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 March 31, 2022

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	**47-3765675**
(State or other jurisdiction of incorporation or organization)	**(IRS Employer Identification No.)**
120 Presential Way, Suite 330, Woburn, Massachusetts	**01801**
(Address of principal executive offices)	**(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
Warrants, each warrant exercisable for one share of common stock, each at an exercise price of $5.00 per share	BFRIW	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

As of May 12, 2022, there were 17,104,749, 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.
BALANCE SHEETS
(*In thousands, except par value and share amounts*)

	March 31, 2022 (Unaudited)	December 31, 2021
ASSETS		
Current assets:		
Cash and cash equivalents	$ 22,428	$ 24,545
Accounts receivable, net	5,172	3,784
Other receivables, related party	8,686	8,647
Inventories	4,872	4,458
Prepaid expenses and other current assets	1,373	4,987
Total current assets	**42,531**	**46,421**
Other receivables long term, related party	2,813	2,813
Property and equipment, net	245	267
Intangible asset, net	3,345	3,450
Other assets	268	268
Total assets	**$ 49,202**	**$ 53,219**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 302	$ 658
Accounts payable, related parties	269	282
Acquisition contract liabilities, net	3,242	3,242
Accrued expenses and other current liabilities	8,546	9,654
Total current liabilities	**12,359**	**13,836**
Long-term liabilities:		
Acquisition contract liabilities, net	9,632	9,542
Warrant liability	4,143	12,854
Other liabilities	5,652	5,649
Total liabilities	**$ 31,786**	**$ 41,881**
Commitments and contingencies (see Note 23)		
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, zero shares issued and outstanding as of March 31, 2022 and December 31, 2021	$ -	$ -
Common Stock, $0.001 par value, 300,000,000 shares authorized; 17,104,749 shares issued and outstanding as of March 31, 2022 and December 31, 2021	17	17
Additional paid-in capital	90,717	90,200
Accumulated deficit	(73,318)	(78,879)
Total stockholders' equity	**17,416**	**11,338**
Total liabilities and stockholders' equity	**$ 49,202**	**$ 53,219**

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

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

	Three Months Ended March 31,	
	2022	**2021**
Products revenues, net	$ 9,736	$ 4,731
Revenues, related party	15	13
Total revenues, net	**9,751**	**4,744**
Operating expenses		
Cost of revenues, related party	4,975	2,408
Cost of revenues, other	175	163
Selling, general and administrative	7,616	4,758
Selling, general and administrative, related party	95	164
Restructuring costs	-	281
Change in fair value of contingent consideration	-	498
Total operating expenses	**12,861**	**8,272**
Loss from operations	**(3,110)**	**(3,528)**
Other income (expense)		
Change in fair value of warrant liabilities	8,711	-
Interest expense, net	(33)	(84)
Other income, net	23	79
Total other income (expense)	**8,701**	**(5)**
Income (loss) before income taxes	**5,591**	**(3,533)**
Income tax expense	30	1
Net income (loss)	**$ 5,561**	**$ (3,534)**
Income (loss) per common share:		
Basic	$ 0.33	$ (0.44)
Diluted	$ 0.32	$ (0.44)
Weighted-average common shares outstanding:		
Basic	17,104,749	8,000,000
Diluted	17,133,218	8,000,000

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

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

Three Months Ended March 31, 2022 and 2021

	Common Stock		Additional Paid-In Capital	Accumulated Deficit	Total
	Shares	Amount			
Balance, January 1, 2021	8,000,000	$ 8	$ 46,986	$ (41,166)	$ 5,828
Net loss	-	-	-	(3,534)	(3,534)
Balance, March 31, 2021	8,000,000	$ 8	$ 46,986	$ (44,700)	$ 2,294
Balance, January 1, 2022	17,104,749	$ 17	$ 90,200	$ (78,879)	$ 11,338
Stock-based compensation	-	-	517	-	517
Net income	-	-	-	5,561	5,561
Balance, March 31, 2022	17,104,749	$ 17	$ 90,717	$ (73,318)	$ 17,416

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

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

	Three Months Ended March 31,	
	2022	**2021**
Cash Flows From Operating Activities:		
Net income (loss)	$ 5,561	$ (3,534)
Adjustments to reconcile net income (loss) to cash flows used in operations		
Depreciation	26	33
Amortization of acquired intangible assets	105	105
Change in fair value of contingent consideration	-	498
Change in fair value of warrant liabilities	(8,711)	-
Stock-based compensation	517	-
Provision for inventory obsolescence	-	35
Provision for (recovery of) doubtful accounts	42	-
Non-cash interest expense	89	89
Changes in operating assets and liabilities:		
Accounts receivable	(1,430)	1,509
Other receivables, related party	(38)	-
Prepaid expenses and other assets	3,614	(83)
Inventories	(414)	(1,366)
Accounts payable and related party payables	(366)	(922)
Accrued expenses and other liabilities	(1,107)	193
Cash flows used in operating activities	**(2,112)**	**(3,443)**
Cash flows from investing activities		
Purchases of property and equipment	(5)	-
Cash flows used in investing activities	**(5)**	**-**
Net decrease in cash and cash equivalents	**(2,117)**	**(3,443)**
Cash, cash equivalents and restricted cash, at the beginning of the period	**24,742**	**8,277**
Cash, cash equivalents and restricted cash, at the end of the period	**$ 22,625**	**$ 4,834**
Supplemental disclosure of cash flow information		
Interest paid	$ 4	$ -
Income tax paid, net	$ 30	$ 1
Supplemental non-cash investing and financing activities		
Deferred offering costs included in accrued expenses and other liabilities	$ -	$ 312

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

Biofrontera Inc.
Notes to Financial Statements
(Unaudited)

1. Business Overview

We are a U.S.-based biopharmaceutical company specializing in the commercialization of pharmaceutical products for the treatment of dermatological conditions, in particular, diseases caused primarily by exposure to sunlight that results in sun damage to the skin. Our principal licensed products focus on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer. We also market a licensed topical antibiotic for treatment of impetigo, a bacterial skin infection.

Our principal product is Ameluz®, which is a prescription drug approved for use in combination with our licensor's FDA-approved medical device, the BF-RhodoLED® lamp series, for photodynamic therapy ("PDT") (when used together, "Ameluz® PDT") in the U.S. for the lesion-directed and field-directed treatment of actinic keratosis 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"), by and among us and Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH (collectively, the ("Ameluz Licensor") originally dated as of October 1, 2016, and as subsequently amended on October 8, 2021. Refer to *Note 16, Related Party Transactions*, for further details.

