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, 2023

OR

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

For the transition period from to

Commission file number 001-40943

Biofrontera Inc.
(Exact name of registrant as specified in its charter)

Delaware **(State or other jurisdiction of incorporation or organization)**	**47-3765675** **(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 8, 2023 there were 1,517,628 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, 2023	December 31, 2022
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,422	$ 17,208
Investment, related party	3,341	10,548
Accounts receivable, net	3,793	3,748
Other receivables, related party	2,713	3,658
Inventories, net	16,068	7,168
Prepaid expenses and other current assets	274	810
Total current assets	**29,611**	**43,140**
Other receivables long term, related party	-	2,813
Property and equipment, net	154	204
Operating lease right-of-use assets	1,129	1,375
Intangible asset, net	2,718	3,032
Other assets	492	320
Total assets	**$ 34,104**	**$ 50,884**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,634	1,278
Accounts payable, related parties	6,988	1,312
Acquisition contract liabilities, net	7,211	6,942
Operating lease liabilities	555	498
Accrued expenses and other current liabilities	11,039	10,864
Line of credit	1,697	-
Total current liabilities	**29,124**	**20,894**
Long-term liabilities:		
Acquisition contract liabilities, net	2,500	2,400
Warrant liabilities	842	2,843
Operating lease liabilities, non-current	562	848
Other liabilities	38	21
Total liabilities	**33,066**	**27,006**
Commitments and contingencies (Note 18)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, zero shares issued and outstanding as of September 30, 2023 and December 31, 2022	-	-
Common Stock, $0.001 par value, 15,000,000 shares authorized; 1,367,628 and 1,334,950 shares issued and outstanding as of September 30, 2023 and December 31, 2022	1	1

Additional paid-in capital	104,213	103,396
Accumulated deficit	(103,176)	(79,519)
Total stockholders' equity	**1,038**	**23,878**
Total liabilities and stockholders' equity	**$ 34,104**	**$ 50,884**

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,	
	2023	**2022**	**2023**	**2022**
Product revenues, net	$ 8,879	$ 4,290	$ 23,423	$ 18,467
Revenues, related party	17	32	52	63
Total revenues, net	**8,896**	**4,322**	**23,475**	**18,530**
Operating expenses				
Cost of revenues, related party	4,495	2,127	11,814	9,504
Cost of revenues, other	95	98	262	425
Selling, general and administrative	8,619	7,765	29,874	25,050
Selling, general and administrative, related party	74	171	193	612
Research and development	33	-	44	-
Change in fair value of contingent consideration	200	(2,200)	100	(4,100)
Total operating expenses	**13,516**	**7,961**	**42,287**	**31,491**
Loss from operations	**(4,620)**	**(3,639)**	**(18,812)**	**(12,961)**
Other income (expense)				
Change in fair value of warrant liabilities	598	3,814	2,001	17,896
Warrant inducement expense	-	(2,629)	-	(2,629)
Realized/Unrealized losses in investment, related party	(2,212)	-	(6,635)	-
Interest expense, net	(142)	(89)	(256)	(160)
Other income, net	35	(22)	65	30
Total other income (expense)	**(1,721)**	**1,074**	**(4,825)**	**15,137**
Income (loss) before income taxes	**(6,341)**	**(2,565)**	**(23,637)**	**2,176**
Income tax expense	1	1	20	31
Net income (loss)	**$ (6,342)**	**$ (2,566)**	**$ (23,657)**	**$ 2,145**
Income (loss) per common share:				
Basic	$ (4.64)	$ (2.26)	$ (17.57)	$ 2.19
Diluted	$ (4.64)	$ (2.26)	$ (17.57)	$ 2.19
Weighted-average common shares outstanding:				
Basic	1,366,842	1,136,291	1,346,264	978,018
Diluted	1,366,842	1,136,291	1,346,264	980,251

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

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

Three and Nine Months Ended September 30, 2023

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, June 30, 2023	1,343,538	$ 1	$ 104,006	$ (96,834)	$ 7,173
Issuance of shares in reverse stock split (for fractional shares)	24,090	0	-	-	-
Stock based compensation	-	-	207	-	207
Net loss	-	-	-	(6,342)	(6,342)
Balance, September 30, 2023	1,367,628	$ 1	$ 104,213	$ (103,176)	$ 1,038
Balance, December 31, 2022	1,334,950	$ 1	$ 103,396	$ (79,519)	$ 23,878
Issuance of shares for vested restricted stock units	8,588	0	-	-	-
Issuance of shares in reverse stock split (for fractional shares)	24,090	0	-	-	-
Stock based compensation	-	-	817	-	817
Net loss	-	-	-	(23,657)	(23,657)
Balance, September 30, 2023	1,367,628	$ 1	$ 104,213	$ (103,176)	$ 1,038

Three and Nine Months Ended September 30, 2022

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, June 30, 2022	950,573	$ 1	$ 91,400	$ (74,168)	$ 17,233
Exercise of pre-funded warrants	78,450	0	2,841		2,841
Exercise of PIPE warrants	142,857	0	4,686	-	4,686
Issuance of shares for vested restricted stock units	5,668	0	-	-	-
Stock based compensation	-	-	401	-	401
Net loss	-	-	-	(2,566)	(2,566)
Balance, September 30, 2022	1,177,548	$ 1	$ 99,328	$ (76,734)	$ 22,595
Balance, December 31, 2021	855,237	$ 1	$ 90,216	$ (78,879)	$ 11,338
Issuance of common stock and warrants under private placement, net of issuance costs	92,500	0	116	-	116
Exercise of pre-funded warrants	78,450	0	2,841		2,841
Exercise of PIPE warrants	142,857	0	4,686	-	4,686
Issuance of shares for vested restricted stock units	8,504	0	-	-	-
Stock based compensation	-	-	1,469	-	1,469
Net income	-	-	-	2,145	2,145
Balance, September 30, 2022	1,177,548	$ 1	$ 99,328	$ (76,734)	$ 22,595

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,	
	2023	**2022**
Cash flows from operating activities:		
Net income (loss)	$ (23,657)	$ 2,145
Adjustments to reconcile net income (loss) to cash flows used in operations:		
Depreciation	65	80
Amortization of right-of-use assets	390	-
Amortization of acquired intangible assets	314	314
Realized/Unrealized losses in investment, related party	6,635	-
Change in fair value of contingent consideration	100	(4,100)
Change in fair value of warrant liabilities	(2,001)	(17,896)
Warrant inducement expense	-	2,629
Stock-based compensation	817	1,469
Provision for inventory obsolescence	-	100
Provision for doubtful accounts	158	111
Non-cash interest expense	296	268
Changes in operating assets and liabilities:		
Accounts receivable	(204)	2,111
Other receivables, related party	3,652	5,145
Prepaid expenses and other assets	347	4,121
Inventories	(8,900)	(7,728)
Accounts payable and related party payables	6,137	3,519
Operating lease liabilities	(375)	-
Accrued expenses and other liabilities	197	(216)
Cash flows used in operating activities	**(16,029)**	**(7,928)**
Cash flows from investing activities		
Disbursement for loan receivable	-	(3,033)
Sales of equity investment, related party	560	-
Purchases of property and equipment	(14)	(37)
Cash flows provided by (used) in investing activities	**546**	**(3,070)**
Cash flows from financing activities		
Proceeds from line of credit	13,546	-
Proceeds from issuance of common stock and warrants in private placement, net of issuance costs	-	9,391
Proceeds from exercise of warrants	-	4,630
Repayment of line of credit	(11,849)	-
Cash flows provided by financing activities	**1,697**	**14,021**
Net increase (decrease) in cash and cash equivalents	**(13,786)**	**3,023**
Cash, cash equivalents and restricted cash, at the beginning of the period	**17,408**	**24,742**

Cash, cash equivalents and restricted cash, at the end of the period	**$**	**3,622**	**$**	**27,765**
Supplemental disclosure of cash flow information				
Interest paid	$	31	$	10
Interest paid, related party	$	22		-
Income taxes paid, net	$	21	$	30
Supplemental non-cash investing and financing activities				
Conversion of warrant liability to equity	$	-	$	6,840
Addition of right-of-use assets in exchange for operating lease liabilities	$	147	$	-

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

Biofrontera Inc.
Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Business Overview

Biofrontera Inc. (the "Company" or "Biofrontera") is a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT") and topical antibiotics. The Company's licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions as well as impetigo, a bacterial skin infection. In May 2023, the Company began research and development ("R&D") activities to support PDT growth and will continue to opportunistically invest in these activities going forward. Our research and development program currently aims to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists and improve the effectiveness of our commercial team by letting sales representatives carry approved devices with them allowing for easier product demonstrations and evaluations.

