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

FORM 10-Q

(Mark One)

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

For the quarterly period ended September 30, 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** **(IRS Employer Identification No.)**
120 Presidential Way, Suite 330, Woburn, Massachusetts **(Address of principal executive offices)**	**01801** **(Zip Code)**

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

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, par value $0.001 per share	BFRI	The Nasdaq Stock Market LLC
Preferred Stock Purchase Rights		The Nasdaq Stock Market LLC
Warrants to purchase common stock	BFRIW	The Nasdaq Stock Market LLC

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 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of November 10, 2025 there were 11,648,323 shares outstanding of the registrant's common stock, par value $0.001 per share.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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

	September 30, 2025 (Unaudited)	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,417	$ 5,905
Investment, related party	10	7
Accounts receivable, net	2,995	5,315
Inventories, net	4,329	6,646
Prepaid expenses and other current assets	629	527
Asset held for sale	2,300	2,300
Other assets, related party	733	-
Total current assets	**14,413**	**20,700**
Property and equipment, net	20	80
Operating lease right-of-use assets	488	903
Intangible assets, net	22	35
Other assets	472	383
Total assets	**$ 15,415**	**$ 22,101**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,639	1,856
Accounts payable, related parties, net	2,054	5,344
Operating lease liabilities	307	548
Accrued expenses and other current liabilities	6,553	4,273
Total current liabilities	**12,553**	**12,021**
Long-term liabilities:		
Convertible notes payable, net	4,462	4,098
Warrant liabilities	833	1,250
Operating lease liabilities, non-current	136	276
Other liabilities	12	23
Total liabilities	**17,996**	**17,668**
Commitments and contingencies (see Note 15)		
Stockholders' (deficit) equity:		
Preferred Stock $0.001 par value; 20,000,000 shares authorized	-	-
Series B-2 Convertible Preferred, 2,050 and 3,366 issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	-	-
Series B-3 Convertible Preferred, 6,593 and 6,763 issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	-	-
Series C Convertible Preferred, 8,219 and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	-	-
Series D Convertible Preferred, 3,019 and 0 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	-	-
Common Stock $0.001 par value; 70,000,000 shares authorized; 11,648,323 and 8,873,932 shares issued and outstanding as of September 30, 2025 and December 31, 2024, respectively	12	9
Additional paid-in capital	130,992	121,833
Accumulated deficit	(133,585)	(117,409)
Total stockholders' (deficit) equity	**(2,581)**	**4,433**
Total liabilities and stockholders' equity	**$ 15,415**	**$ 22,101**

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

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Product revenues, net	$ 6,988	$ 9,012	24,605	24,744
Revenues, related party	-	-	-	18
Total revenues, net	**6,988**	**9,012**	**24,605**	**24,762**
Operating expenses				
Cost of revenues, related party	1,922	4,801	7,377	12,839
Cost of revenues, other	123	76	578	496
Selling, general and administrative	10,047	8,425	29,229	25,589
Selling, general and administrative, related party	320	1	396	30
Research and development	854	669	2,932	1,306
Total operating expenses	**13,266**	**13,972**	**40,512**	**40,260**
Loss from operations	**(6,278)**	**(4,960)**	**(15,907)**	**(15,498)**
Other income (expense)				
Change in fair value of warrants	(285)	(680)	417	1,329
Change in fair value of investment, related party	1	(2)	3	(12)
Loss on debt extinguishment	-	-	-	(316)
Interest income (expense), net	(111)	8	(331)	(1,995)
Other income (expense), net	30	(32)	(333)	154
Total other income (expense)	**(365)**	**(706)**	**(244)**	**(840)**
Loss before income taxes	**(6,643)**	**(5,666)**	**(16,151)**	**(16,338)**
Income tax expense	6	3	25	25
Net loss	**$ (6,649)**	**(5,669)**	**(16,176)**	**(16,363)**
Loss per common share:				
Basic and diluted	$ (0.62)	(0.98)	(1.67)	(3.39)
Weighted-average common shares outstanding:				
Basic and diluted	10,776,739	5,773,993	9,674,378	4,833,091

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

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

	Three and Nine Months Ended September 30, 2025						
	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, June 30, 2025	9,234	-	10,138,567	9	122,259	(126,936)	(4,668)
Issuance of Series C Preferred	8,500	-	-	-	8,500		8,500
Issuance of Series D Preferred, net of receivable from shareholder	3,019	-	-	-	-	-	-
Conversion of Series B-2 Preferred into Common	(591)	-	835,083	1	(2)	-	(1)
Conversion of Series C Preferred into Common	(281)	-	449,673	2	(1)	-	1
Release of Restricted Stock Units	-		225,000	-	-	-	-
Stock based compensation	-	-	-	-	236	-	236
Net loss	-	-	-	-	-	(6,649)	(6,649)
Balance, September 30, 2025	19,881	-	11,648,323	12	130,992	(133,585)	(2,581)
Balance, December 31, 2024	10,129	-	8,873,932	9	121,833	(117,409)	4,433
Issuance of Series C Preferred	8,500	-	-	-	8,500	-	8,500
Issuance of Series D Preferred, net of receivable from shareholder	3,019	-	-	-	-	-	-
Conversion of Series B-2 Preferred into Common	(1,316)	-	1,859,508	2	(2)	-	-
Conversion of Series B-3 Preferred into Common	(170)	-	240,210	-	-	-	-
Conversion of Series C Preferred into Common	(281)	-	449,673	1	(1)	-	-
Restricted Stock Units released	-	-	225,000	-			
Stock based compensation	-	-	-	-	662	-	662
Net loss	-	-	-	-	-	(16,176)	(16,176)
Balance, September 30, 2025	19,881	-	11,648,323	12	130,992	(133,585)	(2,581)

	Three and Nine Months Ended September 30, 2024						
	Preferred Stock		Common Stock		Additional Paid-in	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Deficit	Total
Balance, June 30, 2024	12,804	-	5,094,184	5	121,250	(110,344)	10,911
Conversion of Series B Preferred into Common	(1,016)	-	1,435,608	2	(2)	-	-
Stock based compensation					288		288
Net loss						(5,669)	(5,669)
Balance, September 30, 2024	11,788	-	6,529,792	7	121,536	(116,013)	5,530
Balance, 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 into Series B-2 Preferred and common stock	3,790	-	3,952,393	4	3,566	-	3,570
Issuance of Series B-3 upon exercise of warrants	7,998	-	-	-	12,810	-	12,810
Issuance of RSUs	-	-	4,771	-	-	-	-
Stock based compensation	-	-	-	-	720	-	720
Net loss	-	-	-	-		(16,363)	(16,363)
Balance, September 30, 2024	11,788	-	6,529,792	7	121,536	(116,013)	5,530

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

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

	Nine Months Ended September 30,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (16,176)	$ (16,363)
Adjustments to reconcile net loss to cash flows used in operations:		
Depreciation	64	62
Amortization of right-of-use assets	572	541
Amortization of acquired intangible assets	12	325
Realized/unrealized (gain)/ loss in investment, related party	(3)	12
Loss on settlement of lease liability	7	-
Change in fair value of warrant liabilities	(417)	(1,329)
Stock-based compensation	662	720
Allowance for credit losses	(44)	111
Loss on debt extinguishment	-	316
Non-cash interest expense	364	248
Changes in operating assets and liabilities:		
Accounts receivable	2,365	177
Other receivables, related party	68	19
Prepaid expenses and other assets	(191)	34
Other assets, related party	(733)	5,159
Inventories	2,317	4,380
Accounts payable	1,782	(1,281)
Accounts payable, related party , net	(3,358)	(2,037)
Operating lease liabilities	(546)	(511)
Accrued expenses and other liabilities	2,270	164
Cash flows used in operating activities	**(10,985)**	**(9,253)**
Cash flows from investing activities		
Sales of equity investment, related party	-	57
Purchase of intangible assets	-	(50)
Purchases of property and equipment	(3)	(9)
Cash flows used in investing activities	**(3)**	**(2)**
Cash flows from financing activities		
Proceeds from issuance of Series C preferred stock	8,500	-
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 from exercise of warrants	-	7,438
Payment to extinguish line of credit	-	(357)
Payment of principal short-term debt	-	(3,958)
Cash flows provided by financing activities	**8,500**	**10,785**
Net increase (decrease) in cash and cash equivalents	**(2,488)**	**1,530**
Cash, cash equivalents and restricted cash, at the beginning of the period	**6,105**	**1,543**
Cash, cash equivalents and restricted cash, at the end of the period	**$ 3,617**	**$ 3,073**
Supplemental disclosure of cash flow information		
Interest paid	$ 4	$ 1,722
Income taxes paid, net	$ 25	$ 25
Supplemental non-cash financing activities		
Addition of right-of-use assets in exchange for operating lease liabilities	$ 98	$ 27
Conversion of warrant liability to equity	$ -	$ 5,372

The accompanying notes are an integral part of these condensed 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 commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT"). The Company's primary licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions.