Our second prescription drug 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 due to staphylococcus aureus or streptococcus pyogenes. The approved indication is impetigo, a common skin infection. It is approved for use in adults and children 2 months and older. We are currently selling Xepi® for this indication in the U.S. under an exclusive license and supply agreement ("Xepi LSA") with Ferrer Internacional S.A. ("Ferrer") that was acquired by Biofrontera Inc. on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. Refer to *Note 16, Related Party Transactions*, for further details.

Liquidity and Going Concern

The Company's primary sources of liquidity are its existing cash balances and cash flows from equity financing transactions received in 2021. As of March 31, 2022, we had cash and cash equivalents of $22.4 million, compared to $24.5 million as of December 31, 2021.

Since we commenced operations in 2015, we have generated significant losses. For the three months ended March 31, 2022 and 2021, we incurred losses from operations of $3.1 million and $3.5 million, respectively. We incurred net cash outflows from operations of $2.1 million and $3.4 million, for the same periods, respectively. We had an accumulated deficit as of March 31, 2022 of $73.3 million.

The Company's short-term material cash requirements include working capital needs and satisfaction of contractual commitments including auto leases (see *Note 23, Commitments and Contingencies*), Maruho start-up payments of $7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG, a significant shareholder and our former parent company, of $5.6 million (see *Note 13. Accrued Expenses and Other Current Liabilities*). Long-term material cash requirements include potential milestone payments to Ferrer Internacional S.A (see *Note 23. Commitments and Contingencies*) and contingent consideration payments to Maruho (see *Note 3. Acquisition Contract Liabilities).*

Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing efforts as we seek to expand the commercialization of Ameluz® and Xepi® 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 significant costs to continue to comply with corporate governance, internal controls and similar requirements applicable to us as a public company in the U.S. We expect capital expenditures to increase in 2022 to support the increase in our business needs including an ERP system.

These factors raise doubt about our ability to continue as a going concern, which we have determined are mitigated by the following plans. Based on current operating plans and financial forecasts, we expect that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months from the date of issuance of our financial statements. However, we expect to have to obtain either equity or debt financing to support our future long-term growth and to mitigate the risk of our operating costs significantly exceeding the amounts currently estimated. If our current operating plans or financial forecasts change, or we are unable to obtain additional financing, we may need to reduce the discretionary spend on promotional expenses, branding, marketing consulting and defer some hiring. While we expect to continue being flexible in our spending over the next twelve months, we do not consider there to be a need to significantly revise our operations currently.

2. Summary of Significant Accounting Policies

Basis for Preparation of the Financial Statements

The accompanying unaudited interim 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 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 March 31, 2022, the Company's operating results for the three months ended March 31, 2022 and 2021, and the Company's cash flows for the three months ended March 31, 2022 and 2021. The accompanying financial information as of December 31, 2021 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, 2021, filed with the SEC on April 11, 2022.

All amounts shown in these financial statements and accompanying notes are in thousands, 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, 2021, included in the Company's Annual Report on Form 10-K. There have been no significant changes to these policies during the three months ended March 31, 2022.

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, valuation 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 Issued Accounting Pronouncements

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, which requires organizations that lease assets to recognize on the balance sheet the assets and liabilities for the rights and obligations created by those leases. The new guidance requires that a lessee recognize assets and liabilities for leases with lease terms of more than twelve months and recognition, presentation and measurement in the financial statements will depend on the lease classification as a finance or operating lease. In addition, the new guidance will require disclosures to help investors and other financial statement users better understand the amount, timing and uncertainty of cash flows arising from leases. The JOBS ACT provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows us to delay the adoption of this new standard until it would otherwise apply to private companies. The new standard will be effective for us for fiscal years beginning after December 15, 2021, and interim periods within fiscal years beginning after December 15, 2022. The Company is currently evaluating the impact of adopting this guidance.

In June 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 will be effective for us on January 1, 2023. The Company is currently evaluating the impact of adopting this guidance.

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.

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 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)	March 31, 2022	December 31, 2021
Short-term acquisition contract liabilities:		
Contingent consideration	$ -	$ -
Start-up cost financing	3,600	3,600
Contract asset	(358)	(358)
Acquisition contract liabilities, net	$ 3,242	$ 3,242
Long-term acquisition contract liabilities:		
Contingent consideration	$ 6,200	$ 6,200
Start-up cost financing	3,700	3,700
Contract asset	(268)	(358)
	$ 9,632	$ 9,542
Total acquisition contract liabilities:		
Contingent consideration	$ 6,200	$ 6,200
Start-up cost financing	7,300	7,300
Contract asset	(626)	(716)
	$ 12,874	$ 12,784

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 March 31, 2022 and December 31, 2021 and indicates the fair value hierarchy of the valuation inputs the Company utilized to determine such fair value:

(in thousands)	Level	March 31, 2022	December 31, 2021
Liabilities:			
Contingent Consideration	3	$ 6,200	$ 6,200
Warrant liability- Purchase warrant	3	$ 4,143	$ 12,854

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 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, 2020	**$**	**7,602**
Change in fair value of contingent consideration		498
Balance at March 31, 2021	**$**	**8,100**
Balance at December 31, 2021	**$**	**6,200**
Change in fair value of contingent consideration		-
Balance at March 31, 2022	**$**	**6,200**

Warrant Liability

Warrants issued in conjunction with the private placement to an institutional shareholder which closed on December 2, 2021 were accounted for as liabilities in accordance with ASC 815-40. Pre-funded common stock purchase warrants to purchase up to 1,507,143 shares of our common stock at a nominal exercise price (the "Pre-funded Warrants") were exercised in 2021 and the common stock purchase warrants to purchase up to 2,857,143 shares of our common stock at an exercise price of $5.25 per share (the Purchase Warrants") are presented within warrant liability in the accompanying balance sheets. The warrant liability is measured at fair value at inception and on a recurring basis, with changes in fair value presented within the statements of operations.

The Company utilizes a Black-Scholes option pricing model to estimate the fair value of the Purchase 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 liability which could also result in material non-cash gain or loss being reported in our statements of operations.

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

(in thousands)		
Fair value at December 31, 2021	$	12,854
Change in fair value of warrant liability		(8,711)
Fair value at March 31, 2022	$	4,143

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®.

We generated $9.6 million of Ameluz® revenue, $0.1 million Xepi® revenue, and $0.1 million of BF-RhodoLED® lamps revenue during the three months ended March 31, 2022. We generated $4.5 million of Ameluz® revenue, minimal Xepi® revenue, and $0.2 million of BF-RhodoLED® lamps revenue during the three months ended March 31, 2021.