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

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® lamp series, for PDT. In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement ("Ameluz LSA") with Biofrontera Pharma ("Pharma") GmbH and Biofrontera Bioscience GmbH ("Bioscience" and together, the "Ameluz Licensor").

Our second prescription drug licensed product is Xepi® (ozenoxacin cream, 1%), a topical non-fluorinated quinolone that inhibits bacterial growth. It is approved for use in the United States in adults and children 2 months and older. We are currently selling Xepi® for this indication in the United States under an exclusive license and supply agreement, as amended ("Xepi LSA") with Ferrer Internacional S.A. ("Ferrer") that was assumed by Biofrontera on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc.("Cutanea"). There has been limited revenue during the current reporting periods and recent developments with the third-party manufacturer that was providing our supply of Xepi® have resulted in further delays of our commercialization of the product. However, Ferrer is qualifying a new Contract manufacturer, Cambrex, which is expected to begin production in 2024.

Reverse Stock Split

On June 28, 2023, the Company, filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation (the "Amendment") with the Secretary of State of the State of Delaware to (i) effect a 1-for-20 reverse stock split (the "Reverse Stock Split") of the Company's common stock, par value $0.001 per share (the "Common Stock"), and (ii) effect a related proportional reduction in the number of the Company's authorized shares of Common Stock from 300,000,000 to 15,000,000 (the "Authorized Share Reduction").

Pursuant to the Amendment, the Reverse Stock Split and Authorized Share Reduction was effective at 11:59 p.m. on July 3, 2023 (the "Split Effective Time"), and the Common Stock began trading on the Nasdaq Capital Market on a post-split basis on July 5, 2023. The par value and other terms of the Common Stock were not affected.

Following the Split Effective Time, every 20 shares of Biofrontera Common Stock issued and outstanding were automatically combined and reclassified into one share of Common Stock. Outstanding equity-based awards, warrants and other equity rights were proportionately adjusted pursuant to their terms and the number of shares authorized and reserved for issuance upon vesting of restricted stock units or exercise of stock options and warrants were reduced proportionately. No fractional shares were issued as a result of the Reverse Stock Split. Stockholders who would otherwise hold a fractional share as a result of the Reverse Stock Split received an additional share of Common Stock.

Under the terms of the applicable warrant agreement, the number of shares of Common Stock issuable on exercise of each warrant will be proportionately decreased. Specifically, following effectiveness of the Reverse Stock Split, every 20 shares of Common Stock that may be purchased pursuant to the exercise of public warrants now represents one share of Common Stock that may be purchased pursuant to such warrants. Accordingly, for the Company's warrants trading under the symbol "BFRIW", every 20 warrants will be exercisable for one share of Common Stock at an exercise price of $100.00 per share of Common Stock.

The Reverse Stock Split affected all stockholders uniformly and did not alter any stockholder's percentage interest in the Company's equity (other than as a result of the rounding up of fractional shares). All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect the Reverse Stock Split as if it had been effective from the beginning of the earliest period presented, unless otherwise stated. All outstanding securities entitling their holders to purchase shares of Common Stock or acquire shares of Common Stock, including stock options, restricted stock units, and warrants, were adjusted as a result of the Reverse Stock Split.

Liquidity and Going Concern

The Company's primary sources of liquidity are its existing cash balances, cash collected from the sales of its products, proceeds from the sale of our investment, related party, and cash flows from a revolving line of credit. As of September 30, 2023, we had cash and cash equivalents of $3.4 million and investment, related party of $3.3 million, compared to $17.2 million and $10.5 million as of December 31, 2022, respectively.

Since we commenced operations in 2015, we have generated significant losses. For the nine months ended September 30, 2023 and 2022, we incurred loss from operations of $18.8 million and $13.0 million, respectively. We incurred net cash outflows from operations of $16.0 million and $7.9 million, for the same periods, respectively. We had an accumulated deficit as of September 30, 2023 of $103.2 million. Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing, medical affairs, and dermatology community outreach efforts as we seek to expand the commercialization of our licensed products in the United States.

In connection with our assessment of going concern considerations under applicable accounting standards, the Company's management has determined that substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed consolidated financial statements were issued.

The future viability of the Company is dependent on its ability to continue to execute its growth plan and raise additional capital or find alternative methods of financing to fund its operations during the first half of 2024, and until cash flow from operations is sufficient, if ever. We have implemented plans to improve our working capital position, particularly around inventory levels, and do not expect to need a delivery until sometime in Q3 2024, depending on actual sales until then. Management believes that the anticipated implementation of such plans, together with the recent net capital raise of $4.1 million (See Note 21, *Subsequent Events*) will provide the opportunity for the Company to continue as a going concern. However, no assurance can be given that the Company will be successful in these efforts.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. There could be a material adverse effect on the Company and its financial statements if management's plans are not achieved on a timely basis.

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. generally accepted accounting principles ("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, 2023, the Company's operating results for the three and nine months ended September 30, 2023 and 2022, and the Company's cash flows for the nine months ended September 30, 2023 and 2022. The accompanying financial information as of December 31, 2022 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 reaudited consolidated financial statements for the fiscal years ended December 31, 2022 and 2021 ("reaudited Consolidated Financial Statements"), and the revised Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal years ended December 31, 2022 and December 31, 2021 ("revised MD&A"), filed in a Current Report on From 8-K with the SEC on October 3, 2023.

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 reaudited Consolidated Financial Statements.:

Reverse Stock Split

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

Research and Development Costs

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

Use of Estimates

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

Recently Adopted Accounting Pronouncements

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

3. Acquisition Contract Liabilities

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

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

The contingent consideration was recorded at acquisition-date fair value using a Monte Carlo simulation with an assumed discount rate of approximately 6.0% over the applicable term. The contingent consideration is recorded within acquisition contract liabilities, net. The amount of contingent consideration that could be payable is not subject to a cap under the agreement. The Company re-measures contingent consideration and re-assesses the underlying assumptions and estimates at each reporting period utilizing a scenario-based method. The contingent consideration liability was valued at $2.5 million with payments coming due May of 2028 through May 2031.

Acquisition contract liabilities, net consist of the following:

(in thousands)	September 30, 2023	December 31, 2022
Short-term acquisition contract liabilities:		
Start-up cost financing	7,300	7,300
Contract asset	(89)	(358)
Acquisition contract liabilities, net	$ 7,211	$ 6,942
Long-term acquisition contract liabilities:		
Contingent consideration	$ 2,500	$ 2,400
Total acquisition contract liabilities:		
Contingent consideration	$ 2,500	$ 2,400
Start-up cost financing	7,300	7,300
Contract asset	(89)	(358)
Total acquisition contract liabilities, net	$ 9,711	$ 9,342

4. 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, 2023 and December 31, 2022 and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

(in thousands)	Level	September 30, 2023	December 31, 2022
Assets:			
Investment, related party	1	$ 3,341	$ 10,548
Liabilities:			
Contingent Consideration	3	$ 2,500	$ 2,400
Warrant liability – 2022 Purchase Warrants	3	$ 366	$ 1,129
Warrant liability - 2022 Inducement Warrants	3	$ 476	$ 1,714

Investment, related party

As of September 30, 2023 and December 31, 2022, the Company has an investment in 5,745,678 and 6,446,946, respectively of common shares of Biofrontera AG, a company traded on the Frankfurt Stock Exchange and a significant shareholder of Biofrontera. The fair value of this investment was determined with Level 1 inputs through references to quoted market prices. See *Note 6. Investment Related Party and Note 13. Related Party Transactions.*

Contingent Consideration

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

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

(in thousands)		
Balance at December 31, 2022	**$**	**2,400**
Change in fair value of contingent consideration		100
Balance at September 30, 2023	**$**	**2,500**
Balance at December 31, 2021	**$**	**6,200**
Change in fair value of contingent consideration		(4,100)
Balance at September 30, 2022	**$**	**2,100**

Warrant Liabilities

The warrant liabilities are comprised of (i) currently outstanding warrants to purchase 170,950 shares of Common Stock originally issued in a private placement on May 16, 2022, expiring five and one-half years after the issue date and with an exercise price of $55.40 per share (the "Purchase Warrants"), and (ii) a warrant to purchase 214,286 shares of Common Stock issued on July 26, 2022, expiring on December 1, 2026 with an exercise price of $33.20 per share (the "Inducement Warrants") and were accounted for as liabilities in accordance with ASC 815-40 and are presented within warrant liabilities in the accompanying consolidated balance sheets. The warrant liabilities are measured at fair value at inception and on a recurring basis, with changes in fair value presented within the consolidated statements of operations.

