to apply to transactions in the Company's securities even after termination of your service to the Company. If you possess material, nonpublic information when your service to the Company terminates, you may not trade in the Company's securities until that information has become public or is no longer material.

f) Covered Persons must "pre-clear" all trading in securities of the Company in accordance with the procedures set forth in Part II, Section 3 below.

g) This Policy also applies to any entities that you influence or control, including any corporations, trusts, or partnerships. Transactions in the Company's securities by these controlled entities should be treated - for the purposes of this Policy and applicable securities laws - as if they were for your own account.

h) You are responsible to ensure that you and your family members comply with this Policy. In all cases, the responsibility for determining whether an individual is in possession of material, nonpublic information rests with that individual, and any action on the part of the Company or the Compliance Officer or any other employee, officer or director does not in any way constitute legal advice or insulate you from liability under applicable securities laws.

3. Definitions

a) **Material**. Insider Trading restrictions come into play only if the information you possess is "material". Materiality, however, involves a relatively low threshold. Information is generally regarded as "material" if it has market significance, that is, if its public dissemination is likely to affect the market price of securities, or if it otherwise is information that a reasonable investor would want to know before making an investment decision. Information dealing with the following subjects is reasonably likely to be found material in particular situations (note that this list is not intended to be an exclusive list):

- earnings information and financial results;
- the Company's strategic plans;
- significant changes in the Company's prospects or objectives;
- pharmaceutical approvals and other regulatory actions by the US Food & Drug Administration ("FDA") or other regulators;
- significant write-downs in assets or increases in reserves;
- developments regarding significant litigation or investigations by any governmental authority;
- liquidity problems;
- changes in earnings estimates or unusual gains or losses in major operations;
- major changes in management;
- changes in dividends;
- significant financing transactions;
- award or loss of a significant contract;
- changes in debt ratings;
- proposals, plans or agreements, even if preliminary in nature, involving mergers, acquisitions, divestitures, recapitalizations, strategic alliances, licensing arrangements, or purchases or sales of substantial assets; and
- offerings of Company securities.

Material information is not limited to historical facts but may also include projections and forecasts. With respect to a future event, such as a merger, acquisition or introduction or regulatory approval of a new product or product candidate, the point at which negotiations or product developments are determined to be material is determined by balancing the probability that the event will occur against the magnitude of the effect the event would have on a company's operations or share price should it occur. Thus, information concerning an event that would have a large effect on the share price, such as a merger, may be material even if the possibility that the event will occur is relatively low. **When in doubt whether information is considered material, you should either consult with the Compliance Officer or assume that the information is material.**

b) **Nonpublic**. Insider Trading prohibitions come into play only when you possess information that is material and "nonpublic". The fact that information has been disclosed to a few members of the public does not make it public for Insider Trading purposes. To be considered public, the information must have been disseminated in a manner designed to reach the investor community generally, and the investors must be given the opportunity to absorb the information.

Nonpublic information may include:

- information available to a select internal group of directors, officers and employees of the Company;
- information available to a select group of analysts or brokers or institutional investors;
- undisclosed facts that are the subject of rumors, even if the rumors are widely circulated; and
- information that has been entrusted to the Company on a confidential basis until a public announcement of the information has been made and enough time has elapsed for the market to respond to a public announcement of the information (normally two trading days).

As with questions of materiality, if in doubt whether information is considered public, you should either consult with the Compliance Officer or assume that the information is nonpublic and treat it as confidential.

c) **Compliance Officer.** The Company has appointed the Corporate Counsel as the Compliance Officer for this Policy. The duties of the Compliance Officer include, but are not limited to, the following:

- assisting with implementation and enforcement of this Policy;
- circulating this Policy to all employees and ensuring that this Policy is amended as necessary to remain up to date with Insider Trading laws;
- pre-clearing all trading in securities of the Company by Covered Persons in accordance with the procedures set forth in Part II, Section 3 below;
- providing approval of any US Rule 10b5-1 plans under Part II, Section 1(c) below;
- providing a reporting system with an effective whistleblower protection mechanism, which you can find under the following link: www.lighthouse-services.com/biofrontera; and
- preparing and maintaining insider lists for review by financial market authorities upon request.

4. Blackout Periods and Trading Windows

a) **Quarterly Blackout Periods.** Announcement of quarterly financial results almost always has the potential to have a material effect on the market for its securities. Therefore, to avoid even the appearance of trading based on material, non-public information, and to assist compliance with Insider Trading laws, the Company has created the following blackout periods during which all Company employees may not trade in the securities of the Company.