Related party revenue relates to an agreement with Biofrontera Bioscience GmbH ("Bioscience") for BF-RhodoLED® leasing and installation service. Refer to *Note 16, 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, 2020	**$ 217**	**$ 52**	**$ 15**	**$ 43**	**$ 327**
Provision related to current period sales	1	87	3	23	114
Credit or payments made during the period	(120)	(88)	(2)	(25)	(235)
Balance at March 31, 2021	**$ 98**	**$ 51**	**$ 16**	**$ 41**	**$ 206**
Balance at December 31, 2021	**$ 43**	**$ 101**	**$ 48**	**$ 54**	**$ 246**
Provision related to current period sales	**3**	165	5	45	218
Credit or payments made during the period	**(5)**	(150)	(17)	(52)	(224)
Balance at March 31, 2022	**$ 41**	**$ 116**	**$ 36**	**$ 47**	**$ 240**

6. Accounts Receivable, net

Accounts receivable are mainly attributable to the sale of Ameluz®, the BF-RhodoLED® and Xepi®. It is expected that all trade receivables will be settled within twelve months of the balance sheet date.

The allowance for doubtful accounts was $60,000 and $18,000 as of March 31, 2022 and December 31, 2021, respectively.

7. Other Receivables, Related Party

The Company has recorded a receivable of $11.3 million due from Biofrontera AG for its 50% share of a legal settlement for which both parties are jointly and severally liable for the total settlement amount of $22.5 million. The Company has a contractual right to repayment of its share of the settlement payment from Biofrontera AG under the Settlement Allocation Agreement entered into on December 9, 2021 and amended on March 31, 2022, which provided that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share. Of the total receivable $8.4 million is short-term and $2.8 million is long-term. As of May 11, Biofrontera AG has not paid the first reimbursement amount to the Company. We determined that the potential of Biofrontera AG to default on its obligation was less than probable. This is supported by the March 31, 2022 Amended Settlement Allocation Agreement between the Company and Biofrontera AG. The Amended Allocation Agreement 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 has been recorded as of March 31, 2022 or December 31, 2021.

The remaining $0.2 million of other receivables, related party pertains to service agreements and chargebacks. See *Note 16- Related Party Transactions*.

8. Inventories

Inventories are comprised of Ameluz®, Xepi® and the BF-RhodoLED® finished products.

In assessing the consumption of inventories, the sequence of consumption is assumed to be based on the first-in-first-out (FIFO) method. There was no provision for obsolescence recorded for the three months ended March 31, 2022. We recorded a provision of $35,000 for Xepi® inventory obsolescence, for the three months ended March 31, 2021.

9. Prepaid Expenses and Other Current Assets

Prepaid expenses and other current assets consist of the following:

(in thousands)	March 31, 2022	December 31, 2021
Receivable for common stock warrants proceeds	$ -	$ 3,258
Prepaid expenses	723	$ 824
Security deposits	128	149
Other	522	756
Total	$ 1,373	$ 4,987

10. Property and Equipment, Net

Property and equipment, net consists of the following:

(in thousands)	March 31, 2022	December 31, 2021
Computer equipment	$ 87	$ 85
Computer software	27	27
Furniture & fixtures	81	81
Leasehold improvement	368	368
Machinery & equipment	114	112
Property and equipment, gross	677	673
Less: Accumulated depreciation	(432)	(406)
Property and equipment, net	$ 245	$ 267

Depreciation expense was $26,000 and $33,000, for the three months ended March 31, 2022, and 2021, respectively, which was included in selling, general and administrative expense on the statements of operations.

11. Intangible Asset, Net

Intangible asset, net consists of the following:

(in thousands)	March 31, 2022	December 31, 2021
Xepi® license	$ 4,600	$ 4,600
Less: Accumulated amortization	(1,255)	(1,150)
Intangible asset, net	$ 3,345	$ 3,450

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 March 31, 2022 and 2021 was $0.1 million.

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. The Company did not recognize any impairment charges during the three months ended March 31, 2022 or March 31, 2021.

12. Statement of Cash Flows Reconciliation

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

(in thousands)	March 31, 2022	December 31, 2021
Cash and cash equivalents	$ 22,428	$ 24,545
Short-term restricted cash	47	47
Long-term restricted cash	150	150
Total cash, cash equivalent, and restricted cash shown on the statements of cash flows	$ 22,625	$ 24,742

13. Accrued Expenses and Other Current Liabilities

Accrued expenses and other current liabilities consist of the following:

(in thousands)	March 31, 2022	December 31, 2021
Legal settlement (See note 23)	$ 5,625	$ 5,625
Employee compensation and benefits	1,440	2,384
Professional fees	514	570
Product revenue allowances and reserves	240	246
Other	727	829
Total	$ 8,546	$ 9,654

14. Other Long-Term Liabilities

Other long-term liabilities consist of the following:

(in thousands)	March 31, 2022	December 31, 2021
Legal settlement – noncurrent (See note 23)	$ 5,625	$ 5,625
Other	27	24
Total	$ 5,652	$ 5,649

15. 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 for the three-month periods ended March 31, 2022 and 2021. Income tax expense incurred for the three months ended March 31, 2022 and 2021 relates to state income taxes. At March 31, 2022 and December 31, 2021, the Company had no unrecognized tax benefits.

The Company continues to be in a cumulative loss position and as such, is maintaining a full valuation allowance.

Interest and penalty charges, if any, related to unrecognized tax benefits would be classified as income tax expense in the accompanying statements of operations. As of March 31, 2022, and December 31, 2021, the Company has no accrued interest related to uncertain tax positions. Since the Company is in a loss carryforward position, it is generally subject to examination by the U.S. federal, state, and local income tax authorities for all tax years in which a loss carryforward is available.