The Company utilizes a Black-Scholes option pricing model to estimate the fair value of the Purchase Warrants and Inducement Warrants which is considered a Level 3 fair value measurement. Certain inputs utilized in our Black-Scholes pricing model may fluctuate in future periods based upon factors which are outside of the Company's control. A significant change in one or more of these inputs used in the calculation of 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 statements of operations.

The fair value for the Level 3 warrants at September 30, 2023 was estimated using a Black-Scholes pricing model based on the following assumptions:

	Purchase	**Inducement**
Stock price	$ 8.77	$ 8.77
Expiration term (in years)	4.13	3.17
Volatility	80.0%	80.0%
Risk-free Rate	4.63%	4.73%
Dividend yield	0.0%	0.0%

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

	Purchase	Inducement
Stock price	$ 18.40	$ 18.40
Expiration term (in years)	4.88	3.92
Volatility	70.0%	75.%
Risk-free Rate	3.96%	4.07%
Dividend yield	0.0%	0.0%

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

	Nine Months Ended September 30,	
	2023	2022
Fair value at beginning of period	$ 2,843	$ 12,854
Issuance of new warrants	-	13,217
Exercise of warrants	-	(6,840)
Change in fair value of warrant liabilities	(2,001)	(15,267)
Fair value at end of period	$ 842	$ 3,964

5. Revenue

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

Related party revenue relates to an agreement with Bioscience for BF-RhodoLED® leasing and installation service. Refer to *Note 13, Related Party Transactions*.

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

(in thousands):	Returns	Co-pay assistance program	Prompt pay discounts	Government and payor rebates	Total
Balance at December 31, 2021	**$ 43**	**$ 101**	**$ 48**	**$ 54**	**$ 246**
Provision related to current period sales	8	503	16	164	691
Credit or payments made during the period	(5)	(400)	(23)	(149)	(577)
Balance at September 30, 2022	**$ 46**	**$ 204**	**$ 41**	**$ 69**	**$ 360**
Balance at December 31, 2022	**$ 48**	**$ 9**	**$ 5**	**$ 20**	**$ 82**
Provision related to current period sales	4	156	3	266	429
Credit or payments made during the period	-	(145)	(2)	(231)	(378)
Balance at September 30, 2023	**$ 52**	**20**	**6**	**55**	**133**

6. Investment, Related Party

As of September 30, 2023 and December 31, 2022, our investment in equity securities consisted solely of 5,745,678 and 6,446,946, respectively of common shares of Biofrontera AG, a significant shareholder. (See *Note 13. Related Party Transactions*). Of these shares, 3,377,346 are not fully in our control to vote or dispose of as we see fit as they are not held in a brokerage account registered in our name, however, we are currently engaged with advisors to transfer such shares to our brokerage account. Equity securities gains and losses include unrealized gains and losses from changes in fair values during the period on equity securities we still own, as well as gains and losses on securities we sold during the period. As reflected in the consolidated statements of cash flows, we received proceeds from sales of equity securities of approximately $0.6 million during the nine months ended September 30, 2023.

Unrealized losses on investment, related party were $1.9 million and $6.2 million, respectively, for the three and nine months ended September 30, 2023. There were no unrealized gains and losses for the three and nine months ended September 30, 2022.

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2023	2022	2023	2022
Net losses recognized during the period on equity securities	$ (2,212)	$ -	$ (6,635)	$ -
Less: Net realized losses on equity securities sold	345	-	420	-
Unrealized losses recognized during the reporting period on equity securities still held at the reporting date	$ (1,867)	$ -	$ (6,215)	$ -

7. Accounts Receivable, net

Accounts receivables are mainly attributable to the sale of Ameluz®. It is expected that all trade receivables will be settled within twelve months of the balance sheet date. Trade accounts receivable are stated at their net realizable value. The allowance for credit losses reflects our best estimate of expected credit losses of the receivables determined on the basis of historical experience and current information. In developing the estimate for expected credit losses, trade accounts 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 receivables, we considered our historical experience with certain customers, regulatory and legal environments and other relevant current and future forecasted macroeconomic factors. If we become

aware of any customer-specific factors that impact credit risk, specific allowances for these known troubled accounts are recorded.

The allowance for credit losses was $0.2 million and $0.1 million as of September 30, 2023 and December 31, 2022, respectively.

8. Other Receivables, Related Party

As of September 30, 2023 the Company has a receivable, related party of $2.7 million primarily due from Biofrontera AG for its 50% share of the balance of a legal settlement (See *Note 18. Commitments and Contingencies – Legal proceedings*) for which both parties are jointly and severally liable. The Company has a contractual right to repayment of its share of the settlement payments, plus interest and other miscellaneous settlement costs, from Biofrontera AG under the Settlement Allocation Agreement ("Allocation Agreement") entered into on December 9, 2021 and as amended on March 31, 2022, which provides that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share. The Allocation Agreement, as amended, provides certain remedies to the Company, if Biofrontera AG fails to make timely reimbursements, which the Company may implement in its sole discretion, including the ability to charge interest at a rate of 6.0% per annum for each day that any reimbursement is past due and the ability to offset any overdue reimbursement amounts against payments owed to Biofrontera AG by the Company (including amounts owed under the Company's license and supply agreement for Ameluz®). As such, no reserve for the receivable was deemed necessary as of September 30, 2023 or December 31, 2022.

9. Intangible Asset, Net

Intangible asset, net consists of the following:

(in thousands)	September 30, 2023	December 31, 2022
Xepi® license	$ 4,600	$ 4,600
Less: Accumulated amortization	(1,882)	(1,568)
Intangible asset, net	$ 2,718	$ 3,032

The Xepi® license intangible asset was recorded at acquisition-date fair value of $4.6 million and is amortized on a straight-line basis over the useful life of 11 years. Amortization expense for the three months ended September 30, 2023 and 2022 was $0.1 million and $0.3 million for the nine months ended September 30, 2023 and 2022.

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

The Company performed an impairment analysis because of this situation and determined no impairment charges were deemed necessary during the three and nine months ended September 30, 2023.

10. 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"). The FDIC provides coverage of up to $250,000 per depositor, per financial institution. At September 30, 2023, approximately $3.0 million of the Company's cash balances were in excess of FDIC limits. The Company has not experienced any losses on these accounts and management does not believe that the Company is exposed to any significant risks.

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

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

(in thousands)	September 30, 2023	December 31, 2022
Cash and cash equivalents	$ 3,422	$ 17,208
Long-term restricted cash	200	200
Total cash, cash equivalents, and restricted cash shown on the consolidated statements of cash flows	$ 3,622	$ 17,408

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	September 30, 2023	December 31, 2022
Legal settlement (See note 18)	$ 6,028	$ 6,207
Employee compensation and benefits	2,948	2,850
Professional fees	1,253	1,353
Product revenue allowances and reserves	134	82
Other	676	372
Total	$ 11,039	$ 10,864

12. Line of Credit

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

Advances under the Loan Agreement bear interest at the 30-Day Adjusted Term Secured Overnight Financing Rate ("SOFR Rate"), set monthly on the first day of the month based on 30-Day Term SOFR plus a spread adjustment of 15 basis points and subject to a floor of 2.25%, plus 4.00% calculated and charged monthly in arrears. In the event of a called event of default, a default interest rate of 3.00% percent shall be added to the aforementioned rate. Under the terms of the Loan Agreement, amounts available for advances would be subject to a borrowing base, which is a formula based on certain eligible receivables and inventory, and a block on such availability in the amount of $650,000. Currently, our borrowing capacity is based on our eligible receivables with an additional $1.0 million borrowing capacity based on inventory. The borrowing base is up to 85% of accounts receivable, plus the least of (a) $1.0 million for inventory and (b) 85% of accounts receivable, less borrowing base reserve, if any, as defined in the Loan Agreement. The Loan Agreement also includes an Unused Line Fee Rate of 0.375% of the Credit Limit less all outstanding advances, which shall be paid on a monthly basis.

