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, 2025

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.)**
660 Main Street, 1st Floor **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
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, 2025, 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 $6.9 million, based on the closing price of the registrant's common stock.

As of March 16, 2026, there were 11,648,323 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, 2025 are incorporated by reference into Part III of this Form 10-K.

TABLE OF CONTENTS

BASIS OF PRESENTATION

As used in this Annual Report on Form 10-K for the fiscal year ended December 31, 2025 (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.

TRADEMARKS, TRADE NAMES, AND SERVICE MARKS

All trademarks, trade names, and service marks appearing in this Form 10-K are the property of their respective owners. Solely for convenience, the trademarks and trade names in this Form 10-K are referred to without the symbols ® and ™, but such references should not be construed as any indication that their respective owners will not assert their rights thereto to the fullest extent under applicable law. We do not intend to use or display other companies' trademarks, trade names, or service marks to imply a relationship with, or endorsement or sponsorship of us by, any other companies.

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 products;
- our ability to expand, manage and maintain our direct sales and marketing efforts, including our ability to obtain the financing to develop our marketing strategy, if needed;
- changes in our relationship with our manufacturing partners and the possible impact of tariffs;
- our ability to manufacture our products;
- our ability to adequately protect our intellectual property and operate the 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 ("GPOs") in the healthcare industry;
- the willingness of healthcare providers to purchase our 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 products;
- the fact that product quality issues or product defects may harm our business;
- any claims brough against the Company, including but not limited to product liability claims, claims of patent infringement, or claims challenging the validity of our intellectual property;
- 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 products;
- our ability to obtain and maintain the regulatory approvals necessary for the marketing of our 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 engaging in the development, manufacturing, and commercialization of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's products, which include Ameluz as well as the BF-RhodoLED and RhodoLED XL lamp series (together, the "RhodoLED Lamps"), are used for the treatment of actinic keratosis ("AK"), a common skin condition characterized by the growth of pre-cancerous lesions (or "AKs"). With our national commercial team, we generate revenue by selling our products directly to dermatology offices and groups.

We were formed in 2015 as Biofrontera Inc., a Delaware corporation, and a wholly owned subsidiary of Biofrontera AG, a stock corporation organized under the laws of Germany. In 2021, we completed our initial public offering. 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 through Discovery, our wholly owned subsidiary that was formed in Germany in 2022. 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.

On October 20, 2025, we entered into i) an Asset Purchase Agreement (the "Transfer Agreement") and ii) an Earnout Agreement (together with the Transfer Agreement, the "Agreements"), with the Biofrontera Group, pursuant to which the Company acquired all rights in the United States to Ameluz and RhodoLED (the "Strategic Transaction"). See *Note 3. Asset Acquisition* and *Note 16. Related Party Transactions* for additional information.

On November 6, 2025, the Company completed the sale of the intangible asset relating to its Xepi product line, a long-lived asset previously classified as held for sale. See *Note 9. Assets Held for Sale*, for additional information.

Our Strategy

Our principal objective is to improve patient outcomes in the non-melanoma space through adoption and use of our 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 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; and

- strategically manage our 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, 2025, the Company had a total of 92 employees comprised of 75 employees (72 full-time and three part-time) in the United Sates and 19 employees located in Germany (12 full-time and seven part-time).

Significant Customers

We have a wide and diverse customer base with no single customer dominating our revenues. At December 31, 2025, no customer represented more than 10% of the net accounts receivable balance. For the year ended December 31, 2025, no customer represented more than 10% of net revenues. However, many of our existing and potential customers for our products have combined or could choose to combine in the near future to form GPOs in an effort to lower costs. See *GPO Risk Factor in Item 1A. Risk Factors- Risks Related to Our Business Strategy*.

Ameluz and RhodoLED Lamps

Our principal 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 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]

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 fast growing cells at a faster rate compared to healthy cells; and

- the second step is activation of the photosensitizer by controlled exposure to a selective light source in the presence of oxygen to selectively destroy the fast growing cells.

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, 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, leading educational, CME- and non-CME programs, participating in thought leader advisory boards and focus groups, and offering reimbursement resources in order to educate the market on the use and benefits of Ameluz PDT.

---

[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 products in the United States through the use of our own commercial organization. We have a single sales force who markets all our products across the dermatology space. We launched the commercialization of Ameluz in combination with the RhodoLED lamp for the treatment of AK 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 three well established PDT Current Procedural Terminology ("CPT") Codes related to Ameluz PDT treatments: 1) code number 96567, which has an average reimbursement of $129.26 per light treatment, 2) code number 96573, which has an average reimbursement of $217.44 per light treatment performed by qualified health care professional, or 3) code number 96574 which has an average reimbursement of $266.87 per debridement of a hyperkeratotic AK lesion followed by a light treatment performed by a qualified health care professional.

Our R&D programs

Effective June 1, 2024, 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. 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.

Effective October 20, 2025, we acquired all rights in the United States to Ameluz and the RhodoLED Lamps for all indications currently approved by the Food and Drug Administration (the "FDA") as well as all future FDA-approved indications.

A summary of our clinical trials is below:

			Clinical Phase				
Product	**Indication / comments**	**Pre-clinical**	I	II	III	**Approval process**	**Status**
Ameluz	Superficial basal cell carcinoma					●	Submitted to FDA in Q4 2025.
Ameluz	Moderate to severe acne			●			Last-patient-out of treatment phase in Q3 2025. Phase 2 data obtained in Q1 2026. Clinical Study Report ("CSR") for treatment phase expected Q3 2026.
Ameluz	Actinic Keratosis				●		Trunk & extremities applying 1-3 tubes of Ameluz. Last-patient-out of treatment phase in Q3 2025. CSR for treatment phase expected Q2 2026. Reg. filing for sNDA is expected for Q3 2026 for field treatment of AKs on extremities and neck and trunk.
Ameluz	Actinic Keratosis		●				Trunk & extremities pharmacokinetics study applying 3 tubes of Ameluz. Last-patient-out in Q4 2025. CSR expected Q2 2026. Reg. filing expected together with trunk and extremities phase 3 study in Q3 2026.
Ameluz	Actinic Keratosis				●		AK Pain Reduction; Plan to start enrollment in 2027

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 AKs on the face and scalp, which corresponds to the current approval of Ameluz and was launched in June 2024. The RhodoLED XL enables the illumination of larger areas, thus allowing the simultaneous treatment of several AKs 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 2027. Regulatory submission for the trunk and extremities label change is planned for the second quarter of 2026.

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 in the composite endpoint, 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 November 2025 a Supplemental New Drug Application was submitted to the FDA, applying for the approval of the treatment of sBCC by PDT with Ameluz and the BF-RhodoLED or the RhodoLED XL lamp. The FDA has accepted the filing and set a Prescription Drug User Fee Act date of September 28, 2026.

Furthermore, the FDA approved a new formulation of Ameluz that lacks propylene glycol and reduces the accumulation of certain contaminants over time. A corresponding patent application was granted by the United States Patent and Trademark Office, (the "USPTO"), extending protection of Ameluz to 2043. The new formulation has been implemented in all US productions of Ameluz since 2024.

Seasonality

Traditional PDT treatments using a lamp are usually performed more frequently during the winter. As such, our revenue is subject to some seasonality and has historically been higher during the first and fourth quarters of the year than during the second and third quarters.

Principal Suppliers & Manufacturers

Historically, we have relied on Biofrontera Pharma (the "Former Ameluz Licensor") as the principal supplier and manufacturer of our products. However, in conjunction with a Strategic Transaction, the Company assumed full control of the Ameluz New Drug Application and Investigational New Drug, enabling the Company to take full responsibility for all aspects of manufacturing Ameluz and the RhodoLED Lamps in the U.S.

Pursuant to the Strategic Transaction, we will temporarily continue to rely on the Former Ameluz Licensor for the manufacturing of Ameluz until we secure all necessary licenses and implement all necessary contracts to fully assume these responsibilities. In preparation of the same, we have entered into an agreement for the primary procurement of our active pharmaceutical ingredient ("API") with Midas Pharma GmbH, located in Germany. We have also identified a secondary source of API and anticipate entering into a similar agreement with this supplier.

Production of Ameluz is carried out by a contract manufacturer, Glaropharm AG in Switzerland, as well as a second contract manufacturer located in Germany, Pharbil Waltrop GmbH, who has recently been qualified for manufacturing of Ameluz to ensure stability of the supply chain and help manage possible tariff impacts. Production of the RhodoLED Lamps is currently carried out by the Former Ameluz Licensor in Leverkusen, Germany, which responsibility will be transferred to Discovery pursuant to the Strategic Transaction. See Part 1, Item 7, "Overview and Recent Developments" for more information concerning the Strategic Transaction.

We centralize our customer sales support and back-office functions through our headquarters in Woburn, Massachusetts.

Intellectual Property

We rely on a combination of patents, trademarks, copyrights, trade secrets and other proprietary know-how and regulatory exclusivities, as well as contractual protections, to establish and protect our intellectual property rights. We consider the overall protection of our intellectual property rights to be of material value and act to protect these rights from infringement.

We have patent protection related to our innovative technologies and developments in connection with our nanoemulsion technology, the RhodoLED Lamps and general PDT illumination procedures.

All patents awarded by the USPTO to the Company that are material to an understanding of the Company are listed in the table below:

No.	Patent No./ Application Serial No.	Issue Date/ Filing Date	Title	Expiration Date
1.	12,208,278	January 28, 2025	Illumination for photodynamic therapy	September 23, 2041
2.	11,219,781	January 11, 2022	Illumination for photodynamic therapy	June 5, 2039
3.	11,235,169	February 1, 2022	Illumination device for photodynamic therapy, method for treating a skin disease and method for operating an illumination device	October 15, 2040
4.	Dl,021,120	April 2, 2024	LED Panel for a photodynamic therapy lamp	April 2, 2039
5.	Dl,052,103	November 19, 2024	Photodynamic Therapy Lamp Head	November 19, 2039
6.	D1,067,446	March 18, 2025	Photodynamic Therapy Lamp	March 18, 2040
7.	11,540,981	January 3, 2023	Nanoemulsion formulation with improved stability and cell penetration	February 7, 2028
8.	12,280,146	April 22, 2025	Nanoemulsion without propylene glycol	December 8, 2043
9.	12,409,112	September 9, 2025	Pressurized nanoemulsion	April 6, 2043
10.	11,642,411	May 9, 2023	Photodynamic therapy comprising two light exposures at different wavelengths	April 23, 2039

Patents pending filed by the Company that are material to an understanding of the Company are as follows:

No.	Patent No./ Application Serial No.	Issue Date/ Filing Date	Title	Expiration Date
1.	18/984,614	December 17, 2024	Illumination for photodynamic therapy	December 17, 2044
2.	17/071,496	October 15, 2020	Illumination device for photodynamic therapy, method for treating a skin disease and method for operating an illumination device	October 15, 2040
3.	18/248,672	April 11, 2023	Illumination device for photodynamic therapy, method for treating a skin disease and method for operating an illumination device	April 11, 2043
4.	19/122,218	April 17, 2025	Illumination device for photodynamic therapy, method for treating a skin disease and method for operating an illumination device	April 17, 2045
5.	29/926,745	January 31, 2024	LED Panel for a photodynamic therapy lamp	January 31, 2039
6.	29/968,470	October 16, 2024	Photodynamic Therapy Lamp Head	October 16, 2039
7.	29/989,162	February 10, 2025	Photodynamic Therapy Lamp	February 10, 2040
8.	19/334,025	April 5, 2024	Nanoemulsion without propylene glycol	April 6, 2043
9.	19/334,331	April 5, 2024	Pressurized nanoemulsion	April 6, 2043
10.	18/188,373	March 22, 2023	Photodynamic therapy comprising two light	April 23, 2039

exposures at different wavelengths

Commercial Partners and Agreements

Ameluz and RhodoLED Lamps License Service Agreement

On February 19, 2024, the Company entered into the Second Amended and Restated License and Supply Agreement (the "Second A&R Ameluz LSA") with the Former Ameluz Licensor, effective February 13, 2024. Among other things, the Second A&R Ameluz LSA established the "Transfer Price" of Ameluz at 25% for all purchases in 2024 and 2025. The Transfer Price covered the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance, and patent administration.

Under the Second A&R Ameluz LSA, the Former Ameluz Licensor was responsible for obtaining and maintaining the rights to all FDA approvals (and any required maintenance thereafter) needed for the Former 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 Former Ameluz Licensor was responsible to maintain a pharmacovigilance database and to respond appropriately to all relevant queries of any regulatory authority pertaining to pharmacovigilance. Biofrontera was required to provide reasonable support relating to any regulatory issues relating to pharmacovigilance and/or product recalls, obtaining all state licenses or any other similar approvals required to market Ameluz and/or the RhodoLED Lamps in the United States, and carrying 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. The Second A&R Ameluz LSA was terminated in connection with the Strategic Transaction. See Part 1, Item 7, "Overview and Recent Developments" for more information concerning the Strategic Transaction.

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.

New Drug Application ("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 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 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. Until June 1, 2025, under the Second A&R Ameluz LSA, these requirements were handled by both us and our licensor. See Part 1, Item 7, "Overview and Recent Developments" for more information concerning the Second A&R Ameluz LSA. 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 rely, in part, on our 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 the development 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. Detection 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:

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

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

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

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

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 also imposes two additional post-market requirements on manufacturers, 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. Our code of conduct, Board committee charters, and certain other corporate governance policies are also posted on the Investor Relations section of our website.

Item 1A. Risk Factors

Our business, results of operations and financial condition and the industry in which we operate are subject to various risks. We have listed below the most significant risk factors we believe to be 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. References to past events are examples only and are not intended to be a complete listing or to indicate the likelihood of similar events occurring in the future. You should read this summary together with the more detailed description of each risk factor contained below, as well as 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. These disclosures reflect the Company's beliefs and opinions as to factors that could materially and adversely affect the Company and its securities in the future. Some of these material risks include:

Summary of Material Risk Factors

Risks Related to our Products

- If generic versions of Ameluz enter the market, we may need to reduce the price of Ameluz significantly, which would reduce revenues, and may cause us to lose significant market share.
- Our business depends substantially on the success of Ameluz. If we 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 we or our manufacturing partners, as applicable, fail to manufacture our 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.
- Breakdowns, failures, or suboptimal performance of our manufacturing equipment could disrupt operations, increase costs, impair product quality, and materially and adversely affect our business, financial condition, and results of operations.
- If our efforts to protect the proprietary nature of our intellectual property related to our products are not adequate, we may not be able to compete effectively in our market.
- We are currently and have been involved in intellectual property lawsuits related to our products. Similar suits may also arise in the future, which could be expensive, time-consuming and unsuccessful.
- Our international business dealings with our manufacturing partners may pose currency risks.
- Competing products and future emerging products may erode sales of our products.
- Geopolitical instability, trade disputes, and tariffs imposed on imports could materially increase our costs, disrupt our supply chain, and adversely affect our business, financial condition, and results of operations.

Risks Related to Our Business and Strategy

- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our products, which could make it difficult for us to sell our products.
- Healthcare legislative changes may have a material adverse effect on our business and results of operations.
- If we are unable to maintain effective marketing and sales capabilities we may be unable to generate revenue growth.
- If we are unable to establish and maintain relationships with GPOs, our future revenues and/or future profitability could be jeopardized. The United States market for Ameluz for the treatment of AK may be smaller than we have estimated.
- Even if we obtain additional regulatory approvals extending our products' indications, they may not gain market acceptance or become widely accepted among members of the medical community.
- We are subject to healthcare laws and regulations. Our failure to comply with those laws and regulations could have a material adverse effect on our results of operations and financial condition.
- A recall of our drug or medical products, or the discovery of serious safety issues with our drug or medical products, could have a significant negative impact on us.
- 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.
- We will need to grow our organization and we may experience difficulties in managing this growth.
- Our business and operations could suffer in the event of system failures or cyber-attacks.
- If lawsuits are brought against us, we may incur substantial liabilities.
- Our subsidiary and certain third-party employees are subject to foreign laws.
- Third party claims of intellectual property infringement may affect our ability to sell our products and may also prevent or delay our product discovery and development efforts.
- 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.
- Our 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 unable to obtain regulatory approval for additional indications of our products on a timely basis or at all, our business could be substantially harmed.
- 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 products.

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.

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

- Our share price may be volatile, and you may be unable to sell your shares and/or warrants at or above the offering price.
- If we fail to maintain compliance with applicable listing standards, our common stock and publicly traded warrants could be delisted from Nasdaq.
- Warrants are exercisable for our common stock, which, if exercised, would result in dilution to our stockholders.
- 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.
- Certain provisions of our outstanding warrants, our charter documents, and Delaware law could prevent a takeover that stockholders consider favorable and could also reduce the market price of our stock.
- 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 Our Products

Generic versions of Ameluz may enter the market following the expiration of our patents, which may lead to significant reductions in the price of Ameluz and significant decreases in our market share.

The process of developing generic topical dermatological products presents specific challenges that may deter potential generic competitors. If generic competitors do enter the market, this may cause a significant drop in the price of Ameluz and our United States market share for Ameluz, materially and adversely impacting our results of operations, business, and stock price.

We hold several patent families protecting our products, including 1) a patent family that protects the technology relating to nanoemulsions that expires in December 2027, 2) a patent family that protects the current Ameluz formulations (without propylene glycol) that expires in 2043, and 3) several patent families regarding illumination protocols used in or planned for Ameluz PDT and covering the RhodoLED Lamps. However, we cannot guarantee that these patents (or additional patents for which we have applied, if issued) will adequately protect us against copying by competitors.

