Biofrontera Inc.

November 30, 2021

Management's Discussion and Analysis

For the three and nine months ended September 30, 2021

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

You should read the following discussion and analysis of our financial condition and results of operations together with our financial statements and related notes included in Part I, Item 1 of this Quarterly Report on Form 10-Q and our final prospectus for our initial public offering ("IPO") filed with the Securities and Exchange Commission (the "SEC") pursuant to Rule 424(b) under the Securities Act of 1933on November 1, 2021 ("Final Prospectus"). Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and related financing, includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those factors set forth in the "Risk Factors" section in our Final Prospectus, actual results may differ materially from our forward-looking statements.

Forward-Looking Statements

The Private Securities Litigation Reform Act of 1995 provides a "safe harbor" for forward-looking statements. Certain statements in this Quarterly Report on Form 10-Q constitute "forward-looking statements". Such statements include statements regarding the efficacy and intended use of our technologies under development, the timelines and strategy for bringing such products to market, the timeline for regulatory review and approval of our products, the availability of funding sources for continued development of such 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 the risks that:

- Currently, our sole source of revenue is from sales of products we license from other companies. If we fail to comply with our obligations in the agreements under which we license rights from such third parties, or if the license agreements are terminated for other reasons, we could lose license rights that are important to our business.

- Certain important patents for our licensed product Ameluz® expired in 2019. Although the process of developing generic topical dermatological products for the first time presents specific challenges that may deter potential generic competitors, generic versions of Ameluz® may enter the market following the recent expiration of these patents. If this happens, we may need to reduce the price of Ameluz® significantly and may lose significant market share.

- Our business depends substantially on the success of our principal licensed product Ameluz®. If the Biofrontera Group is unable to successfully obtain and maintain regulatory approvals or reimbursement for Ameluz® for existing and additional indications, our business may be materially harmed.

- The Biofrontera Group currently depends on a single unaffiliated contract manufacturer to manufacture Ameluz® and has recently contracted with a second unaffiliated contract manufacturer to begin producing Ameluz®. If the Biofrontera Group fails to maintain its relationships with these manufacturers or if both of these manufacturers are unable to produce product for the Biofrontera Group, our business could be materially harmed.

- If our licensors or our licensors' manufacturing partners, as applicable, fail to manufacture Ameluz®, BF-RhodoLED® lamps, Xepi® or other marketed products in sufficient quantities and at acceptable quality and cost levels, or to fully comply with current good manufacturing practice, or cGMP, or other applicable manufacturing regulations, we may face a bar to, or delays in, the commercialization of the products under license to us or we will be unable to meet market demand, and lose potential revenues.

- The Biofrontera Group is currently involved in lawsuits to defend or enforce patents related to our licensed products and they or another licensor may become involved in similar suits in the future, which could be expensive, time-consuming and result in an adverse outcome.

- The COVID-19 global pandemic has negatively affected our sales and operations and may continue to do so.

- We are fully dependent on our collaboration with the Biofrontera Group for our supply of Ameluz® and BF-RhodoLED® lamps and future development of the Ameluz® product line and on our collaboration with Ferrer for our supply of Xepi® and future development of Xepi® and may depend on the Biofrontera Group, Ferrer or additional third parties for the supply, development and commercialization of future licensed products or product candidates. Although we have the authority under the Ameluz LSA with respect to the indications that the Biofrontera Group is currently pursuing with the FDA (as well as certain other clinical studies identified in the Corrected Amendment to the Ameluz LSA) to take over clinical development, regulatory work and manufacturing from the Biofrontera Group under certain circumstances if they are unable or unwilling to perform these functions appropriately, the sourcing and manufacture of our licensed products as well as the regulatory approvals and clinical trials related to our licensed products are currently controlled, and will likely continue to be controlled for the foreseeable future, by our existing and future collaborators. Our lack of control over some of these functions could adversely affect our ability to implement our strategy for the commercialization of our licensed products.

- We are involved in significant litigation, along with the Biofrontera Group, which has consumed and may continue to consume significant resources and management time, and adverse resolution of this litigation could require us to pay significant damages and possibly prevent us from selling certain of our licensed products, which would severely and materially adversely impact our business, prospects, financial condition or results of operations.

- Insurance coverage and medical expense reimbursement may be limited or unavailable in certain market segments for our licensed products, which could make it difficult for us to sell our licensed products.