The interest rate as of September 30, 2023 was 5.48% and interest expense for the nine months ended September 30, 2023 was negligible. The Company recorded approximately $0.2 million of costs related to the line of credit as an asset to be amortized on a straight-line basis over the term of the line of credit. The Company recognized minimal amortization expense in connection with this Line of Credit for the nine months ended September 30, 2023, which is recorded as interest expense on the accompanying consolidated statement of operations.

13. Related Party Transactions

License and Supply Agreement

On October 8, 2021, we entered into an amendment to the Ameluz LSA under which the price we pay per unit will be based upon our sales history. Under the agreement, the Company obtained an exclusive, non-transferable license to use Pharma's technology to market and sell the licensed products, Ameluz® and BF-RhodoLED® and must purchase the licensed products exclusively from Pharma. As a result of this amendment, the purchase price we pay the Ameluz Licensor for Ameluz® will be determined in the following manner:

- fifty percent of the anticipated net price per unit until we generate $30 million in revenue from sales of the products we license from the Ameluz Licensor during a given Commercial Year (as defined in the Ameluz LSA);

- forty percent of the anticipated net price per unit for all revenues we generate between $30 million and $50 million from sales of the products we license from the Ameluz Licensor; and

- thirty percent of the anticipated net price per unit for all revenues we generate above $50 million from sales of the products we license from the Ameluz Licensor.

Purchases of the licensed products during the three and nine months ended September 30, 2023 were $5.1 million and $18.8 million, respectively, and $5.2 million and $16.6 million, respectively for the three and nine months ended September 30, 2022. Amounts due and payable to Pharma as of September 30, 2023 and December 31, 2022 were $7.0 million and $1.3 million, respectively, which were recorded in accounts payable, related parties in the consolidated balance sheets.

Service Agreements

In December 2021, we entered into an Amended and Restated Master Contract Services Agreement, or "Services Agreement", which provides for the execution of statements of work that will replace the applicable provisions of our previous intercompany services agreement dated January 1, 2016, or 2016 Services Agreement, by and among us, Biofrontera AG, Biofrontera Pharma and Biofrontera Bioscience, enabling us to continue to use the IT resources of Biofrontera AG and its wholly owned subsidiaries (the "Biofrontera Group") as well as providing access to the Biofrontera Group's resources with respect to quality management, regulatory affairs and medical affairs. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, and pharmacovigilance, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine 1) if they will be needed, and 2) whether they can or should be obtained from other third-party providers. As of September 30, 2023, we have migrated away from Biofrontera AG to third party providers for most of our significant IT services. Expenses related to the service agreement were $0.1 million and $0.2 million for the three and nine months ended September 30, 2023 and $0.2 million and $0.6 million for the three and nine months ended September 30, 2022, respectively. These expenses were recorded in selling, general and administrative, related party. Amounts due to Biofrontera AG related to the service agreement as of September 30, 2023 and December 31, 2022 were $0.2 million and $0.2 million, respectively, which were offset against other receivables, related party in the consolidated balance sheet.

Clinical Lamp Lease Agreement

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

Total revenue related to the clinical lamp lease agreement was minimal and $0.1 million for the three and nine months ended September 30, 2023, respectively and minimal for the three and nine months ended September 30, 2022, and was recorded as revenues, related party. Amounts due from Bioscience for clinical lamp and other reimbursements were approximately $0.1 million as of September 30, 2023 and December 31, 2022, which were recorded as other receivables, related party in the consolidated balance sheets.

Others

The Company has recorded a receivable of $2.8 million and $6.4 million as of September 30, 2023 and December 31, 2022, respectively, due from Biofrontera AG for its 50% share of the balance of a legal settlement for which both parties are jointly and severally liable. (See *Note 8. Other Receivables, Related Party*). There was no interest income recognized for the nine months ended September 30, 2023 and $0.1 million of interest income for the nine months ended September 30, 2022, in connection with this receivable.

As of September 30, 2023, our investment, related party is valued at $3.3 million and consists of 5,745,678 common shares of Biofrontera AG, a significant shareholder of the Company. *See Note 6. Investment, Related Party.*

14. Stockholders' Equity

Under the Company's Certificate of Amendment to the Amended and Restated Certificate of incorporation, effective July 3, 2023, the Company is authorized to issue 15,000,000 shares of Common Stock and 20,000,000 shares of preferred stock, par value $.001 per share. See *Note 1. Reverse Stock Split* for information and disclosures relating to adjustments for the 1-for-20 Reverse Stock Split.

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

15. Equity Incentive Plans and Share-Based Payments

2021 Omnibus Incentive Plan

In 2021, our Board of Directors adopted and our shareholders approved, the 2021 Omnibus Incentive Plan ("2021 Plan). Under the original 2021 Plan, 137,500 shares are reserved and authorized for awards and the maximum contractual term is 10 years for stock options issued under the 2021 Plan. On December 12, 2022, the 2021 Plan was amended by our stockholders and the number of shares authorized for awards under the 2021 Plan was increased by 129,490 to 266,990. As of September 30, 2023, there were 163,362 shares available for future awards under the amended 2021 Plan.

Non-qualified stock options

We maintain the 2021 Plan for the benefit of our officers, directors and employees. Employee stock options granted under the 2021 Plan generally vest in equal annual installments over three years and are exercisable for a period of up to ten years from the grant date. Non-employee director options vest in equal monthly installments following the date of grant and will be fully vested on the one-year anniversary of the date of grant. All stock options are exercisable at a price as set by the Company at the time of the grant but shall not be less than the market value of the common shares underlying the option on the grant date.

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

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

	Nine Months Ended September 30,	
	2023	**2022**
Expected volatility	70% - 95%	55% - 70%
Expected term (in years)	6.0	5.24 -6.0
Risk-free interest rate	3.5% - 3.9%	1.34% - 4.10%
Expected dividend yield	0.0%	0.0%

Share-based compensation expense of approximately $0.1 million and $0.5 million was recorded in selling, general and administrative expenses on the accompanying consolidated statement of operations for the three and nine months ended September 30, 2023, respectively and $0.3 million and $0.6 million for the three and nine months ended September 30, 2022.

Options outstanding and exercisable under the employee share option plan as of September 30, 2023 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, 2022	86,951	$ 62.16		
Granted	22,477	$ 13.98		
Exercised	-	$ -		
Canceled or forfeited	(31,480)	$ 53.58		
Outstanding at September 30, 2023	77,948	$ 51.74	8.45	$ 0
Exercisable at September 30, 2023	24,210	$ 62.23	7.75	$ 0

(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, 2023.

As of September 30, 2023, there was $1.0 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 1.8 years.

Share-Based Compensation (RSUs)

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

Share-based compensation expense of $0.1 million and $0.3 million for the RSUs for the three and nine months ended September 30, 2023, respectively, and $0.1 million and $0.9 million for the three and nine months ended September 30, 2022 and was recorded in selling, general and administrative expenses in the accompanying consolidated statements of operations.

	Shares	Weighted Average Remaining Contractual Term	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	17,176		$ 52.20
Awarded	-		$ -
Vested	(8,588)		$ 52.20
Canceled or forfeited	(3,817)	0.63	$ -
Outstanding at September 30, 2023	4,771	0.63	$ 52.20

As of September 30, 2023, there was $0.2 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 0.6 years.

16. Interest Expense, net

Interest expense, net consists of the following:

	For three months ended September 30,		For nine months ended September 30,	
(in thousands)	2023	2022	2023	2022
Interest expense	$ (43)	$ (3)	$ (77)	$ (10)
Interest expense, related party	$ (22)	$ -	$ (22)	$ -
Contract asset interest expense	(90)	(89)	(268)	(268)
Interest income – related party	-	1	-	110
Interest income – other	13	2	111	8
Interest expense, net	$ (142)	$ (89)	$ (256)	$ (160)

Interest expense is comprised primarily of interest on our Loan and Security Agreement with MidCap Business Credit LLC.