Our business depends substantially on the success of our principal product, Ameluz. If we 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 we have received marketing approval in the United States for Ameluz for lesion- and field-directed treatment of AK 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 Ameluz 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;
- any contract manufacturing facilities maintaining regulatory compliance;
- compliance with applicable law for our sales force and marketing efforts;
- any contract manufacturing facility producing sufficient quantities at acceptable quality;
- sourcing sufficient quantities of raw materials used to manufacture our products;
- continued acceptable safety and effectiveness profiles for our products;
- maintaining current reimbursement coverage for our existing indication, and expanding reimbursement to cover future indications;
- obtaining and maintaining patent and trade secret protection and regulatory exclusivity; and
- protecting our intellectual property rights.

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

Because we have received approval from the FDA to market in the United States Ameluz in combination with PDT using the BF-RhodoLED lamp series, any new lamp we may license would require new approval from the FDA. We cannot assure that we 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.

If we or our 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 cGMP or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of our products or be unable to meet market demand, and lose potential revenues.

The manufacture of our products requires significant expertise and capital investment. We would need to spend substantial time and expense to replace our respective contract manufacturers if any such contract manufacturer failed to deliver products in the quality and quantities we demand or failed to meet any regulatory or cGMP requirements. We take precautions to help safeguard 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 insurance may not cover losses related to our products in any particular case. In addition, regardless of the level of insurance coverage, damage to our facilities may have a material adverse effect on our business, financial condition and operating results.

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

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 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.

Breakdowns, failures, or suboptimal performance of our manufacturing equipment could disrupt operations, increase costs, impair product quality, and materially and adversely affect our business, financial condition, and results of operations.

Our manufacturing operations depend on the reliable performance and availability of our manufacturing equipment. Unplanned breakdowns, accelerated wear, and other performance issues can occur despite preventive maintenance and monitoring, resulting in production outages or slowdowns, yield losses, quality deviations, rework and scrap, missed delivery schedules, and higher costs for expedited freight, overtime, or alternative sourcing that compress margins.

The timing and magnitude of equipment failures are inherently difficult to predict. Significant breakdowns or repeated failures can lead to extended downtime while we diagnose issues, procure spare parts, or obtain specialized third-party service. Lead times for critical components—particularly custom or long-lead items—can be lengthy and volatile, and repair vendors may have limited availability during peak periods. In some cases, replacement rather than repair may be required, resulting in substantial capital expenditures. If we are unable to timely repair or replace equipment, we could lose sales, incur contractual penalties or liquidated damages, or face increased warranty claims. Our insurance may not cover fully, or at all, lost production, margin shortfalls, replacement costs, or consequential damages, and any recoveries could be delayed, contested, or subject to deductibles and coverage limits. Any significant disruption in our manufacturing capability could have a material adverse effect on our business, financial condition, results of operations, and cash flows.

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

We rely upon a combination of patents, trade secret protection and confidentiality agreements to protect the intellectual property related to our products. 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 we 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, our patents and patent applications may not adequately protect our intellectual property or prevent others from designing around our claims. If the breadth or strength of protection provided by the issued patents and patent applications we hold with respect to our products is threatened, it could threaten our ability to commercialize our products. Further, if the clinical trials for our products are related, the period of time during which we could market our 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 we were the first to file any patent application related to our products.

In addition to the protection afforded by patents, we rely on trade secret protection and confidentiality agreements to protect proprietary know-how that is not patentable, processes for which patents are difficult to enforce and any other elements of our product discovery and development processes that involve proprietary know-how, information or technology that is not covered by patents. Although we may require our 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. Our trade secrets also could be independently discovered by our competitors, in which case, we would not be able to prevent use of such trade secrets by our competitors. The enforcement of a claim alleging that a party illegally obtained and was using our trade secrets could be difficult, expensive and time consuming and the outcome would be unpredictable. There exists a risk that we 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 products. 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, we may encounter significant problems in protecting and defending our intellectual property in the United States, in the EU and in other countries. If we 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.

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

Interference or derivation proceedings provoked by third parties or brought by the USPTO may be necessary to determine the priority of inventions with respect to our patents or patent applications. An unfavorable outcome 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.

Our international dealings 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 any third-party vendors in the local currency of the country in which such 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.

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

Reimbursement issues affect the economic competitiveness of our products as compared to other therapies. See the section entitled "*Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our products, including with respect to future indications of our products, which could make it difficult for us to sell our products*" included below in this Item 1A.

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 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 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.

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.

Geopolitical instability, trade disputes, and tariffs imposed on imports could materially increase our costs, disrupt our supply chain, and adversely affect our business, financial condition, and results of operations.

Our business operates in a global trade environment that is subject to inherent and evolving geopolitical risks. Recent actions by the U.S. government, including the imposition of significant tariffs on imports from certain countries, have substantially heightened uncertainty in international trade. Because our products are exclusively imported from Europe, our business is particularly sensitive to any tariffs, duties, and other trade restrictions imposed on European goods entering the United States. Any such measures could materially increase the cost of our products and reduce our margins, particularly if we are unable to pass increased costs on to our customers through price adjustments or otherwise offset these impacts.

In addition to direct tariff exposure, our business may be adversely affected by retaliatory trade measures imposed by foreign governments in response to U.S. trade policy, which could further disrupt global supply chains, increase the cost of raw materials and components sourced by our European suppliers, and create additional logistical and regulatory complexity.

The trade policy landscape remains highly fluid and unpredictable. The uncertainty surrounding trade policy has contributed to significant volatility in the financial markets, which could adversely affect our stock price, increase our cost of capital, and limit our ability to access the capital markets on favorable terms. There can be no assurance that the current tariff regime will not be expanded or that additional trade restrictions will not be imposed that would further impact our business. We may be unable to fully mitigate the adverse effects of tariffs and trade restrictions, and any failure to do so could have a material adverse effect on our business, financial condition, results of operations, and prospects.

Risks Related to Our Business and Strategy

Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our products, including with respect to future indications of our products, which could make it difficult for us to sell our 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 that we provide to the payor supporting scientific, clinical and cost-effectiveness data for the use of our products. We may not be able to provide data sufficient to gain acceptance with respect to coverage and reimbursement or a particular reimbursement amount. If reimbursement of future products or extended indications for existing products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, we may be unable to achieve or sustain profitability.

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

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

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

In order to grow the market for our 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 products are expensive and time consuming and can potentially delay the growth of sales of our 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 products, which would limit our revenue growth.

If we are unable to establish and maintain relationships with group purchasing organizations, our future revenues and/or future profitability could be jeopardized.

A growing number of end-users of our products have relationships with GPOs, whereby such GPOs provide such end-users access to a broad range of pharmaceutical and medical device products from multiple suppliers at competitive prices. Hospitals and other end-users contract with the GPO of their choice for their purchasing needs. In 2025, the amount of revenue we received from end-user customers that are members of GPOs increased significantly.

Establishing and maintaining strong relationships with these GPOs will require us to be a reliable supplier, remain price competitive and comply with FDA regulations. The GPOs with whom we have relationships may have relationships with manufacturers that sell competing products, and such GPOs may earn higher margins from these products or combinations of competing products or may prefer products other than ours for other reasons. If we are unable to establish or maintain our GPO relationships, sales of our products and related revenues could be negatively impacted.

The United States market size for Ameluz for the treatment of AK may be smaller than we have estimated.

The public data regarding the market for AK 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 AK 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 AK treatments in the United States, and we often use such data for our business and planning purposes.

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

Future indications for Ameluz may not receive wide acceptance among hospitals, physicians, health care payors, patients and others in the medical community. Market acceptance of any of these indications for our products depends on a number of factors, including:

- 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 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 product or product candidates as well as competitive products;
- the perceived advantages of our products over alternative treatments;
- the cost of treatment in relation to alternative products; and
- the availability of adequate reimbursement and pricing by third party payors and government authorities, including any conditions for reimbursement required by such third-party payors and government authorities.

If future indications for Ameluz are approved but fail to achieve market acceptance among physicians, patients, payors, or others in the medical community in the United States, we may not be able to significantly increase our revenues, which could have an adverse effect on our business, prospects, financial condition and results of operations.

We are subject to extensive laws and regulations. Our failure to comply with those laws and regulations could have a material adverse effect on our business, reputation, results of operations, and financial condition.

We are subject to extensive laws and regulation by governmental authorities in the United States and Germany. Such laws and regulations relate to healthcare, manufacturing, state and federal anti-kickback rules, anti-corruption, federal false claims, privacy, security, financial disclosure, anti-trust, Physician Payment Sunshine Act reporting, fair trade, marketing, and advertising, among others. Any government investigation of alleged violations of laws or regulations could require that we expend significant time and resources in response and could generate negative publicity. 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, sanctions. damages, fines, warning letters, product seizures, recalls, injunctions, suspension, shutdown of production, withdrawal or revocation of regulatory approvals, 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 the value of our company, our results of operations and financial condition, and our ability to operate our business commercialize and generate revenues from our products. For a discussion of manufacturing regulations and requirements applicable to our business and related risks, see the section entitled "*If we or our 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 cGMP or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of our products or be unable to meet market demand, and lose potential revenues*" included above in this Item 1A.

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

A government-mandated or voluntary recall by us or one of our distributors could occur as a result of an unacceptable risk to health, component failures, manufacturing errors, design or labeling defects or other deficiencies and issues. Recalls of our products would divert managerial and financial resources and have an adverse effect on our reputation, financial condition and operating results, which could impair our ability to market, sell or produce our products in a cost-effective and timely manner. In February 2024, our former licensor of Ameluz, 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 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, we are required to report to the FDA any event which reasonably suggests that our product may have caused or contributed to a death or serious injury or in which our product malfunctioned and, if the malfunction of the same or similar device marketed by us were to recur, would likely cause or contribute to death or serious injury. The FDA also requires reporting of serious, life-threatening, unexpected and other adverse drug experiences and the submission of periodic safety reports and other information. Product malfunctions or other adverse event reports may result in a voluntary or involuntary product recall and other adverse actions, which could divert managerial and financial resources, impair our ability to market, sell or manufacture our 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 products could result in future voluntary corrective actions, such as recalls or customer notifications, or regulatory agency action, which could include inspection, mandatory recall or other enforcement action. Any corrective action, whether voluntary or involuntary, will require the dedication of our time and capital, distract our management from operating their business and may harm our reputation and financial results as well as threaten our marketing authority for such products.

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 products will be limited.

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

As of December 31, 2025, we had 92 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 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 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 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 cyber-related 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 products and product candidates could be delayed.

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

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

- costs to defend litigation and other proceedings;
- a diversion of management's time and our resources;
- decreased demand for our products;
- injury to our reputation;
- withdrawal of clinical trial participants;
- 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 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 products and any 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.

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

All employees of our wholly owned subsidiary, Biofrontera Discovery GmbH, and a majority of the employees and former employees of Biofrontera AG, our former 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 us, our employees, Biofrontera AG, and/or Biofrontera AG's former employees (many of whom are now employees of Biofrontera Discovery, GmbH) pertaining to alleged non-adherence to the provisions of this act that may impact our ability to commercialize our products. There is a risk that the compensation that we or Biofrontera AG provided to employees who assign patents may be deemed to be insufficient. German law may require that the compensation due to such employees for the use of the patents is increased. In those cases where employees have not assigned their interests, we may need to pay compensation for the use of those patents. If we are required to pay additional compensation or face other disputes under the German Act on Employees' Inventions, the impact on us could adversely affect our results of operations.

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

Our commercial success depends in part on 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, as well as our ability to challenge the patents of others, in the future. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our products may give rise to claims of infringement of the patent rights of others.

Third parties may assert that we are employing their proprietary technology without authorization. There may be third party patents of which we are currently unaware with claims to materials, formulations, devices, methods of manufacture or methods for treatment related to the use or manufacture of our products. Because patent applications can take many years to issue, there may be currently pending patent applications which may later result in issued patents that our products or product candidates may infringe. In addition, third parties may obtain patents in the future and claim that use of our technologies infringe upon such patents. If any third-party patents were held by a court of competent jurisdiction to cover the manufacturing process of our pharmaceutical products and medical devices, 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 our products unless we obtained a license under the applicable patents, or until such patents expire or they are finally determined to be held invalid or unenforceable. Similarly, if any third-party patent were held by a court of competent jurisdiction to cover aspects of our medical devices, formulations of our pharmaceutical products, 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 are unable to obtain a necessary license to a third-party patent on commercially reasonable terms, or at all, our ability to commercialize our products may be impaired or delayed, which could in turn significantly harm our business.

Parties making claims against us may seek and obtain injunctive or other equitable relief, which could effectively block our ability to sell our products and to further commercialize our 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 may need to obtain licenses from third parties to advance their research or allow commercialization of our products. We may fail to obtain any of these licenses at a reasonable cost or on reasonable terms, if at all. In that event, we would be unable to further commercialize our products, which could harm our business significantly.

Biofrontera has been served with complaints alleging patent infringement. See *Note 20. Commitments and Contingencies – Legal Claims* for more information regarding these cases.

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 or raise additional capital or find financing until cash flow from operations is sufficient, if ever. As of March 11, 2026, our unaudited cash was $3.6 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. As of December 31, 2025, we had an accumulated deficit of $127.9 million.

Our ability to become profitable depends on our ability to further commercialize our principal product, Ameluz. Even if we are successful in increasing our product sales, we may never achieve or sustain profitability. 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 AKs 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,

We have entered into various financing arrangements to raise capital since our inception. 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 products or potential products in the United States
- the timing of regulatory approvals, demand for our products, our ability to market and sell our 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 products or other plans for strategic growth. We also could be required to license our rights to our products and product candidates to third parties on unfavorable terms. In addition, any equity financing would likely result in dilution to 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 note(s) 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 14. 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 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 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.

Our 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 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 products and from achieving or maintaining market acceptance of our 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 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 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 products;
- our inability to demonstrate to the satisfaction of the FDA that our 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 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 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 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 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 products, which would limit our ability to increase our revenues, materially and adversely affecting our results of operations and business.

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 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 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 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 products.

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.

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.

Risks Related to Our Securities and Ownership of Our Common Stock

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 discussed in this section and elsewhere throughout this Form 10-K. More specifically, we expect our operating results to be subject to quarterly fluctuations due to (in part) seasonality in the demand for traditional PDT treatment using a lamp 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.

Others factors beyond our control that may lead to volatility in our share price include:

- 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 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 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 products, and our ability to obtain intellectual property protection for our 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 significantly harm our business.

If we fail to regain and 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. The Company has, on multiple occasions, received notices of non-compliance from Nasdaq and each time been given the ability to regain compliance. On December 31, 2025, we received a letter (the "Notice") from the Listing Qualifications Department of Nasdaq notifying the Company that the listing of its common stock was not in compliance with Nasdaq Listing Rule 5550(a)(2), as the closing bid price of the Company's common stock was less than $1.00 per share for the previous 34 consecutive business days. Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until June 30, 2026, to regain compliance with Rule 5550(a)(2). To regain compliance, during this 180-day compliance period, the closing bid price of the Company's common stock must be at least $1.00 per share for a minimum of 10 consecutive business days.

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 regain and 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.

We have issued several warrants, which are exercisable for our common stock, and issued 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 16, 2026, 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"), Series C Convertible Preferred Stock ("Series C Preferred Stock") and Series D Convertible Preferred Stock ("Series D Preferred Stock"). See *Note 17. Stockholders' Equity and Note 19. Net Loss Per Share* in our consolidated financial statements for additional details.

All of the shares issuable upon exercise of these warrants or the conversion of the Series B Preferred Stock and Series C 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, Series C and Series D 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.

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.

Certain provisions of our outstanding warrants, 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 the 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. Furthermore, certain provisions of our outstanding warrants could also 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.

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.

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 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, 2,192,736 liability classified Warrants remain outstanding. See *Note 17. Stockholders' Equity* in our audited financial statements for the fiscal year ended December 31, 2025 and 2024 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," 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 11,400 square feet under a lease agreement with an initial term expiring in February 2031.

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 22. *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, 2025, 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, 2025.

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. 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." For more information on forward-looking statement, see the section titled "Special Note Regarding Forward-Looking Statements" included in Part 1 of this Form 10-K. The following discussion should also be read in conjunction with the financial statements and the Notes thereto appearing elsewhere in this Form 10-K.

Overview and Recent Developments

Biofrontera Inc. (the "Company" or "Biofrontera") is a United States based biopharmaceutical company engaging in the development, manufacturing, and commercialization of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's products, which include Ameluz as well as the BF-RhodoLED and RhodoLED XL lamp series (together, the "RhodoLED Lamps"), are used for the treatment of actinic keratosis ("AK"), a common skin condition characterized by the growth of pre-cancerous skin lesions ("AKs"). With our national commercial team, we generate revenue by selling our products directly to dermatology offices and groups.

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.