The Company includes its wholly owned subsidiary Biofrontera Discovery GmbH ("Discovery"), a limited liability company organized under the laws of Germany, formed on February 9, 2022, as a German presence to facilitate our relationship with Biofrontera Pharma GmbH ("Biofrontera Pharma") and Biofrontera Bioscience GmbH ("Biofrontera Bioscience" and together with Biofrontera Pharma, the "Ameluz Licensor") and manage our clinical trial work.

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® Lamps, for PDT (when used together, "Ameluz® PDT"). In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. Prior to the closing of the Strategic Transaction on October 20, 2025, we were selling Ameluz® for this indication in the United States under an exclusive license and supply agreement (as amended, the "Second A&R Ameluz LSA") with the Ameluz Licensor, both of which are related parties.

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 with Biofrontera AG

On June 30, 2025, the Company signed a binding agreement (the "Term Sheet") with its former parent company Biofrontera AG and its subsidiaries, Biofrontera Pharma and Biofrontera Bioscience (together, the "Biofrontera Group") pursuant to which the Company agreed to acquire all rights in the United States (the "U.S. Rights") to Ameluz® and RhodoLED® (the "Strategic Transaction"). In connection with the Strategic Transaction, additional agreements were executed, and the transfer of the U.S. Rights was completed on October 20, 2025. As a result of these actions, the Company will pay a monthly earnout of 12% in years where Ameluz® revenue in the United States is at or below $65.0 million and 15% in years where Ameluz® revenue in the United States exceeds $65.0 million. The earnout replaces the transfer pricing model under the Company's Second A&R Ameluz LSA effective as of February 13, 2024 by and among the Company, and the Biofrontera Group. See *Note 11. Related Party Transactions* and *Note 17. Subsequent Events* 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"). See *Note 11. Related Party Transactions* and N*ote 17. Subsequent Events* for additional information.

The transaction was funded through an $11 million investment by existing investors, $8.5 million of which was funded at the time the Term Sheet was executed and the remaining $2.5 million was funded on October 24, 2025, following the closing of the Strategic Transaction. See *Note 12. Stockholders' Equity* and *Note 17. Subsequent Events*.

Liquidity and Going Concern

These consolidated financial statements have been prepared in accordance with U,S. generally accepted accounting principles ("U.S. GAAP") assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since we commenced operations in 2015, we have generated significant losses. The Company incurred net cash outflows from operations of $11.0 million and $9.3 million for the nine months ended September 30, 2025 and 2024, respectively. The Company had an accumulated deficit as of September 30, 2025 of $133.6 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 received in a private placement of Series C Preferred Stock (received in two separate tranches of $8.5 million in July 2025 and $2.5 million in October 2025). As of September 30, 2025, we had cash and cash equivalents of $3.4 million, compared to $5.9 million as of December 31, 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the issuance date of this report.

The Company plans to address the conditions that raise substantial doubt regarding its ability to continue as a going concern by, among other things, utilizing external financing options, including a short-term line of credit, as well as finalizing the sale of its Xepi product line on November 6, 2025. See *Note 17. Subsequent Events*. 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 Financial Statements

The accompanying unaudited interim condensed consolidated financial statements of the Company have been prepared pursuant to the rules and regulations of the Securities and Exchange Commission ("SEC") for interim financial reporting. Certain information and footnote disclosures normally included in the annual financial statements prepared in accordance with U.S. GAAP have been condensed or omitted pursuant to such rules and regulations. In the Company's opinion, the unaudited condensed consolidated financial statements include all material adjustments, all of which are of a normal and recurring nature, necessary to present fairly the Company's financial position as of September 30, 2025, the Company's operating results for the three and nine months ended September 30, 2025 and 2024, and the Company's cash flows for the nine months ended September 30, 2025 and 2024. The accompanying financial information as of December 31, 2024 is derived from audited financial statements. Interim results are not necessarily indicative of results for a full year. The information included in this Quarterly Report on Form 10-Q should be read in conjunction with the Company's Annual Report on Form 10-K for the year ended December 31, 2024, filed with the SEC on March 20, 2025.

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.

With the exception of the accounting policies below, there have been no new or material changes to the significant accounting policies discussed in the Company's Form 10-K for the year ended December 31, 2024.

Reclassification of Prior Year Presentation

Certain prior period amounts have been reclassified for consistency with the current period presentation. The reclassification was limited to the condensed consolidated statements of cash flow and had no impact on the reported results of operations. Specifically, for prior year presentation, accounts payable-related parties of $2.0 million was reclassed from accounts payable to accounts payable, related party, net.

The Nasdaq Stock Market, LLC ("Nasdaq") Compliance

On May 8, 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 33 consecutive business days.

The notice had 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 had a period of 180 calendar days, or until November 5, 2025, to regain compliance with the rule referred to in this paragraph. The Company has since then regained compliance with Listing Rule 5550(a)(2). See *Note 17. Subsequent Events* for additional information.

On May 21, 2025, the Company received a notice from Nasdaq notifying the Company that, because the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended March 31, 2025 was $0.5 million, the Company was no longer in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1), which requires that a listed company's stockholders' equity be at least $2.5 million. Additionally, as of the date of the notice and as of September 30, 2025, the Company did not meet either of the alternative requirements of maintaining a market value of listed securities of $35 million or achieving a net income from continuing operations of $0.5 million in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

The notice had no immediate effect on the listing or trading of the Company's securities on Nasdaq. The Company submitted a plan to regain compliance with the Nasdaq Listing Rule 5550(b)(1) to Nasdaq and on July 24, 2025 was subsequently granted an extension of time to regain compliance with this rule on or before October 24, 2025. As of the date of this Report, the Company believes its stockholders' equity exceeds $5 million, which exceeds the amount required for continued listing on Nasdaq under Nasdaq Listing Rule 5550(b)(1). Nasdaq will continue to monitor the Company's ongoing compliance with the stockholders' equity requirement and, if at the time of its next periodic report the Company does not evidence compliance, it may be subject to delisting. See *Note 17. Subsequent Events* for additional information.

Use of Estimates

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

Recently Issued Accounting Pronouncements

In December 2023, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") 2023-09, Income Taxes (Topic 740) – *Improvements to Income Tax Disclosures*. The ASU requires that an entity disclose specific categories in the effective tax rate reconciliation as well as provide additional information for reconciling items that meet a quantitative threshold. Further, the ASU requires certain disclosures of state versus federal income tax expense and taxes paid. The amendments in this ASU are required to be adopted for fiscal years beginning after December 15, 2024. Early adoption is permitted and the amendments should be applied on a prospective basis. ASU 2023-09 did not have any impact on the interim disclosures in 2025. We are evaluating the effect that this guidance will have on our annual consolidated financial statements and related disclosures.