- From December 16 until the end of the second trading day following public announcement of fourth quarter and year-end financial results;
- From March 6 until the end of the second trading day following public announcement of first quarter financial results;
- From June 16 until the end of the second trading day following public announcement of second quarter financial results; and
- From September 16 until the end of the second trading day following public announcement of third quarter financial results.

b) **Other Blackout Periods.** From time to time, other types of material, nonpublic information regarding the Company (such as negotiation of mergers, acquisitions or dispositions or new product approvals or other developments) may be pending and not be publicly disclosed. While such material, nonpublic information, is pending, the Company may impose special blackout periods during which all or a specific group of Company employees are prohibited from trading in the Company's securities. If the Company imposes a special blackout period, it will notify the affected employees in writing.

c) **Trading Windows.** Company employees are permitted to trade in the Company's securities when no blackout period, as described above, is in effect. Generally, this means that Company employees can trade during the period beginning on the second trading day after the publication of the quarterly financial results and ending 15 days after the end of the Company's fiscal quarter. However, even during a trading window, Company employees who are in possession of any material, nonpublic information are prohibited from trading in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close a trading window, if a special blackout period under Part I, Section 4(b) above is imposed and will re-open the trading window once the special blackout period has ended.

5. Violations of Insider Trading Laws

Penalties for trading on or communicating material, nonpublic information under the securities laws of the United States, can be severe, both for individuals involved in such unlawful conduct and their employers and supervisors.

Legal penalties may include jail terms, criminal fines, civil penalties, and civil enforcement injunctions. Given the severity of the potential penalties, compliance with this Policy is mandatory.

In addition to legal penalties, employees who violate this Policy or any applicable Insider Trading laws may be subject to disciplinary action by the Company, including dismissal for cause. The Company reserves the right to determine, on its own discretion and based on the information available, whether this policy has been violated. The Company may determine that a specific conduct violates this Policy, whether or not the conduct also violates the law. It is not necessary for the Company to await the filing or conclusion of a civil or criminal action against the alleged violator before taking disciplinary action.

6. Questions about the Policy

If you have any questions regarding any of the provisions of this Policy, please contact the Company's CFO, Corporate Counsel, or Compliance Department (compliance@bfinc.com).

7. Inquiries from Investors, Media, Analysts, Etc.

From time to time, you may be asked questions concerning various activities of the Company outside the scope of your regular duties. Such inquiries may come from the media, securities exchanges, analysts and others regarding the Company's business, rumors, trading activity, current and future prospects and plans, acquisition or divestiture activities and other similar important information.

It is very important that all such communications on behalf of the Company be made through an appropriately designated officer. Failure to do so could result in violations of securities laws. Accordingly, all inquiries of this nature must be forwarded to the Company's CFO, Corporate Counsel, or Compliance Department (compliance@bfinc.com).

PART II

In accordance with Section 16 of the Securities Exchange Act of 1934 and the underlying rules and regulations promulgated by the U. S. Securities and Exchange Commission ("SEC"), the second part of this policy imposes special additional trading restrictions that apply to (i) each member of the Company's Board of Directors, (ii) officers of the Company at the level of Vice President and above, and (iii) all other employees who are informed by the Compliance officer that they have been deemed by the Company as a "Section 16 Person" (collectively, "Covered Persons").

1. Blackout Periods and Trading Windows

a) **Blackout Periods.** As with all Company employees, Covered Persons are subject to certain blackout periods, as described in Part I, Section 4(a, b) above.

b) **Trading Windows** Subject to Part II, Section 2 below, Covered Persons are permitted to trade in the Company's securities when no blackout period is in effect. Generally, this means that Covered Persons can trade during the period beginning on the second trading day after the publication of the quarterly financial results and ending 15 days after the end of the Company's fiscal quarter However, even during a trading window, a Covered Person who is in possession of any material, nonpublic information is prohibited from trading in the Company's securities until the information has been made publicly available or is no longer material. In addition, the Company may close a trading window if a special blackout period under Part II, Section 1(b) above is imposed and will re- open the trading window once the special blackout period has ended.

c) **Retirement Plan Blackout Periods**. Directors and executive officers of the Company are prohibited from trading in the Company's securities during a blackout period imposed under an "individual account" retirement or pension plan of the Company, during which at least 50% of the plan participants are unable to purchase, sell or otherwise acquire or transfer an interest in the Company's securities, due to a temporary suspension of trading by the Company or the plan fiduciary.

d) **Exception**. These trading restrictions do not apply to transactions under a pre-existing written plan, contract, instruction, or arrangement under Rule 10b5-1 under the U.S. Securities Exchange Act of 1934 (an "Approved 10b5- 1 Plan") that:

- has been reviewed and approved at least one month in advance of any trades thereunder by the Compliance Officer (or, if revised or amended, such revisions or amendments have been reviewed and approved by the Compliance Officer at least one month in advance of any subsequent trades);
- was entered into in good faith by the Covered Person at a time when the Covered Person was not in possession of material, nonpublic information about the Company; and
- gives a third party the discretionary authority to execute such purchases and sales, outside the control of the Covered Person, so long as such third party does not possess any material, nonpublic information about the Company; or explicitly specifies the security or securities to be purchased or sold, the number of securities, the prices and/or dates of transactions, or other formula(s) describing such transactions.