16. Related Party Transactions

License and Supply Agreement

On October 1, 2016, the Company executed an exclusive license and supply agreement with Biofrontera Pharma GmbH ("Pharma"), which was amended in July 2019 to increase the Ameluz® transfer price per unit from 35.0% to 50.0% of the anticipated net selling price per unit as defined in the agreement. It was further amended on October 8, 2021 so that the price we pay per unit will be based upon our sales history, although the minimum number of units to purchase per year remains unchanged. As a result of this amendment, the purchase price we pay Biofrontera Pharma for Ameluz® will range from 30% to 50% of the anticipated net price per unit based on our level of annual revenue. Refer to *Item I. Business - Commercial Partners and Agreements* in our Annual Report on Form 10-K for the year ended December 31, 2021 for further details. Under the agreement, the Company obtained an exclusive, non-transferable license to use the 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 months ended March 31, 2022 and 2021 were $5.2 million and $3.0 million, respectively, and recorded in inventories in the balance sheets, and, when sold, in cost of revenues, related party in the statements of operations. Amounts due and payable to Pharma as of March 31, 2022 and December 31, 2021 were $0.3 million and $0.3 million, respectively, which were recorded in accounts payable, related parties in the 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. If we deem that the Biofrontera Group should continue to provide these services, we will execute a statement of work under the Services Agreement with respect to such services. 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. Expenses related to the service agreement were $0.1 million and $0.2 million for the three months ended March 31, 2022 and 2021, respectively which were recorded in selling, general and administrative, related party. There were no amounts due to Biofrontera AG related to the service agreement as of March 31, 2022. Amounts due to Biofrontera AG related to the service agreement were $0.2 million as of December 31, 2021 which were recorded in accounts payable, related parties in the balance sheets.

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 approximately $15,000 and $13,000 for the three months ended March 31, 2022 and 2021, respectively and recorded as revenues, related party. Amounts due from Bioscience for clinical lamp and other reimbursements were approximately $99,000 and $92,000 as of March 31, 2022 and December 31, 2021, respectively, which were recorded as other receivables, related party in the balance sheets.

Reimbursements from Maruho Related to Cutanea Acquisition

Pursuant to the Cutanea acquisition share purchase agreement, we received start-up cost financing and reimbursements for certain costs. These restructuring costs Maruho agreed to pay are referred to as "SPA costs" under the arrangement and are to be accounted for as other income. Refer to *Note 3, Acquisition Contract Liabilities*.

There were no amounts reimbursed relating to SPA costs for the three months ended March 31, 2022. For the three months ended March 31, 2021, the amounts reimbursed relating to SPA costs were $0.1 million and were recorded as other income in the statements of operations as the related expenses were incurred. As of March 31, 2022 and December 31, 2021 amounts due from Maruho, primarily relating to SPA cost reimbursements, were $56,000 for each of the periods and were recorded in other receivables, related parties in the balance sheets.

Others

The Company receives expense reimbursement from Biofrontera AG and Biofrontera Bioscience on a quarterly basis for costs incurred on behalf of these entities. Total expense reimbursements were $0.1 million for the three months ended March 31, 2022 and 2021, which were netted against expenses incurred within selling, general and administrative expenses.

The Company has recorded a receivable of $11.3 million due from Biofrontera AG for its 50% share of a legal settlement for which both parties are jointly and severally liable for the total settlement amount of $22.5 million. The Company has a contractual right to repayment of its share of the settlement payment from Biofrontera AG under the Settlement Allocation Agreement entered into on December 9, 2021 and amended on March 31, 2022, which provided that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share. The amended agreement 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®). The Company has accrued $56,000 of interest income as of March 31, 2022. Of the total receivable of $11.3 million, $8.5 million is short-term and $2.8 million is a long-term receivable.

17. Restructuring costs

We restructured the business of Cutanea and incurred restructuring costs which were subsequently reimbursed by Maruho. Restructuring costs primarily relate to the winding down of Cutanea's operations. There were no restructuring costs for the three months ended March 31, 2022. For the three months ended March 31, 2021, restructuring costs were incurred in the amount of $0.3 million.

18. Stockholders' Equity

Under the Company's amended and restated certificate of incorporation, dated December 21, 2020, the Company is authorized to issue 300,000,000 shares of common stock, par value $0.001 per share and 20,000,000 shares of preferred stock, par value $0.001 per share.

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.

19. 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 2021 Plan, 2,750,000 shares are reserved and authorized for awards and the maximum contractual term is 10 years for stock options issued under the 2021 Plan.

Non-qualified stock options

During the quarter ended March 31, 2022, the Company granted non-qualified stock options to certain employees to purchase 28,378 shares of common stock under the 2021 Omnibus Incentive Plan. The options were granted to employees on March 2, 2022 with an exercise price of $2.96 and a contractual term of ten years. These stock options had a grant-date fair value of $44,000 and vest annually over a three-year period, subject to the recipient's continued service with the Company through the applicable vesting dates.

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

The fair value of each option grant was estimated on the grant date of March 2, 2022, using the Black-Scholes option pricing model with the following assumptions: fair value of the underlying unit of $2.96, expected volatility of 55.0%, risk free rate of 1.79%, term of 6 years and a dividend yield of 0.

Share-based compensation expense of approximately $0.1 million was recorded in selling, general and administrative expenses on the accompanying statement of operations for the three months ended March 31, 2022. There was no stock based compensation for the three months ended March 31, 2021.

Options outstanding and exercisable under the employee share option plan as of March 31, 2022 and a summary of option activity during the three months then ended is presented below.

	Shares	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term	Aggregate Intrinsic Value (1) (in 000's)
Outstanding at December 31, 2021	613,614	$ 4.77	9.94	1,687
Granted	28,378	$ 2.96		
Exercised	-	$ -		
Canceled or forfeited	(38,096)	$ 4.77		
Outstanding at March 31, 2022	603,896	$ 4.68	9.53	$ 10
Exercisable at March 31, 2022	-	$ -	-	$ -

(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 March 31, 2022.

As of March 31, 2022, there was $1.3 million of unrecognized compensation cost related to unvested stock options, which is expected to be recognized over a weighted-average period of approximately 2.70 years.

Share-Based Compensation (RSUs)

There were no RSU's granted during the three months ended March 31, 2022. During the year ended December 31, 2021, the Company granted to certain members of management 170,068 restricted stock units, or RSUs. The fair value of each RSU is estimated based on the closing market price of the Company's common stock on the grant date.

The RSUs had a grant-date fair value of $0.8 million and will be fully vested on June 9, 2022, six months after the grant date, subject to the recipient's continued service with the Company through the applicable vesting dates. Share-based compensation expense of $0.4 million for the RSUs was recorded in selling, general and administrative expenses in the accompanying statement of operations for the three months ended March 31, 2022. There was no share-based compensation for the three months ended March 31, 2021.

As of March 31, 2022, there was $0.3 million of unrecognized compensation cost related to unvested RSUs, which is expected to be recognized over a weighted-average period of approximately 0.19 years.

20. Interest Expense, net

Interest expense, net consists of the following:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Interest expense	(4)	-
Contract asset interest expense	(89)	(89)
Interest income	60	5
Interest expense, net	$ (33)	$ (84)

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.

21. Other Income, net

Other income, net consists of the following:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Reimbursed SPA costs	$ -	$ 98
Other, net	23	(19)
Other income, net	$ 23	$ 79

Other, net, primarily includes gain (loss) on foreign currency transactions and gain on termination of operating leases.