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

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

In September 2025, the FASB issued ASU 2025-06, *Intangibles - Goodwill and Other - Internal-Use Software* (Subtopic 350-40): *Targeted Improvements to the Accounting for Internal-Use Software,* which updates accounting for internal-use software by eliminating the concept of development stages. Under the updated guidance, software costs are capitalized once management has authorized and committed to funding the project, and it is probable that the project will be completed and the software will be used to perform the function intended. The provisions of ASU 2025-06 are effective for annual reporting periods beginning after December 15, 2027, and interim reporting periods within those annual reporting periods. Early adoption is permitted, and the guidance may be applied prospectively, retrospectively, or via a modified prospective transition method. We are currently evaluating the effect of adopting ASU 2025-06 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 2025-06 on our consolidated financial statements and related disclosures.

3. Fair Value Measurements

The following table presents information about the Company's assets that are measured at fair value on a recurring basis at September 30, 2025 and December 31, 2024 and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

(in thousands)	Level	September 30, 2025	December 31, 2024
Assets:			
Investment, related party	1	$ 10	$ 7
Liabilities:			
Warrant liability – 2023 Purchase Warrants	3	$ 687	$ 1,030
Warrant liability - 2022 Purchase Warrants	3	$ 65	$ 98
Warrant liability – 2022 Inducement Warrants	3	$ 81	$ 122
Total Liabilities		$ 833	$ 1,250

Investment, related party

As of September 30, 2025 and December 31, 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 outstanding (i) warrants to purchase 170,950 shares of the Company's 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 12. Stockholders' Equity* for additional details.

The 2023 Purchase Warrants and 2022 Purchase Warrants, as well as the 2022 Inducement 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 Company utilizes a Black-Scholes-Merton ("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 of these warrants was determined using the BSM model based on the following range of assumptions for the three and nine months ended September 30, 2025: fair value of the underlying common stock of $0.71 to $0.99, expected volatility of 100%, risk free rate of 3.58% to 3.87%, remaining contractual term of 3.09 to 3.59 years and a dividend yield of 0%. The expected life of the warrants is assumed to be equivalent to their remaining contractual term.

The following table presents the changes in the Level 3 warrant liabilities measured at fair value (in thousands):

	Nine Months Ended September 30,	
	2025	2024
Fair value at beginning of period	$ 1,250	$ 4,210
Issuance of new warrants	-	4,092
Exercise of warrants	-	(5,372)
Change in fair value of warrant liabilities	(417)	(1,329)
Fair value at end of period	$ 833	$ 1,601

4. Revenue

We generate revenue primarily through the sales of our licensed 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.

5. Cash Balances and Statement of Cash Flows Reconciliation

The Company maintains its cash balances at financial institutions that are insured by the Federal Deposit Insurance Corporation ("FDIC"). At September 30, 2025, approximately $2.7 million of the Company's cash balances were in excess of FDIC limits. The Company has not experienced any losses on these accounts and management does not believe that the Company is exposed to any significant risks with respect to these accounts.

Restricted cash consists primarily of deposits of cash collateral held in accordance with the terms of our corporate credit cards. Long-term restricted cash was recorded in other assets in the condensed 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)	September 30, 2025	December 31, 2024
Cash and cash equivalents	$ 3,417	$ 5,905
Long-term restricted cash	200	200
Total cash, cash equivalents, and restricted cash shown on the consolidated statements of cash flows	$ 3,617	$ 6,105

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

6. 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 receivables are segmented into pools of assets depending primarily on delinquency status, and fixed 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 September 30, 2025 and December 31, 2024, respectively.

7. Inventories

Inventories consist of finished goods of Ameluz® and the RhodoLED® lamps.

There was no provision for obsolescence recorded for the nine months ended September 30, 2025 and a negligible amount for the year ended December 31, 2024.

8. Asset Held for Sale

Asset held for sale consists of the following:

(in thousands)	September 30, 2025	December 31, 2024
Xepi® license	$ 4,600	$ 4,600
Less: Accumulated amortization	(2,300)	(2,300)
Asset held for sale	$ 2,300	$ 2,300

The Xepi product line has been held for sale since the third quarter of 2024, when the Company determined that the intangible asset met the criteria to be classified as held for sale in accordance with ASC 360-10-45-9. The Company has classified the asset as held for sale under current assets in the condensed consolidated balance sheets, and finalized the sale on November 6, 2025 (See *Note. 17 Subsequent Events*). The carrying amount of the asset at the time of classification was $2.3 million, which was the lower of its carrying value or estimated fair value less cost to sell. No gain or loss was recognized in the Condensed Statement of Operations upon classification as an asset held for sale and the related revenue and expenses associated with the asset were de-minimus. There have been no subsequent changes to fair value as of September 30, 2025 and the date of this report. This divestiture does not represent a strategic shift that will have a major effect on our consolidated results of operations and therefore is not being reported as discontinued operations.

The Xepi® license intangible asset was recorded at acquisition date fair value of $4.6 million and was amortized on a straight-line basis over the useful life of 11 years.

9. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	September 30, 2025	December 31, 2024
Employee compensation and benefits	2,974	2,428
Professional fees	2,241	632
Research and development	657	542
Other	681	671
Total	$ 6,553	$ 4,273

10. Debt

Convertible Notes Payable

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

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

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

The Notes provide for customary events of default and contain conversion limitations, providing that no conversion may be made if the aggregate number of shares of Common Stock beneficially owned by the holder would exceed 9.99% immediately after conversion. There were no events of default at September 30, 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.

During the three and nine months ended September 30,2025 the Company recognized interest expense of approximately $0.1 million and $0.4 million, respectively, and minimal discount amortization. As of September 30, 2025 and December 31, 2024, the outstanding balance of the Notes was $4.5 million and $4.1 million, respectively, which is shown net of the remaining unamortized issuance cost of $0.1 million.

11. Related Party Transactions

We consider Biofrontera AG and its consolidated subsidiaries to be a related party, as prior to the Strategic Transaction closing on October 20, 2025, we relied on the Biofrontera Group as the sole supplier of Ameluz® and the RhodoLED® Lamps.

Amounts due and payable to Biofrontera Group as of September 30, 2025 and December 31, 2024 were $2.0 million and $5.3 million, respectively, and were recorded in accounts payable, related parties net of applicable accounts receivable in the condensed consolidated balance sheets.

Strategic Transaction with Biofrontera Group

On June 30, 2025, the Company signed a binding Term Sheet with the Biofrontera Group pursuant to which the Company agreed to acquire all rights in the United States to Ameluz® and RhodoLED®. In connection with the Strategic Transaction, additional agreements were executed, and the transfer of the U.S. Rights was completed on October 20, 2025. As a result of these actions, the Company will pay a monthly earnout of 12% in years where Ameluz® revenue in the United States is at or below $65.0 million and 15% in years where Ameluz® revenue in the United States exceeds $65.0 million. The earnout replaces the transfer pricing model under the Company's Second A&R Ameluz LSA effective as of February 13, 2024 by and among the Company, and the Biofrontera Group. See *Note 17. Subsequent Events.*

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 12. Stockholders Equity*.

In addition, the Company 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 15. 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) if the board consists of eight or more directors the right to appoint two individuals. No appointments have been made through the filing date.

Inventory Purchases

Purchases of the licensed products (inclusive of estimated and actual purchase price adjustments) were $2.7 million and $7.7 million during the three and nine months ended September 30, 2025, respectively, and $2.2 million and $3.3 million during the three and nine months ended September 30, 2024, respectively. These purchases were recorded in inventories in the condensed consolidated balance sheets, and, when sold, 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 in the US, including but not limited to product production, quality control, pharmacovigilance, regulatory activities as well as rent for the three and nine months ended September 30, 2025 were $0.3 million and $0.5million, respectively.

12. 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. As of September 30, 2025, there were 11,648,323 shares of Common Stock outstanding.

As of September 30, 2025 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 September 30, 2025 is presented below.

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

Series B 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) warrants to purchase 8,000 shares of Series B-3 Convertible Preferred Stock, par value $0.001 per share (the "Series B-3 Preferred Stock"), for an aggregate offering price of $8.0 million (the "2024 Preferred Warrants"). 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. All of the 2024 Preferred Warrants were exercised for Series B-3 Preferred Stock during the second quarter of 2024. As of September 30, 2025, there were 2,050 shares of Series B-2 Preferred Stock and 6,593 shares of Series B-3 Preferred Stock issued and outstanding (convertible into 12,212,599 shares of Common 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 September 30, 2025. See rights and preferences of the Series B Preferred Stock as previously disclosed in the Company's Form 10-K for the year ended December 31, 2024.