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

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

17. Net Earnings (Loss) per Share

Basic net earnings (loss) per common share are calculated by dividing net income by the weighted average number of common shares outstanding during the period. Diluted net earnings per common share are calculated by dividing net income (loss) by the diluted weighted average number of common shares outstanding during the period. The diluted shares include the dilutive effect of stock-based awards based on the treasury stock method. In periods where a net loss is recorded, no effect is given to potentially dilutive securities, since the effect would be anti-dilutive.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Net income (loss)	$ (6,342)	$ (2,566)	$ (23,657)	$ 2,145
Shares:				
Basic weighted average common shares outstanding	1,366,842	1,136,291	1,346,264	978,018
Add: Effect of dilutive securities				

Stock options and restricted stock units	-	-	-	2,233
Diluted weighted average common shares outstanding	1,366,842	1,136,291	1,346,264	980,251
Net earnings (loss) per share:				
Basic	$ (4.64)	$ (2.26)	$ (17.57)	$ 2.19
Diluted	$ (4.64)	$ (2.26)	$ (17.57)	$ 2.19

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:

Nine Months Ended September 30,	2023	2022
Common stock warrants	459,856	459,856
Common stock options and RSUs	82,719	55,620
Unit Purchase Options	20,182	20,182

Common Stock warrants include Purchase Warrants, Inducement Warrants and warrants issued in the Initial Public Offering.

18. Commitments and Contingencies

Leases

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

The Company has also entered into a master lease agreement for its vehicles. After an initial non-cancelable twelve-month period, each vehicle is leased on a month-to-month basis. Based on historical retention experience of approximately three years, the vehicles have varying expiration dates through January 2027.

The components of lease expense for the three and nine months ended September 30, 2023 were as follows (in thousands except lease term and discount rate):

Lease expense	Operating Leases
Amortization of ROU assets (operating lease cost)	$ 390
Interest on lease liabilities	54
Total lease expense	$ 444

Other Information	
Operational cash flow used for operating leases	$ 428
Weighted -average remaining lease term (in years)	2.01
Weighted -average discount rate	6.75%

Future lease payments under non-cancelable leases as of September 30, 2023 were as follows (in thousands):

Years ending December 31,	Future lease commitments
2023	$ 171
2024	584
2025	393
2026	44
2027	1
Total future minimum lease payments	1,193
Less imputed interest	(76)
Total lease liability	$ 1,117

Reported as:	
Operating lease liability, current	$ 555
Operating lease liability, non-current	562
Total	$ 1,117

Cutanea payments

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

We have filed for arbitration against Maruho with the International Chamber of Commerce regarding issues with Maruho's contract manufacturer that were not disclosed at the time of the Share Purchase Agreement and therefore are withholding the repayment of the start-up cost financing until a decision is reached through the arbitration process. The arbitration notes that Maruho breached the agreement with Cutanea due to undisclosed manufacturing issues and seeks damages as well as a declaration that we are not obligated to repay Maruho. As such, the required contractual payments noted above have not been made as of the financial statement filing date.

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

Milestone payments with Ferrer Internacional S.A.

Under the Xepi LSA, we are obligated to make payments to Ferrer upon the occurrence of certain milestones. Specifically, we must pay Ferrer i) $2,000,000 upon the first occasion when annual net sales of Xepi® under the Xepi LSA exceed $25,000,000, and ii) $4,000,000 upon the first occasion annual net sales of Xepi® under the Xepi LSA exceed $50,000,000. No Xepi® milestones have been achieved as of the financial statement filing date.

Licensing Agreement with Optical Tools

On December 2, 2022, the Company entered into the technology transfer agreement with Optical Tools LLC ("Optical Tools"), and 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 shall 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 during the three or nine months ended September 30, 2023.

Legal proceedings

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

Settlement Agreement with DUSA Pharmaceuticals Inc.

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

While Biofrontera AG has agreed to pay fifty percent of the settlement costs, we remain jointly and severally liable to DUSA Pharmaceuticals Inc. ("DUSA") for the full cash settlement amount, meaning that in the event Biofrontera AG does not pay all or a portion of the amount it owes under the settlement agreement, DUSA could compel us to pay Biofrontera AG's share. As of September 30, 2023, we have reflected a legal settlement liability in the amount of $6.0 million for the remaining payments due under the settlement, including the estimated remaining cost of the forensic expert and a related receivable from related party of $2.8 million for the remaining legal settlement costs to be reimbursed in accordance with the Settlement Allocation Agreement, which provided that the settlement payments, including the cost of the forensic expert, would first be made by the Company and then reimbursed by Biofrontera AG for its share. Pursuant to the Settlement Agreement, if DUSA believes Biofrontera has violated any terms of the settlement and release agreement, the parties must engage in certain alternative dispute resolution activities, including a meeting between company representatives and non-binding mediation before a court action can be initiated.

Settlement Agreement with Biofrontera AG

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

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

In addition, the Settlement Agreement contains provisions to maintain Biofrontera AG's representation on the Board of Directors as long as it holds at least 20% of the Company's outstanding common stock and to limit further increases in the size of the Board of Directors or changes to the Company's stockholder rights plan. Under the Settlement Agreement, Biofrontera AG also agrees, subject to certain conditions, to vote in support of the directors nominated by, and the proposals recommended by, the Board of Directors.

Legal Claim

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

The Company denies the Plaintiffs' claims and intends to defend these matters vigorously. Based on the Company's assessment of the facts underlying the above claims, the uncertainty of litigation and the preliminary stage of the case, the Company cannot estimate the

possibility of a material loss, nor the potential range of loss that may result from this action. If the final resolution of the matter is adverse to the Company, it could have a material impact on the Company's financial position, results of operations, or cash flows.

19. Retirement Plan

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

Matching contribution costs paid by the Company for the three and nine months ended September 30, 2023 were $0.1 million and $0.2 million, respectively and $0.1 million and $0.2 million for the three and nine months ended September 30, 2022, respectively.

20. Reclassification of Prior Year Presentation

Certain prior year amounts have been reclassified to their own line items within the Consolidated Statement of Operations and Consolidated Statements of Cash Flow. Specifically, warrant inducement expense of $2.6 million was reclassed from change in fair value of warrant liabilities for prior year presentation. These reclassifications had no effect on the reported results of operations.

21. Subsequent Events

We have completed an evaluation of subsequent events after the balance sheet date of September 30, 2023 through the date this Quarterly Report on Form 10-Q was submitted to the SEC.

Capital Raise

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

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

Warrant Amendment

As previously reported in a Current Report on Form 8-K filed with the SEC on May 20, 2022, the Company issued (i) a common stock purchase warrant, dated May 16, 2022 and exercisable until November 18, 2027, to purchase up to 170,950 shares of Common Stock, at an exercise price of $55.40 and (ii) a common stock purchase warrant, dated July 26, 2022 and exercisable until December 1, 2026, to purchase up to 214,286 shares of Common Stock at an exercise price of $33.20 (collectively, the "Existing Warrants") to an institutional investor.

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

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

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, including statements which may be preceded by the words "intends," "may," "will," "plans," "expects," "anticipates," "projects," "predicts," "estimates," "aims," "believes," "hopes," "potential" or similar words. Forward-looking statements are not guaranties of future performance, are based on certain assumptions and are subject to various known and unknown risks and uncertainties, many of which are beyond our control. Actual results may differ materially from the expectations contained in the forward-looking statements.

Factors that may cause such differences include, but are not limited to:

- our reliance on sales of products we license from other companies as our sole source of revenue;
- the success of our competitors in developing generic topical dermatological products that successfully compete with our licensed products;
- the success of our principal licensed product Ameluz®;
- the ability of Biofrontera Pharma, Biofrontera Bioscience and Ferrer Internacional S.A. ("Ferrer"), referred to collectively as our ("licensors") to establish and maintain relationships with contract manufacturers that are able to supply us with enough of the licensed products to meet our demand;
- the ability of our licensors or our licensors' manufacturing partners, as applicable, to supply Ameluz®, BF-RhodoLED® lamps, Xepi® or other licensed products that we market in sufficient quantities and at acceptable quality and cost levels, and to fully comply with current good manufacturing practice or other applicable manufacturing regulations;
- the ability of our licensors to successfully defend or enforce patents related to our licensed products;

- the availability of insurance coverage and medical expense reimbursement for our licensed products;
- the impact of legislative and regulatory changes;
- competition from other pharmaceutical and medical device companies and existing treatments, such as simple curettage and cryotherapy;
- our success in achieving profitability;
- our ability to obtain additional financing as needed to implement our growth strategy;
- the effect of the COVID-19 global pandemic, including mitigation efforts and economic effects;
- our ability to retain and recruit key personnel;
- such other risks identified in *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, 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 Annual Report on Form 10-K for the fiscal year ended December 31, 2022. 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.