Strategic Transaction

On October 20, 2025, we entered into i) an Asset Purchase Agreement (the "Transfer Agreement") and ii) an Earnout Agreement (together with the Transfer Agreement, the "Agreements"), with Biofrontera AG and its consolidated subsidiaries (the "Biofrontera Group"), pursuant to which the Company finalized the agreements to acquire all rights in the United States (the "U.S. Rights") to Ameluz and RhodoLED (the "Strategic Transaction"). Pursuant to the terms of the Agreements, retroactive to June 1, 2025, the Company will pay a monthly earnout of 12% of United States revenues of Ameluz in years when United States net sales are $65.0 million or less and an earnout of 15% on all revenue in years when United States net sales of Ameluz exceed $65.0 million, continuing until the expiration of patent protection on Ameluz allows for generic competition in the United States (if not terminated sooner by agreement of the parties). The earnout replaces a transfer pricing model under the Company's Second A&R Ameluz LSA by and among the Company and the Biofrontera Group, which has now been terminated pursuant to the Agreements. The new structure reduces overall cost for the Company and is expected to accelerate the Company's timeframe to reach break-even.

In exchange for the U.S. Rights, in addition to the aforementioned earnout and an agreement to transfer all costs associated with the U.S. business, Biofrontera AG received 3,019 shares of Series D Convertible Preferred Stock, par value $0.001 per share (the "Series D Preferred Stock").

With the completion of the Strategic Transaction, the Company assumed full control of the Ameluz New Drug Application and Investigational New Drug, enabling the Company to manage ongoing and future clinical development activities independently, and to take full responsibility for all aspects of manufacturing and marketing Ameluz and the RhodoLED lamps in the U.S. The patent and trademark transfers further strengthen the Company's intellectual property portfolio and market position in the U.S.

On November 6, 2025, the Company entered into an Asset Purchase Agreement with an unaffiliated party, providing for the sale of the intangible asset relating to the Company's product, Xepi, for initial proceeds of $3 million with the potential for up to an additional $7 million in milestone payments. This divestiture does not represent a strategic shift that will have a major effect on our consolidated results of operations. See *Note 9. Assets Held for Sale*, for additional information.

Compliance with Nasdaq Listing Standards

On December 31, 2025, the Company received a letter from Nasdaq notifying the Company that the listing of the Common Stock was not in compliance with Nasdaq Listing Rule 5550(a)(2) as the closing bid price of the Common Stock was less than $1.00 per share for the previous 34 consecutive business days. The notice has no present impact on the listing or trading of the Company's securities on Nasdaq. Under Nasdaq Listing Rule 5810(c)(3)(A), the Company has a period of 180 calendar days, or until June 30, 2026, to regain compliance with the rule referred to in this paragraph.

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

Strategy

Our principal objective is to improve patient outcomes through adoption and use of our 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 AKs 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 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; and

- strategically managing our 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 Ameluz and the BF-RhodoLED Lamps. We have financed our operating and capital expenditures through cash proceeds generated from our product sales, 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 Ameluz and the BF-RhodoLED Lamps. Our long-term financial objectives include consistent revenue growth and expanding operating margins. Accordingly, we are focused on product sales expansion to drive revenue growth and improve operating efficiencies, including effective resource utilization, information technology leverage, and overhead cost management.

[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 sales of our 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 products are:

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

Cost of Revenues, Related Party

Cost of revenues, related party, relating to inventory purchased before the Strategic Transaction, is comprised of purchase costs of our products, Ameluz and RhodoLED Lamps from Biofrontera Pharma GmbH and insignificant inventory adjustments due to scrapped, expiring and excess products.

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 products and professional fees for legal, consulting and accounting services, as well as depreciation and amortization.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party, relate to the services provided by the Biofrontera Group, primarily for regulatory support and pharmacovigilance. These expenses were 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.

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 trial sites, 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 R&D are expensed as incurred.

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.

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.

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, (ii) gain on sale of asset held for sale, and (iii) 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, 2025 and December 31, 2024

The following table summarizes our results of operations for the years ended December 31, 2025 and December 31, 2024:

(*in thousands*)	**2025**	**2024**	**Change**
Product revenues, net	$ 41,705	$ 37,303	4,402
Revenues, related party	-	18	(18)
Revenues, net	**41,705**	**37,321**	**4,384**
Operating expenses:			
Cost of revenues, related party	10,111	17,855	(7,744)
Cost of revenues, other	853	752	101
Selling, general and administrative	37,751	33,793	3,958
Selling, general and administrative, related party	619	42	577
Research and development	3,719	2,089	1,630
Total operating expenses	53,053	54,531	(1,478)
Loss from operations	**(11,348)**	**(17,210)**	**5,862**
Change in fair value of warrant liabilities	899	1,680	(781)
Change in fair value of investment, related party	2	(14)	16
Loss on debt extinguishment	-	(316)	316
Interest expense, net	(452)	(2,035)	1,583
Other income (expense), net	388	158	230
Loss before income taxes	**(10,511)**	**(17,737)**	**7,226**
Income tax expenses	25	22	3
Net loss	**$ (10,536)**	**$ (17,759)**	**$ 7,223**

Product Revenues, net

Net product revenue for 2025 increased $4.4 million, or 11.8% compared to 2024. The increase was primarily driven by organic growth of Ameluz sales volume of $4.1 million and a $0.7 million increase due to an increased Ameluz unit price. We still continued to grow net revenues despite the impact of group purchasing organizations for independent dermatology offices' efforts to erode prices. The Ameluz driven revenue increase was offset by a $0.3 million decline in sales of RhodoLED Lamps due to the initial surge of sales of BF-RhodoLED XL in 2024 in connection with its launch. BF-RhodoLED sales have been consistent with expectations and we plan to continue to sell both the BF-RhodoLED and RhodoLED XL.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party decreased $7.7 million, or 43.4% compared to 2024 driven by changes in the purchase price of Ameluz primarily due to changes in the Company's commercial arrangements with the Biofrontera Group. In connection with the Strategic Transaction, the Company transitioned from the transfer pricing model in place under the now terminated Second A&R Ameluz LSA to a significantly lower cost structure. Under the new arrangement, the cost of revenues per unit reduced to approximately 5% beginning in July 2025, compared to a range of approximately 25% to 50% of revenue applying to sales in 2024 and from January 1, 2025 through June 1, 2025. Sales subject to the new rate of approximately 5% represented approximately 45% of total Ameluz sales volume for 2025. In addition, $2.1 million of purchase price accrued relating to units purchased in 2025 under the Second A&R Ameluz LSA was forgiven in connection with the Strategic Transaction, further reducing the cost of revenues in 2025. These decreases were partially offset by earnout payments made in 2025 under the Agreements to the Biofrontera Group of $2.2 million.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for 2025 increased $4.0 million, or 11.7% compared to 2024. The increase was primarily driven by a $6.6 million rise in general and administrative expenses, largely attributable to higher external legal costs and expenses related to patent claims. See *Note 20. Commitments and Contingencies – Legal Proceedings*. This increase was partially offset by a $1.1 million reduction in direct sales personnel expenses resulting from a decrease in headcount from 2024 to 2025, $1.0 million in savings related to lower sales support activity levels, including $0.4 million due to Xepi Prescription Drug User fee write-off, a $0.3 million decrease in intangible asset amortization, and a $0.2 million decrease in bad debt expense.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party increased by $0.6 million in 2025 compared to 2024, primarily due to the commercialization, regulatory and manufacturing-related expenses incurred following the Strategic Transaction. See *Note 3. Asset Acquisition*.

Research and Development Expense

R&D expenses for the year ended December 31, 2025 increased $1.6 million as compared to the year ended December 31, 2024. The increase was attributable to our responsibility over clinical trial activities for Ameluz in the United States for the full year 2025, which we assumed control of starting June 1, 2024.

The following table summarizes the major categories of our R&D expenses for the years ended December 31, 2025 and 2024:

	2025	2024
Actinic keratosis	$ 1,486	$ 682
Moderate to severe acne	349	267
Superficial basal cell carcinoma	320	148
Portable devices	22	94
Personnel-related costs	1,527	756
Other research and development	15	142
	$ 3,719	$ 2,089

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was driven primarily by the decrease in the underlying value of the Company's common stock during 2025 as compared to 2024.

Interest Expense, net

Interest expense decreased by $1.6 million due to the decrease in the interest rate applicable to the outstanding convertible notes issued in November of 2024 (with an original balance of $4.2 million), as compared to the term loan with a balance of $4.0 million that matured on July 5, 2024.

Net Income to Adjusted EBITDA Reconciliation for years ended December 31, 2025 and 2024

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 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.

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.

Loss on debt extinguishment: Effective as of January 4, 2024, we voluntarily terminated the Loan and Security Agreement dated May 8, 2023 with MidCap Business Credit LLC 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.

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.

Gain on sale of asset held for sale: The gain on the sale of an asset held for sale increases net income but is excluded from adjusted EBITDA because it is a non-recurring, non-operating item. While it may appear in other income, net, it is subtracted when calculating adjusted EBITDA to reflect normalized, recurring operational performance and avoid overstating operational profitability.

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, 2025 and 2024:

	Years ended December 31,	
	2025	**2024**
Net loss	**$ (10,536)**	**$ (17,759)**
Interest expense, net	452	2,035
Income tax expenses	25	22
Depreciation and amortization	138	421
EBITDA	**(9,921)**	**(15,281)**
Gain on sale of asset held for sale	(700)	-
Change in fair value of warrant liabilities	(899)	(1,680)
Change in fair value of investment, related party	(2)	14
Loss on debt extinguishment	-	316
Stock based compensation	951	1,019
Expensed issuance costs	-	354
Adjusted EBITDA	**$ (10,571)**	**$ (15,258)**
Adjusted EBITDA margin	-25.4%	-40.9%

Adjusted EBITDA

Adjusted EBITDA increased from ($15.3) million for the year ended December 31, 2024 to ($10.6) million for the year ended December 31, 2025. The improvement was primarily driven by higher gross profit resulting from increased sales and a reduction in cost of revenues following the Strategic Transaction. Adjusted EBITDA also benefited from lower selling, general and administrative expenses, reflecting more disciplined cost management, lower commercial activity levels, and optimization of personnel resources during the year. These improvements were partially offset by higher legal expenses related to patent claims and increased research and development expenses. Our Adjusted EBITDA margin increased from (40.9%) for the year ended December 31, 2024 to (25.4%) for the year ended December 31, 2025, as the favorable impact of the higher gross profit and improved operating cost discipline outweighed the effect of the increased legal and research and development expenses.

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 $13.4 million and $10.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company's accumulated deficit was $127.9 million. The Company's primary sources of liquidity are its cash collected from the sales of its products and cash flows from financing transactions, including $11.0 million of gross proceeds received in a private placement of Series C Preferred Stock in 2025. As of December 31, 2025, we had cash and cash equivalents of $6.4 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.

The Company plans to address the conditions that raise substantial doubt regarding its ability to continue as a going concern by, among other things, continuing to expand the commercialization of Ameluz in the United States while controlling expenses, expected realization of an additional $1.0 million in milestone payments from the sale of the Xepi intangible asset, and, if necessary, securing additional capital through equity or debt financings. However, there can be no assurance that the Company will be successful in obtaining sufficient funding on acceptable terms, if at all. If the Company is unable to raise additional 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 consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were 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)	**2025**	**2024**
Net cash used in operating activities	$ (13,361)	$ (10,270)
Net cash provided by (used in) investing activities	2,998	(3)
Net cash provided by financing activities	10,850	14,835
Net increase in cash and restricted cash	$ 487	$ 4,562

Operating Activities

During the year ended December 31, 2025, operating activities used $13.4 million of cash, primarily resulting from our net loss of $10.5 million, and net cash used by changes in our operating assets and liabilities of $3.5 million, adjusted for the add back of non-cash expense of $0.7 million. Non-cash expense includes stock-based compensation of $1.0 million, non-cash interest expense of $0.5 million, reduction of right of use assets of $0.7 million and depreciation and amortization in the aggregate of $0.1 million, offset by a change in fair value of warrant liabilities of $0.9 million, gain on asset held for sale of $0.7 million, and allowance for credit losses of $0.1 million.

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, and net cash used by changes in our operating assets and liabilities of $6.2 million, adjusted for the add back of non-cash expense of $1.3 million. Non-cash expense includes 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 offset by a change in fair value of warrant liabilities of $1.7 million.

Investing Activities

During the year ended December 31, 2025, the Company received $3.0 million in proceeds from the sale of the intangible asset relating to its Xepi product line, which was previously classified as held for sale. See *Note 10. Asset Held for Sale* for additional details.

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.

Financing Activities

During the year ended December 31, 2025, net cash from financing activities of $10.9 million consisted of proceeds received in accordance with a securities purchase agreement dated June 27, 2025, for the issuance of 11,000 shares of Series C Convertible Preferred Stock. See *Note* 17. *Stockholders' Equity- Series C Convertible Preferred Stock*, for additional details.

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.

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.

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 *20. 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 *20. Commitments and Contingencies – Legal Claims* for more details.

Intangible Assets and Impairment Assessment

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

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

Contingent Consideration

In evaluating whether variable consideration should be included in the transaction price (in the sale of asset held for sale and the sales-based earnout consideration in the Strategic Transaction), the Company applies judgement in assessing whether it is probable that milestones or expected timing or magnitude of future net sales will be met. The Company will recognize the constrained variable consideration, if any, in the period in which the associated uncertainty is resolved.

In connection with the sale of the Company's intangible asset related to Xepi, the $7.0 million of potential milestone payments related to achieving annual net sales thresholds were fully constrained at the sale date due to significant uncertainty regarding the buyer's future sales performance. This uncertainty is driven by factors outside the Company's control including the buyer's commercialization strategy, pricing decisions, and general market conditions. Additionally, the asset lacked sufficient historical revenue performance to reliably predict the likelihood of achievement.

In connection with certain asset acquisition transactions, the Company may agree to pay contingent consideration based on the future performance of the assets acquired. Pursuant to the terms of the Agreements, the Company will pay an earnout of 12% in years where Ameluz revenues in the United States are less than $65.0 million and an earnout of 15% in years when Ameluz revenues in the United States exceed $65.0 million, continuing until the expiration of patent protection on Ameluz. The accounting for contingent consideration requires management to assess whether the obligation should be recognized and measured at the acquisition date. In certain circumstances, the Company may determine that the fair value of the earnout obligation cannot be reasonably estimated at the acquisition date due to significant uncertainties regarding the timing and magnitude of future net sales. Changes in actual net sales relative to expectations could result in the recognition of material expense in future periods when the contingency is resolved.

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 sheet of Biofrontera Inc. (the "Company") as of December 31, 2025, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025, and the results of its operations and its cash flows for the year ended December 31, 2025, 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ CBIZ CPAs P.C.

CBIZ CPAs P.C.

We have served as the Company's auditor since 2023 (such date takes into account the acquisition of the certain assets of Marcum LLP by CBIZ CPAs P.C. effective November 1, 2024).

Morristown, New Jersey
March 19, 2026

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 sheet of Biofrontera Inc. (the "Company") as of December 31, 2024, the related consolidated statements of operations, stockholders' equity and cash flows for the year ended December 31, 2024, and the related notes (collectively referred to as the "financial statements"). In our opinion, based on our audit, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2024, and the results of its operations and its cash flows for the year 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 audit. 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 audit in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides a reasonable basis for our opinion.

/s/ Marcum LLP

Marcum LLP

We have served as the Company's auditor from 2023 to 2025.

