

**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 June 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	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

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 August 9, 2023 there were 1,367,628 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)

	<u>June 30, 2023</u>	<u>December 31, 2022</u>
	<u>(Unaudited)</u>	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 4,453	\$ 17,208
Investment, related party	5,935	10,548
Accounts receivable, net	2,193	3,748
Other receivables, related party	4,001	3,658
Inventories, net	14,785	7,168
Prepaid expenses and other current assets	929	810
Total current assets	32,296	43,140
Other receivables long term, related party	-	2,813
Property and equipment, net	175	204
Operating lease right-of-use assets	1,107	1,375
Intangible asset, net	2,823	3,032
Other assets	504	320
Total assets	\$ 36,905	\$ 50,884
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	1,243	1,278
Accounts payable, related parties	4,657	1,312
Acquisition contract liabilities, net	7,121	6,942
Operating lease liabilities	489	498
Accrued expenses and other current liabilities	10,736	10,864
Line of credit	1,106	-
Total current liabilities	25,352	20,894
Long-term liabilities:		
Acquisition contract liabilities, net	2,300	2,400
Warrant liabilities	1,440	2,843
Operating lease liabilities, non-current	600	848
Other liabilities	40	21
Total liabilities	29,732	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 June 30, 2023 and December 31, 2022	-	-
Common Stock, \$0.001 par value, 15,000,000 shares authorized; 1,367,628 and 1,359,040 shares issued and outstanding as of June 30, 2023 and December 31, 2022	27	27
Additional paid-in capital	103,980	103,370
Accumulated deficit	(96,834)	(79,519)
Total stockholders' equity	7,173	23,878
Total liabilities and stockholders' equity	\$ 36,905	\$ 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)

	<u>Three months ended June 30,</u>		<u>Six months ended June 30,</u>	
	<u>2023</u>	<u>2022</u>	<u>2023</u>	<u>2022</u>
Product revenues, net	\$ 5,830	\$ 4,441	\$ 14,544	\$ 14,177
Revenues, related party	18	16	36	31
Total revenues, net	5,848	4,457	14,580	14,208
Operating expenses				
Cost of revenues, related party	2,772	2,402	7,319	7,377
Cost of revenues, other	116	152	167	327
Selling, general and administrative	11,456	9,669	21,254	17,285
Selling, general and administrative, related party	92	346	119	441
Research and development	11	-	11	-
Change in fair value of contingent consideration	100	(1,900)	(100)	(1,900)
Total operating expenses	14,547	10,669	28,770	23,530
Loss from operations	(8,699)	(6,212)	(14,190)	(9,322)
Other income (expense)				
Change in fair value of warrants	375	5,371	1,403	14,082
Change in fair value of investment, related party	(1,482)	-	(4,424)	-
Interest expense, net	(79)	(38)	(114)	(71)
Other income, net	62	29	30	52
Total other income (expense)	(1,124)	5,362	(3,105)	14,063
Income (loss) before income taxes	(9,823)	(850)	(17,295)	4,741
Income tax expense	14	-	20	30
Net income (loss)	\$ (9,837)	\$ (850)	\$ (17,315)	\$ 4,711
Income (loss) per common share:				
Basic	\$ (7.23)	\$ (0.90)	\$ (12.73)	\$ 5.24
Diluted	\$ (7.23)	\$ (0.90)	\$ (12.73)	\$ 5.22
Weighted-average common shares outstanding:				
Basic	1,360,739	941,175	1,359,894	898,444
Diluted	1,360,739	941,175	1,359,894	902,209

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 Six Months Ended June 30, 2023

	<u>Common Stock</u>		<u>Additional Paid- In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance, March 31, 2023	1,359,040	\$ 27	\$ 103,721	\$ (86,997)	\$ 16,751
Issuance of shares for vested restricted stock units	8,588	-	-	-	-
Stock based compensation	-	-	259	-	259
Net loss	-	-	-	(9,837)	(9,837)
Balance, June 30, 2023	<u>1,367,628</u>	<u>\$ 27</u>	<u>\$ 103,980</u>	<u>\$ (96,834)</u>	<u>\$ 7,173</u>
Balance, December 31, 2022	1,359,040	\$ 27	\$ 103,370	\$ (79,519)	\$ 23,878
Issuance of shares for vested restricted stock units	8,588	-	-	-	-
Stock based compensation	-	-	610	-	610
Net loss	-	-	-	(17,315)	(17,315)
Balance, June 30, 2023	<u>1,367,628</u>	<u>\$ 27</u>	<u>\$ 103,980</u>	<u>\$ (96,834)</u>	<u>\$ 7,173</u>

Three and Six Months Ended June 30, 2022

	<u>Common Stock</u>		<u>Additional Paid- In Capital</u>	<u>Accumulated Deficit</u>	<u>Total</u>
	<u>Shares</u>	<u>Amount</u>			
Balance March 31, 2022	855,238	\$ 17	\$ 90,717	\$ (73,318)	\$ 17,416
Issuance of common stock and warrants under private placement, net of issuance costs	92,500	2	114	-	116
Issuance of shares for vested restricted stock units	2,835	-	-	-	-
Stock based compensation	-	-	551	-	551
Net loss	-	-	-	(850)	(850)
Balance, June 30, 2022	<u>950,573</u>	<u>\$ 19</u>	<u>\$ 91,382</u>	<u>\$ (74,168)</u>	<u>\$ 17,233</u>
Balance, December 31, 2021	855,238	\$ 17	\$ 90,200	\$ (78,879)	\$ 11,338
Issuance of common stock and warrants under private placement, net of issuance costs	92,500	2	114	-	116
Issuance of shares for vested restricted stock units	2,835	-	-	-	-
Stock based compensation	-	-	1,068	-	1,068
Net income	-	-	-	4,711	4,711
Balance, June 30, 2022	<u>950,573</u>	<u>\$ 19</u>	<u>\$ 91,382</u>	<u>\$ (74,168)</u>	<u>\$ 17,233</u>

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

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

	Six Months Ended June 30,	
	2023	2022
Cash flows from operating activities:		
Net income (loss)	\$ (17,315)	\$ 4,711
Adjustments to reconcile net income (loss) to cash flows used in operations		
Depreciation	44	54
Amortization of right-of-use assets	265	-
Amortization of acquired intangible assets	209	209
Change in fair value of investment, related party	4,424	-
Change in fair value of contingent consideration	(100)	(1,900)
Change in fair value of warrant liabilities	(1,403)	(14,082)
Stock-based compensation	610	1,068
Provision for inventory obsolescence	-	100
Provision for doubtful accounts	64	133
Non-cash interest expense	190	179
Changes in operating assets and liabilities:		
Accounts receivable	1,491	1,650
Other receivables, related party	2,397	5,602
Prepaid expenses and other assets	(302)	3,698
Inventories	(7,617)	(4,449)
Accounts payable and related party payables	3,380	1,280
Operating lease liabilities	(255)	-
Accrued expenses and other liabilities	(107)	(240)
Cash flows used in operating activities	(14,025)	(1,987)
Cash flows from investing activities		
Sales of equity investment, related party	178	-
Purchases of property and equipment	(14)	(36)
Cash flows provided by (used) in investing activities	164	(36)
Cash flows from financing activities		
Proceeds from line of credit	5,700	-
Proceeds from issuance of common stock and warrants in private placement, net of issuance costs	-	9,391
Repayment of line of credit	(4,594)	-
Cash flows provided by financing activities	1,106	9,391
Net increase (decrease) in cash and cash equivalents	(12,755)	7,368
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	\$ 4,653	\$ 32,110
Supplemental disclosure of cash flow information		
Interest paid	\$ -	\$ 4
Income taxes paid, net	\$ -	\$ 30

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 Inc. 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 Licensors.

Our principal licensed product is Ameluz[®], which is a prescription drug approved for use in combination with the RhodoLED[®] lamp series, for PDT (when used together, “Ameluz[®] PDT”). In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp. We are currently selling Ameluz[®] for this indication in the U.S. under an exclusive license and supply agreement (“Ameluz LSA”) with Biofrontera Pharma (“Pharma”) GmbH and Biofrontera Bioscience GmbH (together 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 in 2024. Once the new third-party manufacturer is qualified, we expect the supply of Xepi[®] will meet future needs.

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 June 30, 2023, we had cash and cash equivalents of \$4.5 million and investment, related party of \$5.9 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 six months ended June 30, 2023 and 2022, we incurred loss from operations of \$14.2 million and \$9.3 million, respectively. We incurred net cash outflows from operations of \$14.0 million and \$2.0 million, for the same periods, respectively. We had an accumulated deficit as of June 30, 2023 of \$96.8 million.

The Company’s short-term material cash requirements include working capital needs and satisfaction of contractual commitments (see *Note 18. Commitments and Contingencies*), Maruho start-up cost financing repayments of \$7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG of \$2.4 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. We also expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. In addition, we expect to incur costs to continue to comply with corporate governance, regulatory reporting and other requirements applicable to us as a public company in the U.S.

In connection with our assessment of going concern considerations under applicable accounting standards, the Company’s management has determined that, based on our growth plans, upcoming inventory purchases, and a final settlement payment, substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed 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 until cash flow from operations is sufficient. Management believes that actions presently being taken to obtain additional funding and implement its strategic plans provide the opportunity for the Company to continue as a going concern. No assurance can be given that the Company will be successful in these efforts. Accordingly, management has concluded that substantial doubt exists about the company’s ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

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

2. Summary of Significant Accounting Policies

Basis for Preparation of the 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 June 30, 2023, the Company’s operating results for the three and six months ended June 30, 2023 and 2022, and the Company’s cash flows for the six months ended June 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 Annual Report on Form 10-K for the year ended December 31, 2022, filed with the SEC on March 13, 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.

The Company’s significant accounting policies are discussed in *Note 2—Summary of Significant Accounting Policies* within the notes to financial statements for the year ended December 31, 2022, included in the Company’s Annual Report on Form 10-K. There have been no significant changes to these policies during the three and six months ended June 30, 2023 except for those noted below:

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.

Reverse Stock Split

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

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

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 Co, Ltd. 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 agreed to provide \$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”).

In connection with this acquisition in 2019, we recorded the \$7.3 million in start-up cost financing, a \$1.7 million contract asset related to the benefit associated with the non-interest-bearing start-up cost financing and \$6.5 million of contingent consideration related to the estimated profits from the sale of Cutanea products to be shared equally with Maruho (see *Note 18. Commitment and contingencies – Cutanea payments*).

The contract asset related to the start-up cost financing is amortized on a straight-line basis using a 6.0% interest rate over the 57-month term of the financing arrangement, which ends on December 31, 2023. The contract asset is shown net of the related start-up cost financing within acquisition contract liabilities, net.

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 contingent consideration that could be payable was valued at \$2.3 million with payments coming due May of 2028 through May 2030. The Company re-measures contingent consideration and re-assesses the underlying assumptions and estimates at each reporting period utilizing a scenario-based method.