Series C Convertible Preferred Stock

As a condition precedent for the Strategic Transaction, the Company entered into a securities purchase agreement with certain accredited investors, 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 (the "Series C Preferred Stock") 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. See *Note 17. Subsequent Events* for additional information on the second tranche.

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. As of September 30, 2025, there were 8,219 shares of Series C Preferred Stock issued and outstanding with the following terms, pursuant to the Series C Certificate of Designation:

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

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. There were 3,019 shares of Series D Preferred Stock issued and outstanding as of September 30, 2025. The Series D Preferred Stock was issued on July 2, 2025, however, the related Strategic Transaction was not finalized until October 20, 2025, creating a receivable for the issuance of equity shares as of September 30, 2025. In accordance with *ASC 505-10-45-2 Receivables for Issuance of Equity* reporting the receivable as an asset is generally not appropriate. Therefore, the related receivable for the issuance of Series D Preferred Stock was recognized net of the issuance in equity. The Series D Preferred Stock was booked at par value and the fair value will be applied once the asset acquisition is completed in October of 2025. See *Note 17. Subsequent Events.*

The following is a summary of the terms of the Series D Preferred Stock 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) if the board consists of eight or more directors the right to appoint two individuals. No appointments have been made through the filing date.

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 10. Debt*, for additional details.

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 Special Shareholder Meeting on September 16, 2025, the Series C Preferred and Series D Preferred holders are entitled to receive the same form of consideration upon a liquidation event. Accordingly, the Series C Preferred and Series D Preferred stock were reclassified as permanent equity on our consolidated balance sheets and consolidated statements of change in stockholders' equity as of September 30, 2025, due to the limited exception under ASC 480-10-S99-3A(3)(f).

13. Equity Incentive Plans and Share-Based Payments

2021 Omnibus Incentive Plan

In 2021, the Board adopted, and our stockholders 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 September 30, 2025, there were 1,096,532 shares available for future awards under the amended 2021 Plan.

Non-qualified stock options

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 binomial lattice pricing model ("Lattice") 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 used in the Lattice model for the stock options granted in the third quarter were: valuation date stock price of $0.90 to $0.92, 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.

Share-based compensation expense related to stock options of approximately $0.2 million and $0.5 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 three and nine months ended September 30, 2025, respectively. Share-based compensation expense related to stock options of $0.2 million and $0.3 million was recorded in selling, general and administrative expenses, with a negligible amount recorded as research and development, for the three and nine months ended September 30, 2024, respectively.

Options outstanding and exercisable under the employee share option plan as of September 30, 2025, and a summary of option activity during the nine months then ended is presented below.

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1)
Outstanding at December 31, 2024	1,358,718	3.88	9.36	$ 5
Granted	754,192	1.00	-	-
Exercised	-	-	-	-
Canceled or forfeited	(122,622)	2.90	-	-
Outstanding at September 30, 2025	1,990,288	2.85	7.61	-
Exercisable at September 30, 2025	515,894	7.49	8.04	-

(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 September 30, 2025 and December 31, 2024.

As of September 30, 2025, there was $0.9 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 1.5 years.

Share-Based Compensation (RSUs)

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

Share-based compensation expense for the RSUs was $0.1 million and $0.2 million for the three and nine months ended September 30, 2025, respectively and was negligible and $0.1 million for the three and nine months ended September 30, 2024, respectively, and was recorded in selling, general and administrative expenses in the accompanying consolidated statements of operations.

As of September 30, 2025, there was $0.3 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a period of approximately 1.25 years.

The following table summarizes the activity for RSUs during the nine months ended September 30, 2025:

	Shares	Weighted Average Remaining Contractual Term	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2024	450,000	-	$ 1.06
Awarded	187,500	-	$ 0.90
Vested	(225,000)	-	$ 1.06
Canceled or forfeited	-	-	$ -
Outstanding at September 30, 2025	412,500	1.02	$ 0.99

14. Net Loss per Share

Basic net loss per common share is calculated by dividing net loss 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 loss per share attributable to common stockholders (in thousands, except share and per share data):

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	2024	2025	2024
Net loss	$ (6,649)	$ (5,669)	$ (16,176)	$ (16,363)
Weighted average common shares outstanding, basic and diluted	10,776,739	5,773,993	9,674,378	4,833,091
Net loss per share, basic and diluted	$ (0.62)	$ (0.98)	$ (1.67)	$ (3.39)

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

September 30,	2025	2024
Common stock warrants	2,269,356	2,269,356
Common stock options and RSUs	2,400,572	1,775,444
Unit Purchase Options	20,182	20,182
Shares related to Series B-2 convertible preferred stock	2,896,650	6,636,981
Shares related to Series B-3 convertible preferred stock	9,315,909	10,026,859
Shares related to Series C convertible preferred stock	13,152,537	-
Shares related to Series D convertible preferred stock	4,831,185	-
Convertible Notes	5,859,849	-
Total	40,746,240	20,728,822

Common Stock warrants include the 2022 Purchase Warrants, 2023 Purchase Warrants, 2022 Inducement Warrants and warrants issued in the Company's initial public offering.

15. Commitments and Contingencies

Leases

On July 30, 2025 the Company entered into an agreement to lease new office space at 660 Main Street, Woburn, MA. The lease term is for 63 months and is scheduled to commence on December 1, 2025. 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. The lease has not been recognized on the balance sheet as the commencement date has not occurred. Total future rent payments not yet reflected on the balance sheet will be approximately $1.6 million over the full term.

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

The Company has also entered into a master lease agreement for its vehicles. After an initial non-cancelable twelve-month period, each vehicle is leased on a month-to-month basis. Based on historical retention experience of approximately three years, the vehicles have varying expiration dates through August 2028.

Future lease payments under non-cancellable leases as of September 30, 2025 were as follows (in thousands):

Years ending December 31,	Future lease commitments
Remainder of 2025	$ 138
2026	257
2027	63
2028	14
Thereafter	-
Total future minimum lease payments	$ 472
Less imputed interest	(29)
Total lease liability	$ 443
Reported as:	
Operating lease liability, current	$ 307
Operating lease liability, non-current	136
Total	$ 443

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 three and nine months ended September 30, 2025 or 2024.

Second A&R Ameluz LSA and Term Sheet Sales Commitments

The Second A&R Ameluz LSA, as amended by the Term Sheet, shall continue in full force and effect until the date of the Strategic Transaction of October 20 2025, at which time it shall be terminated.

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

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

As agreed to in connection with the Strategic Transaction and pursuant to the Term Sheet, until the earlier to occur of (i) the total cumulative Royalty paid to Sellers from June 1, 2025 to May 31, 2031 exceeds $50 million, or (ii) the expiration of patent protection on the Products allows for generic competition with the Products in the United States (collectively, the “Minimum Royalty Term”), we are subject to a minimum annual Ameluz sales volume of 80,000

tubes. If such minimum annual volume is not met during the Minimum Royalty Term and the Company does not otherwise pay minimum annual royalties of 12% of the net revenues of 80,000 tubes of Ameluz, the Biofrontera Group shall be entitled to minimum annual royalties of 12% of the net revenues of 80,000 tubes of Ameluz plus annual interest of 4%. Except in the case of certain limited exceptions, our failure to achieve this sales volume during this timeframe for two consecutive years will constitute a termination event, unless waived by the Ameluz Licensor.

Ameluz Minimum Research and Development Costs

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

Milestone payments with Ferrer Internacional S.A.

Under the license and supply agreement (as amended, the "Xepi LSA") with Ferrer Internacional S.A. ("Ferrer"), we are obligated to make payments to Ferrer upon the occurrence of certain milestones. Specifically, we must pay Ferrer (i) $2,000,000 upon the first occasion when annual net sales of Xepi® under the Xepi LSA exceed $25,000,000, and (ii) $4,000,000 upon the first occasion annual net sales of Xepi® under the Xepi LSA exceed $50,000,000. No payments or accruals for such payments were made during the three and nine months ended September 30, 2025 or 2024 related to Xepi® milestones.