Note About Reverse Stock Split

All information included in these consolidated financial statements has been adjusted, on a retrospective basis, to reflect our 1-for-20 Reverse Stock Split as if it had been effective from the beginning of the earliest period presented, unless otherwise stated.

Overview

Biofrontera Inc (the "Company" or "Biofrontera"). is a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with a focus on photodynamic therapy ("PDT") and topical antibiotics. The Company's licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions as well as impetigo, a bacterial skin infection. In May 2023, the Company began research and development ("R&D") activities to support PDT growth and will continue to opportunistically invest in these activities going forward. Our research and development program currently aims to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists and improve the effectiveness of our commercial team by letting sales representatives carry approved devices with them allowing for easier product demonstrations and evaluations.

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

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with the RhodoLED® lamp series, for PDT. In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses ("AK") of mild-to-moderate severity on the face and scalp. We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement ("Ameluz LSA") between Biofrontera and the Ameluz Licensors.

Our second prescription drug licensed product is Xepi® (ozenoxacin cream, 1%), a topical non-fluorinated quinolone that inhibits bacterial growth. Currently, no antibiotic resistance against Xepi® is known and it has been specifically approved by the FDA for the treatment of impetigo, a common skin infection, due to Staphylococcus aureus or Streptococcus pyogenes. It is approved for use in the United States in adults and children 2 months and older. We are currently selling Xepi® for this indication in the United States. under an exclusive license and supply agreement, as amended ("Xepi LSA") with Ferrer Internacional S.A. ("Ferrer") that was assumed by Biofrontera on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc.("Cutanea"). There has been limited revenue during the current reporting periods and recent developments with the third-party manufacturer that was providing our supply of Xepi® have resulted in further delays of our commercialization of the product. However, Ferrer is qualifying a new Contract manufacturer, Cambrex, which is expected to begin production early 2024.

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

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

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

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

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

We believe that important measures of our results of operations include product revenue, operating income (loss) and adjusted EBITDA (a non-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.

Key factors affecting our performance

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

Seasonality

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

Supply Chain

While our Licensors take reasonable precautions to ensure the successful production of our commercially licensed products, their contract manufacturers may experience a myriad of business difficulties (i.e., workforce instability, supply chain issues, erosion of customer base, etc.) that could impact their financial solvency. In December 2021, we were notified by Ferrer of third-party manufacturing delays for the Xepi® product. Although we have inventory of Xepi® on hand, we expect a delay in further shipments of Xepi® for the next 6 to 12 months. Despite these delays, our total revenues will not be significantly impacted since the majority of our revenues are from sales of Ameluz®. We continue to monitor the impacts of the supply chain on our business and are focused on ensuring the stability of the supply chains for Ameluz® and BF-RhodoLED®.

Components of Our Results of Operations

Product Revenue, net

We generate product revenues through the third-party sales of our licensed products Ameluz®, BF-RhodoLED® lamps and Xepi®. Revenues from product sales are recorded net of discounts, rebates and other incentives, including trade discounts and allowances, product returns, government rebates, and other incentives such as patient co-pay assistance. Revenue from the sales of our BF-RhodoLED® lamp and Xepi® are relatively insignificant compared with revenues generated through our sales of Ameluz®.

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

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

Related Party Revenues

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

Cost of Revenues, Related Party

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

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

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

Cost of Revenues, Other

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

Selling, General and Administrative Expense

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

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party, primarily relate to the services provided by our significant stockholder, Biofrontera AG, for IT support, and pharmacovigilance. In December 2021, we entered into an Amended and Restated Master Contract Services Agreement, or "Services Agreement", which provides for the execution of statements of work that supersede the applicable provisions of the 2016 Services Agreement. The Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us, including IT and pharmacovigilance support for as long as we deem necessary. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, pharmacovigilance, and Investor Relations services, and are continuously assessing the other services historically provided to us by Biofrontera AG to determine 1) if they will be needed, and 2) whether they can or should be obtained from other third-party providers. As of September 30, 2023, we have migrated most of our significant IT services from Biofrontera AG to third party providers.

Research and Development

Our current research and development programs aim to improve the capabilities of our BF-RhodoLED® lamps to better fulfill the needs of dermatologists and improve the effectiveness of our commercial team.

Change in Fair Value of Contingent Consideration

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

Change in Fair Value of Warrant Liabilities

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

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

Warrant Inducement Expense

The warrant inducement expense represents the accounting fair value of consideration issued to induce conversion of the 2021 Purchase Warrant. On July 26, 2022, the Company entered into the Inducement Letter, in which the Company agreed to lower the exercise price of the 2021 Purchase Warrant and issue a new warrant (the "Inducement Warrant") in exchange for $4.6 million in proceeds.

Change in Fair Value of Investment, Related Party

Our investment is 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 along with gains and losses on securities we sold during the period. For the investments held in foreign currencies, the change in fair value attributable to changes in foreign exchange rates is also included in gains and losses in the consolidated statement of operations.

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

Interest Expense, net

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

Other Income (Expense), net

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

Income Taxes

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

Results of Operations

Comparison of the Three Months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the three months ended September 30, 2023 and 2022:

(*in thousands)*	2023	2022	Change
Product revenues, net	$ 8,879	$ 4,290	$ 4,589
Related party revenues	17	32	(15)
Revenues, net	**8,896**	**$ 4,322**	**4,574**
Operating expenses:			
Cost of revenues, related party	4,495	2,127	2,368
Cost of revenues, other	95	98	(3)
Selling, general and administrative	8,619	7,765	854
Selling, general and administrative, related party	74	171	(97)
Research and development	33	-	33
Change in fair value of contingent consideration	200	(2,200)	2,400
Total operating expenses	13,516	7,961	5,555
Loss from operations	**(4,620)**	**(3,639)**	**(981)**
Change in fair value of warrant liabilities	598	3,814	(3,216)
Warrant inducement expense	-	(2,629)	2,629
Change in fair value of investment, related party	(2,212)	-	(2,212)
Interest expense, net	(142)	(89)	(53)
Other income (expense), net	35	(22)	57
Loss before income taxes	**(6,341)**	**(2,565)**	**(3,776)**
Income tax expenses	1	1	-
Net loss	**$ (6,342)**	**$ (2,566)**	**$ (3,776)**

Product Revenue, net

Net product revenue for the three months ended September 30, 2023 increased by $4.6 million, or 107.0% as compared to the three months ended September 30, 2022. This increase was driven by a higher volume of Ameluz revenue in Q3 2023, caused in part by an expansion of our sales force in 2023, higher adoption of Ameluz by dermatologists, as well as the buy-in impact due to a price increase. Our price for Ameluz increased by 5% on October 1, 2023, causing some dermatologists to accelerate their purchases of Ameluz in Q3 2023. We increased our price on April 1, 2022, and thus revenues in Q3 2022 were not impacted by the effects of the previous increase.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party for the three months ended September 30, 2023 increased by $2.4 million, or 111.3% as compared to the three months ended September 30, 2022. This was driven by the increase in Ameluz product revenue. Cost of revenues, related party, is directly correlated to the selling price of Ameluz under the Ameluz LSA.

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the three months ended September 30, 2023 increased by $0.9 million, or 11.0% as compared to the three months ended September 30, 2022. The increase was primarily driven by $0.8 million of personnel costs, due to higher sales and medical headcount. This increase reflects a realignment of our workforce strategy to reduce selling, general and administrative costs and deploy some of these costs to revenue generating functions. The increase was further driven by $0.4 million of legal expenses and $0.1 million of increase sales and marketing expense. These expenses were offset by a decrease of $0.3 million in non-recurring issuance costs, related to our liability classified warrants incurred in Q3 2022.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was an increase of $0.2 million for the three months ended September 30, 2023 compared to a decrease of $2.2 million for the three months ended September 30, 2022. The change in fair value of contingent consideration is driven by the estimated profit share the Company is required to pay under the Share Purchase Agreement. The estimated profit share was reduced in Q3 2022 after receiving notification of third-party manufacturing delays that impacted the timing of sales expansion and improved market positioning of the Xepi® product.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was $0.6 million for three months ended September 30, 2023 compared to $3.8 million for the three months ended September 30, 2022. The change in fair value of warrant liabilities was driven primarily by changes in the underlying value of the Common Stock.