Acquisition contract liabilities, net consist of the following:

(in thousands)	<u>June 30, 2023</u>	<u>December 31, 2022</u>
<i>Short-term acquisition contract liabilities:</i>		
Start-up cost financing	7,300	7,300
Contract asset	(179)	(358)
Acquisition contract liabilities, net	\$ 7,121	\$ 6,942
<i>Long-term acquisition contract liabilities:</i>		
Contingent consideration	\$ 2,300	\$ 2,400
<i>Total acquisition contract liabilities:</i>		
Contingent consideration	\$ 2,300	\$ 2,400
Start-up cost financing	7,300	7,300
Contract asset	(179)	(358)
Total acquisition contract liabilities, net	\$ 9,421	\$ 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 June 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)	<u>Level</u>	<u>June 30, 2023</u>	<u>December 31, 2022</u>
<i>Assets:</i>			
Investment, related party	1	\$ 5,935	\$ 10,548
<i>Liabilities:</i>			
Contingent Consideration	3	\$ 2,300	\$ 2,400
Warrant liability – 2022 Purchase Warrants	3	\$ 668	\$ 1,129
Warrant liability - 2022 Inducement Warrants	3	\$ 772	\$ 1,714

Investment, related party

As of June 30, 2023 and December 31, 2022, the Company had 6,280,396 and 6,446,946, respectively of common shares of Biofrontera AG, a significant shareholder. The fair value of this investment was determined with Level 1 inputs through references to quoted market prices. See 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. Finally, the discounted payments are summed together to arrive at the value of the contingent consideration. The scenario-based method incorporates the following key assumptions: (i) the forecasted product profit amounts, (ii) the remaining contractual term, (iii) a metric risk premium, and (iv) a payment discount rate. The Company re-measures contingent consideration and re-assesses the underlying assumptions and estimates at each reporting period.

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 June 30, 2023	\$ 2,300
Balance at December 31, 2021	\$ 6,200
Change in fair value of contingent consideration	(1,900)
Balance at June 30, 2022	\$ 4,300

Warrant Liabilities

The warrant liabilities are comprised of (i) a warrant to purchase 170,950 shares of common stock 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”), 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 at June 30, 2023 was estimated using a Black-Scholes pricing model based on the following assumptions:

	Purchase	Inducement
Stock price	\$ 10.40	\$ 10.40
Expiration term (in years)	4.38	3.42
Volatility	90.0%	85.0%
Risk-free Rate	4.20%	4.37%
Dividend yield	0.0%	0.0%

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

	Six Months Ended June 30,	
	2023	2022
Fair value at beginning of period	\$ 2,843	\$ 12,854
Issuance of new derivative liabilities	-	9,274
Change in fair value of warrant liability	(1,403)	(14,082)
Fair value at end of period	\$ 1,440	\$ 8,046

5. Revenue

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

Related party revenue relates to an agreement with Biofrontera Bioscience GmbH (“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	5	380	11	129	525
Credit or payments made during the period	(5)	(300)	(20)	(115)	(440)
Balance at June 30, 2022	\$ 43	\$ 181	\$ 39	\$ 68	\$ 331
Balance at December 31, 2022	\$ 48	\$ 9	\$ 5	\$ 20	\$ 82
Provision related to current period sales	3	62	3	134	202
Credit or payments made during the period	-	(71)	(2)	(59)	(132)
Balance at June 30, 2023	\$ 51	-	6	95	152

6. Investment, Related Party

As of June 30, 2023 and December 31, 2022, our investment in equity securities consisted solely of 6,280,396 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 \$0.2 million during the six months ended June 30, 2023.

Unrealized gains and losses on investment, related party are summarized as follows:

(in thousands)	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net losses recognized during the period on equity securities	\$ (1,482)	\$ -	\$ (4,424)	\$ -
Less: Net losses recognized during the period on equity securities sold	75	-	75	-
Unrealized losses recognized during the reporting period on equity securities still held at the reporting date	\$ (1,407)	\$ -	\$ (4,349)	\$ -

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.

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

8. Other Receivables, Related Party

As of June 30, 2023 the Company has a receivable of \$4.0 million due from related parties of which \$3.7 million is 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 June 30, 2023 or December 31, 2022.

9. Intangible Asset, Net

Intangible asset, net consists of the following:

(in thousands)	June 30, 2023	December 31, 2022
Xepi® license	\$ 4,600	\$ 4,600
Less: Accumulated amortization	(1,777)	(1,568)
Intangible asset, net	\$ 2,823	\$ 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 June 30, 2023 and 2022 was \$0.1 million and \$0.2 million for the six months ended June 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. In June 2023, upon receiving notification of complications with renewing the marketing authorization of the Xepi® product linked to the bankruptcy of the former contract manufacturer, we deemed it necessary to assess the recoverability of our Xepi® asset group. Future cash flows were estimated over the expected remaining useful life of the asset group, and we determined that, on an undiscounted basis, expected cash flows exceeded the carrying amount of the asset group.

The Company did not recognize any impairment charges during the three and six months ended June 30, 2023 and 2022.

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 June 30, 2023, approximately \$4.2 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.

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)	June 30, 2023	December 31, 2022
Cash and cash equivalents	\$ 4,453	\$ 17,208
Long-term restricted cash	200	200
Total cash, cash equivalent, and restricted cash shown on the consolidated statements of cash flows	\$ 4,653	\$ 17,408

11. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	June 30, 2023	December 31, 2022
Legal settlement (See note 18)	\$ 6,094	\$ 6,207
Employee compensation and benefits	2,816	2,850
Professional fees	1,163	1,353
Product revenue allowances and reserves	152	82
Other	511	372
Total	\$ 10,736	\$ 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 limited to our eligible receivables, pending consent from Biofrontera AG to allow Midcap to obtain title to Biofrontera Inc.’s inventory in the event of bankruptcy. The borrowing base is up to 85% of accounts receivable, plus the least of (a) \$3.3 million, (b) 50% of inventory, and (c) 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 June 30, 2023 was 5.31% and interest expense for the six months ended June 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 six months ended June 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. 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.

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. There was no consideration paid for the transfer of the license.

Purchases of the licensed products during the three and six months ended June 30, 2023 were \$10.4 million and \$13.7 million, respectively, and \$6.2 million and \$11.5 million, respectively for the three and six months ended June 30, 2022. The purchases were recorded in inventories in the consolidated balance sheets, and, when sold, in cost of revenues, related party in the consolidated statements of operations. Amounts due and payable to Pharma as of June 30, 2023 and December 31, 2022 were \$4.7 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 June 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 for the three and six months ended June 30, 2023 and \$0.3 million and \$0.4 million for the three and six months ended June 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 June 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 Biofrontera Bioscience GmbH ("Bioscience") to provide lamps and associated services.

Total revenue related to the clinical lamp lease agreement was minimal for the three and six months ended June 30, 2023 and 2022, and was recorded as revenues, related party. Amounts due from Bioscience for clinical lamp and other reimbursements were approximately \$0.5 million and \$0.1 as of June 30, 2023 and December 31, 2022, respectively, which were recorded as other receivables, related party in the consolidated balance sheets.

Others

The Company has recorded a receivable of \$3.7 million and \$6.4 million as of June 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 six months ended June 30, 2023 and \$0.1 million of interest income for the six months ended June 30, 2022, in connection with this receivable.

As of June 30, 2023, our investment, related party is valued at \$5.9 million and consists of 6,280,396 common shares of Biofrontera AG, a significant shareholder of the Company. 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.

14. Stockholders' Equity

Under the Company's amended and restated certificate of incorporation, dated December 21, 2020, the Company is authorized to issue 15,000,000 shares of common stock, par value \$0.001 per share and 20,000,000 shares of preferred stock, par value \$.001 per share. *See Note 20. Subsequent Events* for information and disclosures relating to adjustments related to the Reverse Stock Split.

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

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 June 30, 2023, there were 152,301 shares available for future awards under the amended 2021 Plan. See *Note 20. Subsequent Events* for information and disclosures relating to adjustments related to the Reverse Stock Split.

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:

	Six Months Ended June 30,	
	2023	2022
Expected volatility	70% - 95%	55% - 65%
Expected term (in years)	6.0	5.24 - 6.0
Risk-free interest rate	3.5% - 3.9%	1.79% - 2.90%
Expected dividend yield	0.0%	0.0%

Share-based compensation expense of approximately \$0.2 million and \$0.4 million was recorded in selling, general and administrative expenses on the accompanying consolidated statement of operations for the three and six months ended June 30, 2023, respectively and \$0.2 million and \$0.3 million for the three and six months ended June 30, 2022.

Options outstanding and exercisable under the employee share option plan as of June 30, 2023 and a summary of option activity during the six 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	(20,419)	\$ 54.14		
Outstanding at June 30, 2023	89,009	\$ 51.84	8.65	\$ 13
Exercisable at June 30, 2023	26,042	\$ 64.95	7.54	\$ -

(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 June 30, 2023.

As of June 30, 2023, there was \$1.4 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.1 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 \$0.2 million for the RSUs for the three and six months ended June 30, 2023, respectively, and \$0.4 million and \$0.8 million for the three and six months ended June 30, 2022 and was recorded in selling, general and administrative expenses in the accompanying consolidated statements of operations.

	Shares	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value	Weighted Average Grant Date Fair Value
Outstanding at December 31, 2022	17,176		\$	\$ 52.2
Awarded	-		\$	\$ -
Vested	(8,588)		\$	\$ 52.2
Canceled or forfeited	(3,817)		\$	\$ -
Outstanding at June 30, 2023	4,771	0.88	\$ 50	\$ 52.2

As of June 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 0.9 years.

16. Interest Expense, net

Interest expense, net consists of the following:

(in thousands)	For three months ended June 30,		For six months ended June 30,	
	2023	2022	2023	2022
Interest expense	\$ (32)	\$ (3)	\$ (33)	\$ (7)
Contract asset interest expense	(89)	(89)	(179)	(179)
Interest income – related party	40	53	94	110
Interest income – other	2	1	4	5
Interest expense, net	\$ (79)	\$ (38)	\$ (114)	\$ (71)

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.

17. Net Earnings (Loss) per Share

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

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

	Three Months Ended		Six Months Ended	
	June 30,		June 30,	
	2023	2022	2023	2022
Net income (loss)	\$ (9,837)	\$ (850)	\$ (17,315)	\$ 4,711
Shares:				
Basic weighted average common shares outstanding	1,360,739	941,175	1,359,894	898,444
Add: Effect of dilutive securities				
Stock options and restricted stock units	-	-	-	3,765
Diluted weighted average common shares outstanding	1,360,739	941,175	1,359,894	902,209
Net earnings (loss) per share:				
Basic	\$ (7.23)	\$ (0.90)	\$ (12.73)	\$ 5.24
Diluted	\$ (7.23)	\$ (0.90)	\$ (12.73)	\$ 5.22

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

June 30,	2023	2022
Common stock warrants	1,877,630	1,806,202
Common stock options and RSUs	106,034	42,428
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 September 2025.

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

Lease expense	Operating Leases
Amortization of ROU assets (operating lease cost)	\$ 265
Interest on lease liabilities	37
Total lease expense	\$ 302

Other Information

Operational cash flow used for operating leases	\$ 293
Weighted -average remaining lease term (in years)	2.08
Weighted -average discount rate	6.31%

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

Years ending December 31,	Future lease commitments
2023	\$ 270
2024	541
2025	350
Total future minimum lease payments	1,161
Less imputed interest	(72)
Total lease liability	\$ 1,089

Reported as:

Operating lease liability, current	\$ 489
Operating lease liability, non-current	600
Total	\$ 1,089

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 (“ICC”) 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.