Legal proceedings

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

Legal Claims

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

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

Separately, on June 26, 2024 and June 27, 2024, Sun filed two complaints against Biofrontera, Biofrontera AG, Biofrontera Pharma, and Biofrontera Bioscience with the United States District Court for the District of Massachusetts (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 Massachusetts District Court 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 Final Determination is currently expected by February 2, 2026, though the timing of the Commission's decision may be impacted by the federal government shutdown that started on October 1, 2025.

The Company denies Sun's patent claims and intends to defend them vigorously in the above-referenced matters. In addition, Biofrontera has challenged the validity of the Sun Patents by filing separate petitions for inter partes review at the United States Patent Trial and Appeal Board ("PTAB") for each of the Sun Patents. One such petition was instituted by the PTAB on February 24, 2025, while the PTAB issued a discretionary denial of the other petition on July 2, 2025. The PTAB's final written decision on the instituted petition is expected on or before February 24, 2026.

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 an adverse ruling by the Commission or at the Massachusetts District Court. Money damages are not available to Sun through the case before the Commission, and an adverse ruling could result in a limited 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.

16. Segment Reporting

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

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

The following table presents selected financial information with respect to the Company's single operating segment for the three and nine months ended September 30, 2025 and 2024**:**

	Three Months Ended September 30,		Nine Months Ended September 30,	
(in thousands)	2025	2024	2025	2024
Revenues, net	**$ 6,988**	**$ 9,012**	**$ 24,605**	**$ 24,762**
Operating expenses:				
Cost of revenues	2,045	4,877	7,955	13,336
Direct sales	2,297	2,224	5,873	6,532
Sales support	1,931	1,914	6,127	6,560
General and administrative	5,551	3,847	16,563	11,301
Research and development	854	669	2,932	1,306
Other operating expenses	588	441	1,062	1,225
Total operating expenses	13,266	13,972	40,512	40,260
Loss from operations	**(6,278)**	**(4,960)**	**(15,907)**	**(15,498)**
Other income (expense), net	(365)	(706)	(244)	(840)
Loss before income taxes	**(6,643)**	**(5,666)**	**(16,151)**	**(16,338)**
Income tax expense	6	3	25	25
Net loss	**$ (6,649)**	**$ (5,669)**	**$ (16,176)**	**$ (16,363)**

17. Subsequent Events

We have completed an evaluation of subsequent events after the balance sheet date of September 30, 2025 through the date this Quarterly Report on Form 10-Q was submitted to the SEC and determined that the following material subsequent events required disclosure.

Closing of Strategic Transaction with Biofrontera AG

On October 20, 2025, the Company executed i) an Asset Purchase Agreement (the "Transfer Agreement") and ii) an Earnout Agreement (the "Earnout Agreement", and collectively with the Transfer Agreement, the "Agreements"), with the Biofrontera Group, pursuant to which the Company finalized the agreements to acquire the U.S. Rights to Ameluz® and RhodoLED®.

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. The earnout replaces a transfer pricing model under the Company's Second A&R Ameluz LSA, which is now terminated pursuant to the Agreements.

On October 24, 2025, following execution of the Agreements, the Company closed the second tranche of 2,500 Series C Preferred Shares (the "Subsequent Closing"), the gross proceeds from which are $2.5 million before deducting estimated offering expenses payable by the Company. The Company intends to use the net proceeds from the Subsequent Closing to fund the acquisition and transfer costs associated with the Strategic Transaction and other general corporate purposes.

Nasdaq Compliance

As described further below, on each of November 4, 2025 and November 6, 2025, the Company received a notice (the "November 4 Notice" and the "November 6 Notice," respectively) from Nasdaq notifying the Company that it has regained compliance with the continued listing requirements under Nasdaq Listing Rule 5550(b)(1) and Nasdaq Listing Rule 5550(a)(2).

Nasdaq Listing Rule 5550(b)(1)

In the November 4 Notice, Nasdaq notified the Company that, based on certain disclosures in the Current Report on Form 8-K filed by the Company on October 24, the Company is in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1). However, the Company may be subject to delisting if the Company fails to evidence compliance with Rule 5550(b)(1) upon filing its next periodic report.

Nasdaq Listing Rule 5550(b)(2)

On May 8, 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 33 consecutive business days.

The notice had 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 had a period of 180 calendar days, or until November 5, 2025, to regain compliance with the rule referred to in this paragraph.

In the November 6 Notice, Nasdaq notified the Company that, because the closing bid price of the Company's common stock was $1.00 per share or greater for the preceding 11 consecutive business days, the Company has regained compliance with Listing Rule 5550(a)(2), and that this matter is now closed.

Xepi- Closing of Asset Purchase Agreement

On November 6, 2025 (the "Closing Date"), the Company entered into an Asset Purchase Agreement (the "APA") with Pelthos Therapeutics Inc., an unaffiliated party, providing for the sale of all of the assets relating to the Company's product, Xepi® (ozenoxacin) cream.

The purchase price for the acquired assets is a maximum of $10.0 million, payable as follows:

1) $3.0 million in cash, paid on the Closing Date;
2) Subject to availability of certain commercial quantities of Xepi® and other terms and conditions of the APA, $1.0 million within thirty (30) days following the availability of such commercial quantities;
3) The right to receive certain earnout consideration upon the achievement of the milestone events, as further described below:

    a) $3.0 million upon the initial achievement of $10.0 million in annual net sales of Xepi®; and
    b) $3.0 million upon the initial achievement of $15.0 million in annual net sales of Xepi®

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

Management's discussion and analysis ("MD&A") provides supplemental information, which sets forth the major factors that have affected our financial condition and results of operations and should be read in conjunction with the Condensed Consolidated Financial Statements and related notes. The following information should provide a better understanding of the major factors and trends that affect our earnings performance and financial condition, and how our performance during the first three quarters of 2025 compare with prior-year periods. Throughout this section, Biofrontera Inc., including its wholly owned subsidiary, Biofrontera Discovery GmbH ("Discovery" or "subsidiary"), is referred to as "Company," "we," "us," or "our." References to "*Licensors*" refer collectively to Biofrontera Pharma, Biofrontera Bioscience and Ferrer. References to "*Ameluz Licensor"* refer collectively to Biofrontera Pharma and Biofrontera Bioscience.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain statements in this Form 10-Q constitute "forward-looking statements". Such statements include estimates of our expenses, future revenue, capital requirements, our need for additional financing, statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing licensed products to market, the timeline for regulatory review and approval of our licensed products, and other statements that are not historical facts. The words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential", "target", "goal", "assume", "would", "could" or similar words are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should read this Form 10-Q 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 may cause such differences include, but are not limited to:

- our ability to achieve and sustain profitability;
- our ability to compete effectively in selling our licensed products;
- our ability to expand, manage and maintain our direct sales and marketing organizations, including our ability to obtain the financing to develop our marketing strategy, if needed;
- changes in our relationship with our Licensors;
- our Licensors' ability to manufacture our licensed products;
- our Licensors' ability to adequately protect their intellectual property and operate their business without infringing upon the intellectual property rights of others;
- our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing;
- market risks regarding consolidation and group purchasing organizations in the healthcare industry;
- the willingness of healthcare providers to purchase our licensed products if coverage, reimbursement and pricing from third-party payors for our products, or procedures using our products significantly declines;
- our ability to market, commercialize, achieve market acceptance for and sell our licensed products;
- any product quality issues, product defects, or product liability claims;
- our ability to comply with Nasdaq continued listing standards (discussed in more detail below);
- our ability to comply with the requirements of being a public company;
- the progress, timing and completion of research, development and preclinical studies and clinical trials for our licensed products;
- our Licensors' ability to obtain and maintain the regulatory approvals necessary for the marketing of our licensed products in the United States, and;
- such other risks identified in *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2024 (as filed with the Securities and Exchange Commission ("SEC") on March 20, 2025, the "Form 10-K"), Item 1A of Part II of this Quarterly Report on Form 10-Q and any other filings with the SEC.