22. Net 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.

Basic and diluted net income (loss) per share attributable to common stockholders is calculated as follows:

	Three Months Ended March 31,	
(only dollars are in thousands)	**2022**	**2021**
Net income (loss)	$ 5,561	$ (3,534)
Shares		
Basic weighted average common shares outstanding	17,104,749	8,000,000
Add: Effect of dilutive securities		
Stock options and restricted stock units	28,469	-
Diluted weighted average common shares outstanding	17,133,218	8,000,000
Net earnings (loss) per share:		
Basic	$ 0.33	$ (0.44)
Diluted	$ 0.32	$ (0.44)

The following table sets forth the potential common shares that were not included in the diluted per share calculations for the three months ended March 31, 2022 because the exercise price was greater than their average market value and they would be anti-dilutive:

March 31,	2022	2021
Common stock warrants	4,349,537	4,349,537
Common stock options	575,518	613,614
Restricted Stock Units	-	170,068

23. Commitments and Contingencies

Facility Leases

The Company leases its corporate headquarters under an operating lease that expires in November 2025. The Company provided the landlord with a security deposit in the amount of $0.1 million, which was recorded as other assets in the balance sheets.

Rent expense is recorded on a straight-line basis through the end of the lease term. The Company incurred rent expense, in the amount of $0.1 million and $0.2 million for the three months ended March 31, 2022 and 2021, which was included in selling, general, and administrative expenses.

Auto Leases

The Company also leases autos for its field sales force with a lease payment term of 40 months. The Company incurred auto lease expense of $0.1 million for the three months ended March 31, 2022 and 2021.

The minimum aggregate payments of all future lease commitments as of March 31, 2022, are as follows:

(in thousands)

Years ending December 31,	Future lease commitments
Remainder of 2022	$ 665
2023	522
2024	473
2025	352
Thereafter	-
Total	$ 2,012

Cutanea earnout payments

We are obligated 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 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 payments were made for the three months ended March 31, 2022 or 2021 related to Xepi® milestones.

Legal proceedings

At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of FASB ASC Topic 450, *Contingencies*. The Company expenses as incurred the costs related to such legal proceedings. We are not presently a party to any pending 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 to settle the claims in the litigation. The Company will be responsible for $11.25 million of the aggregate settlement amount, plus interest accrued at a rate equal to the weekly average one-year constant maturity Treasury yield and agreed to pay in three annual installments. The first installment of $11.3 million (of which $5.6 million was Biofrontera AG's portion) was paid in December 2021 by the Company.

While Biofrontera AG has agreed to pay a portion of the settlement, both parties remain jointly and severally liable for the full settlement amount, meaning that in the event Biofrontera AG does not pay all or a portion of the amount it owes under the agreement, the claimant could compel the Company to pay Biofrontera AG's share. If either the Company or Biofrontera AG violates the terms of the settlement agreement, this could nullify the settlement and the Company may lose the benefits of the settlement and be liable for a greater amount. As of March 31, 2021, we have recorded a legal settlement liability in the amount of $11.3 million for the remaining payments due and a related receivable from related party of $11.3 million, in accordance with the Settlement Allocation Agreement entered into on December 9, 2021, which provided that the settlement payments would first be made by the Company and then reimbursed by Biofrontera AG for its share.

24. 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.

For the three months ended March 31, 2022 and 2021, matching contribution costs paid by the Company were $64,000 and $61,000, respectively.

25. Subsequent Events

We have completed an evaluation of subsequent events after the balance sheet date of March 31, 2022 through the date this Quarterly Report on Form 10-Q was submitted to the SEC. We have concluded that no subsequent events have occurred that require recognition in the financial statements or disclosure in the notes to the financial statements.

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 such 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 effect of the COVID-19 global pandemic, including mitigation efforts and economic effects;
- 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.
- our success in remediating material weaknesses in our internal control over financial reporting and in establishing adequate internal controls over financial reporting;
- our ability to retain and recruit key personnel;
- our success in making the transition to operate as a public company;
- such other risks identified in *Item 1A. Risk Factors* in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021 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, 2021. We urge investors and security holders to read those documents free of charge at the SEC's web site at www.sec.gov. We do not undertake to publicly update or revise our forward-looking statements as a result of new information, future events or otherwise, except as required by law.

Overview

We are a U.S.-based biopharmaceutical company specializing in the commercialization of pharmaceutical products for the treatment of dermatological conditions, in particular, diseases caused primarily by exposure to sunlight that result in sun damage to the skin. Our principal licensed product focuses on the treatment of actinic keratoses, which are skin lesions that can sometimes lead to skin cancer. We also market a topical antibiotic for treatment of impetigo, a bacterial skin infection.

Our principal licensed product is Ameluz®, which is a prescription drug approved for use in combination with our licensor's FDA-approved medical devices, the BF-RhodoLED® lamp series consisting of the BF-RhodoLED® and the RhodoLED® XL lamps, for photodynamic therapy in the United States 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"), by and among us and Biofrontera Pharma GmbH and Biofrontera Bioscience GmbH (collectively, the ("Ameluz Licensor") originally dated as of October 1, 2016, and as subsequently amended on October 8, 2021. Under the Ameluz LSA, we hold the exclusive license to sell Ameluz® and the BF-RhodoLED® lamp in the United States for all indications currently approved by the FDA as well as all future FDA-approved indications that the Ameluz Licensor may pursue. We are obliged to purchase Ameluz® and the RhodoLED® devices exclusively from the Licensor. Under the Ameluz LSA, the Licensor is obliged to manufacture, perform regulatory work and sponsor certain clinical trials on its own expense. In consideration, we are obligated to pay a transfer price of 30-50% of our net sales of Ameluz®. We have the authority under the Ameluz LSA in certain circumstances to i) take over clinical development with respect to the indications the Ameluz Licensor is currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA), ii) take over the regulatory and manufacturing responsibilities from the Ameluz Licensor, and iii) to offset the costs of such operations by adjusting the transfer price for Ameluz® or to reduce the transfer price at a fixed ratio. The Ameluz Licensor does not have any obligation under the Ameluz LSA, as amended, to perform or finance clinical trials to promote new indications beyond those they are currently pursuing with the FDA (as well as certain other clinical studies identified in the Ameluz LSA). Under the Ameluz LSA, further extensions of the approved indications for Ameluz® photodynamic therapy in the United States are anticipated.