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.

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 committed, among other things, to take the following actions:

- the Company will appoint as a Class I Director a director nominated by Biofrontera AG. See *Note 20. Subsequent Events – New Board Member for details regarding the new appointment.*
- 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 2023 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.

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.

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 six months ended June 30, 2023 and 2022, respectively.

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.

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 Agreement, DUSA could compel us to pay Biofrontera AG’s share. If either we or Biofrontera AG violates the terms of the settlement agreement, we or Biofrontera AG may be liable for a greater amount. If we become liable for more than our agreed share of the aggregate settlement amount, either of these events could have a material adverse effect on our business, prospects, financial condition and/or results of operations. As of June 30, 2023, we have reflected a legal settlement liability in the amount of \$6.1 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 \$3.7 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.

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 were \$0.1 million and negligible for the three months ended June 30, 2023 and 2022, and \$0.2 million and \$0.1 million for the six months ended June 30, 2023 and 2022, respectively.

20. Subsequent Events

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

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 the Reverse Stock Split of the Company’s 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 Inc. 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).

New Board Member

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.

Mr. Lanckriet was appointed to the Board upon the nomination of Biofrontera AG, a significant stockholder of the Company, pursuant to a settlement agreement dated as of April 11, 2023, between the Company, each member of its Board of Directors at that time and Biofrontera AG. See Note 18, “*Commitments and Contingencies*”.

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"), 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 Inc. 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 (when used together, "Ameluz® PDT"). In the United States, the PDT treatment is used for the lesion-directed and field-directed treatment of actinic keratoses ("AK") of mild-to-moderate severity on the face and scalp. AKs are premalignant lesions of the skin that can potentially develop into skin cancer (squamous cell carcinoma) if left untreated.¹ International treatment guidelines list photodynamic therapy as the "gold standard" for treating AK, especially multiple AKs and the surrounding photodamaged skin.² We are currently selling Ameluz® for this indication in the U.S. under an exclusive license and supply agreement ("Ameluz LSA") between Biofrontera, Inc. 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.

COVID-19

The COVID-19 global pandemic still affects our business and presents challenges particularly regarding our supply chain. Although, we are optimistic that our business will continue to thrive throughout 2023 and beyond, the ultimate extent of the impact of any epidemic, pandemic, outbreak, or other public health crisis on our business, financial condition and results of operations will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of such epidemic, pandemic, outbreak, or other public health crisis and actions taken to contain or prevent the further spread, including the effectiveness of vaccination and booster vaccination campaigns, among others. Accordingly, we cannot predict the extent to which our business, financial condition and results of operations will continue to be affected. We remain focused on maintaining a strong balance sheet, liquidity and financial flexibility and continue to monitor developments as we deal with the disruptions and uncertainties from a business and financial perspective relating to COVID-19 and variants thereof.

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 June 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.

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 June 30, 2023 and 2022

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

<i>(in thousands)</i>	<u>2023</u>	<u>2022</u>	<u>Change</u>
Product revenues, net	\$ 5,830	\$ 4,441	\$ 1,389
Related party revenues	18	16	2
Revenues, net	<u>5,848</u>	<u>\$ 4,457</u>	<u>1,391</u>
Operating expenses:			
Cost of revenues, related party	2,772	2,402	370
Cost of revenues, other	116	152	(36)
Selling, general and administrative	11,456	9,669	1,787
Selling, general and administrative, related party	92	346	(254)
Research and development	11	-	11
Change in fair value of contingent consideration	100	(1,900)	2,000
Total operating expenses	<u>14,547</u>	<u>10,669</u>	<u>3,878</u>
Loss from operations	<u>(8,699)</u>	<u>(6,212)</u>	<u>(2,487)</u>
Change in fair value of warrant liabilities	375	5,371	(4,996)
Change in fair value of investment, related party	(1,482)	-	(1,482)
Interest expense, net	(79)	(38)	(41)
Other income (expense), net	62	29	33
Loss before income taxes	<u>(9,823)</u>	<u>(850)</u>	<u>(8,973)</u>
Income tax expenses	14	-	14
Net loss	<u>\$ (9,837)</u>	<u>\$ (850)</u>	<u>\$ (8,987)</u>

Product Revenue, net

Net product revenue was \$5.8 million and \$4.4 million for the three months ended June 30, 2023 and 2022, respectively, an increase of \$1.4 million, or 31.3%. This increase is driven by a higher volume of Ameluz revenue in Q2 2023, caused in part by an expansion of our sales force in 2023, higher adoption of Ameluz by dermatologists, as well as the absence of a buy-in impact due to a price increase. Our price for Ameluz increased by 5% on April 1, 2022, causing dermatologists to accelerate their purchases of Ameluz in Q1 2022 prior to the price increase, some of which would typically be purchased in Q2 2022. We have not raised the price of Ameluz in 2023, and thus revenues in Q2 2023 were not impacted by the effects of a price increase.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party was \$2.8 million and \$2.4 million for the three months ended June 30, 2023 and 2022, respectively, an increase of \$0.4 million, or 15.4%. 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 were \$11.5 million and \$9.7 million for the three months ended June 30, 2023 and 2022, respectively, an increase of \$1.8 million, or 18.5%. The increase was primarily driven by \$1.0 million of personnel costs, comprised of \$0.5 million of increased salary due to higher headcount and \$0.5 million of severance due to a reduction in force. These changes reflect 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 \$1.0 million of non-recurring legal expenses. These expenses were offset by a decrease of \$0.2 million in business insurance.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was a decrease of \$2.0 million for the three months ended June 30, 2023 compared to the three months ended June 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.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a decrease of \$5.0 million for three months ended June 30, 2023. The change in fair value of warrant liabilities was driven primarily by changes in the underlying value of the common stock.

Change in fair value of investment, related party

The change in fair value of investment, related party was a decrease of \$1.5 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 Six Months ended June 30, 2023 and 2022

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

<i>(in thousands)</i>	<u>2023</u>	<u>2022</u>	<u>Change</u>
Product revenues, net	\$ 14,544	\$ 14,177	\$ 367
Related party revenues	36	31	5
Revenues, net	14,580	14,208	372
Operating expenses:			
Cost of revenues, related party	7,319	7,377	(58)
Cost of revenues, other	167	327	(160)
Selling, general and administrative	21,254	17,285	3,969
Selling, general and administrative, related party	119	441	(322)
Research and Development	11	-	11
Change in fair value of contingent consideration	(100)	(1,900)	1,800
Total operating expenses	28,770	23,530	5,240
Loss from operations	(14,190)	(9,322)	(4,868)
Change in fair value of warrant liabilities	1,403	14,082	(12,679)
Change in fair value of investment, related party	(4,424)	-	(4,424)
Interest expense, net	(114)	(71)	(43)
Other income, net	30	52	(22)
Income (loss) before income taxes	(17,295)	4,741	(22,036)
Income tax expenses	20	30	(10)
Net Income (loss)	\$ (17,315)	\$ 4,711	\$ (22,026)

Product Revenue, net

Net product revenue was \$14.5 million and \$14.2 million for the six months ended June 30, 2023 and 2022, respectively, an increase of \$0.4 million, or 2.6%. The increase was primarily driven by a higher volume of Ameluz sales in Q2 2023 due to the expansion of the sales team of \$0.1 million, a higher average Ameluz selling price in 2023 of \$0.1 million, and a higher volume of RhodoLED[®] lamp sales of \$0.1 million.

Operating Expenses

Selling, General and Administrative Expenses

Selling, general and administrative expenses were \$21.3 million and \$17.3 million for the six months ended June 30, 2023 and 2022, respectively, an increase of \$4.0 million, or 23.0%. The increase was primarily driven by external legal expenses related to a legal settlement of \$1.2 million, other non-recurring legal costs of \$0.8 million, personnel-related expenses of \$1.7 million which include expenses related to our expanded workforce offset by some non-customer facing roles, and sales travel related expenses of \$0.3 million.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party were \$0.1 million and \$0.4 million for the six months ended June 30, 2023 and 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 a decrease of \$1.8 million for the three months ended June 30, 2023 compared to the three months ended June 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, which has decreased from the prior year.

Change in Fair Value of Warrant Liabilities

The change in fair value of warrant liabilities was a decrease of \$12.7 million for the six months ended June 30, 2022. The change in fair value of warrant liabilities was driven primarily by a decrease in the underlying value of our common stock.

Change in fair value of investment, related party

The change in fair value of investment related party was a decrease of \$4.4 million, driven by changes in the quoted market price of the common stock of Biofrontera AG.

Net Income (Loss) to Adjusted EBITDA Reconciliation for the Three and Six Months Ended June 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 non-cash.

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.

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 six months ended June 30, 2023 and 2022:

	Three months ended June 30,		Six months ended June 30,	
	2023	2022	2023	2022
Net income (loss)	\$ (9,837)	\$ (850)	\$ (17,315)	\$ 4,711
Interest expense, net	79	38	114	71
Income tax expense	14	-	20	30
Depreciation and amortization	253	132	518	263
EBITDA	(9,491)	(680)	(16,663)	5,075
Change in fair value of contingent consideration	100	(1,900)	(100)	(1,900)
Change in fair value of warrant liabilities	(375)	(5,371)	(1,403)	(14,082)
Change in fair value of investment, related party	1,482	-	4,424	-
Legal settlement expenses	107	261	1,225	313
Stock compensation expense	259	551	610	1,068
Adjusted EBITDA	\$ (7,918)	\$ (7,139)	\$ (11,907)	\$ (9,526)
Adjusted EBITDA margin	-135.4%	-160.2%	-81.7%	-67.0%

Adjusted EBITDA

Adjusted EBITDA decreased from (\$7.1) million during the three months ended June 30, 2022 to (\$7.9) million for the three months ended June 30, 2023. The decrease in Adjusted EBITDA is primarily driven by an increase in our selling, general, and administrative costs of \$1.9 million, partially offset by increased revenues of \$1.4 million, net of increased cost of revenues of \$0.3 million.

Adjusted EBITDA decreased from (\$9.5) million during the six months ended June 30, 2022 to (\$11.9) million for the six months ended June 30, 2023. The decrease in Adjusted EBITDA is primarily driven by an increase in selling, general and administrative of \$2.9 million, due primarily to increased personnel costs related to increased headcount to expand key customer facing roles and severance agreements as part of a reduction in force. This is partially offset by an increase in our revenues of \$0.4 million and a decrease in our cost of revenues of \$0.2 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 June 30, 2023, we had cash and cash equivalents of \$4.5 million, compared to \$17.2 million as of December 31, 2022.

Since we commenced operations in 2015, we have generated significant losses. For the six months ended June 30, 2023 and 2022, we incurred loss from operations of \$14.2 million and \$9.3 million, respectively. We incurred net cash outflows from operations of \$14.0 million and \$2.0 million, for the same periods, respectively. We had an accumulated deficit as of June 30, 2023 of \$96.8 million.

The Company's short-term material cash requirements include working capital needs and satisfaction of contractual commitments including facility and auto leases (see *Note 18. Commitments and Contingencies*), Maruho start-up cost financing repayments of \$7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG of \$2.4 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. We also expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. In addition, we expect to incur costs to continue to comply with corporate governance, regulatory reporting and other requirements applicable to us as a public company in the U.S.