More detailed information about us and the risk factors that may affect the realization of forward-looking statements, including the forward-looking statements in this Quarterly Report on Form 10-Q, is set forth in our filings with the SEC, including our Form 10-K. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

Overview

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

Prior to the closing of the Strategic Transaction on October 20, 2025, we were selling Ameluz® in the United States under an exclusive license and supply agreement, the Second Amended and Restated License and Supply Agreement, effective as of February 13, 2024 with the Ameluz Licensor (the "Second A&R Ameluz LSA"). The Second A&R Ameluz LSA reduced the price we pay per unit, based on certain percentages of the anticipated net selling price ("Transfer Price") of Ameluz® from 50% to 25% which covers the cost of goods, royalties on sales, and services including all regulatory efforts, agency fees, pharmacovigilance and patent administration for all purchases in 2024 and 2025.

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

Recent Key Developments

Strategic Transaction with Biofrontera AG

On June 30, 2025, the Company signed a binding agreement (the "Term Sheet") with its former parent company Biofrontera AG and its subsidiaries, Biofrontera Pharma and Biofrontera Bioscience (together, the "Biofrontera Group") pursuant to which the Company agreed to acquire all rights in the United States (the "U.S. Rights") to Ameluz® and RhodoLED® (the "Strategic Transaction"). In connection with the Strategic Transaction, additional agreements were executed, and the transfer of the U.S. Rights was completed on October 20, 2025. As a result of these actions, the Company will pay a monthly earnout of 12% in years where Ameluz® revenue in the United States is at or below $65.0 million and 15% in years where Ameluz® revenue in the United States exceeds $65.0 million. The earnout replaces the transfer pricing model under the Company's Second A&R Ameluz LSA effective as of February 13, 2024 by and among the Company, and the Biofrontera Group. The new structure reduces overall cost for the Company and is expected to accelerate the Company's timeframe to reach break-even.

With the completion of this agreement, the Company now assumes full responsibility for manufacturing, regulatory, quality management, pharmacovigilance, and commercialization of Ameluz® and the RhodoLED® portfolio in the U.S. The Company expects the full transfer of assets and personnel to be completed by late fourth quarter of 2025 or early in the first quarter of 2026.

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 at the time the Term Sheet was executed and the remaining $2.5 million was funded on October 24, 2025 following the closing of the Strategic Transaction.

Xepi- Closing of Asset Purchase Agreement

On November 6, 2025 (the "Closing Date"), the Company entered into an Asset Purchase Agreement (the "APA") with Pelthos Therapeutics Inc., an unaffiliated party, providing for the sale of all of the assets relating to the Company's product, Xepi® (ozenoxacin) cream.

The purchase price for the acquired assets is a maximum of $10.0 million, payable as follows:

1) $3.0 million in cash, paid on the Closing Date;
2) Subject to availability of certain commercial quantities of Xepi® and other terms and conditions of the APA, $1.0 million within thirty (30) days following the availability of such commercial quantities;
3) The right to receive certain earnout consideration upon the achievement of the milestone events, as further described below:

    a) $3.0 million upon the initial achievement of $10.0 million in annual net sales of Xepi®; and
    b) $3.0 million upon the initial achievement of $15.0 million in annual net sales of Xepi®

Compliance with Nasdaq Listing Standards

As described further below, on each of November 4, 2025 and November 6, 2025, the Company received a notice (the "November 4 Notice" and the "November 6 Notice," respectively) from Nasdaq notifying the Company that it has regained compliance with the continued listing requirements under Nasdaq Listing Rule 5550(b)(1) and Nasdaq Listing Rule 5550(a)(2).

Nasdaq Listing Rule 5550(b)(2)

On May 8, 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 33 consecutive business days.

The notice had 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 had a period of 180 calendar days, or until November 5, 2025, to regain compliance with the rule referred to in this paragraph.

In the November 6 Notice, Nasdaq notified the Company that, because the closing bid price of the Company's common stock was $1.00 per share or greater for the preceding 11 consecutive business days, the Company has regained compliance with Listing Rule 5550(a)(2), and that this matter is now closed.

Nasdaq Listing Rule 5550(b)(1)

On May 21, 2025, the Company received a notice from Nasdaq notifying the Company that, because the Company's stockholders' equity as reported in its Quarterly Report on Form 10-Q for the period ended March 31, 2025 was $0.5 million, the Company was no longer in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1), which requires that a listed company's stockholders' equity be at least $2.5 million. Additionally, as of the date of the notice and as of September 30, 2025, the Company did not meet either of the alternative requirements of maintaining a market value of listed securities of $35 million or achieving a net income from continuing operations of $0.5 million in the most recently completed fiscal year or in two of the last three most recently completed fiscal years.

As a result of the Strategic Transaction and the Subsequent Closing, as of October 24, 2025, the Company believes its stockholders' equity exceeds $5 million which exceeds the minimum amount required for continued listing on Nasdaq under Nasdaq Listing Rule 5550(b)(1).

In the November 4 Notice, Nasdaq notified the Company that, based on certain disclosures in the Current Report on Form 8-K filed by the Company on October 24, the Company is in compliance with the continued listing requirement under Nasdaq Listing Rule 5550(b)(1). Nasdaq will continue to monitor the Company's ongoing compliance with the stockholders' equity requirement and, if at the time of its next periodic report the Company does not evidence compliance, it may be subject to delisting.

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.

Geopolitical Uncertainty and Tariffs

Recent actions by the U.S., including the imposition of significant tariffs on imports from certain countries, have heightened uncertainty in the global trade environment. These tariffs, along with potential retaliatory measures by other countries, may increase inflationary pressure and raise the costs of our products, which are exclusively imported from Europe. While several tariff announcements have been followed by announcements of limited exemptions

and temporary pauses, these actions have caused substantial uncertainty and volatility in financial markets, and may result in further retaliatory measures. We may be unable to fully offset the impacts of tariffs by adjusting the pricing of our products.

Seasonality

Our historical results of operations may not be comparable to our results of operations in future periods, and our results of operations may not be directly comparable from period to period due to seasonality.

Traditional photodynamic therapy treatments using a lamp are performed more frequently during the winter, as a result 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.

Our Strategy

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

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

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

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

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

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

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

Components of Our Results of Operations

Product Revenues, Net

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

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

- the level of orders generated by our sales force;

- the level of prescriptions and institutional demand for our licensed products; and

- unit sales prices.

Revenues, Related Party

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

Cost of Revenues, Related Party

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

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, and medical affairs professionals. Other selling, general and administrative expenses include marketing, trade, and other commercial costs necessary to support the commercial operation of our licensed products and professional fees for legal, consulting and accounting services. Selling, general and administrative expenses also include the amortization of our intangible assets and our legal settlement expenses.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party, relate to the services provided by Biofrontera AG, primarily for regulatory support and pharmacovigilance . These expenses are charged to us based on costs incurred plus 6% in accordance with the Amended and Restated Master Contact Services Agreement entered into in December 2021 (the "2021 Services Agreement"). The 2021 Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us, including regulatory and pharmacovigilance support for as long as we deem necessary. We currently have statements of work in place regarding regulatory affairs, medical affairs, and pharmacovigilance, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine (i) if they will be needed, and (ii) whether they can or should be obtained from other third-party providers.

Research and Development

Our R&D expenses include costs directly attributable to the clinical development of Ameluz®, including personnel-related expenses, the cost of services provided by outside contractors, including services related to the Company's clinical trials, facilities, depreciation, and other direct and allocated expenses. Along with our Ameluz® clinical trials, our R&D program also aims to improve the capabilities of our RhodoLED® Lamps to better fulfill the needs of dermatologists and improve the effectiveness of our commercial team by letting sales representatives carry approved devices with them, allowing for easier product demonstrations and evaluations. All costs associated with research and development are expensed as incurred.

Change in Fair Value of 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.