Morristown, New Jersey
March 20, 2025

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

	December 31,	
	2025	**2024**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,392	$ 5,905
Investment, related party	9	7
Accounts receivable, net	7,291	5,315
Inventories	1,426	6,646
Prepaid expenses and other current assets	2,279	527
Asset held for sale	-	2,300
Other assets, related party	686	-
Total current assets	**18,083**	**20,700**
Inventories, long term	3,729	-
Property and equipment, net	2,158	80
Operating lease right-of-use assets	1,584	903
Intangible assets, net	2,650	35
Other assets	360	383
Total assets	**$ 28,564**	**$ 22,101**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,855	1,856
Accounts payable, related parties, net	4,811	5,344
Operating lease liabilities	332	548
Accrued expenses and other current liabilities	4,897	4,273
Total current liabilities	**11,895**	**12,021**
Long-term liabilities:		
Convertible notes payable	4,589	4,098
Warrant liabilities	351	1,250
Operating lease liabilities, non-current	1,240	276
Other liabilities	9	23
Total liabilities	**18,084**	**17,668**
Commitments and contingencies (see Note 20)		
Stockholders' equity:		
Convertible Preferred Stock, $0.001 par value, 20,000,000 shares authorized, no Series B-1; 2,050 and 3,366 Series B-2; 6,593 and 6,763 Series B-3; 10,719 and 0 Series C and 3,019 and 0 Series D shares issued and outstanding as of December 31, 2025 and 2024, respectively	-	-
Common Stock, $0.001 par value, 70,000,000 shares authorized; 11,648,323 and 8,873,932 shares issued and outstanding as of December 31, 2025 and 2024, respectively	12	9
Additional paid-in capital	138,413	121,833
Accumulated deficit	(127,945)	(117,409)
Total stockholders' equity	**10,480**	**4,433**
Total liabilities and stockholders' equity	**$ 28,564**	**$ 22,101**

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,	
	2025	**2024**
Product revenues, net	$ 41,705	$ 37,303
Revenues, related party	-	18
Total revenues, net	**41,705**	**37,321**
Operating expenses		
Cost of revenues, related party	10,111	17,855
Cost of revenues, other	853	752
Selling, general and administrative	37,751	33,793
Selling, general and administrative, related party	619	42
Research and development	3,719	2,089
Total operating expenses	**53,053**	**54,531**
Loss from operations	**(11,348)**	**(17,210)**
Other income (expense)		
Change in fair value of warrant liabilities	899	1,680
Change in fair value of investment, related party	2	(14)
Loss on debt extinguishment	-	(316)
Interest expense, net	(452)	(2,035)
Other income, net	388	158
Total other income (expense)	**837**	**(527)**
Loss before income taxes	**(10,511)**	**(17,737)**
Income tax expense	25	22
Net loss	**$ (10,536)**	**$ (17,759)**
Loss per common share:		
Basic and diluted	$ (1.04)	$ (3.22)
Weighted-average common shares outstanding:		
Basic and diluted	10,171,921	5,516,334

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, 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 at December 31, 2024	**10,129**	**$ -**	**8,873,932**	**$ 9**	**$ 121,833**	**$ (117,409)**	**$ 4,433**
Issuance of Series C Preferred, net of offering costs	11,000	-	-		10,850	-	10,850
Issuance of Series D Preferred, net of receivable from shareholder	3,019	-	-		4,782	-	4,782
Conversion of Series B-2 and B-3 Preferred into common stock	(1,486)	-	2,099,718	2	(2)	-	-
Conversion of Series C Preferred into common stock	(281)	-	449,673	1	(1)	-	-
Issuance of shares for restricted stock units	-	-	225,000	-	-	-	-
Stock based compensation	-	-	-	-	951		951
Net Loss	-	-	-	-	-	(10,536)	(10,536)
Balance at December 31, 2025	**22,381**	**$ -**	**11,648,323**	**$ 12**	**$ 138,413**	**$ (127,945)**	**$ 10,480**

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,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (10,536)	$ (17,759)
Adjustments to reconcile net loss to cash flows used in operations		
Depreciation and amortization	138	421
Reduction in the carrying amount of right-of-use assets	730	728
Stock-based compensation	951	1,019
Non-cash interest expense	491	297
Allowance for credit losses	(69)	162
Change in fair value of warrant liabilities	(899)	(1,680)
Gain on sale of asset held for sale	(700)	-
Loss from termination of operating leases	19	-
Realized/unrealized loss in investment, related party	(2)	14
Loss on debt extinguishment	-	316
Changes in operating assets and liabilities:		
Accounts receivable	(1,907)	(315)
Other receivables, related party	-	2
Prepaid expenses and other assets	(1,728)	(141)
Other assets, related party	(686)	5,159
Inventories	1,445	4,233
Accounts payable	(2)	(1,452)
Accounts payable, related parties, net	(533)	(355)
Operating lease liabilities	(683)	(689)
Accrued expenses and other liabilities	610	(230)
Cash flows used in operating activities	**(13,361)**	**(10,270)**
Cash flows from investing activities		
Proceeds from sale of asset held for sale	3,000	-
Sales of investment, related party	-	57
Purchase of intangible assets	-	(50)
Purchases of property and equipment	(2)	(10)
Cash flows provided by (used in) investing activities	**2,998**	**(3)**
Cash flows from financing activities		
Proceeds from issuance of Series C preferred stock, net of offering costs	10,850	-
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
Payment of principal short-term debt	-	(4,315)
Cash flows provided by financing activities	**10,850**	**14,835**
Net increase in cash and cash equivalents	**487**	**4,562**
Cash, cash equivalents and restricted cash, at the beginning of the year	**6,105**	**1,543**
Cash, cash equivalents and restricted cash, at the end of the year	**$ 6,592**	**$ 6,105**
Supplemental disclosure of cash flow information		
Interest paid	$ 6	$ 1,728
Income tax paid, net	$ 25	$ 24
Supplemental non-cash investing and financing activities		
Preferred stock issued as consideration in asset purchase acquisition (See *Note 3. Asset Acquisition*)	$ 4,782	$ -
Property, plant and equipment acquired	2,126	-
Intangible asset acquired	2,656	-
Addition of right-of-use assets in exchange for operating lease liabilities	$ 1,371	$ 55

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

1. Organization and Business Overview

Biofrontera Inc., a Delaware Corporation, (the "Company," "we," "us," "our," or "Biofrontera") is a United States based biopharmaceutical company engaging in the development, manufacturing, and commercialization of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's products, which include Ameluz® as well as the BF-RhodoLED® and RhodoLED® XL lamp series (together, the "RhodoLED® Lamps"), are used for the treatment of actinic keratosis ("AK"), a common skin condition characterized by the growth of pre-cancerous skin lesions (or "AKs"). With our national commercial team, we generate revenue by selling our products directly to dermatology offices and groups.

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 through Biofrontera Discovery GmbH ("Discovery"), our wholly owned subsidiary that was formed in Germany in 2022. 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.

On October 20, 2025, we entered into i) an Asset Purchase Agreement (the "Transfer Agreement") and ii) an Earnout Agreement (together with the Transfer Agreement, the "Agreements"), with Biofrontera AG and its consolidated subsidiaries (the "Biofrontera Group"), pursuant to which the Company finalized the agreements to acquire all rights in the United States (the "U.S. Rights") to Ameluz and RhodoLED (the "Strategic Transaction"). See *Note 3. Asset Acquisition and Note 16. Related Party Transactions* for additional information.

In exchange for the U.S. Rights, in addition to the aforementioned earnout and an agreement to transfer all costs associated with the U.S. business, Biofrontera AG received 3,019 shares of Series D Convertible Preferred Stock, par value $0.001 per share (the "Series D Preferred Stock").

The transaction was funded through an $11 million investment by existing investors, $8.5 million of which was funded in connection with a binding term sheet agreement effective June 30, 2025 with the Biofrontera Group (the "Term Sheet") with the remaining $2.5 million funded on October 24, 2025, following the closing of the Strategic Transaction.

On November 6, 2025, the Company completed the sale of the long-lived intangible asset relating to its Xepi product line, previously classified as held for sale. See *Note 10. Assets Held for Sale*, for additional information.

Liquidity and Going Concern

The accompanying consolidated 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 $13.4 million and $10.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025, the Company's accumulated deficit was $127.9 million. The Company's primary sources of liquidity are its cash collected from the sales of its products, and cash flows from financing transactions including net proceeds of $10.9 million received in a private placement of Series C Preferred Stock in 2025. As of December 31, 2025, we had cash and cash equivalents of $6.4 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.

The Company plans to address the conditions that raise substantial doubt regarding its ability to continue as a going concern by, among other things, continuing to expand the commercialization of Ameluz in the United States while controlling expenses, expected realization of an additional $1.0 million in milestone payments from the sale of the Xepi intangible asset and, if necessary, securing additional capital through equity or debt financings. However, there can be no assurance that the Company will be successful in obtaining sufficient funding on acceptable terms, if at all. If the Company is unable to raise additional 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 consolidated financial statements do not include any adjustments to the carrying amounts and classification of assets, liabilities, and reported expenses that may be necessary if the Company were 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 Accounting Standards Update ("ASU") 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, 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.

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, contingent liability recognition, variable consideration and asset acquisitions. 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.

Restricted Cash

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards *(see Note 6. 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 AK 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, and accounts receivable. 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 limited suppliers to provide 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. If we fail to maintain relationships with suppliers and manufacturers or they are unable to produce product, our business could be materially harmed.

Inventories

Inventories 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 raw materials, work in process and 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
Manufacturing equipment	10-20 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.

Asset Acquisitions

The Company evaluates acquisitions of assets and other similar transactions to assess whether or not the transaction should be accounted for as a business combination or asset acquisition by first applying the screen test in ASC 805-10-55-5A through 55-5C to determine if substantially all of the fair value of the gross assets acquired is concentrated in a single identifiable asset or group of similar identifiable assets. If the screen test is met, the transaction is accounted for as an asset acquisition. If the screen test is not met, further determination is required as to whether or not the Company has acquired inputs and processes that have the ability to create outputs, which would meet the requirements of a business.

If the acquired set of assets does not meet the definition of a business, the transaction is recorded as an asset acquisition and the cost of a group of assets acquired in an asset acquisition shall be allocated to the individual assets acquired or liabilities assumed based on their relative fair values and shall not give rise to goodwill. See *Note 3. Asset Acquisition* to the consolidated financial statements for additional information.

Contingent Consideration

In evaluating whether variable consideration should be included in the transaction price (in the sale of asset held for sale and the sales-based earnout consideration in the Strategic Transaction), the Company applies judgement in assessing whether it is probable that milestones or expected timing or magnitude of future net sales will be met. The Company will recognize the constrained variable consideration, if any, in the period in which the associated uncertainty is resolved.

Intangible Assets

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

Leases

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. Rent abatements are considered lease incentives and are included in the determination of total lease consideration. Total lease payments are recognized on a straight line basis over the lease term.

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 10. 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 *20. 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 Financial Accounting Standards Board ("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.

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 *Note 4. Fair Value Measurements* for additional information..

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 expense was $0.1 million for each of the years ended December 31, 2025 and 2024, 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 earnout. Logistics and distribution costs totaled $0.7 million and $0.6 million for the years ended December 31, 2025 and 2024, 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 fair value of restricted stock units ("RSUs") is measured as the grant date price of the Company's shares. The Company estimates the grant-date fair value of the stock options using the BSM model or a Binomial (Cox-Ross-Rubenstein) Lattice ("Lattice") model. The selection of valuation model depends on the specific terms and conditions of the options including vesting, contractual term and other features that may impact the expected exercise behavior of the option holders. 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.

Both models require 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.

For awards valued using the Lattice model, additional assumptions may include exercise multiples, and early-exercise behavior.

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 each of the years ended December 31, 2025 and December 31, 2024.

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. Depreciation expense and amortization expense previously presented separately in the consolidated statements of cash flows have been combined into a single line item. The reclassification was limited to the consolidated statements of cash flow and had no impact on the reported results of operations.

Recently Issued or Adopted Accounting Pronouncements

We evaluate ASUs issued by the FASB. ASUs not included in our disclosures were assessed and determined to either be not applicable or are not expected to have a significant impact on our 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 with early adoption permitted. We adopted ASU 2023-09 in the fourth quarter of 2025 and applied it prospectively, as disclosed in *Note 15. Income Taxes*.

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.

In July 2025, the FASB issued ASU 2025-05, *Financial Instruments—Credit Losses (Topic 326): Measurement of Credit Losses for Accounts Receivable and Contract Assets*, which provides a practical expedient for estimating expected credit losses on current trade receivables and contract assets arising from revenue transactions. This ASU is effective for public business entities for annual reporting periods beginning after December 15, 2025, with early adoption permitted, and must be applied prospectively. We are currently evaluating the effect that this guidance will have on our consolidated financial statements and related disclosures.

In September 2025, the FASB issued ASU 2025-07, *Derivatives and Hedging (Topic 815) and Revenue from Contracts with Customers (Topic 606)*, which provides updates to refine the scope of the guidance on derivatives in ASC 815 and clarify the guidance on share-based noncash payments from customers in ASC 606. The derivative scope refinement excludes non-exchange-traded contracts with derivative accounting apart from variables based on market rates, prices and indices, variables based on the price or performance of a financial asset or liability of one of the parties to a contract, contracts involving the issuer's own equity evaluated under ASC 815-40 and call or put options on debt instruments. The amendments in ASU 2025-07 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods and should be applied either prospectively or on a modified retrospective basis. We are currently evaluating the effect of adopting ASU 2025-07 on our consolidated financial statements and related disclosures.

In November 2025, the FASB issued ASU 2025-11, *Interim Reporting (Topic 270)*: Narrow-Scope Improvements, which clarifies interim disclosure requirements. The guidance is effective for the Company's interim reporting periods within annual reporting periods beginning after December 15, 2027. Early adoption is permitted. We are evaluating the effect that this guidance will have on our consolidated financial statements and related disclosures.

In December 2025, the FASB issued ASU 2025-12, *Codification Improvements* (ASU 2025-12), which addresses 33 issues, representing amendments to ASC topics that clarify, correct errors or make minor improvements. The amendments in ASU 2025-12 are effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods within those annual reporting periods. Early adoption is permitted in both interim and annual periods in which financial statements have not yet been issued or made available for issuance. If an entity adopts the amendments in this ASU in an interim period, it must adopt them as of the beginning of the annual period that includes that interim period. An entity may elect to early adopt the amendments on an issue-by-issue basis. We are currently evaluating the effect of adopting ASU 2025-12 on our consolidated financial statements and related disclosures.

3. Asset Acquisition

On October 20, 2025, the Company completed an asset acquisition with Biofrontera Group, pursuant to which the Company acquired certain intangible assets, including intellectual property, inventory (offset by assumed liabilities) and fixed assets in exchange for shares of the Company's preferred stock, and an earnout arrangement. The transaction was accounted for as an asset acquisition because the acquired set of assets did not meet the definition of a business.

The preferred stock issued was measured at its fair value of $4.8 million on the acquisition date and included in the cost of the acquired assets, comprised of $2.1 million in fixed assets, $2.7 million of intangible assets and $2.6 million of inventory, offset by $2.6 million of assumed liabilities.

At the acquisition date, the Company evaluated the terms of the earnout arrangement and concluded that the amount of contingent consideration was not reasonably estimable due to the significant uncertainty associated with the timing and magnitude of future net sales. Accordingly, no amount related to the earnout was included in the initial measurement of the cost of the acquired assets. The Company has elected to account for contingent consideration in an asset acquisition as the contingency is resolved (earned and payable). No contingent consideration liability is recognized for amounts not yet earned.

The earnout consideration is calculated and payable on a monthly basis, based on sales performance. See *Note 16. Related Party Transactions* for details. Earnout payments of $2.2 million were recognized during the period and included in cost of revenues on the consolidated statement of operations, of which $0.8 million was reflected in accrued expenses and an additional $0.7 million in accounts payable, related party as of December 31, 2025.

If the Company does not achieve the Minimum Order Amount as defined in *Note 20. Commitments and Contingencies* for two consecutive calendar years starting in January 1, 2026, then the Biofrontera Group will have the right to terminate the Agreements and recover all assets transferred to the Company.

4. Fair Value Measurements

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

(in thousands)	Level	December 31, 2025	December 31, 2024
Assets:			
Investment, related party	1	$ 9	$ 7
Liabilities:			
Warrant liability – 2023 Purchase Warrants	3	$ 289	$ 1,030
Warrant liability – 2022 Purchase Warrants	3	$ 28	$ 98
Warrant liability – 2022 Inducement Warrants	3	$ 34	$ 122
Total Liabilities		$ 351	$ 1,250

Investment, related party

As of December 31, 2025 and 2024, the Company owned 3,019 common shares of Biofrontera AG. The fair value of this investment was determined with Level 1 inputs through references to quoted market prices.

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 *17. 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 BSM model to estimate the fair value of the warrant liabilities which is considered a Level 3 fair value measurement. Certain inputs utilized in our BSM 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, 2025 and December 31, 2024 was estimated using a BSM model based on the following assumptions:

	December 31, 2025	December 31, 2024
Stock price	$ 0.57	$ 1.09
Expiration term (in years)	2.84	3.84
Volatility	105%	105%
Risk-free Rate	3.51%	4.27%
Dividend yield	0.0%	0.0%

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

	December 31, 2025	December 31, 2024
Fair value at beginning of year	$ 1,250	$ 4,210
Issuance of new warrants	-	4,092
Exercise of warrants	-	(5,372)
Change in fair value of warrant liability	(899)	(1,680)
Fair value at end of year	$ 351	1,250

5. Revenue

We generate revenue primarily through the sales of our products, Ameluz and BF-RhodoLED lamps. Traditional PDT treatments using a lamp are usually performed more frequently during the winter. As such, our revenue is subject to some seasonality and has historically been higher during the first and fourth quarters than during the second and third quarters.

6. 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, which at times may exceed federally insured 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, 2025	December 31, 2024
Cash and cash equivalents	$ 6,392	$ 5,905
Long-term restricted cash	200	200
Total cash and cash equivalent, and restricted cash shown on the statements of cash flows	$ 6,592	$ 6,105

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

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 $0.1 million and $0.2 million as of December 31, 2025 and 2024, respectively.

8. Inventories

Inventories consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Inventory, short-term:		
Finished product	$ 1,426	$ 6,646
Work in process	-	-
Raw materials	-	-
Total inventory, short-term	$ 1,426	$ 6,646
Inventory, long term		
Finished product	$ 1,102	$ -
Work in process	649	-
Raw materials	1,978	-
Total inventory, long-term	$ 3,729	$ -
Total inventories	$ 5,155	$ 6,646

9. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Value-added tax receivable	$ 1,218	$ 57
Licenses	403	59
Clinical trials	171	61
Insurance	151	168
Other	336	182
Total	$ 2,279	$ 527

10. Asset Held for Sale

On November 6, 2025, the Company completed the sale of the intangible asset related to its Xepi product line, which was previously classified as held for sale.

Prior to the sale, the asset met the criteria to be classified as held for sale in the third quarter of 2024, as outlined in ASC 360, and was measured at the lower of its carrying amount or fair value less costs to sell. No further depreciation was recorded while the asset was classified as held for sale.

The consideration included fixed consideration of $3.0 million and up to $7.0 million of variable consideration contingent upon the buyer's future activities. Variable consideration is accounted for in accordance with ASC 610-20 and is included in the transaction price only to the extent that it is probable that a significant reversal of a gain will not occur.