In connection with our assessment of going concern considerations under applicable accounting standards, the Company's management has determined that based on our growth plans, upcoming inventory purchases, and a final settlement payment, substantial doubt exists about our ability to continue as a going concern for at least one year from the date the unaudited condensed 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 until cash flow from operations is sufficient. Management believes that actions presently being taken to obtain additional funding and implement its strategic plans provide the opportunity for the Company to continue as a going concern. No assurance can be given that the Company will be successful in these efforts. Accordingly, management has concluded that substantial doubt exists about the company's ability to continue as a going concern for a period of at least 12 months from the date of issuance of these financial statements.

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

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:

<i>(in thousands)</i>	Six Months Ended June 30,	
	2023	2022
Net cash used in operating activities	\$ (14,025)	\$ (1,987)
Net cash provided by (used) in investing activities	164	(36)
Net cash provided by financing activities	1,106	9,391
Net increase (decrease) in cash and restricted cash	\$ (12,755)	\$ 7,368

Operating Activities

During the six months ended June 30, 2023, operating activities used \$14.0 million of cash, primarily resulting from our loss from operations of \$17.3 million, adjusted for non-cash expense of stock-based compensation of \$0.6 million, non-cash interest expense of \$0.2 million, depreciation and amortization in the aggregate of \$0.5 million, and the change in fair value of investment, related party of \$4.4 million, offset by net cash used by changes in our operating assets and liabilities of \$1.0 million, the change in fair value of contingent consideration of \$0.1 million and the change in fair value of warrant liabilities of \$1.4 million.

During the six months ended June 30, 2022, operating activities used \$2.0 million of cash, primarily resulting from our net income of \$4.7 million, adjusted for non-cash expense of stock-based compensation of \$1.1 million, \$0.3 million depreciation and amortization, \$0.2 million interest expense as well as \$7.6 million of working capital changes which was offset by the change in fair value of warrant liabilities of \$14.1 million and the change in fair value of contingent consideration of \$1.9 million.

Investing Activities

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

During the six months ended June 30, 2022, net cash used in investing activities consisted of the purchase of computer equipment.

Financing Activities

During the six months ended June 30, 2023, net cash from financing activities consisted of a net \$1.1 million of proceeds from our line of credit.

During the six months ended June 30, 2022, net cash from financing activities consisted of \$9.4 million of proceeds from the sale of common stock and warrants in a private placement.

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 *Item 8, “Financial Statements and Supplementary Data,”* our Annual Report on Form 10-K.

Critical Accounting Estimates

A summary of our critical accounting estimates is included in the Company’s Annual Report on Form 10-K for the year ended December 31, 2022. There were no material changes to our critical accounting estimates for the three months ended June 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 June 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 June 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.

3.1	Certificate of Amendment to the Amended and Restated Certificate of Incorporation of Biofrontera Inc. (incorporated by reference to Exhibit 3.1 of the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission on July 3, 2023)
10.1*#	Confidential Settlement and General Release Agreement, dated as of May 25, 2023, between the Company and Erica Monaco
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: August 11, 2023

By: /s/ Hermann Luebbert

Name: Hermann Luebbert

Title: Chief Executive Officer & Chairman
(Principal Executive Officer)

Date: August 11, 2023

By: /s/ E. Fred Leffler III

Name: E. Fred Leffler, III

Title: Chief Financial Officer
(Principal Financial Officer)

Confidential Settlement and General Release Agreement

This Confidential Settlement and General Release Agreement (the "Agreement") is entered into by and among Biofrontera Inc., a Delaware Corporation and Erica Monaco ("Employee"). Biofrontera Inc., a Delaware Corporation, and its parent companies, divisions, affiliates, subsidiaries, operating companies, otherwise related entities, predecessors, successors, assigns and any entity under common control with Biofrontera, Inc. are collectively referred to herein as "Company." The Company and Employee are collectively referred to herein as the "Parties," and each as a "Party."

WHEREAS, Employee is and will remain employed by the Company as its Chief Executive Officer until May 26, 2023 (the "Separation Date");

WHEREAS, Employee and the Company entered into an employment agreement dated August 11, 2021, which was amended in part, on April 1, 2022 ("Employment Contract");

WHEREAS, Employee sent a resignation letter dated May 8, 2023 informing the Board of Directors that she intended to terminate her Employment Contract and that her last day of employment would be Wednesday, November 8, 2023 (the "Resignation Letter");

WHEREAS, Employee and the Company desire to settle fully and finally all Claims (as defined below) Employee has or may have against the Company, including, but not limited to, those relating to or arising out of or in connection with Employee's employment with, and separation from the Company;

NOW, THEREFORE, in consideration of the mutual promises and agreements set forth in this Agreement (including those referenced both above and below), and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, and with the mutual intent to be legally bound by the terms of this Agreement, the Parties agree as follows:

1. **NO ADMISSION AND SUPPLEMENTAL GENERAL RELEASE**

This Agreement is intended solely as a compromise of disputed claims and neither the fact of The Company's entry into this Agreement, the fact of the settlement reflected in this Agreement, nor the terms hereof or any acts undertaken pursuant hereto, shall constitute an admission or concession by the Company regarding liability or the validity of any claims or allegations. By entering into this Agreement, the Company is not admitting any liability to Employee and all such liability is expressly denied. The Parties have mutually agreed that in lieu of the notice period outlined in the Employment Contract, the Separation Date shall be May 26, 2023. If requested by the Company, Employee agrees to sign a supplemental general release of claims the day after her last

day of employment ("Supplemental General Release"). The Supplemental General Release will state the following:

SUPPLEMENTAL GENERAL RELEASE

In exchange for the promises made in this Agreement by the Company, as and for consideration for Employee's complete waiver and release of all claims against the Company and all its past and present insurers, owners, parents, subsidiaries, divisions, family members, affiliates, related companies or entities, predecessors, successors, contractors, assigns, administrators, executors, officers, directors, trustees, board members, agents, representatives, attorneys, and employees (hereinafter collectively referred to as "RELEASEES" OR "Released Parties"), Employee hereby fully, forever, irrevocably and unconditionally releases, remises and discharges, RELEASEES and RELEASEES' insurers, owners, parents, subsidiaries, divisions, family members, affiliates, related companies or entities, predecessors, successors, assigns, administrators, executors, officers, directors, trustees, agents, attorneys, heirs, personal representatives, TriNet, any PEO, and employees, from all actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, bonuses, controversies, agreements, promises, claims, charges, complaints, and demands whatsoever in law or in equity, whether existing or contingent, known or unknown, which against the RELEASEES, you or your heirs, executors, administrators, successors, and/or assigns may now have or hereafter can, shall, or may have for, upon, or by reason of any matter, cause, or thing whatsoever, arising before the date of this Agreement, including but not limited to (i) those which were or could have been the subject of claims and allegations made by you; (ii) those arising under the Family and Medical Leave Act, 29 U.S.C. § 2601 et seq.; the Worker Adjustment and Retraining Notification Act ("WARN"), 29 U.S.C. § 2101 et seq.; the Rehabilitation Act of 1973, 29 U.S.C. § 701 et seq., Executive Order 11246, Executive Order 11141; the Fair Credit Reporting Act, 15 U.S.C. § 1681 et seq., and the Employee Retirement Income Security Act of 1974 ("ERISA"), 29 U.S.C. § 1001 et seq., the National Labor Relations Act, as amended, 29 U.S.C., § 151 et seq.; the Occupational Safety and Health Act; Title VII of the 1964 Civil Rights Act, as amended, 42 U.S.C. § 2000e et seq.; the Americans with Disabilities Act, as amended, 42 U.S.C. § 12111 et seq.; the Age Discrimination in Employment Act ("ADEA"), as amended by the Older Workers Benefit Protection Act, 29 U.S.C. § 621; M.G.L. c. 151B; M.G.L. c. 214 §1C; M.G.L. c. 214 §1B; M.G.L. c. 149, §§ 148 & 150; M.G.L. c. 12, §§11H & 11I;); the Massachusetts Equal Rights Act, M.G.L. c. 93, § 102; Sarbanes-Oxley Act of 2002, Public Law 107-204, including whistleblower Claims under 18 U.S.C. §§ 1514A and 1513(e), any Claims for alleged wages due, overtime or other compensation or payment including any Claim for treble damages, attorneys' fees and costs, and any other federal or state statutory or common law whistleblower or relation-related claims, or any other federal, state or local human rights, civil rights, family or

medical leave (federal or state, including, without limitation any paid family medical leave act or retaliation relating thereto), wage hour, pension or labor law, rule and/or regulation, public policy, contract or tort law, (iii) those arising under all civil laws, criminal laws, any employment contract or common law, including, but not limited to, those relating to age discrimination, sex discrimination, disability/handicap discrimination, race discrimination, color discrimination, national origin discrimination, ancestry discrimination, religious discrimination, military or veteran status discrimination, genetic information discrimination, other unlawful discrimination or retaliation, failure to reasonably accommodate handicap/disability, sexual or other unlawful harassment, aiding or abetting, family leave, medical leave, discharge, constructive discharge, failure to hire or promote, failure to reinstate in or restore to a position, failure to provide notice of rights, restraint of rights, interference with or denial of rights, promissory estoppel, breach of contract, breach of implied covenant of good faith and fair dealing, fraud, retaliation,, defamation, violation of public policy, misrepresentation, deceit, intentional interference with advantageous or contractual relations, intentional or negligent infliction of emotional distress, assault, battery, invasion of privacy, defamation, personal injury, negligence, or conspiracy, and (iv) any other action, claim or grievance against the RELEASEES, from the beginning of the world to the date of this Agreement.

Employee further acknowledges that Employee has received payment, salary, and wages in full for all services rendered in conjunction with Employee's employment with the Company through the date of this Agreement, including payment for all wages, bonuses, and accrued, unused paid time off, and that no other compensation is owed to Employee except as explicitly provided herein. Employee specifically understands that this general release of Claims includes, without limitation, a release of Claims for alleged wages due, overtime, or other compensation or payment, including any Claim for multiple damages, attorneys' fees, costs and expenses, or any Claim arising under Nevada and Massachusetts wage and hour laws, including without limitation, the Massachusetts Wage Act and State Overtime Law and the Massachusetts Pay Equity law, M.G.L. c. 149, §§ 148, 150 et seq. and M.G.L. c. 151, § 1A et seq., as amended; or any other applicable laws governing the payment of wages or compensation, Claims relating to meal breaks, prevailing wage, deductions, reporting pay, unpaid wages, salary, commissions, bonuses, overtime, vacation pay, compensatory time, sick pay, holiday pay, severance pay, expense reimbursements, leaves, retaliation, multiple damages or attorneys' fees, costs and expenses, including, but not limited to any state, federal, or local law governing the payment of wages or compensation. Employee further acknowledges that Employee is unaware of any facts that would support a Claim against the Released Parties for violation of the Fair Labor Standards Act, Massachusetts Wage and Hour law, the Massachusetts Wage Act and Overtime Law, or any other applicable law governing the payment of wages or compensation.