Loss on Debt Extinguishment

Effective January 4, 2024, we voluntarily terminated the Loan and Security Agreement with MidCap Business Credit LLC, for our revolving line of credit and recognized a $0.3 million loss on debt extinguishment upon the early termination related to prepayment fees and the write-off of deferred financing costs.

Interest 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 (expense), net primarily includes (i) gain (loss) on return of leased assets and (ii) gain (loss) on foreign currency transactions.

Income Taxes

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

Results of Operations

Comparison of the Three Months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the three months ended September 30:

(*in thousands*)	**2025**	**2024**	**Change**
Product Revenues, net	**$ 6,988**	**$ 9,012**	**$ (2,024)**
Operating expenses:			
Cost of revenues, related party	1,922	4,801	(2,879)
Cost of revenues, other	123	76	47
Selling, general and administrative	10,047	8,425	1,622
Selling, general and administrative, related party	320	1	319
Research and development	854	669	185
Total operating expenses	13,266	13,972	(706)
Loss from operations	**(6,278)**	**(4,960)**	**(1,318)**
Change in fair value of warrant liabilities	(285)	(680)	395
Change in fair value of investment, related party	1	(2)	3
Interest income (expense), net	(111)	8	(119)
Other income, net	30	(32)	62
Total other expense	(365)	(706)	341
Loss before income taxes	**(6,643)**	**(5,666)**	**(977)**
Income tax expenses	6	3	3
Net loss	**$ (6,649)**	**$ (5,669)**	**$ (980)**

Product Revenue, net

Net product revenue for the three months ended September 30, 2025 decreased by $2.0 million, or 22.5% as compared to the three months ended September 30, 2024. This decrease was primarily driven by a decrease in sales volume of Ameluz® in the third quarter of 2025. The lower sales volume of Ameluz® in the third quarter of 2025 as compared to the same period of 2024 was due to customer buy-in before the increase in the price of Ameluz® in October 2024.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party for the three months ended September 30, 2025 decreased by $2.9 million, or 60.0% as compared to the three months ended September 30, 2024. This was primarily due to the reduced cost structure under the Second A&R Ameluz LSA. See N*ote 11. Related Party Transactions.*

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2025 increased by $1.6 million, or 19.3% as compared to the three months ended September 30, 2024. The increase was primarily driven by increase in legal costs due to patent claims. See *Note 15. Commitments and Contingencies – Legal Proceedings*.

Research and Development Expenses

R&D expenses for the three months ended September 30, 2025 increased by $0.2 million, or 27.7% as compared to the three months ended September 30, 2024. The increase was attributable to higher external investigator fees and clinical site setup costs, reflecting the progress of trials in 2025.

The following table summarizes our R&D expenses by indication:

	Three Months Ended September 30,	
	2025	**2024**
Superficial basal cell carcinoma	$ 42	$ 44
Actinic keratosis	310	206
Moderate to severe acne	53	129
Personnel-related costs	428	203
Other research and development	21	87
	$ 854	$ 669

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was $0.3 million for the three months ended September 30, 2025, as compared to $0.7 million for the three months ended September 30, 2024. The change in fair value of warrant liabilities was driven primarily by a drop in the underlying value of the Company's Common Stock during the third quarter of 2025 as compared to the third quarter of 2024.

Interest expense, net

Interest expense increased by $0.1 million due to the issuance of Senior Secured Convertible Notes of $4.2 million pursuant to a securities purchase agreement entered into on November 21, 2024 with its principal stockholders.

Such Notes bear interest at 10.0% per annum, payable in-kind through the issuance of additional principal on a quarterly basis. See N*ote 10. Debt.*

Comparison of the Nine Months ended September 30, 2025 and 2024

The following table summarizes our results of operations for the nine months ended September 30:

(*in thousands)*	**2025**	**2024**	**Change**
Product revenues, net	$ 24,605	$ 24,744	$ (139)
Related party revenues	-	18	(18)
Revenues, net	**$ 24,605**	**$ 24,762**	**$ (157)**
Operating expenses:			
Cost of revenues, related party	7,377	12,839	(5,462)
Cost of revenues, other	578	496	82
Selling, general and administrative	29,229	25,589	3,640
Selling, general and administrative, related party	396	30	366
Research and development	2,932	1,306	1,626
Total operating expenses	40,512	40,260	252
Loss from operations	**(15,907)**	**(15,498)**	**(409)**
Change in fair value of warrant liabilities	417	1,329	(912)
Change in fair value of investment, related party	3	(12)	15
Loss on debt extinguishment	-	(316)	316
Interest expense, net	(331)	(1,995)	1,664
Other income (expense), net	(333)	154	(487)
Total other income (expense)	(244)	(840)	596
Loss before income taxes	**(16,151)**	**(16,338)**	**187**
Income tax expenses	25	25	-
Net loss	**$ (16,176)**	**$ (16,363)**	**$ 187**

Product Revenues, Net

Net product revenue for the nine months ended September 30, 2025 decreased by $0.1 million, or 0.6% as compared to the nine months ended September 30, 2024. This decrease was driven by a decreased sales volume of Ameluz® contributing a decrease of $1.4 million, offset by an increase of $1.6 million due to a higher unit sales price.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party for the nine months ended September 30, 2025 decreased by $5.5 million, or 42.5% as compared to the nine months ended September 30, 2024. This was driven by the reduced cost structure under the Second A&R Ameluz LSA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2025 increased by $3.6 million, or 14.2% as compared to the nine months ended September 30, 2024. The increase was primarily attributable to a $6.2 million increase in legal expenses driven by patent claims. The increased legal expenses were partially offset by savings in personnel expenses of $1.1 million, mainly due to headcount fluctuations in our direct sales and administrative teams, as well decreases of $0.4 million in expenses relating to sales support functions and $0.6 million in insurance and finance expenses, and savings of $0.5 million in other general and administrative expenses.

Research and Development Expenses

R&D expenses for the nine months ended September 30, 2025 increased by $1.6 million as compared to the nine months ended September 30, 2024. The increase was attributable to our assumption of all clinical trial activities for Ameluz® in the United States effective June 1, 2024. The following table summarizes our research and development expenses by indication:

	Nine Months Ended September 30,	
	2025	**2024**
Superficial basal cell carcinoma	$ 260	$ 153
Actinic keratosis	1,143	338
Moderate to severe acne	284	221
Personnel-related costs	1,209	435
Other research and development	36	159
	$ 2,932	$ 1,306

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was $0.4 million for the nine months ended September 30, 2025, as compared to $1.3 million for the nine months ended September 30, 2024. The change in fair value of warrant liabilities was driven by a mix of a decreased population of outstanding warrant liabilities due to the exercise of warrants for preferred shares in May 2024, coupled with a drop in the underlying value of the Company's Common Stock for each of the nine months ended September 30, 2025 and September 30, 2024.

Interest expense, net

Interest expense decreased by $1.7 million due a lower interest rate applicable to the outstanding convertible notes of $4.2 million issued in November of 2024, compared to the interest rate on the $4.0 million term loan that matured on July 5, 2024 .

Net Loss to Adjusted EBITDA Reconciliation for the Three and Nine Months Ended September 30, 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 U.S. 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 U.S. 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 U.S. GAAP.

Loss on debt extinguishment: Effective as of January 4, 2024, we voluntarily terminated the Loan and Security Agreement 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.

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

Change in fair value of investment, related party: The Company accounts for its investment, related party in accordance with ASC 321, *Investments — Equity Securities*. 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 gain as this is non-recurring and the unrealized change in fair value of investments is excluded as this is 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 the 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 viewers of the financial statements to better understand our financial results.