2. Pre-clearance of Securities Transactions

a) Because Covered Persons are likely to obtain material, nonpublic information on a regular basis, the Company requires all such persons to refrain from trading, even during a trading window under Part II, Section 2 above, without first pre-clearing all transactions in the Company's securities.

b) Subject to the exemption in subsection (h) below, no Covered Person may, directly or indirectly, purchase or sell (or otherwise make any transfer, gift, pledge, or loan of) any Company security at any time without first obtaining prior approval from the Compliance Officer. These procedures also apply to transactions by the Covered Person's spouse, other persons living in the same household and minor children and to transactions by entities over which the Covered Person exercises control.

c) Any Covered Person who would like to hold the Company's securities in a margin account or to pledge the Company's securities as collateral must obtain prior approval from the Compliance Officer. Securities held in a margin account may be sold by the broker without the customer's consent if the customer fails to meet a margin call. Similarly, securities pledged as collateral for a loan may be sold in foreclosure if the borrower defaults on the loan. Because a margin sale or foreclosure sale could occur at a time when a Covered Person has material, nonpublic information or is otherwise not permitted to trade in Company securities, prior approval is needed.

d) All hedging transactions, including prepaid variable forwards, equity swaps, or collars or any other transactions that are designed to or have the effect of hedging or offsetting any decrease in the market value of the Company's securities must receive the prior approval of the Compliance Officer.

e) Short sales of Company securities (*e.g.*, the sale of a security that the seller does not own) may evidence the seller's expectation that the securities will decline in value, and therefore have the potential to signal to the market that the seller lacks confidence in the Company's prospects. Short sales may also reduce a seller's incentive to seek to improve the Company's performance. As a result, Covered Persons must receive prior approval from the Compliance Officer for any short sales of the Company's securities.

f) Transactions in options may cause Covered Persons to focus on short-term performance at the expense of the Company's long-term objectives. Accordingly, Covered Persons must obtain prior approval from the Compliance Officer before trading in put options, call options or other derivative securities related to the Company's securities, on an exchange or in any other organized market. This restriction does not apply to the grant or exercise of employee and director options issued by the Company.

g) The Compliance Officer shall record the date each request is received and the date and time each request is approved or disapproved. Unless revoked, a grant of permission will normally remain valid until the close of trading two business days following the day on which it was granted. If the transaction does not occur during the two-day period, pre-clearance of the transaction must be re- requested.

h) Pre-clearance is not required for purchases and sales of securities under an Approved 10b5- 1 Plan. With respect to any purchase or sale under an Approved 10b5-1 Plan, the third-party effecting transactions on behalf of the Covered Person should be instructed to send duplicate confirmations of all such transactions to the Compliance Officer.

ACKNOWLEDGMENT AND CERTIFICATION

I, the person signing below, hereby acknowledge receipt of the Company's Insider Trading Policy. I have read and understand (or has had explained) such Policy and agree to be governed by and to always comply with such Policy in connection with the purchase and sale of securities and the confidentiality of nonpublic information.

If I become aware of any violation of this Policy, I agree to promptly notify the Compliance Officer and/or use the Company's anonymous Whistleblower Hotline www.lighthouse- services.com/biofrontera to report the violation.

_____
(Signature)

_____
(Please print name)

_____
(Date)

Exhibit 21.1

List of Subsidiaries of the Company

Discovery GmbH	Germany
Biofrontera Life Science LLC	Texas

Exhibit 23.1

INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM'S CONSENT

We consent to the incorporation by reference in the Registration Statement of Biofrontera Inc. on Form S-1 (File No. 333-265467, 333-268124, 333-274871, 333-276535, 333-277811, and 333-279090) and Form S-8 (File No. 333-265463 and 333-283208) of our report dated March 20, 2025, which includes an explanatory paragraph as to the Company's ability to continue as a going concern, with respect to our audits of the consolidated financial statements of Biofrontera Inc. as of December 31, 2024 and 2023 and for the years ended December 31, 2024 and 2023, which report is included in this Annual Report on Form 10-K of Biofrontera Inc. for the year ended December 31, 2024.

/s/ Marcum LLP

Marcum LLP
Morristown, New Jersey
March 20, 2025

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: 3/20/2025

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: 3/20/2025

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, 2024 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: 3/20/2025

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, 2024 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: 3/20/2025

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.