Warrant Inducement Expense

The warrant inducement expense was $2.6 million for the three months ended September 30, 2022. The change was driven by changes in the underlying value of the Common Stock, related to the modification and exercise of the 2021 Purchase Warrant in Q3 2022.

Change in fair value of investment, related party

The change in fair value of investment, related party was a decrease of $2.2 million, driven by changes in the quoted market price of the common stock of Biofrontera AG and losses on such securities we sold during the period.

Comparison of the nine months ended September 30, 2023 and 2022

The following table summarizes our results of operations for the nine months ended September 30, 2023 and 2022:

(*in thousands)*	**2023**	**2022**	**Change**
Product revenues, net	$ 23,423	$ 18,467	$ 4,956
Related party revenues	52	63	11
Revenues, net	**23,475**	**$ 18,530**	**4,945**
Operating expenses:			
Cost of revenues, related party	11,814	9,504	2,310
Cost of revenues, other	262	425	(163)
Selling, general and administrative	29,874	25,050	4,824
Selling, general and administrative, related party	193	612	(419)
Research and Development	44	-	44

Change in fair value of contingent consideration	100	(4,100)	4,200
Total operating expenses	42,287	31,491	10,796
Loss from operations	**(18,812)**	**(12,961)**	**(5,851)**
Change in fair value of warrant liabilities	2,001	17,896	(15,895)
Warrant inducement expense	-	(2,629)	2,629
Change in fair value of investment, related party	(6,635)	-	(6,635)
Interest expense, net	(256)	(160)	(96)
Other income, net	65	30	35
Income (loss) before income taxes	**(23,637)**	**2,176**	**(25,813)**
Income tax expenses	20	31	(11)
Net Income (loss)	**$ (23,657)**	**$ 2,145**	**$ (25,802)**

Product Revenue, net

Net product revenue for the nine months ended September 30, 2023 increased by $4.9 million, or 26.8% as compared to the nine months ended September 30, 2022. The increase was primarily driven by a higher volume of Ameluz sales in Q3 2023 due to the expansion of the sales team and higher adoption of Ameluz by dermatologists of $4.8 million and the impact of a higher average Ameluz selling price in 2023 of $0.1 million.

Cost of Revenues, Related Party

Cost of revenues, related party for the nine months ended September 30, 2023 increased by $2.3 million, or 24.3% as compared to the nine months ended September 30, 2022. This was driven by the increase in Ameluz product revenue. Cost of revenues, related party, is directly correlated to the selling price of Ameluz under the Ameluz LSA.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses for the nine months ended September 30, 2023 increased by $4.8 million, or 19.3% as compared to the nine months ended September 30, 2022. The increase was primarily driven by personnel-related expenses of $2.9 million, reflecting a realignment of our workforce strategy to reduce selling, general and administrative costs and deploy some of these costs to revenue generating functions. The increase is further driven by sales related travel and medical education expenses of $0.7 million, external legal expenses related to a legal settlement of $1.2 million and other non-recurring legal costs of $1.2 million; partially offset by issuance costs related to liability classified warrants of $1.0 million incurred in 2022 and a decrease of $0.6 million in business insurance.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses for the nine months ended September 30, 2023 decreased by $0.4 million, or 68.5% as compared to the nine months ended September 30, 2022. Related party expenses are based on statements of work issued under the Services Agreement with the Biofrontera Group. We currently have statements of work in place regarding IT, regulatory affairs, medical affairs, pharmacovigilance, and investor relations services. The decrease is driven by the Company utilizing fewer IT services from the Biofrontera Group in the current year when compared to the prior year.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was an increase of $0.1 million for the nine months ended September 30, 2023, compared to a decrease of $4.1 million for the nine months ended September 30, 2022. The change in fair value of contingent consideration is driven by the estimated profit share the Company is required to pay under the Share Purchase Agreement. The estimated profit share was reduced in Q3 2022 after receiving notification of third-party manufacturing delays that impacted the timing of sales expansion and improved market positioning of the Xepi® product.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a decrease of $2.0 million for the nine months ended September 31, 2023 and a decrease of $17.9 million for the nine months ended September 30, 2022. The change in fair value of warrant liabilities was driven primarily by a decrease in the underlying value of our Common Stock.

Warrant Inducement Expense

The warrant inducement expense was $2.6 million for the nine months ended September 30, 2022. The change was driven by changes in the underlying value of the Common Stock, related to the modification and exercise of the 2021 Purchase Warrant in July 2022.

Change in fair value of investment, related party

The change in fair value of investment, related party was a decrease of $6.6 million, driven by changes in the quoted market price of the common stock of Biofrontera AG and losses on such securities we sold during the period.

Net Income (Loss) to Adjusted EBITDA Reconciliation for the Three and Nine Months Ended September 30, 2023 and 2022

We define adjusted EBITDA as net income or loss before interest income and expense, income taxes, depreciation and amortization, and other non-operating items from our consolidated 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. generally accepted accounting principles ("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.

Change in fair value of contingent consideration: Pursuant to the Share Purchase Agreement, the profits from the sale of Cutanea products will be shared equally between Maruho and Biofrontera until 2030. The fair value of the contingent consideration was

determined to be $6.5 million on the acquisition date and is re-measured at each reporting date, with changes in fair value presented within the consolidated statements of operations. We exclude the impact of the change in fair value of contingent consideration as this is not currently payable and is a non-cash adjustment.

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

Warrant inducement expense: The warrant inducement expense was determined using the Black-Scholes option pricing model and was calculated as the difference between the fair value of the 2021 Purchase Warrant prior to, and immediately after, the reduction in the exercise price on the date of repricing in addition to the fair value of the Inducement Warrant issued and is presented within the statement of operations. We exclude the impact of the change in fair value of the warrant modification as this is non-cash.

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

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

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

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 income (loss) to Adjusted EBITDA for the three and nine months ended September 30, 2023 and 2022:

	Three months ended September 30,		Nine months ended September 30,	
	2023	2022	2023	2022
Net income (loss)	**$ (6,342)**	**$ (2,566)**	**$ (23,657)**	**$ 2,145**
Interest expense, net	142	89	256	160
Income tax expense	1	1	20	31
Depreciation and amortization	251	130	769	394
EBITDA	**(5,948)**	**(2,346)**	**(22,612)**	**2,730**
Change in fair value of contingent consideration	200	(2,200)	100	(4,100)
Change in fair value of warrant liabilities	(598)	(3,814)	(2,001)	(17,896)
Warrant inducement expense	-	2,629	-	2,629
Change in fair value of investment, related party	2,212	-	6,635	-
Legal settlement expenses	-	-	1,225	-
Stock compensation expense	207	401	817	1,469
Expensed issuance costs	-	320	-	1,045
Adjusted EBITDA	**$ (3,927)**	**$ (5,010)**	**$ (15,836)**	**$ (14,123)**
Adjusted EBITDA margin	***-44.1%***	***-115.9%***	***-67.5%***	***-76.2%***

Adjusted EBITDA

Adjusted EBITDA increased from ($5.0) million during the three months ended September 30, 2022 to ($3.9) million for the three months ended September 30, 2023. The increase in Adjusted EBITDA is primarily driven by higher revenues of $4.6 million, net of increased cost of revenues of $2.4 million; partially offset by an increase in our selling, general, and administrative costs of $1.2 million.

Adjusted EBITDA decreased from ($14.1) million during the nine months ended September 30, 2022 to ($15.8) million for the nine months ended September 30, 2023. The decrease in Adjusted EBITDA is primarily driven by an increase in selling, general and administrative costs of $4.5 million, due primarily to increased personnel costs related to increased headcount to expand key customer facing roles and severance agreements relating to the realignment of our workforce strategy. This is partially offset by an increase in our revenues of $4.9 million, net of increased cost of revenues of $2.1 million. We expect our revenues to continue to increase throughout the remainder of the year as our commercial team increases productivity after an expansion earlier in the year.

Liquidity and Capital Resources

The Company's primary sources of liquidity are its existing cash balances, cash collected from the sales of its products, proceeds from the sale of our investment, related party, and cash flows from a revolving line of credit. As of September 30, 2023, we had cash and cash equivalents of $3.4 million and investment, related party of $3.3 million, compared to $17.2 million and $10.5 million as of December 31, 2022, respectively.