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

We use adjusted EBITDA to measure our performance from period to period and to compare our results to those of our competitors. In addition to adjusted EBITDA being a significant measure of performance for management purposes, we also believe that this presentation provides useful information to investors regarding financial and business trends related to our results of operations and that when non-U.S. GAAP financial information is viewed with U.S. 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 three and nine months ended September 30, 2025 and 2024:

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2025	**2024**	**2025**	**2024**
Net loss	**$ (6,649)**	**$ (5,669)**	**$ (16,176)**	**$ (16,363)**
Interest (income) expense, net	111	(8)	331	1,995
Income tax expenses	6	3	25	25
Depreciation and amortization	25	129	76	387
EBITDA	**(6,507)**	**(5,545)**	**(15,744)**	**(13,956)**
Loss on debt extinguishment	-	-	-	316
Change in fair value of warrant liabilities	285	680	(417)	(1,329)
Change in fair value of investment, related party	(1)	2	(3)	12
Stock based compensation	236	288	426	720
Expensed issuance costs	-	-	-	354
Adjusted EBITDA	**$ (5,987)**	**$ (4,575)**	**$ (15,738)**	**$ (13,883)**
Adjusted EBITDA margin	***-85.7%***	***-50.8%***	***-64.0%***	***-56.1%***

Adjusted EBITDA

Adjusted EBITDA decreased $1.4 million from ($4.6) million for the three months ended September 30, 2024 to ($6.0) million for the three months ended September 30, 2025. This is the result of the increases in selling, general and administrative expenses and research and development expenses, which were partially offset by the increase in gross profit.

Adjusted EBITDA for the nine months ended September 30, 2025 decreased $1.9 million from ($9.3) million for the nine months ended September 30, 2024 to ($13.9) million for the nine months ended September 30, 2025. This decrease is mainly due to the increase in legal expenses, partially offset by savings in other selling, general and administrative expenses and the increase in gross profit of $5.2 million.

Liquidity and Capital Resources

These consolidated financial statements have been prepared in accordance with U,S. generally accepted accounting principles ("U.S. GAAP") assuming the Company will continue as a going concern. The going concern assumption contemplates the realization of assets and satisfaction of liabilities in the normal course of business.

Since we commenced operations in 2015, we have generated significant losses. The Company incurred net cash outflows from operations of $11.0 million and $9.3 million for the nine months ended September 30, 2025 and 2024, respectively. The Company had an accumulated deficit as of September 30, 2025 of $133.6 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 received in a private placement of Series C Preferred Stock, (received in two separate tranches of $8.5 million in July 2025 and $2.5 million in October 2025).) As of September 30, 2025, we had cash and cash equivalents of $3.4 million, compared to $5.9 million as of December 31, 2024. These factors raise substantial doubt about the Company's ability to continue as a going concern for a period of at least twelve months from the issuance date of this report.

The Company plans to address the conditions that raise substantial doubt regarding its ability to continue as a going concern by, among other things, utilizing external financing options, including a short-term line of credit, as well as finalizing the sale of its Xepi product line on November 6, 2025. 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:

	Nine Months Ended September 30,	
(in thousands)	**2025**	**2024**
Net cash used in operating activities	$ (10,985)	(9,253)
Net cash provided by (used) in investing activities	(3)	(2)
Net cash provided by financing activities	8,500	10,785
Net increase (decrease) in cash and restricted cash	**$ (2,488)**	**1,530**

Operating Activities

During the nine months ended September 30, 2025, operating activities used $11.0 million of cash, primarily resulting from our loss from operations of $16.2 million, adjusted for non-cash expense of stock-based compensation of $0.7 million, depreciation and amortization in the aggregate of $0.6 million, non-cash interest expense of $0.4 million, and net cash used by changes in our operating assets and liabilities of $4.0 million, partially offset by the change in fair value of warrant liabilities of $0.4 million.

During the nine months ended September 30, 2024, operating activities used $9.3 million of cash, primarily resulting from our loss from operations of $16.4 million, adjusted for non-cash expense of stock-based compensation of $0.7 million, non-cash interest expense of $0.2 million, loss on debt extinguishment of $0.3 million, depreciation and amortization in the aggregate of $0.9 million, and net cash used by changes in our operating assets and liabilities of $6.1 million, offset by the change in fair value of warrant liabilities of $1.3 million

Investing Activities

During the nine months ended September 30, 2025, net cash used in investing activities consisted of negligible fixed asset purchases.

During the nine months ended September 30, 2024, net cash used in investing activities consisted of $0.1 million of capitalized software and computer purchases, which were partially offset by the proceeds from the sales of equity investments.

Financing Activities

During the nine months ended September 30, 2025, net cash from financing activities consisted of proceeds received in June 2025 in accordance with a securities purchase agreement dated June 27, 2025, for the issuance of Series C Preferred Stock, and initially recorded as an advance from certain stockholders as the stock was not issued until July 1, 2025. On July 1, 2025, upon issuance of the Series C Preferred Stock, the advance from stockholders was settled and reclassed to equity. See *Note 12. Stockholders' Equity*, for additional details.

During the nine months ended September 30, 2024, net cash from financing activities consisted of proceeds of $7.7 million, net of capitalized issuance costs, from the issuance of preferred stock and warrants, and $7.4 million from the exercise of warrants for preferred stock, offset by repayments of $4.0 million on our short-term loan, repayments of $0.2 million on our line of credit 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 U.S. GAAP. The preparation of the financial statements in accordance with U.S. 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 fair value measurements, valuation of intangible assets and impairment assessment, and stock compensation. Estimates are based on historical experience and other assumptions that are considered appropriate in the circumstances. They are continuously reviewed but may vary from the actual values.

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

Critical Accounting Estimates

A summary of our critical accounting estimates is discussed in the section entitled "Critical Accounting Estimates" in *Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations* in our Form 10-K. There were no material changes to our critical accounting estimates for the nine months ended September 30, 2025.

Off-balance Sheet Arrangements

Other than those items reflected in *Note 18. Commitments and Contingencies* 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 3. 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 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Chief Financial Officer, evaluated, as of the end of the period covered by this Form 10-Q, the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934 (the "Exchange Act")). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2025, our disclosure controls and procedures were effective at the reasonable assurance level.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the most recent fiscal quarter ended September 30, 2025 that materially affected, or are reasonably likely to materially affect, our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act).

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings in which we are involved, see *Note 15. Commitments and Contingencies* under the subsection titled "Legal Proceedings" in our Notes to Consolidated Financial Statements in Part I, Item 1 of this Quarterly Report on Form 10-Q.

Item 1A. Risk Factors

As a smaller reporting company, we are not required to provide disclosure pursuant to this item in this Form 10-Q.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

Not applicable.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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

Exhibit No.

10.1	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)
10.2	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)
10.3	Employment Agreement dated July 18, 2025 (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)
31.1*	Certification of Principal Executive Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
31.2*	Certification of Principal Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1*	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
32.2*	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document and included in Exhibit 101)

* Filed herewith.
\# Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

BIOFRONTERA INC.

Date: November 12, 2025

By: */s/ Hermann Luebbert*
Name: Hermann Luebbert
Title: Chief Executive Officer & Chairman
(*Principal Executive* Officer)

Date: November 12, 2025

By: */s/ E. Fred Leffler III*
Name: E. Fred Leffler, III
Title: Chief Financial Officer
(Principal Financial Officer)

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 Luebbert, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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(s) 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 me 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(s) 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 person 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: November 12, 2025

By: */s/ Hermann Luebbert*
Hermann Luebbert
Chief Executive Officer & 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, Eugene Frederick Leffler, III, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q 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(s) 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 me 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(s) 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 person 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: November 12, 2025

By: */s/ E. Fred Leffler III*
E. Fred Leffler, III
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 Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly Report"), pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Hermann Luebbert, Chief Executive Officer of the Company, do hereby certify, to my knowledge:

1. The Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Quarterly Report.

Date: November 12, 2025

By: */s/ Hermann Luebbert*
Hermann Luebbert
Chief Executive Officer & Chairman
(Principal Executive Officer)

* This certification accompanies the Quarterly 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 Quarterly 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 Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2025 as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly Report"), pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, I, Eugene Frederick Leffler, III, Chief Financial Officer of the Company, do hereby certify, to my knowledge:

1. The Quarterly 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 Quarterly Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Quarterly Report.

Date: November 12, 2025

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

* This certification accompanies the Quarterly 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 Quarterly Report), irrespective of any general incorporation language contained in such filing.