This General Release of Claims does not apply to any claims concerning:

- (a) a breach of the Separation Agreement between Employee and the Company;
- (b) any rights to benefits under applicable workers' compensation statutes or government-provided unemployment benefits;
- (c) any rights to vested benefits under the written terms of a qualified employee retirement plan (including but not limited to a 401(k) plan);
- (d) any matters that cannot be lawfully waived.

Employee acknowledges that they may hereafter discover facts different from or in addition to the facts now known or believed to be true as of the Effective Date of this Agreement. Employee agrees that, notwithstanding the discovery of the existence of any such additional or different facts that, if known, may have materially affected her decision to enter into this Agreement, the releases given herein shall be and remain in effect as full, final, and complete releases of the Released Parties, individually and collectively, from the released Claims, and that Employee shall not be entitled to modify or set aside this Agreement, in whole or in part, by reason thereof.

Employee waives any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a claim in which the Company or any other Releasee identified in this Agreement is a party.

2. **SEVERANCE PAYMENT**

Subject to: (i) the Company's receipt of this Agreement signed by Employee; and (ii) this Agreement becoming Effective Date, the Company shall pay Employee the total gross amount of Four Hundred Twenty Four Thousand Thirty Eight Dollars and Forty Seven Cents (\$424,038.47) which is \$450,000.00 less the salary payments made by Company to Employee for work performed between May 8, 2023 and May 26, 2023 (which payments total \$25,961.53). (the "Severance Payment"). Employee understands that the Severance Payment will be paid in bi-weekly installments (until the Lump Sum Portion of the Severance Payment Date, as outlined below), in accordance with the Company's usual payroll practices, beginning on the pay period ending on June 2, 2023. Provided that the Employee complies with all of her obligations in this Agreement, on or before the second payroll date in January, 2024, the Company will pay Employee the balance of the Severance Payment then owed in a lump sum. The second payroll date in January, 2024 shall be the "Lump Sum Portion of the Severance Payment Date".) All payments hereunder shall be less applicable state and federal employment taxes, and other

mandated statutory deductions after all events and conditions have been met or occurred under Sections 2(i)-(ii), and provided that Employee complies with all terms and conditions herein, all of which are material inducements for the Company to enter into this Agreement. The Company shall issue Employee a W-2 form as to the entire portion of the Severance Payment. Employee also affirms that she is under Forty (40) years old.

Employee is owed 100 hours' of PTO amounting to \$21,634.62, as well as \$365.10 in business expenses. On or before May 26, 2023, Company will pay Employee for business expenses and the \$21,634.62 (PTO) owed. Upon payment to Employee for PTO, business expenses and her salary through May 26, 2023, Employee agrees that she has been paid all wages, expenses, earned leave and all other monies owed by the Company and that she is not entitled to any other monies whatsoever (aside from the Severance Payment upon the Effective Date).

Employee acknowledges that Employee is not relying upon advice or representation of the Company with respect to the tax treatment of any portion of the Severance Payment, or any other benefits set forth in this Agreement.

It is understood that the Severance Payment is in full and final satisfaction of any and all Claims (as defined below) that Employee is releasing herein that she may have had from the beginning of time until the date Employee signs this Agreement against any of the Released Parties (as defined below), individually or collectively. Employee and the Company agree that no part of any payment by the Company agree pursuant to this Agreement constitutes (i) a fine or penalty paid to a government under any law or (ii) a payment to a government to settle any actual or potential liability for a punitive fine or penalty under any law.

After the Separation Date there shall be no further vesting of any stock options in the Company. If Employee does not exercise their vested options by the earlier of (i) the date of the original expiration date of the options, or (ii) the date that is ninety (90) days after the Separation Date, Employee's options will expire and be canceled, and Employee will have no further rights with respect to Employee's options.

In connection with the Severance Payment provided to Employee pursuant to this Agreement, the Company shall withhold and remit to the tax authorities the amounts required under applicable law, and Employee shall be responsible for all applicable taxes with respect to such severance benefits under applicable law. Employee acknowledges that they are not relying upon the advice or representation of the Company with respect to the tax treatment of any of the severance benefits set forth in this Agreement, and that Employee has hired counsel and consulted with (or had an opportunity to consult with) appropriate tax professional(s) relating to all issues of taxation pertaining to this Agreement and the payments Employee is receiving, including, without limitation, any

applicable “parachute payments,” and Section 409A of the Internal Revenue Code. For purposes of this Agreement, a termination of employment will mean a “separation from service” as defined in Section 409A of the Internal Revenue Code of 1986 (“*Section 409A*” of the “*Code*”), where required for compliance with Section 409A. This Agreement is intended to comply with the provisions of Section 409A and this Agreement shall, to the extent practicable, be construed in accordance therewith. Terms defined in this Agreement will have the meanings given such terms under Section 409A if and to the extent required to comply with Section 409A.

3. **FINAL COMPENSATION**

Employee acknowledges that the Company has provided Employee with Employee’s final payment of any wages earned through the Separation Date, as well as any accrued but unused vacation time whether or not the parties execute this Agreement. Employee agrees and acknowledges that Employee is not entitled to, nor will Employee receive, any further compensation, benefits, or other pay or remuneration from the Company agree of any kind whatsoever (including, but not limited to salary, wages, benefits, equity or equity-based awards) unless Employee signs and accepts this Agreement and it becomes effective on the Effective Date, in which case Employee will be entitled to only the benefits from the Company agree as expressly provided herein. Employee’s participation in any Company benefits programs shall cease as of the Separation Date. Employee has been made aware of her rights to file for unemployment benefits, as well as her right to obtain insurance coverage at her own expense through COBRA for up to 18 months.

As of the Separation Date, Employee shall also have resigned all positions relating to the Company, including, without limitation, any position on any board, committees, and all other aspects of corporate governance, and as of the Separation Date Employee shall no longer represent that they are affiliated with the Company in any way, except as necessary to fulfill Employee’s cooperation covenants outlined below. Employee also agrees to update all social media in connection with her departure, including, without limitation, LinkedIn.

4. **NO PUBLICATION OF SETTLEMENT**

Employee shall take no steps to state, publish or publicize the fact of the settlement or this Agreement, except to the extent provided in this Agreement, and/or whenever and to the extent that disclosure is ordered by a court of competent jurisdiction or otherwise required by state or federal law or regulation. Provided however, Employee may respond to inquiries about her separation by stating that her employment with the company ended amicably.

Employee acknowledges that due to federal regulations, Employer may be required to publish information related to this Agreement and expressly agrees that any such mandatory disclosures shall not violate this Agreement.

5. **CONFIDENTIAL INFORMATION**

- a. Subject to the permissible disclosures set forth in Subsection 5(e) of this Agreement, the Parties expressly understand and agree that the terms, conditions, and existence of this Agreement (“Confidential Information”) are strictly confidential and shall not be disclosed.
- b. “Confidential Information” shall also include any and all information that was shared between the Parties or their counsel in connection with the negotiation and drafting of this Agreement (as described in the Subsection 5(e)(ii), “Settlement Communications”). The Parties further agree that any and all Settlement Communications are subject to the protection of and confidentiality provided by Fed. R. Evid. 408 and state law counterparts, and all similar rules and confidentiality provisions that may exist under state law.
- c. Employee hereby covenants and agrees that she will not, without express written authorization of the Company, make use of, license, sell, disclose, or otherwise transfer or make available any Confidential Information, except as permitted under Subsection 5(e) of this Agreement.
- d. The Company hereby covenants and agrees that it will not, without express written authorization of Employee, make use of, license, sell, disclose, or otherwise transfer or make available any Confidential Information, except as permitted under Subsection 5(e) of this Agreement.
- e. For the avoidance of doubt, Subsections 5(a), 5(b), 5(c) and 5(d) require that certain information be kept strictly confidential and shall not be disclosed, in whole or in part; provided, however, the parties may disclose such Confidential Information:
 - i. confidentially to their respective attorneys, auditors, accountants, immediate family members, and indemnitors;
 - ii. in the case of the Company only, confidentially to the Company’s employees, agents, vendors and consultants and others who have a business need to know such information in connection with their job responsibilities and/or business operations, and to the Company’s board of directors and executive leadership team;
 - iii. to fulfill their corporate financial reporting obligations;

- iv. in the case of the Company only, for the purpose of disclosure in connection with reports filed with the Securities and Exchange Commission, or any other filings, reports or disclosures that may be required under applicable laws or regulations (including without limitation applicable stock exchange rules and regulations), or requested by, including without limitation, governmental or regulatory bodies, or as the result of any legal action, claim, charge or complaint;
- v. as required by law, including but not limited to making disclosure, to the extent required by law, in connection with reporting to tax authorities,
- vi. to the extent required to enforce this Agreement or as otherwise permitted by this Agreement; and/or
- vii. with the prior written consent of the other Party.

Except as otherwise provided in this Section 5(e), if a person not a Party to this Agreement requests or demands from a Party or their attorneys, by subpoena or other legal process, the disclosure of Confidential Information, the recipient of the subpoena or non-party request, or its attorneys, shall, as soon as practicable and if lawfully permitted, notify the other Party, in writing, and give the Parties a reasonable period of time to respond to such subpoena or non-party request before the recipient takes any action in response to the subpoena or non-party request. In no way shall the foregoing be construed in such a way as to in any way limit, invalidate, or otherwise alter or displace any other confidentiality agreements entered into by Employee while under the employ of the Company. This Section 5 is intended to supplement, and not replace, any prior agreement entered into by Employee with respect to confidential information, and for sake of clarity, Employee agrees that they have other obligations to protect the confidential information of the Company that survive the Separation Date, as outlined herein.

6. **GENERAL RELEASE**

In exchange for the promises made in this Agreement by the Company, as and for consideration for your complete waiver and release of all claims against the Company and all its past and present insurers, owners, parents, subsidiaries, divisions, family members, affiliates, related companies or entities, predecessors, successors, contractors, assigns, administrators, executors, officers, directors, trustees, board members, agents, representatives, attorneys, TriNet, any PEO, and employees (hereinafter collectively referred to as "RELEASEES" OR "Released Parties"), Employee hereby fully, forever, irrevocably and unconditionally releases, remises and discharges, RELEASEES and RELEASEES' insurers, owners, parents, subsidiaries, divisions, family members, affiliates, related companies or entities, predecessors, successors, assigns, administrators, executors, officers, directors, trustees, agents, TriNet and any PEO, attorneys, heirs,