Since we commenced operations in 2015, we have generated significant losses. For the nine months ended September 30, 2023 and 2022, we incurred loss from operations of $18.8 million and $13.0 million, respectively. We incurred net cash outflows from operations of $16.0 million and $7.9 million, for the same periods, respectively. We had an accumulated deficit as of September 30, 2023 of $103.2 million. Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing,

medical affairs, and dermatology community outreach efforts as we seek to expand the commercialization of our licensed products in the United States.

In connection with our assessment of going concern considerations under applicable accounting standards, the Company's management has determined that substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed consolidated financial statements were issued.

The future viability of the Company is dependent on its ability to continue to execute its growth plan and raise additional capital or find alternative methods of financing to fund its operations during the first half of 2024, and until cash flow from operations is sufficient, if ever. We have implemented plans to improve our working capital position, particularly around inventory levels. We have not placed any orders nor plan to place any orders for 2024 deliveries in 2023. We expect to need a delivery sometime in Q3 2024, depending on sales between now and then, and will place the appropriate orders in early 2024. Management believes that the anticipated implementation of such plans, together with the recent net capital raise of $4.1 million will provide the opportunity for the Company to continue as a going concern. However, no assurance can be given that the Company will be successful in these efforts.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of the uncertainties described above. There could be a material adverse effect on the Company and its financial statements if management's plans are not achieved on a timely basis.

Our future use of operating cash and capital requirements will depend on many forward-looking factors, including the following:

- the costs of our commercialization activities for Ameluz®;
- the extent to which we acquire or invest in licensed products, businesses and technologies;
- the extent to which we choose to establish collaboration, co-promotion, distribution or other similar agreements for our licensed products;
- the cost to fulfill our contractual obligations for various operating leases on vehicles and office space;
- the ability to liquidate our investment in equity securities on a timely basis; and
- the requirement to pay back $7.3 million of start-up cost financing to Maruho and make any contingent profit- sharing payments to Maruho in connection with the Cutanea acquisition.

We will continue to assess our operating costs and expenses and our cash and cash equivalents and, if circumstances warrant, we will make appropriate adjustments to our operating plan.

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)	**2023**	**2022**
Net cash used in operating activities	$ (16,029)	$ (7,928)
Net cash provided by (used) in investing activities	546	(3,070)
Net cash provided by financing activities	1,697	14,021
Net increase (decrease) in cash and restricted cash	**$ (13,786)**	**$ 3,023**

Operating Activities

During the nine months ended September 30, 2023, operating activities used $16.0 million of cash, primarily resulting from our loss from operations of $23.7 million, adjusted for non-cash expense of stock-based compensation of $0.8 million, non-cash interest expense of $0.3 million, depreciation and amortization in the aggregate of $0.8 million, net cash used by changes in our operating assets and liabilities of $0.9 million, the change in fair value of contingent consideration of $0.1 million and the change in fair value of investment, related party of $6.6 million; partially offset by the change in fair value of warrant liabilities of $2.0 million.

During the nine months ended September 30, 2022, operating activities used $7.9 million of cash, primarily resulting from our net income of $1.1 million, decreased by the non-cash change in fair value of warrant liabilities of $15.3 million and the change in fair value of contingent consideration of $3.4 million and offset by the non-cash expense of stock-based compensation of $1.5 million, $0.4 million depreciation and amortization, $0.3 million interest expense as well as $7.3 million of working capital changes.

Investing Activities

During the nine months ended September 30, 2023, net cash provided by investing activities of $0.5 million consisted of the proceeds from the sales of equity investments, partially offset by the purchase of machinery & computer equipment.

During the nine months ended September 30, 2022 investing activities used $3.1 million, primarily resulting from the distribution of a short-term loan of $3.1 million, which was repayable at the option of the holder, Quirin PrivatbankAG, in cash or in shares of Biofrontera AG acquired with the funds from the loan.

Financing Activities

During the nine months ended September 30, 2023, net cash from financing activities consisted of a net $1.7 million of proceeds from our line of credit.

During the nine months ended September 30, 2022, net cash from financing activities was $14 million driven entirely by proceeds from the sale of Common Stock and warrants in a private placement, as well as the exercise of warrants.

Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our consolidated financial statements, which have been prepared in accordance with generally accepted accounting principles of the United States, or 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 of contingent consideration, warrant liabilities, 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 *our reaudited consolidated financial statements for the fiscal years ended December 31, 2022 and 2021 ("reaudited Consolidated Financial Statements"), filed in a Current Report on From 8-K with the SEC on October 3, 2023.*

Critical Accounting Estimates

A summary of our critical accounting estimates is included in the Company's revised Management's Discussion and Analysis of Financial Condition and Results of Operations for the fiscal years ended December 31, 2022 and December 31, 2021 ("revised MD&A"), filed in a Current Report on From 8-K with the SEC on October 3, 2023 for the year ended December 31, 2022. There were no material changes to our critical accounting estimates for the nine months ended September 30, 2023.

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 Exchange Act). Based on that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2023, 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, 2023 that materially affected, or is reasonably likely to materially affect, our internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act).

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

For information regarding legal proceedings in which we are involved, (see Note 18 - 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. However, as of the date of this Quarterly Report, other than as set forth below, there have been no material changes with respect to those risk factors previously disclosed under "Risk Factors" included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2022, as filed with the Securities and Exchange Commission on March 13, 2023 (the "Form 10-K"). The following should be carefully considered, together with other information in this Quarterly Report on Form 10-Q, our Form 10-K, and our other filings with the SEC before making investment decisions regarding our Common Stock.

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

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

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

There is substantial doubt about our ability to continue as a "going concern."

In connection with our assessment of going concern considerations under applicable accounting standards, the Company's management has determined that our growth plans, upcoming inventory purchases and a final settlement payment to DUSA Pharmaceuticals, Inc. substantial doubt exists about our ability to continue as a going concern through approximately one year from the date the unaudited condensed financial statements included in Item 1. "Financial Statements" were issued. The future viability of the Company is dependent on its ability to continue to execute its growth plan and raise additional capital or find alternative methods of financing to fund its operations. There can be no guarantee that the actions presently being taken by the Company will be successful in raising additional capital or finding alternative methods of financing. If the Company is not successful in these endeavors, it would likely have a material adverse effect on the Company's business, results of operations and financial condition.

For additional discussion of the risks and uncertainties that affect our business, see "Item 1A. Risk Factors" included in our Form 10-K.

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

None

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.	
4.1	Form of Common Warrant (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
4.2	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.2 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
10.1	Securities Purchase Agreement, dated October 30, 2023, by and between Biofrontera Inc. and an institutional investor (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the SEC on November 2, 2023)
10.2	Placement Agency Agreement, dated October 30, 2023, by and between Biofrontera Inc. and Roth Capital Partner, LLC (incorporated by reference to Exhibit 10.2 to the Company's Form 8-K filed with the SEC on November 2, 2023)
10.3	Amendment to Common Stock Purchase Warrants, dated October 30, 2023, by and between Biofrontera Inc. and institutional investor (incorporated by reference to Exhibit 10.3 to the Company's Form 8-K filed with the SEC on November 2, 2023)
10.4	Amendment No. 1 to Settlement Agreement dated as of October 12, 2023, between Biofrontera Inc., Hermann Luebbert, John J. Borer, Loretta M. Wedge, Beth J. Hoffman, Kevin D. Weber and Biofrontera AG (incorporated by reference to Exhibit 10.1 of the Company's Current Report on Form 8-K filed with the SEC on October 13, 2023)
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 9, 2023

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

Date: November 9, 2023

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

Exhibit 31.1

Certification

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

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

5. The registrant's other certifying officer(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) 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 9, 2023

By: */s/ Hermann Luebbert*

Hermann Luebbert
Chief Executive Officer & Chairman
(Principal Executive Officer)

Exhibit 31.2

Certification

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

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

5. The registrant's other certifying officer(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) 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 9, 2023

By: */s/ E. Fred Leffler III*

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

Exhibit 32.1

Certification*

In connection with the Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.§ 1350), I, Hermann Luebbert, Chief Executive Officer of the Company, do hereby certify, to the best of 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 9, 2023

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*

In connection with the Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended September 30, 2023 as filed with the Securities and Exchange Commission on the date hereof (the "Quarterly Report") pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C.§ 1350), I, Eugene Frederick Leffler, III, Chief Financial Officer of the Company, do hereby certify, to the best of 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 9, 2023

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.