- Healthcare legislative changes may have a material adverse effect on our business and results of operations.

- We face significant competition from other pharmaceutical and medical device companies and our operating results will suffer if we fail to compete effectively. We also must compete with existing treatments, such as simple curettage and cryotherapy, which do not involve the use of a drug but have gained significant market acceptance.

- We have a history of operating losses and anticipate that we will continue to incur operating losses in the future and may never sustain profitability.

- If we fail to obtain additional financing, we may be unable to complete the commercialization of Xepi® and other products we may license.

- Prof. Dr. Lübbert currently serves as Chairman of the management board and CEO of our parent and significant shareholder, Biofrontera AG, and, as a result, has and may continue to have, statutory, fiduciary and other duties to Biofrontera AG causing conflicts of interest with respect to his duties to us and his duties to Biofrontera AG and in determining how to devote himself to our affairs and the affairs of Biofrontera AG.

- We have identified a material weakness in our internal control over financial reporting, resulting from a control deficiency related to the oversight of third-party service providers. 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 controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect our business and stock price.

- Biofrontera AG is our significant shareholder and is able to exert significant control over matters subject to stockholder approval and its interests may conflict with ours or yours in the future.

- We continue to be a "controlled company" within the meaning of Nasdaq listing standards, and as a controlled company we qualify for exemptions from certain corporate governance requirements.

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 Final Prospectus. 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 licensed products focus 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 device, the BF-RhodoLED® lamp, for photodynamic therapy in the United States 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 the Ameluz LSA. 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 Biofrontera Group may pursue. We have the authority under the Ameluz LSA in certain circumstances to take over clinical development, regulatory work and manufacturing from the Biofrontera Group, with respect to the indications the Biofrontera Group is currently pursuing with the FDA (as well as certain other clinical studies identified in the Corrected Amendment to the Ameluz LSA). However, the Biofrontera Group 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 Corrected Amendment to 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 the Xepi LSA 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 BF-RhodoLED® lamp for the treatment of minimally to moderately thick actinic keratosis of the face and scalp and positioning Ameluz® to be a leading photodynamic therapy product in the United States, 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 existing portfolio products that are in the pipeline for the U.S. market through the LSAs with our licensors, Pharma, Bioscience and Ferrer.

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 current parent company, Biofrontera AG.

We devote a substantial portion of our cash resources to the commercialization of our licensed products, Ameluz®, the BF-RhodoLED® lamp and Xepi®. We have financed our operating and capital expenditures through cash proceeds generated from our product sales and proceeds received in connection with the Intercompany Revolving Loan Agreement with Biofrontera AG. On December 31, 2020, the outstanding principal balance on the intercompany loan was converted into shares of common stock. On March 31, 2021, we entered into the Second Intercompany Revolving Loan Agreement with Biofrontera AG for $20.0 million of committed sources of funds for a two-year term. As of September 30, 2021, there was no loan principal balance outstanding under the Second Intercompany Revolving Loan.

On November 2, 2021, we completed an initial public offering ("IPO") and issued and sold 3,600,000 units ("Units"), each consisting of (i) one share of our common stock, par value $0.001 per share (the "Shares") and (ii) one warrant of the Company (the "Warrants") entitling the holder to purchase one Share at an exercise price of $5.00 per Share. In addition, the underwriters exercised in full their option to purchase up to an additional 540,000 Warrants to cover over-allotments. The Units were sold at a price of $5.00 per Unit, and the Company estimates the net proceeds from the IPO to be $15.4 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by the Company. In connection with the IPO, the Company also issued to the underwriters Unit Purchase Options to purchase, in the aggregate, (a) 108,000 Units and (b) an additional 16,200 Warrants (relating to the underwriters' exercise of the over-allotment option in full with respect to the Warrants).

On November 24 and November 26, 2021, investors exercised their warrants to purchase a total of 854,000 shares of common stock at an exercise price of $5.00 per share, resulting in estimated net proceeds of $3.9 million after deducting underwriting discounts and commission.