personal representatives, and employees, from all actions, causes of action, suits, debts, dues, sums of money, accounts, reckonings, bonds, bills, specialties, covenants, contracts, bonuses, controversies, agreements, promises, claims, charges, complaints, and demands whatsoever in law or in equity, whether existing or contingent, known or unknown, which against the RELEASEES, you or your heirs, executors, administrators, successors, and/or assigns may now have or hereafter can, shall, or may have for, upon, or by reason of any matter, cause, or thing whatsoever, arising before the date of this Agreement, including but not limited to (i) those which were or could have been the subject of claims and allegations made by you; (ii) those arising under the Family and Medical Leave Act, 29 U.S.C. § 2601 *et seq.*; the Worker Adjustment and Retraining Notification Act (“WARN”), 29 U.S.C. § 2101 *et seq.*; the Rehabilitation Act of 1973, 29 U.S.C. § 701 *et seq.*, Executive Order 11246, Executive Order 11141; the Fair Credit Reporting Act, 15 U.S.C. § 1681 *et seq.*, and the Employee Retirement Income Security Act of 1974 (“ERISA”), 29 U.S.C. § 1001 *et seq.*, the National Labor Relations Act, as amended, 29 U.S.C., § 151 *et seq.*; the Occupational Safety and Health Act; Title VII of the 1964 Civil Rights Act, as amended, 42 U.S.C. § 2000e *et seq.*; the Americans with Disabilities Act, as amended, 42 U.S.C. § 12111 *et seq.*; the Age Discrimination in Employment Act (“ADEA”), as amended by the Older Workers Benefit Protection Act, 29 U.S.C. § 621; M.G.L. c. 151B; M.G.L. c. 214 §1C; M.G.L. c. 214 §1B; M.G.L. c. 149, §§ 148 & 150; M.G.L. c. 12, §§11H & 11I;); the Massachusetts Equal Rights Act, M.G.L. c. 93, § 102; Sarbanes-Oxley Act of 2002, Public Law 107-204, including whistleblower Claims under 18 U.S.C. §§ 1514A and 1513(e), any Claims for alleged wages due, overtime or other compensation or payment including any Claim for treble damages, attorneys’ fees and costs, and any other federal or state statutory or common law whistleblower or relation-related claims, or any other federal, state or local human rights, civil rights, family or medical leave (federal or state, including, without limitation any paid family medical leave act or retaliation relating thereto), wage hour, pension or labor law, rule and/or regulation, public policy, contract or tort law, (iii) those arising under all civil laws, criminal laws, any employment contract or common law, including, but not limited to, those relating to age discrimination, sex discrimination, disability/handicap discrimination, race discrimination, color discrimination, national origin discrimination, ancestry discrimination, religious discrimination, military or veteran status discrimination, genetic information discrimination, other unlawful discrimination or retaliation, failure to reasonably accommodate handicap/disability, sexual or other unlawful harassment, aiding or abetting, family leave, medical leave, discharge, constructive discharge, failure to hire or promote, failure to reinstate in or restore to a position, failure to provide notice of rights, restraint of rights, interference with or denial of rights, promissory estoppel, breach of contract, breach of implied covenant of good faith and fair dealing, fraud, retaliation,, defamation, violation of public policy, misrepresentation, deceit, intentional interference with advantageous or contractual

relations, intentional or negligent infliction of emotional distress, assault, battery, invasion of privacy, defamation, personal injury, negligence, or conspiracy, and (iv) any other action, claim or grievance against the RELEASEES, from the beginning of the world to the date of this Agreement.

Employee further acknowledges that Employee has received payment, salary, and wages in full for all services rendered in conjunction with Employee's employment with the Company through the date of this Agreement, including payment for all wages, bonuses, and accrued, unused paid time off, and that no other compensation is owed to Employee except as explicitly provided herein. Employee specifically understands that this general release of Claims includes, without limitation, a release of Claims for alleged wages due, overtime, or other compensation or payment, including any Claim for multiple damages, attorneys' fees, costs and expenses, or any Claim arising under Nevada and Massachusetts wage and hour laws, including without limitation, the Massachusetts Wage Act and State Overtime Law and the Massachusetts Pay Equity law, M.G.L. c. 149, §§ 148, 150 *et seq.* and M.G.L. c. 151, § 1A *et seq.*, *as amended*; or any other applicable laws governing the payment of wages or compensation, Claims relating to meal breaks, prevailing wage, deductions, reporting pay, unpaid wages, salary, commissions, bonuses, overtime, vacation pay, compensatory time, sick pay, holiday pay, severance pay, expense reimbursements, leaves, retaliation, multiple damages or attorneys' fees, costs and expenses, including, but not limited to any state, federal, or local law governing the payment of wages or compensation. Employee further acknowledges that Employee is unaware of any facts that would support a Claim against the Released Parties for violation of the Fair Labor Standards Act, Massachusetts Wage and Hour law, the Massachusetts Wage Act and Overtime Law, or any other applicable law governing the payment of wages or compensation.

This General Release of Claims does not apply to any claims concerning:

- (a) a breach of this Agreement;
- (b) any rights to benefits under applicable workers' compensation statutes or government-provided unemployment benefits;
- (c) any rights to vested benefits under the written terms of a qualified employee retirement plan (including but not limited to a 401(k) plan);
- (d) any matters that cannot be lawfully waived.

Employee acknowledges that they may hereafter discover facts different from or in addition to the facts now known or believed to be true as of the Effective Date (as defined below) of this Agreement. Employee agrees that, notwithstanding the discovery

of the existence of any such additional or different facts that, if known, may have materially affected her decision to enter into this Agreement, the releases given herein shall be and remain in effect as full, final, and complete releases of the Released Parties, individually and collectively, from the released Claims, and that Employee shall not be entitled to modify or set aside this Agreement, in whole or in part, by reason thereof.

Employee waives any right or ability to be a class or collective action representative or to otherwise participate in any putative or certified class, collective or multi-party action or proceeding based on such a claim in which the Company or any other Releasee identified in this Agreement is a party.

7. **RETURN OF COMPANY PROPERTY AND CONTINUED OBLIGATION TO KEEP COMPANY INFORMATION CONFIDENTIAL, COOPERATION OBLIGATIONS, AND DEFEND TRADE SECRETS ACT**

- a. Return of Company property. Employee agrees that they have returned to the Company (or shall return no later than the Separation Date) all keys, files, records (and copies thereof), equipment (including, but not limited to, computer hardware, software, and printers, wireless handheld devices, cellular phones, tablets, etc.), documents, text messages, electronic mail, communications relating to the Company, Board meeting minutes, committee meeting minutes, notes, materials and information related to the Company and any of its subsidiaries or affiliates, Company owned data, notes, proposals, technical bulletins, product manuals, database information, intellectual property, Company identification, and any other Company-owned property in your possession or control and have left intact all electronic Company documents, including but not limited to those that Employee developed or helped to develop during Employee's employment. Employee further confirms that they have canceled all accounts for their benefit, if any, in the Company's name, including but not limited to, credit cards, telephone charge cards, cellular phone, and/or computer accounts. Employee also agrees not to access or use any Company computer, database, computer network or system, voice mail system, electronic mail, device or media of any kind.

Employee acknowledges and reaffirms their obligation under Section 6 of the Employment Contract, and shall additionally agree to keep confidential and not to use or disclose any and all non-public information concerning the Company or any Released Party that Employee acquired during the course of employment with the Company, including, but not limited to, any non-public information concerning the Company's business affairs, investors, Board of Directors, any committee, product knowledge, potential products, clinical trials technology, know how, business prospects, vendors, suppliers, knowledge relating to any acquisition or potential

acquisition, financial condition, and any information that is defined as a Trade Secret under federal or Massachusetts law.

Employee further understands that in addition to the obligations in Section 6 of Employee's employment agreement, the Company has expended, and continues to expend, significant amounts of time, money, and effort to acquire, compile, develop, and maintain the secrecy of, information (whether or not fixed in tangible form, intangible form, electronically stored, or otherwise maintained) that provides the Company with an economic advantage and value, actual or potential, from not being generally known to, and not be readily ascertainable by proper means by, others who might obtain economic advantage or value from its acquisition, disclosure, or use (collectively, "Company Confidential Information").

Employee further understands that Company Confidential Information includes all forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, devices, formulas, designs, prototypes, methods, techniques, processes, procedures, business strategies, customer lists, customer data, programs, and codes, whether tangible or intangible, and regardless of how stored, compiled, or memorialized, whether physically, electronically, graphically, photographically, in writing, or otherwise. Further, Employee understands that Company Confidential Information may include, but is not limited to, trade secrets; marketing data, plans, methods, and strategies; business plans, methods, and strategies; cost structures; pricing structures, plans, and strategies; profit margins; financial information, projections, and forecasts; profit and loss information; contract terms; training materials; internal policies and practices; current and prospective customer lists; vendor lists; Company's current and prospective customer contact information, organizational structure(s), suppliers, vendors and their representatives responsible for considering, entering into, or managing agreements for services and/or products provided by Company or conducting clinical trials or other product development; customer leads or referrals; customer goals, preferences, needs, concerns, and requirements (including customer likes and dislikes) and the manner in which they have been, or plan to be, addressed by Company; customer billing procedures and payment practices; customer information regarding contract and relationship terms and conditions, pricing, price sensitivities, costs, profits, sales, buying patterns, markets, and discounts; plans for future business; purchasing techniques; and information contained in Company's databases.

To the extent not included in the foregoing paragraph, Company Confidential Information may also include, without limitation, production information; inventions; developments; discoveries; concepts; improvements; technical information; software

(source code and/or object code); algorithms; cost structure and other cost data; current and potential sales and sales strategies; management information; usernames and passwords for any networks, website, computer, storage device, hardware, software, or account provided to me by Company, established for Company, or that Employee uses/used primarily for the benefit of Company; and other information concerning the business, products, or services of Company or of any of its existing or prospective customers, consultants, advisors, suppliers, vendors, employees, investors, and anyone else with whom Company does business (collectively, "Business Partners"). Employee understands that Company Confidential Information also includes information that Company receives from its Business Partners or from other third parties to whom Company owes a duty of confidentiality.

Employee also recognizes and agrees that Company takes reasonable steps to identify Company Confidential Information, but that, even with the best of intentions, mistakes happen. Accordingly, Employee is aware that any information that could be considered Company Confidential Information should be treated as such, regardless of whether it is identified as Company Confidential Information, and Employee therefore agrees to treat all such information as though it had been designated as Company Confidential Information.

- b. Cooperation. Prior to and after the Separation Date, Employee will cooperate as reasonably necessary with the Company in (i) the defense or prosecution of any claims or actions now in existence or which may be brought in the future against or on behalf of the Company which relate to events or occurrences that transpired while you were employed by the Company, (ii) to assist the Company in transitioning Employee's duties, complying with all SEC/OSHA and all other regulatory requirements, transitioning Employee's signatory responsibilities, transitioning Employee's role as Transfer Agent, assisting with earnings calls, reports, and public filings (iii) the investigation, whether internal or external, of any matters about which the Company believes Employee may have knowledge or information. Employee's cooperation in connection with such claims, actions, or investigations will include, but not be limited to, being available to meet with counsel (at mutually convenient times) to answer questions or to prepare for discovery or trial and to act as a witness on behalf of the Company or to otherwise give testimony. During and after the Separation Date, Employee also will cooperate as reasonably necessary with the Company in connection with any investigation or review of any federal, state or local regulatory authority as any such investigation or review relates to events or occurrences that transpired while Employee was employed by the Company. The Company will reimburse Employee for any reasonable out-of-pocket expenses incurred in connection with performance of obligations pursuant to this Section,

based on the procedures and standards for reimbursement applicable to employee business expense reimbursement under the Company's policies.

- c. Defend Trade Secrets Act. Employee understands that pursuant to the Defend Trade Secrets Act an individual will not be held criminally or civilly liable under any federal or state trade secret law for the disclosure of a trade secret that (A) is made (i) in confidence to a federal, state, or local government official, either directly or indirectly, or to an attorney; and (ii) solely for the purpose of reporting or investigating a suspected violation of law; or (B) is made in a complaint or other document filed in a lawsuit or other proceeding, if such filing is made under seal. Further, Employee understands that in the event that disclosure of the Company's trade secrets was not done in good faith pursuant to the above, Employee will be subject to substantial damages, including punitive damages and attorney's fees.