Our second prescription drug licensed product in our portfolio 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 adults and children 2 months and older. We are currently selling Xepi® for this indication in the U.S. under an exclusive license and supply agreement ("Xepi LSA") with Ferrer that was acquired by Biofrontera on March 25, 2019 through our acquisition of Cutanea Life Sciences, Inc. ("Cutanea").

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 RhodoLED® lamp for the treatment of minimally to moderately thick actinic keratoses of the face and scalp and positioning Ameluz® to be a leading photodynamic therapy product, by growing our dedicated sales and marketing infrastructure in the United States;

- expanding our sales of Xepi® for treatment of impetigo by improving the market positioning of the licensed product; and

- 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.

Our strategic objectives also include further expansion of our product and business portfolio through various methods to pursue selective strategic investment and acquisition opportunities to expand and support our business growth, including but not limited to:

- in-licensing further products or product opportunities and developing them for the U.S. market;
- procuring products through asset acquisition from other healthcare companies; and
- procuring products through share acquisition of some or all shares of other healthcare companies, including the possible acquisition of shares of our former parent company and significant stockholder, Biofrontera AG.

We devote a substantial portion of our cash resources to the commercialization of our licensed products, Ameluz®, the RhodoLED® lamp series and Xepi®. 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-GAAP measure as defined below). Our sole source of 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

Since the beginning of 2020, COVID-19 has become a global pandemic. As a result of the measures implemented by governments around the world, our business operations have been directly affected. In particular, we experienced a significant decline in demand for our licensed products as a result of different priorities for medical treatments emerging, thereby causing a delay of actinic keratosis treatment for most patients. Our revenue was directly affected by the global COVID-19 pandemic starting in mid-March of 2020. From that point on, rising infection rates and the resulting American Academy of Dermatology's official recommendation to care for patients through remote diagnosis and treatment (telehealth) led to significantly declining patient numbers and widespread, albeit temporary, physician practice closures. As COVID-19 vaccines started to roll-out to the general public in March 2021, we experienced an increase in patients willing to undergo treatment for actinic keratosis. In the fourth quarter of 2021 continuing through the first quarter of 2022, we again saw a seasonally strong increase in sales, indicating a revenue recovery from the global COVID-19 pandemic. However, due to the speed and fluidity with which the COVID-19 pandemic continues to evolve, and the emergence of highly contagious variants, we do not yet know the full extent of the impact of COVID-19 on our business operations. 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 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 and of their manufacturer's (Teligent, Inc.) Chapter 11 bankruptcy filing on October 14, 2021 and in February 2022, Teligent Inc. filed a motion to convert the proceedings into a Chapter 7 liquidation. As Teligent, Inc, is no longer a viable manufacturing option, Ferrer is evaluating options for a new contract manufacturer for Xepi®, but the process of engaging one or more new contract manufacturers to replace Teligent, Inc. will require significant time, including the time it will take the new contract manufacturer(s) to reach a level of production to meet our commercial needs. Although we have inventory of Xepi® on hand, we do not expect it will be enough to complete the commercialization of Xepi® in accordance with the originally planned timeline. Due to the uncertainty of supply chain, we expect a delay in shipments of Xepi® for the next 18 months, however, the Company expects Ferrer to perform its obligations under the Xepi LSA to use its commercially reasonable efforts to qualify an alternative supplier during this period of time. Despite these delays, our total revenues will not be significantly impacted since the majority of our revenues are from sales of Ameluz®. After adjusting our forecast due to supply chain issues, we expect our net Xepi revenues impact to be $0.5 million over the next twelve months. 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 RhodoLED®.

Components of Our Results of Operations

Product Revenue, net

We generate product revenues through the third-party sales of our licensed products Ameluz®, 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 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 RhodoLED® lamps from Biofrontera Pharma GmbH.

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 accounting consolidation, IT support, and pharmacovigilance. These expenses were previously charged to us based on costs incurred plus 6% in accordance with the 2016 Services Agreement. As of December 31, 2021, we entered into the Services Agreement which provides for the execution of statements of work that supersedes 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. 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.

Restructuring Costs

We restructured the business of Cutanea and incurred restructuring costs, which were subsequently reimbursed by Maruho. Restructuring costs primarily relate to Aktipak® discontinuation, personnel costs related to the termination of all Cutanea employees, and the winding down of Cutanea's operations.

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 until the contingency is resolved.

Change in Fair Value of Warrant Liabilities

Common stock warrants to purchase up to 2,857,143 shares of our common stock at an exercise price of $5.25 per share were issued in conjunction with the private placement which closed on December 2, 2021 and were 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 statements of operations.

Interest Expense, net

Interest expense, net, primarily consists of amortization of the contract asset related to the start-up cost financing from Maruho Co. Ltd's. ("Maruho") agreement ("Share Purchase Agreement") to acquire 100% of the Shares of Cutanea Life Sciences, Inc. ("Cutanea"), offset by interest income of 6% per annum for each day that any reimbursement is past due related to the Settlement Allocation Agreement with Biofrontera AG and immaterial amounts of interest income earned on our financing of customer purchases of RhodoLED® lamps.

Other Income, net

Other income, net primarily includes (i) reimbursed Share Purchase Agreement costs, 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 March 31, 2022 and 2021

The following table summarizes our results of operations for the three months ended March 31, 2022 and 2021:

(*in thousands)*	**2022**	**2021**	**Change**
Product revenues, net	$ 9,736	$ 4,731	$ 5,005
Related party revenues	15	13	2
Revenues, net	**9,751**	**$ 4,744**	**5,007**
Operating expenses:			
Cost of revenues, related party	4,975	2,408	2,567
Cost of revenues, other	175	163	12
Selling, general and administrative	7,616	4,758	2,858
Selling, general and administrative, related party	95	164	(69)
Restructuring costs	-	281	(281)
Change in fair value of contingent consideration	-	498	(498)
Total operating expenses	12,861	8,272	4,589
Loss from operations	**(3,110)**	**(3,528)**	**418**
Change in fair value of warrant liabilities	8,711	-	8,711
Interest expense, net	(33)	(84)	51
Other income, net	23	79	(56)
Loss before income taxes	**5,591**	**(3,533)**	**9,124**
Income tax expenses	30	1	29
Net loss	**$ 5,561**	**$ (3,534)**	**$ 9,095**

Product Revenue, net

Net product revenue was $9.8 million and $4.7 million for the first three months of 2022 and 2021, respectively, an increase of $5.0 million, or 105.5%. The increase was primarily driven by the higher volume of Ameluz® orders, which resulted in an increase in Ameluz® revenue of $4.6 million, which was coupled with the impact of price related to Ameluz® of $0.4 million.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party was $5.0 million and $2.4 million for the first three months of 2022 and 2021, respectively, an increase of $2.6 million, or 106.6%. which was driven by the increase in Ameluz® product revenue. Cost of revenues, related party is directly correlated to the selling price under the Ameluz LSA.