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, there has been a significant decline in demand for the Biofrontera Group's products worldwide, and our licensed products in the United States, 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. After negligible sales of our products in April 2020, we observed a slow recovery of our business again in the summer of 2020 and later the first signs of stabilization in line with the usual seasonality. Doctors' offices reopened during the second half of 2020, at least in part, and patients showed increasing willingness to undergo treatment for actinic keratosis. In the fourth quarter of 2020, we again saw a seasonally strong increase in sales. Revenue from product sales was $14.9 million for the nine months ended September 30, 2021, as compared to $10.2 million for the nine months ended September 30, 2020, indicating our revenue is recovering from the global COVID-19 pandemic. January and February revenues were still pre-pandemic in 2020 and substantially lower in January and February 2021, while revenues recovered quickly since March 2021. In order to mitigate the risk from COVID-19, we have taken expedited measures to reduce operating expenses and preserve cash, including headcount reductions, mandatory furloughs, freezing of hiring and discretionary spend, and voluntary salary reductions from the senior leadership. During the COVID-19 pandemic, we have focused our sales strategy in the U.S. market on our flagship product Ameluz® and delayed the targeted re-launch to improve the positioning of our licensed product Xepi®. To a minor extent, Xepi inventories were written down as of December 31, 2020 due to an anticipated expiration of shelf life. As the impact of the COVID-19 pandemic continues, we may experience continued disruptions that could severely impact our business, operations, and sales and marketing. We continue to monitor trends related to COVID-19 and their impact on our business, results of operations and financial condition.

Components of Our Results of Operations

Product Revenue, net

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

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

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

Related Party Revenues

We also generate insignificant related party revenue in connection with an agreement with Bioscience to provide BF-RhodoLED® lamps and associated services.

Cost of Revenues, Related Party

Cost of revenues, related party, is comprised of purchase costs of our licensed products, Ameluz® and BF-RhodoLED® lamps from Pharma.

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 as well as our legal settlement expenses. In connection with the acquisition of Cutanea, we recorded an intangible asset related to the Xepi® license, which is being amortized on a straight-line basis over an estimated useful life of 11 years.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party, primarily relate to the services provided by our parent, Biofrontera AG, for accounting consolidation, IT support, and pharmacovigilance. These expenses were charged to us based on costs incurred plus 6% in accordance with the 2016 Services Agreement. On July 2, 2021, we entered into a new intercompany services agreement ("2021 Services Agreement") which provides for the execution of statements of work that supersedes the applicable provisions of the 2016 Services Agreement. The 2021 Services Agreement enables us to continue relying on Biofrontera AG and its subsidiaries for various services it has historically provided to us, including IT and pharmacovigilance support. We expect to execute a statement of work under the 2021 Services Agreement related to expenses that is consistent with the 2016 Services Agreement based on costs incurred plus 6%. Under the 2021 Services Agreement we have agreed that the applicable provisions related to reimbursement and allocation of expenses in the 2016 Services Agreement will remain in effect until we execute a statement of work under the 2021 Services Agreement that supersedes such provisions.

Restructuring Costs

We restructured the business of Cutanea and incurred restructuring costs, which were subsequently reimbursed by Maruho Co, Ltd. ("Maruho"). Restructuring costs primarily relate to 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 on March 25, 2019 and is re-measured at each reporting date until the contingency is resolved.

Interest Expense, net

Interest expense, net, primarily consists of interest expense incurred under our Revolving Loan Agreement with Biofrontera AG, amortization of the contract asset related to the start-up cost financing from Maruho under the Share Purchase Agreement, and immaterial amounts of interest income earned on our financing of customer purchases of BF-RhodoLED® lamps.

Other Income, net

Other income, net primarily includes (i) reimbursed SPA 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 September 30, 2021 and 2020

The following table summarizes our results of operations for the three months ended September 30, 2021 and 2020:

	Three Months Ended September 30,		
(*in thousands*)	**2021**	**2020**	**Change**
Product revenues, net	$ 4,319	$ 3,236	$ 1,083
Related party revenues	15	16	(1)
Revenues, net	**4,334**	**3,252**	**1,082**
Operating expenses:			
Cost of revenues, related party	2,249	567	1,682
Cost of revenues, other	41	446	(405)
Selling, general and administrative	17,090	4,191	12,899
Selling, general and administrative, related party	160	111	49
Restructuring costs	199	181	18
Change in fair value of contingent consideration	700	100	600
Total operating expenses	20,439	5,596	14,843
Loss from operations	**(16,105)**	**(2,344)**	**(13,761)**
Interest expense, net	(86)	(744)	658
Other income, net	185	164	21
Loss before income taxes	**(16,006)**	**(2,924)**	**(13,082)**
Income tax expenses	6	61	(55)
Net loss	**$ (16,012)**	**$ (2,985)**	**$ (13,027)**