8. **FORUM FOR BREACH AND FORFEITURE UPON BREACH**

The Parties hereby mutually agree to the exclusive jurisdiction of the state or federal courts within Massachusetts for any dispute arising hereunder, including but not limited to disputes with respect to any claim for injunctive relief under this Agreement. Accordingly, with respect to any such court action, Employee (a) submits to the personal jurisdiction of such courts; (b) consents to service of process by regular mail to his last known address; and (c) waives any other requirement (whether imposed by statute, rule of court, or otherwise) with respect to personal jurisdiction or service of process. If Employee commences a legal action or other proceeding against the Company outside of Massachusetts, Employee shall reimburse the other(s) for its reasonable attorneys' fees, costs and expenses if the Company prevails in staying, transferring, dismissing or otherwise defending such action or proceeding, regardless of whether such fees, costs and expenses are incurred in the forum where the action was commenced or in a Massachusetts forum. Furthermore, the prevailing party to any request to enforce Employee's obligations under this Agreement, and specifically this Section (including, but not limited to, pursuant to a temporary restraining order or preliminary injunction), shall be entitled to receive reasonable attorneys' fees, costs and expenses in addition to any other relief sought, available or awarded.

THE PARTIES IRREVOCABLY WAIVE, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, ANY RIGHT THEY MAY HAVE TO A TRIAL BY JURY IN ANY LEGAL PROCEEDING DIRECTLY OR INDIRECTLY ARISING OUT OF OR RELATING TO THIS AGREEMENT. EACH PARTY HERETO CERTIFIES THAT THIS WAIVER IS KNOWINGLY, WILLINGLY, AND VOLUNTARILY MADE.

The Parties hereby agree that any dispute between them relating to, or arising under, this Agreement (except as to injunctive relief) shall be adjudicated through expedited confidential arbitration in Suffolk County, Massachusetts, pursuant to the Employment Arbitration Rules and Procedures of the Judicial Arbitration and Mediation Services (JAMS). If either party initiates arbitration each party shall bear one half (1/2) of the costs of arbitration including, but not limited to, administrative fees, case management fees, expenses of the arbitrator and arbitrator compensation. The requirement that all such claims (except for injunctive relief) must proceed in confidential arbitration is an integral part of this Agreement.

With respect to any request for injunctive relief, the parties agree to file any such claims in Suffolk County, Massachusetts.

Upon proof and a finding at such arbitration of a material breach of any provision of this Agreement, the non-prevailing Party shall be liable for actual damages, as well as costs and expenses incurred by the prevailing Party, including attorneys' fees, costs and expenses relating to the arbitration and proof of the breach. Aside from a breach of the non-disparagement provision and/or indemnification provision, Employee understands that her sole remedy for monetary relief hereunder shall be limited to the balance of any Severance Payment not yet paid.

The existence and content of the arbitral proceedings and any rulings or award shall be kept confidential except (i) to the extent that disclosure may be required of a Party to fulfill a legal duty, or protect or pursue a legal right, including but not limited to any further proceeding to confirm or vacate the arbitration award under applicable law; (ii) with the written consent of all Parties; or (iii) any Party may disclose matters relating to the arbitration or the arbitral proceedings where necessary for the preparation or presentation of a claim or defense in such arbitration.

Any Party filing a petition to confirm the Arbitrator's award and/or to vacate the award shall file any documents containing Confidential Information under seal to the greatest extent permissible by law and, if necessary, shall seek to obtain a court order sealing any documents containing Confidential Information that are included in the court file in order to maintain confidentiality of Confidential Information, to the greatest extent permissible by law, with all Parties having stipulated to the factual and legal grounds for such sealing.

Nothing in this Section shall preclude or limit any Party from seeking and/or receiving equitable relief, including injunctive relief, for any breach or violation of this Agreement.

9. **NON-DISPARAGEMENT AND COMMUNICATION TO PROSPECTIVE EMPLOYERS OF EMPLOYEE**

A. Employee Obligations. To the extent permitted, by law, Employee acknowledges, represents, and agrees that as a condition of Employee's receipt of the Severance Payment and benefits in this Agreement, except as otherwise provided herein, Employee shall not hereafter make any false, disparaging, or derogatory statements about the Company or any of the other Released Parties, whether on social media, or otherwise.

Notwithstanding the foregoing, nothing in this Agreement shall prohibit Employee from (i) making truthful statements or disclosures that are: (i) required by applicable law, regulation, or legal process; (ii) about acts of sexual assault or workplace sexual harassment; the failure to prevent workplace sexual harassment; and retaliation against a person for reporting sexual harassment; or (iii) requesting or receiving confidential legal advice.

Employee agrees to direct all third-party inquiries from prospective employers of Employee to the Company's Human Resources Department, who will provide only Employee's dates of employment with the Company and last position held, consistent with Company policy. To the extent permitted by law, the Company agrees to instruct the officers and directors of the Company not to make any false, disparaging or derogatory statements about Employee.

B. Company Obligations. To the extent permitted, by law, and subject to all regulatory disclosures and requirements of the Company, the Company agrees that current officers and directors, so long as they are employed by the Company, will not make any false, disparaging, or derogatory statements about the Employee, whether on social media, or otherwise.

Notwithstanding the foregoing, nothing in this Agreement shall prohibit the Company's current officers or directors in any respect from (i) making truthful statements or disclosures that are: (i) required by applicable law, regulation, or legal process, or which are necessary for legitimate business purposes.

The prevailing party to any dispute relating to this Section 9 of the Agreement shall be entitled to its reasonable attorneys' fees and costs.

10. **COVENANT NOT TO SUE**

Employee represents and warrants that Employee has not filed any actions, complaints or charges against the Company or any of the other Released Parties, individually or collectively, nor does she have any intention of doing so. Employee shall not file any

actions, complaints or charges against the Company or any of the other Released Parties, individually or collectively, regarding any of the Claims released pursuant to this Agreement. Employee agrees that Employee shall not seek or accept damages of any nature, other equitable or legal remedies for Employee's own benefit, attorneys' fees, costs or expenses from the Company or any of the other Released Parties, individually or collectively, with respect to any Claims released by this Agreement. As a material inducement for the Company to enter into this Agreement, Employee represents that Employee has not assigned to any third party any Claim released by this Agreement. Employee understands that other than as outlined herein, any lawsuit, claim or other action that is filed (other than to enforce the terms of this Agreement) shall be a material breach of this Agreement.

Nothing in this Agreement is intended to or shall be construed to limit Employee's ability to file a charge or participate or cooperate in an investigation or proceeding with the United States Equal Employment Opportunity Commission or comparable state or local agencies investigating unlawful employment discrimination practices (collectively, "Anti-Discrimination Agencies"). The Anti-Discrimination Agencies have the authority to carry out their statutory duties by investigating a charge, issuing a determination, filing a lawsuit, or taking any other action authorized by law. Employee retains the right to participate in any such action, and retain the right to communicate with the Anti-Discrimination Agencies, and such communication shall not be limited by any provision in this Agreement. Nothing in this Agreement shall be construed to limit Employee's ability, without prior authorization from or notification to the Company, to engage in any activity or conduct protected by Section 7 or any other provision of the National Labor Relations Act, such as by way of examples, from filing an unfair labor practice charge, assisting other employees in doing so, assisting in the investigative process of the National Labor Relations Board, and discussing terms and conditions of employment with others; to report possible violations of federal, state, or local law or regulation to any government agency or entity, including but not limited, to the extent applicable, to the Occupational Safety and Health Administration, the Security and Exchange Commission, the Department of Justice, the Congress, and/or any agency Inspector General, or make other disclosures that are protected under the whistleblower provisions of federal, state, or local law or regulation; or to communicate directly with, respond to any inquiry from, or provide testimony before any federal, state, or local regulatory authority, regarding this Agreement or its underlying facts or circumstances. Employee also understands and acknowledge that, by signing this Agreement, she has completely waived her right to receive any individual relief, including monetary damages, in connection with any such claim, charge, complaint, investigation, or proceeding covered by this Section 10 (including without limitation those filed with an Anti-Discrimination Agency), and if Employee is awarded individual relief and/or monetary damages, Employee hereby unconditionally assigns to the Company, and agrees to undertake any and all measures

necessary to effectuate such assignment of, any right or interest Employee may have to receive such individual relief and/or monetary damages. Notwithstanding the foregoing, this Agreement does not limit Employee's right to receive an award for information provided to OSHA, the SEC or to any other government agency where such a waiver is prohibited.

11. **INDEMNIFICATION**

Provided that Employee complies with all covenants in this Agreement including, but not limited to, her duty of cooperation outlined herein (all of which are material), and that Employee has (and will) at all times act(ed) in good faith and consistent with her fiduciary duties and duty of loyalty to the Company, as well as lawfully, in a manner reasonably believed to be in or not opposed to the best interests of the Company, and that Employee has not been adjudged to be liable in any respect to the Company, then the Company shall indemnify Employee for any judgments, awards, penalties, settlements and fines resulting from any suit or legal action (whether civil, criminal, administrative) where such suit or legal action names Employee as a party and alleges claims that occurred during the scope of Employee's employment and Employee was acting within the scope of her duties as Chief Executive Officer of the Company. In such case that indemnification applies, Employee agrees to tender her defense to the Company (or its insurer) and Company (or its insurer) shall select counsel of its choice to represent Employee (which may be the same counsel that represents Company in any lawsuit or other legal action. As a condition precedent hereto, Employee shall immediately notify Company in writing of any suit for which Employee believes they are entitled to indemnification.

12. **NON-SOLICITATION AND NONCOMPETITION OBLIGATIONS OF EMPLOYEE**

Employee recognizes that based upon their position at the Company, Employee developed many relationships with employees, vendors, suppliers and other third parties, and Employee has had access to highly proprietary and confidential information. Accordingly, the Company has a legitimate business interest in maintaining these relationships and in preventing Employee from soliciting or otherwise interfering with these relationships, and competing against the Company. Thus, for a period of One (1) year from the date this Agreement becomes effective, Employee agrees not to, directly or indirectly:

- a. solicit, encourage to leave, persuade or attempt to persuade, hire or assist in hiring, refer to any recruiting person or entity, or otherwise cause or induce in any manner any officer, director, vendor, supplier or employee of the Company to terminate or alter their employment or other relationship with the Company; or

- b. solicit, advise, recommend, interfere with or take any other action intended to or which has the effect of causing any vendor, supplier, or customer of the Company or other third party with whom the Company has a relationship, to terminate, alter or reduce an existing or prospective business or commercial relationship with the Company.
- c. in any capacity (whether on Employee's own behalf, or as a principal, director, officer, employee, consultant, independent contractor, agent, stockholder, member, partner, trustee, joint venture, lender or other investor, or through the agency of any corporation, limited liability company, partnership, association, or agent, or otherwise), engage in or perform:
 - i. any job, position, function, role, or activity that (a) is the same as or similar to that which Employee performed for the Company and (b) involves products, services, or a line of business that is competitive with or that substitutes for or eliminates the need for the products, services, or line of business of the Company in which Employee was involved at any time; or
 - ii. any other job, position, function, role, or activity that would likely or inevitably, even if unintentionally, require or result in the use or disclosure of Company's Confidential Information, trade secrets (as defined in this Agreement or pursuant to any applicable statute, or the use of Company's customer goodwill.