The variable consideration consists of:

- $1.0 million payable upon the buyer achieving commercial production and other terms and conditions of the APA, which was excluded from the transaction price as it was fully constrained at the sales date;
- $3.0 million payable upon the buyer achieving annual net sales of the product of $10.0 million, which was excluded from the transaction price as it was fully constrained at the sales date; and
- $3.0 million payable upon the buyer achieving annual net sales of the product of $15.0 million, which was excluded from the transaction price as it was fully constrained at the sales date.

The Company will recognize the constrained variable consideration in the period in which the associated uncertainty is resolved.

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.

Upon completion of the sale, the asset was derecognized upon transfer of control to the buyer, and the Company recognized a gain of $0.7 million which is included in other income in the consolidated statements of operations for the year ended December 31, 2025. The gain recognized was measured as the difference between the transaction price of $3.0 million and the $2.3 million carrying amount of the asset at the date of sale.

Under the now terminated Xepi license and supply agreement we were obligated to make payments to Ferrer Internacional S.A upon the occurrence of certain milestones. Specifically, we were to pay (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, 2025 or 2024 related to Xepi® milestones.

11. Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	December 31, 2025	December 31, 2024
Manufacturing equipment	$ 2,126	$ -
Computer equipment	102	102
Furniture & fixtures	81	81
Leasehold improvement	-	368
Machinery & equipment	116	142
Property and equipment, gross	2,425	693
Less: Accumulated depreciation	(267)	(613)
Property and equipment, net	$ 2,158	$ 80

Depreciation expense was $0.1 million for each of the years ended December 31, 2025 and 2024, which was included in selling, general and administrative expense on the consolidated statements of operations.

12. Intangible Assets, Net

Intangible assets, net are comprised of the following:

(in thousands)	December 31, 2025	December 31, 2024
Intellectual property	$ 2,656	$ -
Software	50	50
Accumulated amortization	(56)	(15)
Intangible assets, net	$ 2,650	$ 35

On October 20, 2025, the Company completed an asset acquisition in which it acquired certain intangible assets including intellectual property. See *Note 3. Asset Acquisition* for additional details. The intellectual property was recorded at acquisition-date fair value of $2.7 million and is amortized on a straight-line basis over the useful life of 18 years. Amortization expense was negligible for the year ended December 31, 2025 and $0.3 million for the year ended December 31, 2024. Amortization expense is recorded in the consolidated statement of operations within cost of goods sold or selling, general and administrative expense depending on the nature and use of the underlying intangible asset. The weighted average amortization period is 17.7 years. No impairment losses were recognized for intangible assets during the years ended December 31, 2025 and 2024.

Estimated future amortization expense as of December 31, 2025 is as follows:

Year (in thousands)	Amount
2026	$ 163
2027	148
2028	146
2029	146
2030	146
Thereafter	1,901
Total	$ 2,650

13. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	December 31, 2025	December 31, 2024
Employee compensation and benefits	$ 2,805	$ 2,428
Professional fees	1,305	632
Research and development	410	542
Product revenue allowances and reserves	57	58
Other	320	613
Total	$ 4,897	$ 4,273

14. 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 for the year ended December 31, 2024. 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 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, 2025.

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.

In connection with the issuance of the note, the Company incurred $0.2 million of debt issuance costs, consisting of legal fees.

During the year ended December 31, 2025, the Company recognized interest expense of $0.4 million and amortization of issuance costs of $0.1 million. As of December 31, 2025 and December 31, 2024, the outstanding balance of the Notes was $4.6 million and $4.1 million, respectively, which is shown net of the remaining unamortized issuance cost of $0.1 million.

15. Income Taxes

The Company adopted ASU 2023-09, Income Taxes (Topic 740): Improvements to Income Tax Disclosures effective January 1, 2025, on a prospective basis. The disclosures required by the standard are included below for the year ended December 31, 2025. Comparative prior-period disclosures have not been revised.

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

	Year ended December 31,	
	2025	2024
Domestic	$ (10,474)	$ (17,228)
Foreign	(37)	(509)
(Loss) before income taxes	$ (10,511)	$ (17,737)

As a result of the net losses, we have incurred in each fiscal year since inception, we have recorded no provision for federal or foreign income taxes for the years ended December 31, 2025 and December 31, 2024. Income tax expense incurred in 2025 and 2024 relates to state income taxes. At December 31, 2025 and December 31, 2024, the Company had no unrecognized tax benefits.

The following table reconciles the U.S. federal statutory income tax rate to the Company's effective income tax rate for the year ended December 31, 2025 :

	Year Ended December 31, 2025	
(in thousands)	Amount	Percentage
Federal statutory income tax rate	$ (2,207)	21.0%
State and local income taxes, net of federal income tax effect	25	(0.2)%
Foreign tax effects:		
Other foreign jurisdictions	8	(0.1)%
Other Adjustments		
True-up	18	(0.2)%
Changes in valuation allowances	2,330	(22.2)%
Nontaxable or nondeductible items:		
Non-Deductible Expenses	40	(0.4)%
Warrant Revaluation	(189)	1.8%
Effective income tax rate	$ 25	(0.3)%

As previously disclosed for the year ended December 31, 2024, prior to the adoption of ASU 2023-09, the effective income tax rate differed from the federal statutory income tax rate as follows:

	Year Ended December 31, 2024
Federal statutory income tax rate	21.0%
State income taxes, net of federal benefit	4.3%
Permanent differences – non-deductible expense	(1.0)%
Change in fair value of warrant liabilities	2.0%
True-ups	(0.6)%
Federal R&D Credits	(0.0)%
Foreign rate differential	0.1%
Change in deferred tax asset valuation allowance	(25.9)%
Effective income tax rate	(0.1)%

The Company's effective income tax rates for the years ended December 31, 2025 and 2024 were due to state income taxes.

Deferred income taxes reflect the net tax effects of temporary differences between the carrying amount of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. The significant components of the Company's net deferred income taxes were as follows (in thousands):

(in thousands)	December 31, 2025	December 31, 2024
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 43,369	$ 41,154
Intangible assets	4,438	3,794
Property and equipment	149	140
Accrued expenses and reserves	350	404
Stock based compensation	1,135	937
Lease liability	395	215
Other	275	705
Total deferred tax assets	50,111	47,349
Valuation allowance	(49,713)	(47,114)
Total deferred tax assets, net of valuation allowance	398	235
Deferred tax liabilities:		
Operating right-of-use assets	(398)	(235)
Total deferred tax assets	(398)	(235)
Net deferred taxes	$ -	$ -

The changes in the valuation allowance were as follows (in thousands):

	Year Ended December 31, 2025
Beginning balance	$ 47,114
Domestic federal income taxes	2,330
Domestic state & local income taxes	261
Foreign income taxes	8
Total change in valuation allowance	2,599
Ending balance	$ 49,713

The Company's income tax provision for the year ended December 31, 2025 related to state income taxes. The Company has evaluated the positive and negative evidence bearing upon the reliability 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 the year ended December 31, 2025, the valuation allowance increased by $2.6 million, primarily due to book losses generated during the period. 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, 2025, the Company had $173.2 million and $133.3 million of federal and state operating loss carryforwards ("NOLs"), respectively. $163.8 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

Utilization of the Company's NOL carryforwards and research and development credit carryforwards may be subject to a substantial annual limitation due to ownership change limitations that have occurred previously or that could occur in the future in accordance with Internal Revenue Code Section 382 as well as similar state provisions. These ownership changes may limit the amount of NOL and research and development credit carryforwards that can be utilized annually to offset future taxable income and taxes, respectively. In general, an ownership change as defined by Section 382 results from transactions increasing the ownership of certain stockholders or public groups in the stock of a corporation by more than 50% over a three-year period. Since its formation, the Company has raised capital through the issuance of capital stock on several occasions. These financings could result in a change of control as defined by Section 382. The Company has not yet conducted an analysis under Section 382 to determine if historical changes in ownership through December 31, 2025, would limit or otherwise restrict its ability to utilize its NOL and research and development credit carryforwards. In addition, future changes in ownership occurring after December 31, 2025 could affect the limitation in future years, and any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

On July 4, 2025, the One Big Beautiful Bill Act ("OBBBA") was signed into law. Among other provisions, this act includes permanently extended and modified certain expiring provisions of the 2017 Tax Cuts and Jobs Act and restored the immediate expensing of domestic research and development expenses. The Company has evaluated the impacts of these provisions and has concluded the OBBBA does not have a material impact on its consolidated financial statements other than reclassifications of the deferred tax assets.

The Company follows the provisions of ASC Topic 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 consolidated balance sheets; and provides transition and interim period guidance, among other provisions. As of December 31, 2025 and 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 consolidated statements of operations and comprehensive loss. As of December 31, 2025 and 2024, the Company had no reserves for uncertain tax positions. For the years ended December 31, 2025 and 2024, no estimated interest or penalties were recognized on uncertain tax positions.

The Company files federal income tax returns in the United States, Germany and state income tax returns in Massachusetts and various other state jurisdictions. The Company's tax returns for the years ended December 31, 2022 through December 31, 2025 remain open and subject to examination by the Internal Revenue Service and state taxing authorities.

16. Related Party Transactions

We consider the Biofrontera Group to be a related party, as prior to the Strategic Transaction, we relied on the Biofrontera Group as the sole supplier of Ameluz and the RhodoLED Lamps and following the Strategic Transaction, it is a beneficial owner of more than five percent of our Series D Convertible Preferred Stock.

License and Supply Agreement

Under the Second A&R Ameluz LSA (applicable for any tubes purchased through May 31, 2025), the Company had an exclusive, non-transferable license to market and sell its licensed products, Ameluz and RhodoLED Lamps, in the United States and was required to purchase the licensed products exclusively from Biofrontera Pharma GmbH (the "Former Ameluz Licensor"), pursuant to which the price paid per unit was based on certain percentages of the anticipated net selling price (the "Transfer Price") that covered 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.

The Second A&R Ameluz LSA 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 Former Ameluz Licensor to the Company.

The Company entered into a Release of Claims with the Former Ameluz Licensor, dated February 13, 2024, pursuant to which the Company agreed to release the Former Ameluz Licensor from all claims and liabilities arising out of or relating to any failure by the Former 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 Former 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 Former 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 Former 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.

Strategic Transaction with Biofrontera Group

On October 20, 2025, the Company finalized the Agreements with the Biofrontera Group to acquire the U.S. Rights to Ameluz and RhodoLED. See *Note 3. Asset Acquisition*. Pursuant to the terms of the Agreements, retroactive to June 1, 2025, the Company will pay an earnout of 12% in years where Ameluz revenues in the United States are less than $65.0 million and an earnout of 15% in years when Ameluz revenues in the United States exceed $65.0 million, continuing until the expiration of patent protection on Ameluz (if not terminated sooner by agreement of the parties). The earnout replaces a transfer pricing model under the now terminated Second Amended and Restated License and Supply Agreement ("Second A&R Ameluz LSA").

In exchange for the U.S. Rights, in addition to the aforementioned earnout and an agreement to transfer all costs associated with the U.S. business, the Biofrontera Group received 3,019 shares of Series D Preferred Stock on July 2, 2025, par value $0.001 per share, which represents a 10% post-money equity stake in the Company. See *Note 17. Stockholders Equity*.

The Company also agreed to assume the defense of co-defendant Biofrontera Group and all costs associated therewith in connection with certain legal actions pending in the United States which will be paid directly to the legal advisors by the Company. Details of the legal claims are disclosed in *Note 20. Commitments and Contingencies – Legal Claims.*

Effective as of the date of the Strategic Transaction and for the following three years, as long as Biofrontera AG holds any shares of Series D Preferred Stock (or shares of common stock that were converted from Series D Preferred Stock), Biofrontera AG shall have the right to appoint (i) one individual to the Company's board of directors if the board consists of seven or fewer members; or (ii) two individuals to the Company's board of directors if the board consists of eight or more directors. No appointments have been made through the filing date.

Amounts Due and Payable

Amounts due and payable to Biofrontera Group as of December 31, 2025 and 2024 were $4.8 million and $5.3 million, respectively, and were recorded in accounts payable, related parties and when applicable, net of accounts receivable, in the consolidated balance sheets. Amounts due from the Biofrontera Group as of December 31, 2025 were $0.7 million recorded as other assets, related party. There were no amounts due from related parties as of December 31, 2024.

Inventory Purchases

Purchases of the previously licensed products (inclusive of estimated and actual purchase price adjustments) were $7.1 million and $8.3 million during the years ended December 31, 2025 and 2024, respectively. These purchases were recorded in inventories in the consolidated balance sheets, and, when sold, in cost of revenues, related party in the consolidated statements of operations.

Earnout

For the year ended December 31, 2025, the Company expensed $2.2 million in earnouts in connection with the Strategic Transaction related to the sales between the acquisition date and year end. The earnout was recorded in cost of revenues, related party in the consolidated statements of operations .

Other

Total amounts paid to the Biofrontera Group for expenses related to sales of products and services in the US, including but not limited to product production, quality control, pharmacovigilance, regulatory activities as well as rent for the years ended December 31, 2025 and 2024 were $0.8 million and $0.5 million, respectively.

As of December 31, 2025 and 2024, our investment, related party consisted solely of 3,019 common shares of Biofrontera AG. The total investment had minimal value as of December 31, 2025 and 2024. As reflected in the consolidated statements of cash flows, we received proceeds from sales of equity securities of $0.1 million during the year ended December 31, 2024.

In November 2024, the Company issued $4.2 million in an aggregate principal amount of Notes to certain stockholders. See *Note 14. Debt-Convertible Notes Payable*. As of December 31, 2025 and 2024, the outstanding balance of the Notes was $4.6 million and $4.1 million, respectively.

17. Stockholders' Equity

Under the Company's Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation ("Certificate"), filed June 16, 2025, the Company is authorized to issue 70,000,000 shares of 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.

During the years ended December 31, 2025 and 2024, the Company issued shares of common stock upon the exercise of our liability classified warrants, conversions of preferred stock, and vesting of equity awards. The related changes in shares outstanding are reflected in the Consolidated Statement of Stockholder's Equity.

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.

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.

During the year ended December 31, 2025, the Company issued 1,859,508 shares of common stock upon conversion of Series B-2 Preferred Stock, 240,210 shares of common stock upon conversion of Series B-3 Preferred Stock, 449,673 shares of common stock upon conversion of Series C Preferred Stock and 225,000 shares of common stock for restricted stock units.

For each of the years ended December 31, 2025 and 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, 2025 is presented below.

Warrants	Number of Shares	Exercise Price	Expiration Date
Liability classified (See *Note 4. Fair Value Measurements*)	2,192,736	$ 3.55	11/02/2028
Equity classified	76,620	100.00	11/02/2026

Series B Convertible 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) 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 price of $8.0 million. The conversion price of Series B-1 Preferred Stock and Series B-3 Preferred Stock is $0.7074 per share of common stock, such that each Series B share is convertible into 1,413 shares of the 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. 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, 2025.

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.

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 million of warrant liability fair value. As of December 31, 2024, the 2024 Preferred Warrants issued in the Offering had been exercised or expired.

During the year ended December 31, 2025, holders of the Company's Series B-2 Preferred Stock converted 1,316 of these shares into 1,859,508 shares of common stock and holders of the Company's Series B-3 Preferred Stock converted 170 of these shares into 240,210 shares of common stock, in accordance with the applicable conversion provisions of those instruments.

As of December 31, 2025, there were no shares of Series B-1 Preferred Stock issued and outstanding, 2,050 shares of Series B-2 Convertible Preferred Stock, par value $0.001 per share (the "Series B-2 Preferred Stock") and 6,593 shares of the Series B-3 Preferred Stock (collectively the "Series B Preferred Stock") issued and outstanding with the following terms, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred with the Delaware Secretary of State:

Voting Rights. Subject to certain limitations described in the Certificate of Designation with the Delaware Secretary of State, 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. In May 2024, upon the Company's stockholders' approval of an increase in the authorized shares of common stock (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.

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 changes in stockholders' as of December 31, 2025 and 2024, due to the limited exception under ASC 480-10-S99-3A(3)(f).

Series C Convertible Preferred Stock

As a condition precedent to the Strategic Transaction, the Company entered into a securities purchase agreement with certain accredited investors on June 27, 2025, pursuant to which the Company agreed to issue and sell, in a private placement, up to 11,000 shares of Series C Convertible Preferred Stock, par value $0.001 per share at a price of $1,000 per Series C Preferred Share for an aggregate offering price of $11.0 million. The offering consisted of two tranches, of which the first tranche of 8,500 Series C Preferred Shares closed on July 1, 2025 and the second tranche of 2,500 Series C Preferred Shares closed on October 24, 2025.

On June 30, 2025, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred with the Delaware Secretary of State (the "Series C Certificate of Designation") designating 11,000 shares of its authorized and unissued preferred stock as Series C Preferred Stock each with a stated value of $1,000 per share.

During the year ended December 31, 2025, holders of the Company's Series C Preferred Stock converted 281 of these shares into 449,673 shares of common stock in accordance with the applicable conversion provisions of those instruments.

As of December 31, 2025, there were 10,719 shares of Series C Preferred Stock issued and outstanding with the following terms, pursuant to the Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred with the Delaware Secretary of State:

Voting Rights. Holders of Series C Preferred Stock will be entitled to one vote for each whole share of common stock into which their Series C Preferred Stock is then-convertible on all matters submitted to a vote of stockholders, subject to certain limitations.

Conversion. Each share of Series C Preferred Stock is, subject to certain limitations, immediately convertible at the option of the holder thereof into the number of shares of the Company's common stock equal to the original share price of $1,000 divided by $0.6249, rounded down to the nearest whole share.