Cost of Revenues, Other

Cost of revenues, other was consistent at $0.2 million for both the first three months of 2022 and 2021

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $7.6 million and $4.8 million for the first three months of 2022 and 2021, respectively, an increase of $2.9 million, or 60.0%.

The increase was primarily driven by legal expenses of $0.5 million and business insurance of $0.5 million. Headcount costs also increased $0.4 million as a result of (i) resumed hiring in 2022 and (ii) higher commission expenses related to improved sales performance. The increase was further driven by stock compensation expense of $0.5 million, resumed travel of $0.3 million as well as higher year over year consulting expenses of $0.2 million.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party were $0.1 million and $0.2 million for the first three months of 2022 and 2021, respectively, a decrease of $0.1 million or -42.1%. Related party expense is 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. Prior period related party expense was based on costs incurred by Biofrontera AG plus 6% for services provided to us related to accounting consolidation, IT support and pharmacovigilance. Decrease of $0.1 million is mainly related to IT development and quality assurance services. Biofrontera AG provides IT development application services as well as any network issues and hosts Biofrontera, Inc.’s servers.

Restructuring Costs

Restructuring costs were $0.0 million and $0.3 million for 2022 and 2021, respectively, a decrease of $0.3 million, or 100%, which was related to facility exit costs.

Change in Fair Value of Contingent Consideration

The change in fair value of contingent consideration was $0 million and $0.5 million for the first three months of 2022 and 2021, respectively, a decrease of $0.5 million or -100.0%. 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 $8.7 million for 2022. The change in fair value of warrant liabilities was driven by changes in the underlying value of the common stock. There were no warrant liabilities as of March 31, 2021.

Interest Expense, net

Interest expense, net was $33 thousand and $0.1 million for the first three months of 2022 and 2021, respectively. The slight decrease in interest expense was mainly driven by legal settlement interest income in 2022. Interest expense from the straight-line amortization of the contract asset related to start-up cost financing received from Maruho under the Cutanea acquisition purchase agreement was $0.1 million during both periods.

Other Income, net

Other income, net was $23 thousand and $79 thousand in the first three months of 2022 and 2021, respectively, a decrease of $56 thousand or -70.9%. Decrease is primarily related to the decrease in reimbursed costs under the Share Purchase Agreement with Maruho.

Net Income (Loss) to Adjusted EBITDA Reconciliation for the Three Months Ended March 31, 2022 and 2021

We define adjusted EBITDA as net income or loss before interest income and expense, income taxes, depreciation and amortization, and other non-operating items from our statements of operations as well as certain other items considered outside the normal course of our operations specifically described below. Adjusted EBITDA is not a presentation made in accordance with GAAP. Our definition of adjusted EBITDA may vary from the use of similarly-titled measures by others in our industry due to the potential inconsistencies in the method of calculation and differences due to items subject to interpretation. Adjusted EBITDA should not be considered as an alternative to net income or loss, operating income/(loss), cash flows from operating activities or any other performance measures derived in accordance with GAAP as measures of operating performance or liquidity. Adjusted EBITDA has limitations as an analytical tool and should not be considered in isolation or as a substitute for analysis of our results as reported under GAAP.

Change in fair value of contingent consideration: Pursuant to the Share Purchase Agreement, the profits from the sale of Cutanea products 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. 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 Purchase and Pre-funded Warrants issued in conjunction with a private placement equity financing were accounted for as liabilities in accordance with ASC 815-40. The warrant liabilities were measured at fair value at inception and are remeasured at each reporting date, with changes in fair value presented within the statement of operations. We exclude the impact of the change in fair value of warrant liabilities as this is non-cash.

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-GAAP financial information is viewed with GAAP financial information, investors are provided with a more meaningful understanding of our ongoing operating performance.

The below table presents a reconciliation from net income (loss) to Adjusted EBITDA for the three months ended March 31, 2022 and 2021:

	Three Months Ended March 31,	
	2022	**2021**
Net income/(loss)	$ 5,561	$ (3,534)
Interest expense, net	33	84
Income tax expenses	30	1
Depreciation and amortization	131	138
EBITDA	**5,755**	**(3,311)**
Change in fair value of contingent consideration	-	498
Change in fair value of warrant liabilities	(8,711)	-
Adjusted EBITDA	$ (2,956)	$ (2,813)
Adjusted EBITDA margin	**-30.3%**	**-59.3%**

Adjusted EBITDA

Adjusted EBITDA decreased from ($2.8) million for the first three months of 2021 to ($3.0) million for the first three months of 2022. Our adjusted EBITDA margin improved to (30.3%) for the first three months of 2022 from (59.3%) for the first three months of 2021.

Liquidity and Capital Resources

The Company's primary sources of liquidity are its existing cash balances and cash flows from equity financing transactions received in 2021. As of March 31, 2022, we had cash and cash equivalents of $22.4 million, compared to $24.5 million as of December 31, 2021.

Since we commenced operations in 2015, we have generated significant losses. For the three months ended March 31, 2022 and 2021, we incurred losses from operations of $3.1 million and $3.5 million, respectively. We incurred net cash outflows from operations of $2.1 million and $3.4 million, for the same periods, respectively. We had an accumulated deficit as of March 31, 2022 of $73.3 million.

The Company's short-term material cash requirements include working capital needs and satisfaction of contractual commitments including auto leases (see *Note 23, Commitments and Contingencies*), Maruho start-up payments of $7.3 million (see *Note 3. Acquisition Contract Liabilities*), and legal settlement expenses after reimbursement from Biofrontera AG a significant shareholder and former parent company, of $5.6 million (see *Note 13. Accrued Expenses and Other Current Liabilities*). Long-term material cash requirements include potential milestone payments to Ferrer Internacional S.A (See *Note 23. Commitments and Contingencies*) and contingent consideration payments to Maruho (see *Note 3. Acquisition Contract Liabilities).*

Additionally, we expect to continue to incur operating losses due to significant discretionary sales and marketing efforts as we seek to expand the commercialization of Ameluz® and Xepi® 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 significant costs to continue to comply with corporate governance, internal controls and similar requirements applicable to us as a public company in the U.S. We expect capital expenditures to increase in 2022 to support the increase in our business needs including an ERP system.