(EMPLOYEE TO INITIAL BELOW)

EM I understand and agree that the restrictions set forth in this section are independent covenants. I further understand that if I breach my fiduciary duties or unlawfully take, physically or electronically, property belonging to the Company, the Noncompete Period shall be extended to two (2) years. Additionally, with respect to any non-solicitation restrictions, my breach will toll the restrictions from the date of the breach.

EM I understand that this Agreement, including in particular the restrictive covenants in this section, may seriously limit my future flexibility in many ways, including limiting possible job opportunities that I could otherwise accept during the applicable restrictive periods, even though such opportunities may be highly attractive to me or provide greater compensation than any other available opportunities.

13. **ATTORNEY/TAX CONSULTANT ADVICE**

Employee acknowledges that this Agreement is legally binding between Employee and the Company. Employee is hereby advised to review this Agreement carefully, and affirms that she has consulted with (or had an opportunity to consult with) an attorney (and tax consultants) of Employee's choosing before executing this Agreement.

14. **SEVERABILITY**

In the event that any provision or portion of this Agreement shall be determined to be invalid or unenforceable for any reason, such provision or portion shall be enforced to the maximum extent permitted under the law and the remaining provisions or portions of this Agreement shall be unaffected thereby and shall remain in full force and effect to the fullest extent permitted by law; provided, however, that (a) if any court, tribunal or arbitrator were to find that the waiver or release of claims provision in this Agreement is unlawful or unenforceable, or was not entered into knowingly and voluntarily, Employee agrees to execute a new waiver and general release that is lawful and enforceable, and which is consistent with the scope and intent of the waiver and release contained in this Agreement, and (b) if any court, tribunal or arbitrator were to find that the confidentiality and/or arbitration provisions in this Agreement are unlawful or unenforceable, or were not entered into knowingly and voluntarily by Employee, Employee agrees to execute a new confidentiality and/or arbitration covenant that is lawful and enforceable and which is consistent with the scope and intent of the confidentiality and arbitration provisions in this Agreement.

15. **ASSIGNMENT**

Employee may not assign, novate, sub-license, transfer, or otherwise dispose of (collectively, "Transfer") any of Employee's rights or obligations created under this Agreement without the prior written consent of the Company. Any attempted Transfer in violation of this Section 13 shall be null and void ab initio, and this Agreement shall continue to bind only the Parties set forth in this Agreement.

This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and assigns, including (as to the Company only) corporations with which, or into which, the Company may be merged or which may succeed to its respective assets or business.

16. **REPRESENTATION REGARDING MEDICARE**

Employee represents that Employee is not enrolled in the Medicare program, was not enrolled in the Medicare program at any time through the date of this Agreement, and has not received Medicare benefits for medical services or items related to, arising from, or in connection with his employment and/or any of the Claims. Employee represents and warrants that the information provided to the Company regarding Employee's Medicare status, if any, including Employee's name, gender, date of birth, and Social Security Number, is complete, accurate, and current as of the date of this Agreement. Employee represents and warrants that Employee has not received any medical services or items related to, arising from, or in connection with the Claims. Employee represents and

warrants that no Medicaid payments have been made to or on behalf of Employee and that no liens, claims, demands, subrogated interests, or causes of action of any nature or character exist or have been asserted arising from or related to any Claims. Employee further agrees that Employee, and not the Released Parties, individually or collectively, shall be responsible for satisfying all such liens, claims, demands, subrogated interests, or causes of action that may exist or have been asserted or that may in the future exist or be asserted.

To the extent that Employee's representations and warranties related to Employee's Medicare status and receipt of medical services and items related to the Claims are inaccurate, not current, or misleading, Employee agrees to indemnify and hold harmless Released Parties, individually or collectively, from any and all claims, demands, liens, subrogated interests, and causes of action of any nature or character that have been or may in the future be asserted by Medicare and/or persons or entities acting on behalf of Medicare, or any other person or entity, arising from or related to this Agreement, the Severance Payment, any Conditional Payments made by Medicare, or any medical expenses or payments arising from or related to the Claims that is subject to this Agreement or the release set forth herein, including but not limited to: (a) all claims and demands for reimbursement of Conditional Payments or for damages or double damages based upon any failure to reimburse Medicare for Conditional Payments; (b) all claims and demands for penalties based upon any failure to report, late reporting, or other noncompliance with or violation of Section 111 of MMSEA that is based in whole or in part upon late, inaccurate, or inadequate information provided to the Released Parties by Employee or Employee's Counsel or upon any failure of Employee or Employee's Counsel to provide information; and (c) all Medicaid liens. This indemnification obligation includes all damages, double damages, fines, penalties, attorneys' fees, costs, interest, expenses, and judgments incurred by or on behalf of the Released Parties in connection with such claims, demands, subrogated interests, or causes of action.

17. **SECTION HEADINGS**

The section headings contained in this Agreement are for reference purposes only and shall not affect the meaning or interpretation of this Agreement.

18. **WAIVER**

The failure, delay or omission by any Party to enforce any of the provisions of this Agreement will in no way be construed as a waiver of such provisions and will not affect the right of such Party thereafter to enforce each and every provision of this Agreement in accordance with its terms. No waiver of any provision of this Agreement, or breach thereof, shall be deemed a waiver of any other provision or breach of this Agreement. If any Party provides a waiver or consent on one particular occasion, it is effective only as

to that occasion and does not affect other occasions. No terms or provision of this Agreement may be waived or consented to by the Parties unless such waiver is in writing.

19. **GOVERNING LAW**

This Agreement is governed by the laws of the Commonwealth of Massachusetts. The rights and obligations of the parties hereto shall be construed and enforced in accordance with and governed by the laws of the Commonwealth of Massachusetts without regard to conflict of laws provisions.

20. **ENTIRE AGREEMENT**

This Agreement constitutes the entire Agreement between the Parties with respect to the subject matter hereof and supersedes all prior and contemporaneous oral and written agreements and discussions, provided, however, that Employee shall remain bound by Section 6 of her Employment Contract signed by her and Hermann Luebbert on April 1, 2022, as well as any other agreements related to confidentiality, ownership of intellectual property.

21. **TIME FOR CONSIDERATION AND "EFFECTIVE DATE"**

Employee understands and agrees that by entering into this Agreement, Employee is waiving any and all rights or claims Employee may have against the Company and all of the Released Parties, individually or collectively, as set forth herein, and that Employee has received consideration beyond that to which Employee was previously entitled. The waiver of rights and claims does not extend to any rights or claims arising from actions or inactions occurring after the date Employee executes this Agreement. In executing this Agreement, Employee is not relying upon and has not relied upon any representation or statement not set forth herein made by the Company and/or any of the other Released Parties with regard to the subject matter, basis, or effect of this Agreement or otherwise.

Because of the noncompetition restriction, Employee has Seven (7) business days from the date of execution to rescind acceptance of this Agreement. If Employee is paid any monies after May 26, 2023 and then rescinds acceptance of this Agreement, Employee agrees to return the gross amounts of any monies paid to her.

This Agreement becomes enforceable on the 8th business day after the Employee signs the Agreement and does not rescind acceptance (the "Effective Date"). Employee acknowledges that Employee is entering into this Agreement voluntarily and without coercion and that Employee has had the opportunity to and has adequately reviewed the information contained herein.

22. **NOTICES**

All notices, demands, requests or other communications that any Party may desire or be required to give hereunder must be in writing and must be given (a) by hand delivery, or (b) by a recognized overnight courier service providing confirmation of delivery, to the addresses set forth below or at such other address that a Party may specify by notice given to the other Party in accordance with this Section. A notice sent by overnight courier shall be deemed given upon confirmation of delivery.

As to the Company:

Todd J. Bennett, Esq.
Bennett and Belfort, P.C.
24 Thorndike Street, Suite 300
Cambridge, Massachusetts 02141

As to Employee:

Steven Nelson, Esq.
Shea, Dangora & Nelson
566 Boston Road
Billerica, Massachusetts 01821

23. **COUNTERPARTS**

This Agreement may be executed in any number of counterparts, each of which shall be deemed to be an original, but all of which together shall constitute but one and the same instrument. Digital and electronic signatures shall be treated as valid, original signatures.

24. **KNOWING AND VOLUNTARY WAIVER**

The Parties agree that they have carefully read this Agreement and fully understand its meaning and that if he or it signs this Agreement he or it will be waiving all claims as described herein, and that he or it has received consideration in exchange for entering into this Agreement. No Party was coerced into signing this Agreement, and all Parties enter into this Agreement, and agree to all its terms and significance, knowingly and voluntarily, without duress or reservation of any kind, and after having given the matter full and careful consideration. The Parties are hereby advised in writing to consult with an attorney about this Agreement before signing it and have had the opportunity to do so.

25. **MISCELLANEOUS**

This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their administrators, executors, heirs, predecessors, successors, assigns, subsidiaries and affiliates. This Agreement may not be supplemented, changed or modified in any manner, orally or otherwise, except by an instrument in writing of concurrent or subsequent date signed by a duly authorized representative of each of the Parties hereto. This Agreement shall take effect as a sealed instrument.

Employee acknowledges that payment of the Severance Payment and any other benefits provided hereunder is strictly contingent upon Employee's strict compliance with all covenants herein, all of which are material, and failure to comply may result in either or both a delay in payment or complete forfeiture of any Severance Payments or other benefits granted pursuant to this Agreement.

To the extent any provision herein is found to be illegal, this shall affect the efficacy of the remainder of the Agreement.

EMPLOYEE ACKNOWLEDGES THAT EMPLOYEE HAS READ AND FULLY UNDERSTANDS THIS AGREEMENT AND IS VOLUNTARILY ENTERING INTO THIS AGREEMENT. EMPLOYEE FURTHER ACKNOWLEDGES THAT EMPLOYEE HAS BEEN ADVISED AND HAS BEEN GIVEN ADEQUATE TIME AND OPPORTUNITY TO SEEK OUTSIDE COUNSEL OF EMPLOYEE'S CHOOSING TO REVIEW THIS AGREEMENT AND TO ADVISE EMPLOYEE

READ THIS AGREEMENT CAREFULLY. IT IS A LEGALLY BINDING AGREEMENT THAT INCLUDES A WAIVER AND RELEASE OF LEGAL RIGHTS. ALL PARTIES HERETO HAVE FULL AUTHORITY TO EXECUTE THIS AGREEMENT

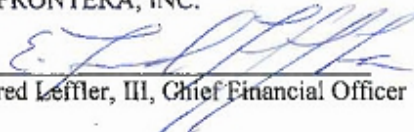
SIGNED AS A SEALED INSTRUMENT BY THE PARTIES BELOW.



Erica Monaco

DATED: May 24, 2023

BIOFRONTERA, INC.

By: 

E. Fred Leffler, III, Chief Financial Officer

DATED: May 25, 2023

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: August 11, 2023

By: */s/ Hermann Luebbert*

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

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: August 11, 2023

By: /s/ E. Fred Leffler III

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

Certification*

In connection with the Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended June 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: August 11, 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.

Certification*

In connection with the Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended June 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: August 11, 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.