Liquidation. Upon any liquidation, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series C Preferred Stock, Series D Preferred Stock, any other classes of capital stock with liquidation rights and common stock, *pro rata* based on the number of shares of common stock held by each such holder, treating for this purpose all shares of Series C Preferred Stock as if they had been converted to common stock immediately prior to such liquidation, without regard to any limitations on conversion or otherwise.

Series D Convertible Preferred Stock

On July 2, 2025, the Company issued 3,019 shares of Series D Convertible Preferred Stock, par value $0.001 per share (the "Series D Preferred Stock"), each at a price of $1,000 per Series D Preferred Stock, in connection with the Term Sheet, as a precursor to the Strategic Transaction. Under the Term Sheet, for a period of twelve months following the date of issuance of the Series D Preferred Stock, the Company shall not issue any additional equity securities or any debt convertible into equity.

In connection with the Strategic Transaction, on June 30, 2025, the Company filed the Certificate of Designation of Preferences, Rights and Limitations of Series D Convertible Preferred Stock with the Delaware Secretary of State (the "Series D Certificate of Designation") designating 3,019 shares of its authorized and unissued preferred stock as Series D Preferred Stock each with a stated value of $1,000 per share.

As of December 31, 2025, there were 3,019 shares of the Series D Preferred Stock issued and outstanding with the following terms, pursuant to the Series D Certificate of Designation:

Voting Rights. Holders of Series D Preferred Stock will be entitled to one vote for each whole share of common stock into which their Series D Preferred Stock is then-convertible on all matters submitted to a vote of stockholders, subject to certain limitations.

Conversion. Each share of Series D Preferred Stock, subject to certain limitations, is immediately convertible at the option of the holder thereof into the number of shares of the Company's common stock equal to the original share price of $1,000 divided by 0.6249, rounded down to the nearest whole share.

Liquidation. Upon any liquidation, the assets of the Company available for distribution to its stockholders shall be distributed among the holders of the shares of Series D Preferred Stock, Series C Preferred Stock, any other classes of capital stock with liquidation rights and common stock, *pro rata* based on the number of shares of common stock held by each such holder, treating for this purpose all shares of Series D Preferred Stock as if they had been converted to common stock immediately prior to such liquidation, without regard to any limitations on conversion or otherwise.

Effective as of the date of the Strategic Transaction and for the following three years, as long as Biofrontera AG holds any shares of Series D Preferred Stock (or shares of common stock that were converted from Series D Preferred Stock), Biofrontera AG shall have the right to appoint (i) one individual to the Company's board of directors if the board consists of seven or fewer members; or (ii) two individuals to the Company's board of directors if the board consists of eight or more directors. No appointments have been made through the filing date.

Redeemable Preferred Stock

At issuance, the Series C Preferred and Series D Preferred Stock were redeemable in the event of a change in control that was not solely within the control of the Company. ASC 480-10-S99-3A(2) of the SEC's Accounting Series Release No. 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. The Series C Preferred and Series D Preferred Stock had preference in liquidation over common stock upon deemed liquidation events that were not solely within the issuer's control. As such the limited scope exception for permanent equity did not apply and the Series C Preferred and Series D Preferred Stock were classified as mezzanine equity at issuance.

Following the Company's Special Shareholder Meeting on September 16, 2025, the holders of Series C Preferred Stock and Series D Preferred Stock are entitled to receive the same form of consideration upon a liquidation event. Accordingly, the Series C Preferred Stock and Series D Preferred Stock were classified as permanent equity on our consolidated balance sheets and consolidated statements of change in stockholders' equity and are presented as such as of December 31, 2025, due to the limited exception under ASC 480-10-S99-3A(3)(f).

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 14. Debt - Convertible Notes Payable*, for additional details.

18. 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, 2025, there were 1,200,101 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 or semi-annually over one year in accordance with the respective award agreements 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 or greater than 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 either a Lattice model, or the BSM model for "plain vanilla' options, each of 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 assumptions and key inputs for the stock options granted in 2025 which were valued using the Lattice model were: exercise price of $1.00, risk-free rate of approx. 4.3%, volatility of 95%, a dividend yield of 0.0%, and an option exercise multiple of 2.50x. The assumptions and key inputs for the stock options granted in 2024 valued using the BSM model were: exercise price of $0.99 to $1.38, risk-free rate of approx. 4.2% to 4.3%, volatility of 100%, expected term of 5.24 to 6 years, and a dividend yield of 0.0%.

The total grant-date fair value of options granted during the years ended December 31, 2025 and 2024 was $0.4 million and $1.1 million, respectively. The weighted average grant-date fair value of options granted during the years ended December 31, 2025 and 2024 was $0.61 and $0.82, respectively.

Share-based compensation expense related to stock options of $0.7 million and $0.8 million was recorded in selling, general and administrative expenses, with a negligible amount recorded as research and development on the accompanying consolidated statement of operations for the years ended December 31, 2025 and 2024, respectively.

Options outstanding and exercisable under the employee share option plan as of December 31, 2025 and 2024, 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, 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	$ -
Granted	719,844	$ 1.00		
Exercised	-	$ -		
Canceled or forfeited	(191,844)	$ 4.65		
Outstanding at December 31, 2025	1,886,718	$ 2.70	7.46	$ -
Exercisable at December 31, 2025	515,408	$ 6.61	8.26	$ -

(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, 2025 and December 31, 2024.

As of December 31, 2025, there was $0.7 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 1.25 years.

Share-Based Compensation (RSUs)

RSUs will vest either annually over two years, or semi-annually over one year in accordance with the respective award agreements, subject to the recipient's continued service with the Company through the applicable vesting dates. The fair value of each RSU is estimated based on the closing market price of the Company's common stock on the grant date.

Share-based compensation expense related to RSUs of $0.3 million and $0.2 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, 2025 and 2024.

As of December 31, 2025, there was $0.2 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of 1.0 years.

The following table summarizes the activity for RSUs during the year ended December 31, 2025 and December 31, 2024:

	Shares	Weighted Average Grant Date Fair Value
Unvested balance at December 31, 2023	4,771	$ 52.20
Awarded	450,000	$ 1.06
Issued	(4,771)	$ 52.20
Forfeited	-	$ -
Unvested balance at December 31, 2024	450,000	$ 1.06
Awarded	187,500	$ 0.90
Issued	(225,000)	$ 1.06
Forfeited	-	$ -
Unvested balance at December 31, 2025	412,500	$ 0.99

19. 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. 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,	
	2025	2024
Net loss	$ (10,536)	$ (17,759)
Weighted average common shares outstanding, basic and diluted	10,171,921	5,516,334
Net loss per share, basic and diluted	$ (1.04)	$ (3.22)

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

December 31,	2025	2024
Common stock warrants	2,269,356	2,269,356
Common stock options and RSUs	2,299,218	1,808,718
Unit Purchase Options	20,182	20,182
Series B-2 convertible preferred stock	2,896,650	14,318,632
Series B-3 convertible preferred stock	9,315,909	-
Series C convertible preferred stock	17,153,187	-
Series D convertible preferred stock	4,831,185	-
Convertible notes	6,006,345	5,384,615
Total	44,792,032	23,801,503

20. Commitments and Contingencies

Leases

The lease for our office space at 120 Presidential Way, Woburn, MA expired in November 2025. The Company elected to not renew the lease and has no remaining commitments under this agreement. Lease expense was recognized through the expiration date, and the ROU asset and related lease liability were derecognized.

On July 30, 2025, the Company entered into an agreement to lease office space for its corporate headquarters at 660 Main Street, Woburn, MA. The lease commenced on December 1, 2025, with an original term of 63 months, terminating on February 28, 2031, unless extended. Under the terms of the agreement, the Company is entitled to a rent-free period for the first three months of the lease and reduced rent payments for months four through nine, followed by periodic escalated payments thereafter. The Company provided the landlord with a security deposit in the amount of $0.2 million, which was recorded as other assets in the consolidated balance sheets.

The Company has a master lease agreement for its vehicles, pursuant to which each vehicle is leased for an initial non-cancelable twelve-month period, and thereafter on a month-to-month basis. Based on historical retention experience of approximately three years, the vehicles have varying expiration dates through January 2029.

The components of lease expense for the years ended December 31, 2025 and 2024 were as follows (in thousands except lease term and discount rate):

Operating Lease expense	December 31, 2025	December 31, 2024
Amortization of ROU assets (operating lease cost)	$ 730	$ 728
Interest on lease liabilities	60	88
Total lease expense	$ 790	$ 816
Other Information		
Operational cash flow used for operating leases	$ 731	$ 778
ROU assets obtained in exchange for lease liabilities	1,371	55
Weighted -average remaining lease term (in years)	4.43	1.55
Weighted -average discount rate	9.88%	8.22%

Future lease payments under non-cancelable leases as of December 31, 2025 were as follows (in thousands):

Years ending December 31,	Future lease commitments
2026	471
2027	393
2028	355
2029	342
2030	351
Thereafter	59
Total future minimum lease payments	$ 1,971
Less imputed interest	$ (399)
Total lease liability	$ 1,572

Reported as:	December 31, 2025
Operating lease liability, current	$ 332
Operating lease liability, non-current	1,240
Total	1,572

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, 2025 or 2024.

Second A&R Ameluz LSA Sales Commitment and Minimum Research and Development Costs

The Second A&R Ameluz LSA, as amended by the Term Sheet, remained in full force and effect until the date of the Strategic Transaction of October 20 2025, at which time it was terminated. The Company was not required to make any payments under the Second A&R Ameluz LSA for the years ended December 31, 2025 and 2024.

Minimum Sales or Minimum Order

Until the earlier to occur of (i) the Company manufactures orders meeting one million tubes of Ameluz during the period from June 1, 2025 through May 31, 2031, or (ii) the expiration of patent protection, which is expected to occur in December 2043 (the "Asset Reversion Term"), starting January 1, 2026 and continuing until the end of the Asset Reversion Term, the Company shall be required to manufacture or order from suppliers at least 80,000 tubes of Ameluz per year (the "Minimum Order Amount").

Supply Agreement

On December 12, 2025, Discovery entered into a Supply Agreement ("Supply Agreement") with Midas Pharma GmbH ("Midas"). Among other things, the Supply Agreement provides that Midas will supply to Discovery or its contract manufacturers, in the aggregate, 100kg of the active pharmaceutical ingredient 5-Aminolevulinic acid Hydrochloride through the second quarter of 2028. Under the terms of the Supply Agreement, Discovery will provide Midas with a twenty-four (24) months non-binding rolling forecast, which shall 1) indicate the anticipated quantity of API required by the company and 2) be updated every twelve (12) months during the term of the agreement.

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., and Sun Pharmaceutical Industries LTD (collectively, "SUN") in which SUN 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. SUN has since amended its complaint to include the allegations contained therein with its existing claims.

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 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 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 (the "Massachusetts District Court") and the International Trade Commission ("the Commission"), both alleging that the RhodoLED-XL infringes either/both 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 investigation before the Commission. A hearing was held in front of an administrative law judge ("ALJ") between June 30, 2025 and July 3, 2025, and on September 30, 2025, the ALJ issued an Initial Determination ("ID") finding the Sun Patents to be valid and that importation of Biofrontera's RhodoLED XL violates Section 337 of the Tariff Act of 1930. The ID may be reviewed by the Commission, following which the Commission may adopt, reverse, or remand the ID to the ALJ for further proceedings. The ID has no immediate effect and will only become effective if adopted by the Commission in its "Final Determination". The Commission's Final Determination is expected by April 30, 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 discretionarily denied by the PTAB on July 2, 2025 on administrative reasons. However, after instituting the other such petition in February of 2025, the PTAB issued final written decision on February 23, 2026 finding all of the claims in the SUN Patent challenged by Biofrontera to be unpatentable.

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 Commission, 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 Massachusetts District Court is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

21. 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 $0.2 million for the years ended December 31, 2025 and 2024, respectively.

22. Segment Reporting

The Company operates as one operating segment, that derives revenue primarily from our principal product, Ameluz, which is a prescription drug approved for use in PDT using our RhodoLED Lamps, for the treatment of AKs. We are currently selling Ameluz for this indication in the United States. 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, 2025, and 2024**:**

(*in thousands)*	**December 31, 2025**	**December 31, 2024**
Revenues, net	**41,705**	**37,321**
Operating expenses:		
Cost of revenues	10,964	18,607
Direct sales	7,963	9,058
Sales support	7,541	8,498
General and administrative	22,866	16,279
Research and development	3,719	2,089
Total operating expenses	53,053	54,531
Loss from operations	**(11,348)**	**(17,210)**
Other income (expense), net	837	(527)
Loss before income taxes	**(10,511)**	**(17,737)**
Income tax expenses	25	22
Net loss	**$ (10,536)**	**$ (17,759)**

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, 2025, 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, 2025 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, 2025.

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, 2025.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2025 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

On December 12, 2025, Discovery entered into a Supply Agreement ("Supply Agreement") with Midas Pharma GmbH ("Midas"). Among other things, the Supply Agreement provides that Midas will supply to Discovery or its contract manufacturers 5-Aminolevulinic Acid Hydrochloride, the active pharmaceutical ingredient used in the manufacture of Ameluz, in amounts as specified therein. Under the terms of the Supply Agreement, Discovery will provide Midas with a twenty-four (24) months non-binding rolling forecast, which shall 1) indicate the anticipated quantity of API required by the company and 2) be updated every twelve (12) months during the term of the agreement. The Supply Agreement has an initial term ending on December 31, 2030, and automatically renews for successive two-year periods unless either party provides at least 12 months' notice of termination prior to expiration of the then-current term. The Supply Agreement is governed by the laws of Germany.

This description of the Supply Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Supply Agreement, a copy of which is attached as Exhibits 10.33, respectively, to this Form 10-K and incorporated herein by reference.

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, 2025, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2025 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, 2025, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2025 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, 2025, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2025 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, 2025, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2025 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, 2025, which will be filed with the Securities and Exchange Commission, pursuant to Regulation 14A, no later than 120 days after the end of the 2025 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).
2.2	Asset and Purchase Agreement dated November 6, 2025 between Biofrontera Inc. and Pelthos Therapeutics Inc. (incorporated by reference to the Company's Form 8-K filed with the SEC on November 7, 2025)
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 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)
3.3	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)
3.4	Certificate of Third Amendment to the Amended and Restated Certificate of Incorporation of Biofrontera Inc., filed June 16, 2025 (incorporated by reference to Exhibit 3.3 to the Company's Quarterly Report on Form 10-Q filed with the SEC on August 13, 2025)
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 Designation of Preferences, Rights and Limitations of the Series C Convertible Preferred Stock (incorporated by reference to Exhibit 3.2 of the Company's Current Report on Form 8-K filed with the SEC on July 1, 2025)
3.7	Certificate of Designation of Preferences, Rights and Limitations of the Series D Convertible Preferred Stock (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the SEC on July 1, 2025)
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 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 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)
10.2	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).

10.3	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)
10.4†	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)
10.5†	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)
10.6†	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)
10.7†	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)
10.8†	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)
10.9†	Employee Stock Purchase Plan (incorporated by reference to Exhibit 10.16 filed with the SEC on October 12, 2021)
10.10	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)
10.11	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)
10.12†	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)
10.13	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)
10.14	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)

10.15	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 28, 2022)
10.16†	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)
10.17	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)
10.18#	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)
10.19	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)
10.20	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)
10.21	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)
10.22	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)

10.23	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)
10.24	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)
10.25	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)
10.26	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)
10.27†	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)
10.28	Form of Securities Purchase Agreement, dated June 27, 2025, 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 July 1, 2025)
10.29	Form of Agreement, dated June 30, 2025, by and among Biofrontera Inc. and Biofrontera AG (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K/A filed with the SEC on July 16, 2025)
10.30	Form of Asset Purchase Agreement, dated October 20, 2025, 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 October 24, 2025)
10.31	Form of Earnout Agreement, dated October 20, 2025, by and among Biofrontera Inc. and the purchasers named therein (incorporated by reference to Exhibit 10.2 of the Company's Current Report on Form 8-K filed with the SEC on October 24, 2025)
10.32†	Employment Agreement dated July 18, 2025—George P. Jones (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on August 11, 2025)
10.33*	Supply Agreement, dated December 12, 2025, by and among Biofrontera Discovery GmbH and Midas Pharma GmbH

19.1	Insider Trading Policy (incorporated by reference to Exhibit 19.1 to the Company's Form 10-K filed with the SEC on March 20, 2025)
21.1	List of Subsidiaries of the Company (incorporated by reference to Exhibit 21.1 to the Company's Form 10-K filed with the SEC on March 20, 2025)
23.1*	Consent of CBIZ CPAs P.C., independent registered public accounting firm
23.2*	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 19, 2026.

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 19, 2026
/s/ E. Fred Leffler E. Fred Leffler	Chief Financial Officer (*Principal Financial Officer)* *(Principal Accounting Officer)*	March 19, 2026
/s/ Beth J. Hoffman Beth J. Hoffman	Director	March 19, 2026
/s/ Heikki Lanckriet Heikki Lanckriet	Director	March 19, 2026

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, 2025 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.