These factors raise doubt about our ability to continue as a going concern, which we have determined are mitigated by the following plans. Based on current operating plans and financial forecasts, we expect that our current cash and cash equivalents will be sufficient to fund our operations for at least the next twelve months from the date of issuance of our financial statements. However, we expect to have to obtain either equity or debt financing to support our future long-term growth and to mitigate the risk of our operating costs significantly exceeding the amounts currently estimated. If our current operating plans or financial forecasts change, or we are unable to obtain additional financing, we may need to reduce the discretionary spend on promotional expenses, branding, marketing consulting and defer some hiring. While we expect to continue being flexible in our spending over the next twelve months, we do not consider there to be a need to significantly revise our operations currently.

The adequacy of our available funds to meet our future operating and capital requirements will depend on many factors, including the amounts of future revenues generated by our products. Due to numerous factors described in more detail under the caption Part I, Item 1A, "Risk Factors" of this Form 10-K and our contractual obligations and commitments, we may require significant additional funds earlier than we currently expect in order to continue to commercialize Ameluz®, BF-RhodoLED® lamp series, and Xepi® and to support the operating, investing, and financing activities of the Company beyond the next twelve months.

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® and Xepi®;
- 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; 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.
- the ability to collect a receivable of $11.3 million from Biofrontera AG (in accordance with the Settlement Allocation Agreement) for reimbursement of legal settlement payments made and to be made on their behalf for which both parties are jointly and severally liable.

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:

	Three Months Ended March 31,	
(in thousands)	**2022**	**2021**
Net cash used in operating activities	$ (2,112)	$ (3,443)
Net cash provided by (used in) investing activities	(5)	-
Net decrease in cash and restricted cash	$ (2,117)	$ (3,443)

Operating Activities

During the first three months of 2022, operating activities used $2.1 million of cash, primarily resulting from our loss from operations of $3.1 million, adjusted for non-cash expense of stock-based compensation of $0.5 million, non-cash interest expense of $0.1 million, and depreciation and amortization in the aggregate of $0.1 million and net cash used by changes in our operating assets and liabilities of $0.3 million.

During the three months ended March 31, 2021, operating activities used $3.4 million of cash, primarily resulting from our net loss of $3.5 million, adjusted for non-cash expense of $0.8 million as an offset and net cash used by changes in our operating assets and liabilities of $0.7 million.

Investing Activities

During the first three months of 2022, net cash used in investing activities in the amount of $5,000 consisted of the purchase of computer equipment.

Financing Activities

During the first three months 2022 and 2021, there was no net cash provided by or used in financing activities.

Accounting Policies and Significant Judgments and Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with 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 and 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 financial statements included in 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, 2021. There were no material changes to our critical accounting estimates for the three months ended March 31, 2022.

Off-balance Sheet Arrangements

Besides the contractual obligations and commitments as discussed in the *Liquidity and Capital Resources*, 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 principal executive officer and principal 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, and as a result of the material weakness described below, our Chief Executive Officer and Senior Director Finance concluded that, as of March 31, 2022, our disclosure controls and procedures were not effective at the reasonable assurance level.

Material Weaknesses in Internal Control Over Financial Reporting

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected on a timely basis.

In connection with the audits of our financial statements as of and for the years ended December 31, 2021 and December 31, 2020, we identified a material weakness in our internal control over financial reporting. The previously identified material weakness pertains to our oversight of work being performed for the Company by third-party service providers; as the Company's management review control over information produced by third-party service providers was not sufficiently precise to identify errors. Specifically, as part of the valuation of an intangible asset in connection with the acquisition of Cutanea, we failed to identify a computational error within the valuation model for the Xepi® intangible asset. In addition, in 2021 an error in the valuation of the same intangible asset was identified relating to insufficient information being provided to the third-party consultant in connection with an impairment assessment.

Relating to the previously identified deficiency pertaining to management's review of work performed by specialists, management has implemented measures designed to improve our internal control over financial reporting including formalized reviews of transactions handled by the specialist. However, in light of the prior year control deficiency, the remediation is still considered to be in process. We will monitor the effectiveness of our remediation plan and will continue to make changes we determine to be appropriate. As a result, management has concluded that the material weakness was not fully remediated as of March 31, 2022.

Management will continue its remediation work by adding steps to the engagement of third-party specialists for assistance with complex or judgmental accounting areas, including checks and balances over the proper flow of information to the specialist to allow for an adequate understanding of the transaction.

As previously noted, we are still in process of remediating this material weakness as of March 31, 2022. If we are unable to remediate this material weakness, or if we identify additional material weaknesses in the future or otherwise fail to maintain an effective system of internal control, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, our stock price.

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 March 31, 2022 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 23 - Commitments and Contingencies under the subsection titled “Legal Proceedings” in our Notes to 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, you should carefully consider the “Risk Factors” included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2021, for a discussion of important factors that could materially affect our business, financial condition and/or operating results.

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

Use of Proceeds from our Initial Public Offering

On October 28, 2021, our registration statement on Form s-1 (File No. 333-257722) relating to the initial public offering (“IPO”) of our common stock became effective.

Proceeds received were used for working capital and general corporate purposes. There has been no material change in the planned use of proceeds from the IPO of our common stock from that described in the Prospectus.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

Not Applicable.

Item 5. Other Information

None

Item 6. Exhibits

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

Exhibit No.	
10.1	Amended Settlement Allocation Agreement dated March 31,2022 between the Company and Biofrontera Bioscience GmbH, Biofrontera Pharma GmbH, Biofrontera Development GmbH, Biofrontera Neuroscience GmbH, (incorporated by reference to Exhibit 10.1 to the Company's Form 8-K filed with the SEC on April 5, 2022).
31.1*	Certification of Principal Executive Officer and Principal Financial Officer pursuant to Section 302 of the Sarbanes Oxley Act of 2002
32.1*	Certification of Principal Executive Officer and 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.

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: May 13, 2022

By: */s/ Erica Monaco*
Name: Erica Monaco
Title: Chief Executive Officer
(*Duly Authorized Officer, Principal Executive Officer and Principal Financial Officer*)

Exhibit 31.1

Certification

I, Erica L. Monaco, 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. I am responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) 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. I have disclosed, based on my most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 13, 2022

By: */s/ Erica L. Monaco*
Erica L. Monaco
Chief Executive Officer
(Principal Executive Officer and Principal Financial Officer)

Exhibit 32.1

Certification*

In connection with the Quarterly Report of Biofrontera Inc. (the "Company") on Form 10-Q for the quarter ended March 31, 2022 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, Erica L. Monaco, 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: May 13, 2022

By: */s/ Erica L. Monaco*
Erica L. Monaco
Chief Executive Officer
(Principal Executive Officer and 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.