Transfer Agent

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

Exhibit 10.33

Supply Agreement

This Supply Agreement ("Agreement") has been made on December 12, 2025 ("Effective Date") by and between

Biofrontera Discovery GmbH, a company with its head office at Hemmelrather Weg 201, D-51377 Leverkusen, Germany (hereinafter called "BIOFRONTERA")

and

Midas Pharma GmbH, a company with its head office at Rheinstr. 49, D-55218 Ingelheim, Germany (hereinafter called "MIDAS")

Preamble

BIOFRONTERA, a wholly-owned subsidiary of Biofrontera Inc., is a pharmaceutical company dedicated to the performance of clinical trials, distribution of drug products and manufacturing of medical devices for the US market.

Whereas, MIDAS has developed and holds a European Active Substance Master File (ASMF) and a US Drug Master File (DMF) for the active pharmaceutical ingredient 5-Aminolevulinic acid Hydrochloride that is currently manufactured exclusively on behalf and order of MIDAS at a third party contract manufacturing organization; and

Whereas, the parent company of BIOFRONTERA, Biofrontera Inc., is in possession of the registration dossier in the USA for a finished pharmaceutical form called Ameluz® with the active substance 5-Aminolevulinic acid Hydrochloride that refers, among others, to the DMF of MIDAS; and

Whereas, BIOFRONTERA is willing to purchase the active pharmaceutical ingredient from MIDAS; and

Whereas, MIDAS is willing to supply the active pharmaceutical ingredient to BIOFRONTERA or, upon request of BIOFRONTERA, directly to its contract manufacturers; and

Now therefore, in consideration of the foregoing recitals, which are expressly incorporated into the body of this Agreement, the Parties mutually agree as follows:

1. Definitions

1.1 "**Agreement**" shall mean this Supply Agreement between BIOFRONTERA and MIDAS.

1.2 "**Agreed Quality**" shall have the meaning as defined in clause 3.1

1.3 "**Affiliate(s)**" shall mean with respect to either Party, any person, partnership, corporation, organization or entity that directly or indirectly controls or is directly or indirectly controlled by or is under common control with such Party. A person or entity shall be regarded as controlling entity, if (i) it owns more than fifty percent of the voting stock or other ownership interest of such other entity; or (ii) it directly or indirectly possesses sufficient authority to direct the adoption and / or execution of the policies, management or operations of such entity by any means whatsoever.

1.4 **"API"** shall mean the active pharmaceutical ingredient 5-Aminolevulinic acid Hydrochloride as manufactured by the MANUFACTURER and supplied by MIDAS.

1.5 "**CEP**" shall mean a Certificate of suitability of Monographs of the European Pharmacopoeia.

1.6 "**Confidential Information**" shall mean all written information provided by MIDAS to BIOFRONTERA or by BIOFRONTERA to MIDAS and with regard to the API or the PRODUCT. The term "Confidential information" as used herein shall also include all terms and conditions of this Agreement.

1.7 "**Confirmed Quantity**" shall have the meaning given to it in clause 6.6

1.8 "**Drug Master File**" or "**DMF**" shall mean the drug master file used for active pharmaceutical ingredients in the United States of America as specified by the U.S. Food & Drug Administration (FDA) of the U.S. Department of Health and Human Services. For the avoidance of doubt, "Drug Master File" or "DMF" within the meaning of this SUPPLY AGREEMENT without exception always refers to a Drug Master File approved by the U.S. Food & Drug Administration (FDA) according to the FDA's Drug Master Files Guidelines.

1.9 "**Effective Date**" shall mean December 12, 2025.

1.10 **"Health Authorities"** shall mean any health authority in a given country, responsible for the evaluation of the registration dossier and the grant of the Marketing Authorization for the PRODUCT.

1.11 **"Hidden Defect"** shall mean all defects present in the API at the time of transfer of risk of the API which cannot be detected by the inspection described in section 7.1.

1.12 **"Initial Contractual Period"** shall have the meaning given to it in Section 13.1.

1.13 **"MANUFACTURER(S)"** shall mean the manufacturer of the API as contracted by MIDAS and named in the DMF, being Procos S.p.A., Italy, as registered manufacturer in the DMF by MIDAS and accepted by the US-FDA.

1.14 **"Marketing Authorization"** shall mean any authorization, which is legally required under applicable laws, regulations or administrative decisions, to launch, market or distribute the PRODUCT in a given country.

1.15 "**Material Breach**" shall mean any breach of this Agreement by one Party which, considering the nature and purpose of the Agreement, makes the continuation of this contractual relationship unreasonable for the non-breaching Party.

1.16 "**Order**" has the meaning set out in clause 6.4. For the avoidance of doubt: The Order itself does not imply any obligation on the part of BIOFRONTERA to pay the agreed price for the ordered API. BIOFRONTERA's obligation to pay shall only arise once:

a) MIDAS has confirmed such order in accordance with 6.7 and

b) BIOFRONTERA has removed the API subject to such Confirmed Order from the Warehouse in accordance with Clause 6.13 and

c) MIDAS has issued a corresponding invoice to BIOFRONTERA in accordance with Clause 5.2.

1.17 "**Order Confirmation**" shall have the meaning given to it in Section 6.6

1.18 "**Party**" shall mean each of the contracting parties, BIOFRONTERA and MIDAS separately, whereas "**Parties**" shall mean all of the contracting parties together.

1.19 "**PRODUCT**" shall mean a semisolid formulation for topical use with the API as one/as the main active ingredient as registered with FDA by the parent company of BIOFRONTERA.

1.20 "**Production Year**" shall have the meaning as defined in clause 6.1

1.21 "**Quality Agreement**" shall mean a separate agreement between MIDAS and BIOFRONTERA governing, without limitation, cGMP and quality issues involved in the manufacture and control of the API and testing and release of the API for sale, entered into by the Parties as referenced to in Annex C.

1.22 "**SPECIFICATION**" shall mean the specification of the API according to the current Certificate of Suitability (CEP) and/or Marketing Authorisation of the PRODUCT as stipulated in detail in the corresponding Quality Agreement.

1.23 "**Third Party**" shall mean any person or entity not being MIDAS or one of its Affiliates or BIOFRONTERA or one of its Affiliates.

1.24 **"Working Day"** shall mean each Day from Monday to Friday, except for national public holidays in Germany and Italy.

1.25 Headings are for convenience only and do not affect interpretation. The following rules apply unless the context requires otherwise.

a) The singular includes the plural and conversely.

b) A gender includes all genders.

c) A reference to a person, corporation, trust, partnership, unincorporated body or other entity includes any of them.

d) A reference to an agreement or document (including, without limitation, a reference to this Agreement) is to the agreement or document as amended, varied, supplemented or replaced, except to the extent prohibited by this Agreement or that other agreement or document.

2. Subject of this Agreement

2.1 BIOFRONTERA contracts MIDAS with the supply of the API in accordance with the terms and conditions of this Agreement.

2.2 MIDAS accepts such appointment.

2.3 Both Parties agree to perform their respective obligations under this Agreement in accordance with the terms and conditions set forth herein and in accordance with all applicable national and European laws, regulations or directives.

3. OBLIGATIONS AND RIGHTS OF MIDAS

3.1 MIDAS' obligation shall be the supply of the API, as manufactured by the MANUFACTURER Procos S.p.A., free of defects, in the agreed upon time and quantity and in accordance with the SPECIFICATION and DMF as well as the Quality Agreement (the "Agreed Quality"). Supply of API from any different MANUFACTURER than Procos S.p.A. shall only be conducted upon prior mutual written consent between the Parties and after approval by the relevant authorities.

3.2 MIDAS has obtained ICH stability data conforming a 60-months initial re-test period for the API.

3.3 At the time of delivery of the API, to the first carrier in accordance with INCOTERMS 2020 CPT, according to the forecasts and orders by BIOFRONTERA, the remaining re-test period for the API shall be not less than 80% of the initial re-test period. However, in exceptional circumstances and cases of additional demands of BIOFRONTERA, provided MIDAS has suitable API available, the Parties shall mutually discuss and agree, if API with less remaining re-test period can be supplied.

3.4 Unless already provided by MIDAS at the Effective Date and in case of changes and updates, MIDAS shall provide BIOFRONTERA with all data and documentation necessary to enable BIOFRONTERA to add and maintain Procos S.p.A, Italy, as MANUFACTURER to Biofrontera Inc.'s Dossier for the PRODUCT. Any such documentation shall be provided by MIDAS as soon as it is available at MIDAS without delay.

3.5 Upon request of BIOFRONTERA, MIDAS shall submit reasonable quantities of working standards and reference impurities of the API to BIOFRONTERA at its own cost, if such standards or reference materials are not elsewhere commercially available.

3.6 MIDAS shall file and maintain the DMF and comply with all obligations as DMF holder according to relevant laws. After termination of this contract, MIDAS shall maintain the DMF active as long as BIOFRONTERA has PRODUCT manufactured with MIDAS API on the market and the associated change/variation is approved.

3.7 MIDAS shall submit and maintain the US-DMF for the API to FDA in USA and provide BIOFRONTERA with a Letter of Authorization.

3.8 MIDAS commits to support BIOFRONTERA and its parent company in a commercially reasonable manner in the preparation and submission of regulatory applications. MIDAS may charge regulatory service fees from BIOFRONTERA and/or its parent company.

4. OBLIGATIONS AND RIGHTS OF BIOFRONTERA

4.1 BIOFRONTERA is entitled to purchase the API from MIDAS (section 6). There is no obligation on the part of BIOFRONTERA to purchase and take delivery of the API. For the avoidance of doubt BIOFRONTERA does not buy API exclusively from MIDAS.

4.2 Notwithstanding the foregoing provisions regarding amounts to be purchased, BIOFRONTERA will only purchase the API if the MANUFACTURER Procos S.p.A. is registered in the DMF by MIDAS and accepted by US-FDA according to Section 1.15.

4.3 For the avoidance of doubt, BIOFRONTERA wishes to be supplied by the MANUFACTURER Procos S.p.A. as stipulated in Section 1.15 of this Agreement and shall not - unless expressly accepted in advance by BIOFRONTERA - buy API from MIDAS that has been produced by another manufacturer and/or any other Third Party contract manufacturer of MIDAS that is not already known to BIOFRONTERA, registered in the DMF and accepted by the US-FDA. However, the acceptance and confirmation of any such newly selected manufacturer will not be unreasonably withheld by BIOFRONTERA.

5. Price and Payment Terms

5.1 The price for the API is listed in Annex A to this Agreement and will be fixed in Euro (EUR). The price is to be understood CPT Switzerland or Germany (INCOTERMS 2020), excluding any fees charged by authorities for or related to the PRODUCT, the API, the DMF and the MANUFACTURER. Should BIOFRONTERA in future require a different delivery destination, the Parties will discuss and agree on the respective terms and conditions for such supply.

Any fees that are charged by any authority to MIDAS and/or MANUFACTURER and that are related to the use of API by BIOFRONTERA for manufacture, marketing or use of a finished pharmaceutical form within the USA shall be borne by BIOFRONTERA, or in case the respective fee is payable by MIDAS or MANUFACTURER, shall be reimbursed to MIDAS.

However, if charges are due to quality issues or non-compliance issues caused by MIDAS or its MANUFACTURER then BIOFRONTERA shall not be obliged to absorb such cost.

5.2 BIOFRONTERA shall pay the agreed upon price for the API as invoiced by MIDAS within thirty (30) days net from date of invoice of MIDAS. Invoicing shall not take place before the time specified in clause 6.13.

5.3 Should the cost- and/or market situation change considerably to the disadvantage of one of the Parties, the Parties shall solve such a problem in a friendly way, balancing the interests of the Parties.

6. Forecasting, Supply, Storage, Use and Payment

6.1 BIOFRONTERA is aware that, starting 2026, MANUFACTURER manufactures once every two calendar years. The next planned productions will take place in 2028, 2030 and so on (“Production Year”), provided BIOFRONTERA has a demand of API and wishes to be supplied. Should MIDAS expect to change the manufacturing frequency defined above for whatever reason, it will notify BIOFRONTERA immediately and with an appropriate lead time.

6.2 BIOFRONTERA will provide MIDAS with a twenty-four (24) months non-binding Rolling Forecast of API quantities BIOFRONTERA expects to order during the following two (2) calendar years. The forecast shall indicate the quantity of API and the expected year of supply. Such forecast shall thereafter be updated by BIOFRONTERA every twelve (12) months during the term of this Agreement. BIOFRONTERA shall deliver the Rolling Forecast to MIDAS by the end of September (30th September) of each calendar year.

6.3 If MIDAS is unable to accommodate any portion of the forecast, it shall notify BIOFRONTERA immediately and not later than 3 months after submission of the Rolling Forecast. The Parties shall agree on any revisions to the forecast.

6.4 Aligned with the forecasts provided by BIOFRONTERA or based on mutually agreed amounts, BIOFRONTERA will request the total quantity to be supplied in a written order ("Order") until the November 30th of each year before any Production Year at the latest. Orders and their respective supply/payment schedules for each production campaign shall be mutually agreed upon and documented in Annex B. The first supply of API according to this AGREEMENT by MIDAS shall be executed in December 2025 as defined in Annex B. Thereafter, starting in 2026, further API supply to replenish the stock with the quantity requested by BIOFRONTERA shall be executed by MIDAS every second year, as defined in chapter 6.1. Deliveries must be made by MIDAS in such a way that the timelines set forth in Annex B can be met. Any unforeseen extra demand that may be requested by BIOFRONTERA shall be supported by MIDAS, provided MIDAS has still suitable API available from a previous production.

6.5 MIDAS shall supply such API quantities to one or two warehouses (Germany and Switzerland) of BIOFRONTERA or BIOFRONTERA´s CMO.

6.6 MIDAS shall accept supply Orders to BIOFRONTERA´s warehouse with written order confirmations within fifteen (15) Working Days from receipt of such Orders ("Order Confirmation"). The Order Confirmation will include the confirmed API quantity ("Confirmed Quantity"), production date and expected delivery date. In case the Order Confirmation does not contain all the afore mentioned items or in case MIDAS does not comment on the received orders at all within such period, MIDAS shall be deemed to have accepted the Orders.

6.7 MIDAS shall deliver the API on Orders accepted by MIDAS to BIOFRONTERA or its contract manufacturers according to the Agreed Quality as defined in clause 3.1 and in containers suitable for storage and transportation of APIs. Moreover, MIDAS shall deliver the API in quantities of 25 kg per individual drum and delivery. If MIDAS wishes to deliver smaller quantities than 25 kg, MIDAS and BIOFRONTERA will mutually agree on the quantities. If no agreement can be reached, the minimum of 25 kg remains. Delivery shall take place CPT Germany or Switzerland (INCOTERMS 2020), as indicated by BIOFRONTERA.

6.8 In case MIDAS expects delays in delivery times or has general delivery problems, MIDAS will immediately inform BIOFRONTERA thereof. If Midas fails to comply with the Delivery Date as stipulated in clause 6.4, Midas shall be in default without further notice on the day following the Delivery Date, i.e. the 1st January of the following calendar year. BIOFRONTERA shall then be entitled to withdraw from the Order without further notice. BIOFRONTERA will be free to buy from another source to prevent an out of stock situation.

6.9 BIOFRONTERA will set up a warehouse (the "Warehouse") on its premises or on the premises of its CMOs or logistic service providers to receive supplies from MIDAS. Upon receipt of API from MIDAS at the Warehouse, BIOFRONTERA shall start incoming goods control according to clause 7.1. A representative sample will be provided to BIOFRONTERA by MIDAS upon order. Sampling will be performed by MANUFACTURER according to GMP and cGMP requirements. The samples must be stored and transported according to cGMP requirements and according to the agreed upon storage conditions (2-8°C) and transportation conditions together with the API. Samples will be invoiced immediately upon delivery with a payment term of 30 days.

6.10 The risk of loss of the API will pass to BIOFRONTERA pursuant to the agreed upon delivery terms according to INCOTERMS 2020, at the latest upon receipt of the API into the Warehouse. BIOFRONTERA shall adequately insure the API supplied by MIDAS which is stored in the Warehouse against fire, water, theft, and damage by third parties. MIDAS shall be entitled to request evidence for the insurance being installed by BIOFRONTERA. Upon request by MIDAS to BIOFRONTERA, MIDAS shall be allowed within maximum 5 working days to survey the inventory of the API stocks at the Warehouse.

6.11 BIOFRONTERA agrees to provide a suitable location to store the API. BIOFRONTERA shall store the API in accordance with GMP specifications as well as in accordance with the requirements of all applicable legal regulations. The API and the area to which the API is to be delivered shall be established at the Warehouses. It shall be BIOFRONTERA's responsibility to ensure that the API is not commingled with other inventory of any warehouse, and remains segregated within BIOFRONTERA's ERP systems as property of MIDAS.

6.12 Notwithstanding the delivery and the passing of risk in the API or any other provision of these conditions, the property in the APIs shall not pass to BIOFRONTERA until the API is paid in full. As long as the API has not been completely paid, BIOFRONTERA shall immediately inform MIDAS in writing if any part of the API becomes subject to rights of third persons or other encumbrances. BIOFRONTERA may resell or process API owned by MIDAS only in the course of its regular business. BIOFRONTERA hereby assigns all claims arising out of such resale or processing to MIDAS. Nevertheless, BIOFRONTERA shall be entitled to receive the payment on the assigned claims. To this end, MIDAS agrees to not demand payment on the assigned claims to the extent BIOFRONTERA complies with all its obligations for payment and does not become subject to an application for insolvency or similar proceedings, or to any stay of payments. Insofar as the foregoing retention of title clause results in securities that exceed the secured claim by more than 10%, MIDAS is obligated to release such securities.In case the Warehouse is located in Germany, BIOFRONTERA is entitled, at any time, to withdraw drums of API (each 25 kg per drum) out of the Warehouse for use in production of its pharmaceutical specialities. BIOFRONTERA commits to inform MIDAS promptly (not later than 5 working days) about the withdrawal of API drums. MIDAS will promptly issue an invoice to BIOFRONTERA for the respective quantity (full drums of 25 kg) at the agreed price with 30 days payment term.At the defined payment date according to Annex B, BIOFRONTERA shall pay (against corresponding invoicing by MIDAS) for the API not yet withdrawn.

6.13 In case the Warehouse is located in Switzerland, Midas will issue an invoice immediately upon delivery to the Warehouse with 30 days payment term.

6.14 BIOFRONTERA commits to follow the "first expiry / first out" principle for the use of material from its Warehouse or the Warehouses of its CMOs.

6.15 BIOFRONTERA commits to inform MIDAS without undue delay in case of any events that may compromise the quality and use of the API stored in the Warehouse of BIOFRONTERA or its CMOs.

6.16 In exceptional cases and upon mutual agreement between the Parties, MIDAS may take back full API drums (25 kg), provided the quality of the product is not compromised and BIOFRONTERA can demonstrate that the incoming goods control and entire storage complies with cGMP and the agreed upon conditions (2-8°C).

7. DEFECTS

7.1 Any complaint regarding obvious qualitative defaults, detectable by a visual inspection, including the taking and analysing of random samples, and/or quantitative shortcomings of the API shall be made in writing by BIOFRONTERA to MIDAS immediately after their discovery, at the latest within twenty (20) Working Days after receipt of the API in the Warehouse. BIOFRONTERA shall simultaneously send samples of the faulty API to MIDAS. If BIOFRONTERA fails to notify MIDAS within such period, BIOFRONTERA shall be deemed to have given its unconditional acceptance regarding the consignment.

7.2 In case of any Hidden Defects, complaints shall be raised by BIOFRONTERA immediately, but not later than ten (10) days after their discovery in writing.

7.3 Claims pursuant to Clause 7.2 are in any case time-barred after the entire re-test period of the API, counted from the delivery of the API to BIOFRONTERA. If BIOFRONTERA fails to notify MIDAS of any Hidden Defects within the period pursuant to Clause 7.2, BIOFRONTERA shall be deemed to have given its unconditional acceptance regarding the consignment.

7.4 In case of timely and justified claims, BIOFRONTERA shall be entitled to its statutory claims, unless otherwise stipulated in this Agreement:

a) In case of short delivery MIDAS shall use all commercially reasonable efforts to deliver the missing quantities within the shortest reasonable period of time. The rights of BIOFRONTERA regulated in clause 6.8 shall remain unaffected.

b) In case of defects, BIOFRONTERA's right to subsequent performance shall be limited as follows:

MIDAS can

(i) replace those quantities of the API which are found to be defective, as long as the performance of such replacement is not impossible, or

(ii) in case the performance of such replacement is impossible or only possible at disproportionate costs, MIDAS shall take back the API which is not in accordance with the Agreed Quality as defined in clause 3.1 and refund the purchase price to BIOFRONTERA.

c) In case of defects, BIOFRONTERA's withdrawal from the respective Confirmed Order shall only be possible after BIOFRONTERA has given MIDAS a reasonable period of eight (8) weeks to remedy the defect.

7.5 It is hereby agreed that in the case that MIDAS does not acknowledge the defect of the API, which BIOFRONTERA has found to be defective; the Parties shall endeavour to settle such disagreement amicably and constructively between themselves. In the event that they fail to agree within twelve (12) weeks after receipt of the notice of defects, the Parties agree to nominate an independent, reputable laboratory, acceptable for both Parties, which shall examine representative samples taken from such consignment, using the methods of analysis indicated in the SPECIFICATION, and the result shall be binding for all Parties. The charges for such examination shall be borne by the Party found to be at fault. Substitute deliveries on the basis of complaints subsequently recognised as not justified will be invoiced to BIOFRONTERA by MIDAS.

7.6 For the avoidance of doubt, the quality requirements of the PRODUCT are detailed in the Quality Agreement. In case of any conflicts or divergencies between this AGREEMENT and the Quality Agreement in respect of quality specific matters, then the provisions of the Quality Agreement shall prevail. For the rest, the provisions of this Agreement shall prevail.

8. Liability

8.1 Unless otherwise provided for in this Agreement and with the exception of the Parties' primary obligations – e.g. MIDAS' obligation to supply the API, as manufactured by the MANUFACTURER Procos S.p.A., in the Agreed Quality as defined in clause 3.1 - the Parties' liability towards each other in case of simple negligence (leichte Fahrlässigkeit) shall be excluded. The Parties' liability to each other in case of damages and losses resulting from gross negligence (grobe Fahrlässigkeit) shall be limited to direct losses, excluding in particular any indirect, punitive or consequential damages or loss of profits, whether based on contract or tort, or arising under applicable law or otherwise.

8.2 The limitation of liability set forth in this Section 8 shall not apply to the injury to life, limb or health, or to the intentional violation of the obligations of this Agreement by a Party.

8.3 All defect and liability claims arising from this contract are subject, to the extent legally possible, to a limitation period of one (1) year from statutory commencement of the limitation period. The running of the limitation period shall not be suspended or interrupted due to the Parties' negotiation of the claim or the claim's circumstances, unless otherwise agreed in writing.

9. Force Majeure

Any delay in the performance of any of the duties or obligations of either Party caused by an event outside the affected Party's reasonable control including those events affecting suppliers of such Party ("Force Majeure"), shall not be considered a breach of this Agreement and the time required for the performance shall be extended for a period equal to the period of such delay. The Party affected shall give prompt notice to the other Party of such cause and shall take whatever reasonable steps are appropriate in that Party's discretion to relieve the effect of such cause as rapidly as possible. Should one of the Parties be prevented from fulfilling its contractual obligations for more than ninety (90) days due to Force Majeure, the other Party shall be entitled to terminate this Agreement irrespective of the general provisions providing for termination in Section 13.

10. Confidentiality

10.1 Neither Party shall disclose any Confidential Information to Third Parties without the prior written consent of the respective disclosing party of such Confidential Information. However, BIOFRONTERA may disclose Confidential Information received from MIDAS to the appropriate regulatory authorities and to its parent company Biofrontera, Inc.. In addition, MIDAS shall be entitled to disclose Confidential Information received from BIOFRONTERA to MANUFACTURER, provided a corresponding confidentiality agreement has been concluded between MIDAS and MANUFACTURER beforehand.

10.2 The above mentioned obligation shall not apply or shall cease to apply to any information which:

a) is in the public domain at the time of disclosure;

b) is published or otherwise becomes part of the public domain through no fault of the receiving party;

c) is known to the receiving party before receipt thereof under this Agreement, as shown by prior written records;

d) becomes available from a Third Party which is not known by receiving party to be prohibited from disclosing such information by contractual or legal obligation to the disclosing Party; or

e) has to be revealed according to a court decision or an administrative order.

10.3 This confidentiality obligation will continue for a period of five (5) years after the termination date of this Agreement. None of the Parties shall be required to disclose to any of the other Parties any information known to be property of or obtained under obligations of secrecy from a Third Party.

11. INDEMNIFICATION

11.1 MIDAS shall defend, indemnify and hold BIOFRONTERA harmless from any Third Party claim or suit resulting from the use or application of the PRODUCTS,

a) if such loss or damage is solely due to a culpable breach of warranties of MIDAS under this Agreement, or

b) is solely due to any grossly negligent or intentionally wrongful breach, error or omission of contractual obligations of MIDAS under this Agreement.

11.2 BIOFRONTERA shall defend, indemnify and hold MIDAS harmless from any Third Party claim or suit on for loss or damages,

a) resulting from a culpable breach of warranties of BIOFRONTERA under this Agreement,

b) resulting from the manufacture, marketing, use or application of the PRODUCT,

c) resulting from any grossly negligent or intentionally wrongful breach, error or omission of BIOFRONTERA in performing its contractual obligations under this Agreement, or

d) resulting from any alleged or proven infringements of Third Party intellectual property rights by the marketing, use or application of PRODUCTS, unless such damages result solely from the breach of this Agreement by MIDAS or are otherwise covered by the indemnity clause of Section 11.1 above.

11.3 Any Party seeking to be indemnified by virtue of this Agreement shall notify the Party from which indemnification is sought promptly in writing of any and all respective claims, actions and proceedings made or instituted against it.

11.4 Each Party (the “Indemnified Party”) shall conduct its own defence against Third Party claims for which it seeks indemnification from the other Party (the “Indemnifying Party”) under this Agreement, but shall make sure that the Indemnifying Party obtains access to all documentation related to the case, and is allowed to participate in defending the case. The Indemnifying Party shall be entitled, but under no obligations, to assist the Indemnified Party’s defence in the respective case to the extent as it may deem the Indemnifying Party appropriate under the circumstances. The Indemnified Party will not agree to any settlement without the Indemnifying Party’s prior written consent.

12. INSURANCE

Both Parties undertake to obtain and to maintain during the term of this Agreement and five (5) years after its termination or expiry in full force and effect a valid commercial general liability insurance with a reasonable coverage. Upon request of the other Party, each Party shall forward the other Party a copy of the respective insurance policy.

13. Term and Termination

13.1 This Agreement shall be initially valid for a period commencing on the Effective Date and Ending on 31st December 2030 ("Initial Contractual Period"). After the Initial Contractual Period, this Agreement shall be automatically renewed for further periods of two (2) years each, unless either Party gives the other Party a twelve (12) months' notice of termination prior to the end of the Initial Contractual Period or any prolongation period.

13.2 Without prejudice to Clause 13.1, this Agreement may be terminated by either Party for an important reason without observing a period of notice.

An important reason would be in particular:

a) debt settlement proceedings (in particular insolvency) are instituted against the assets of the other Party or an application is filed in this respect and, despite specific request, the other Party cannot prove within a reasonable period of time that such application is obviously without foundation;

b) the other Party commits a Material Breach notwithstanding a warning letter admitting the Party in breach a thirty (30) days period to cure such Material Breach.

13.3 All notices of termination have to be made in writing, shall be delivered by prepaid registered Airmail or personal courier. A termination notice issued by the terminating Party shall become effective on the date of receipt by the other Party.

13.4 Expiration or termination of this Agreement will not relieve either Party of any obligation accrued prior to such expiration or termination.

14. Assignment

14.1 Subject to the other terms of this Agreement, neither Party shall have the right or the power to assign any of its rights, or delegate or subcontract the performance of any of its obligations under this Agreement, without the prior written authorization of the other Party, such written authorization not to be unreasonably withheld or delayed.

14.2 The prior written authorization of the other Party shall not be required for a Party to assign its rights and delegate its obligations hereunder, in whole or in part, to an Affiliate.

14.3 In case of an assignment to an Affiliate the assigning Party shall notify the other Party in writing of the extent of the assignment of contractual rights and obligations to the Affiliate, and whether the Affiliate shall be entitled to directly invoice any contractual services to the other Party due to the assignment.

15. Legal Successor

This Agreement shall be binding on and shall inure to the benefit of the Parties and their legal successors. Each Party shall commit its respective successor to enter into and therefore become a new Party to this Agreement.

16. Governing Law and Dispute Resolution

16.1 This Agreement shall be governed and construed in accordance with the laws of Germany without giving effect to the choice of laws principles thereof which would result in the application of the laws of another jurisdiction. The Convention on Contracts for the International Sales of Goods (CISG 1980) shall not apply.

16.2 Any disputes arising between the Parties out of or in connection with this Agreement (including, without limitation, any questions regarding its existence, validity or termination) which cannot be solved by the Parties using their best efforts shall be subject to the courts having jurisdiction over Cologne, Germany.

17. Notices

Unless otherwise provided for herein, any notice required to be given under this Agreement shall be in writing and shall be given by personal delivery or by prepaid registered mail addressed as follows:

Biofrontera Discovery GmbH
Hemmelrather Weg 201
D-51377 Leverkusen, Germany
Prof Dr. Hermann Lübbert
Tel.: +49-151-5284 5131
Email: h.luebbert@bfinc.com

Midas Pharma GmbH
Rheinstraße 49
D-55218 Ingelheim, Germany
Dirk Weidenbach
Tel.: +49-6132-990-113
Email: dirk.weidenbach@midas-pharma.com

or at such other address as such Party has advised the other Party of in writing.

18. Compliance

18.1 The Parties hereby undertake to perform the arrangements contemplated by this Agreement in a manner which is consistent with good business ethics and compliant with i) all applicable national and foreign anti-corruption legislation on combating bribery in international business, including without limitation to the provisions of the United States Foreign Corrupt Practices Act 1977 (the "FCPA") and the U.K. Bribery Act 2010, ii) export control regulations and economic sanctions of any country or intergovernmental or supranational organization including but not limited to the United Nations, the United States of America, Germany, the United Kingdom, Canada and the European Union that are applicable to the performance of activities under this Agreement (together referred to as the "Relevant Requirements").

18.2 In particular, the Parties will not offer, promise or give any improper monetary or other advantage, whether directly or through intermediaries to a public official, for the benefit of that official or of a Third Party, for the purpose of influencing decision or actions with respect to the subject matter of this Agreement.

18.3 The Parties agree further to strictly abide and comply with i) any and all applicable national and supranational data protection laws and regulations, including in particular the General Data Protection Regulation (GDPR) of the EU, ii) all labour laws in the country they operate (including but not limited to laws prohibiting forced and child labour) and iii) all applicable environmental laws and regulations.

18.4 Failure to comply with the provisions of this clause will be deemed a material breach of a material provision of this Agreement and the non-breaching Party shall be entitled to terminate this Agreement with immediate effect upon giving written notice to the breaching Party.

19. Miscellaneous

19.1 If, at any time, any provision of this Agreement is or becomes unenforceable in any respect under the laws of the applicable jurisdiction, the remaining provisions of this Agreement shall remain unaffected thereby. The Parties shall negotiate in good faith and replace the invalid or unenforceable provision by a valid and enforceable provision, which comes closest to the original intention of the Parties.

19.2 This Agreement, including the Annex(es) referred to in this Agreement, shall constitute the entire agreement between the Parties with respect to the subject matter of this Agreement and shall supersede all previous negotiations, agreements, and commitments, whether written or unwritten, with respect to such subject matter.

19.3 No failure of any Party to exercise any power given it under this Agreement, or to insist upon strict compliance with any provision of this Agreement, and no custom or practice of the Parties at variance with the terms of this Agreement shall constitute a waiver of any Party's right to demand strict compliance with the terms of this Agreement.

19.4 All clauses and articles herein were negotiable and negotiated between the Parties without any restriction or limitation. They were left to the free and unrestricted negotiations of the Parties and reflect the result of such negotiations.

19.5 Modifications to the provisions set forth in this Agreement must be confirmed and accepted in writing by duly authorized officers of all Parties. Any oral modification of this section shall be void.

19.6 Headings contained herein are for convenience and reference only and shall not control the interpretation of any term or provision of this Agreement.

19.7 The Parties agree to inform their respective Affiliates of the existence of this Agreement and to commit those Affiliates to respect this Agreement and not to circumvent it by entering into other agreements contradicting the content of this Agreement.

19.8 If not otherwise provided for herein, the Sections 8 (Liability), 10 (Confidentiality), 11 (Indemnification) and 16 (Dispute Resolution) shall survive the termination of this Agreement.

The Parties agree that this Agreement may be executed using industry standard electronic signature software (such as DocuSign) or in pdf format and exchanged by e-mail. Either option shall have the same legal force and effect as the exchange of original documents signed in wet-ink. Each Party hereby waives any right to raise any defense or claim in any proceeding arising under or related to the Agreement, based upon electronic execution of this Agreement. In case of electronic execution, the Parties agree that wet-ink documents will not be exchanged, and the executed Agreement shall be archived electronically.

	Biofrontera Discovery GmbH	**Midas Pharma GmbH**
Name:	Prof. Dr. Hermann Lübbert	Dirk Weidenbach
Title:	Managing Director	Managing Director / COO
Date/ Signature:		Dirk Weidenbach
Name:	Dr. Wiebke Meyer-Wendt	Michelle Dengler
Title:	Vice President Pharmaceutical Operations	Key Account Manager
Date/ Signature:	Wiebke Meyer-Wendt	Michelle Dengler

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No's. 333-288717, 333-265467, 333-268124, 333-277811, 333-279090 and 333-291987) and Form S-8 (File No.'s 333-265463 and 333-283208) of our report dated March 19, 2026, with respect to our audit of the consolidated financial statements of Biofrontera Inc. included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ CBIZ CPAs P.C.

Morristown, New Jersey
March 19, 2026

Exhibit 23.2

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-1 (File No.'s 333-265467, 333-268124, 333-277811, 333-279090, 333-288717, and 333-291987) and Form S-8 (File No.'s 333-265463 and 333-283208) of our report dated March 20, 2025, with respect to our audit of the consolidated financial statements of Biofrontera Inc. as of and for the year ended December 31, 2024, included in this Annual Report on Form 10-K for the year ended December 31, 2025.

/s/ Marcum LLP

Morristown, New Jersey
March 19, 2026

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: 3/19/2026

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: 3/19/2026

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, 2025 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: 3/19/2026

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, 2025 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: 3/19/2026

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.