Product Revenue, net

Net product revenue was $4.3 million and $3.2 million for the three months ended September 30, 2021 and 2020, respectively, an increase of $1.1 million, or 33.5%. The increase was primarily driven by: (i) higher volume of Ameluz® orders, which resulted in an increase in Ameluz® revenue of $1.0 million, and (ii) an increase in the price of Ameluz®, which further increased Ameluz® revenue by $0.2 million.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party was $2.2 million and $0.6 million for the three months ended September 30, 2021 and 2020, respectively, an increase of $1.7 million, or 296.6%. $0.6 million of such increase was driven by the increase in Ameluz® product revenue. Cost of Ameluz is directly correlated to the selling price under the Ameluz LSA with Biofrontera Pharma GmbH. In addition, we received cost reimbursement from Pharma in 2020, which resulted in $1.1 million reduction in cost of revenues, related party during the three months ended September 30, 2020.

Cost of Revenues, Other

Cost of revenues, other was $41,000 and $446,000 for the three months ended September 30, 2021 and 2020, respectively, a decrease of $0.4 million, or 90.8%. The decrease was primarily driven by a $0.4 million provision for Xepi® inventory obsolescence due to product expiry recorded during the three months ended September 30, 2020.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $17.1 million and $4.2 million for the three months ended September 30, 2021 and 2020, respectively, an increase of $12.9 million, or 307.8%. The increase was primarily driven by the legal settlement expense recorded as of September 30, 2021 in the amount of $11.25 million. The increase was further driven by $0.6 million increase in marketing expense as we launched various marketing campaigns for our licensed products. Headcount costs also increased $0.5 million as a result of (i) resumed hiring in 2021, (ii) higher commission expenses related to improved sales performance, and (iii) the impact of cost reimbursement received from Biofrontera Pharma GmbH which resulted in $0.1 million cost reduction during the three months ended September 30, 2020. In addition, sales force travel and in-person trainings expenses increased $0.5 million.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party were $0.2 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively. Related party expense is based on costs incurred by Biofrontera AG plus 6% for services provided to us related to accounting consolidation, IT support and pharmacovigilance.

Restructuring Costs

Restructuring costs were $0.2 million and $0.2 million for the three months ended September 30,2021 and 2020, respectively, both of which are related to facility exit costs.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was an increase of $0.7 million and $0.1 million for the three months ended September 30, 2021 and 2020, respectively. 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.

Interest Expense, net

Interest expense was $0.1 million and $0.7 million for the three months ended September 30, 2021 and 2020, respectively. Interest expense during the three months ended September 30, 2020 included $0.6 million incurred on the intercompany loan issued by Biofrontera AG. The intercompany loan was fully converted into common stock at the end of 2020. In addition, 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 of these periods.

Other Income, net

Other income, net was $0.2 million and $0.2 million for the three months ended September 30, 2021 and 2020, respectively, both of which primarily related to reimbursed costs under the Share Purchase Agreement with Maruho.

Comparison of the Nine Months Ended September 30, 2021 and 2020

The following table summarizes our results of operations for the nine months ended September 30, 2021 and 2020:

(*in thousands*)	Nine Months Ended September 30, 2021	2020	Change
Product revenues, net	$ 14,890	$ 10,230	$ 4,660
Related party revenues	42	47	(5)
Revenues, net	14,932	10,277	4,655
Operating expenses:			
Cost of revenues, related party	7,630	4,025	3,605
Cost of revenues, other	339	617	(278)
Selling, general and administrative	27,412	13,557	13,855
Selling, general and administrative, related party	520	397	123
Restructuring costs	654	861	(207)
Change in fair value of contingent consideration	1,698	238	1,460
Total operating expenses	38,253	19,695	18,558
Loss from operations	(23,321)	(9,418)	(13,903)
Interest expense, net	(255)	(2,113)	1,858
Other income, net	419	796	(377)
Loss before income taxes	(23,157)	(10,735)	(12,422)
Income tax expenses	51	66	(15)
Net loss	**$ (23,208)**	**$ (10,801)**	**$ (12,407)**

Product Revenue, net

Net product revenue was $14.9 million and $10.2 million for the nine months ended September 30, 2021 and 2020, respectively, an increase of $4.7 million, or 45.6%. The increase was primarily driven by (i) higher volume of Ameluz® orders, which resulted in an increase in Ameluz® revenue of $4.1 million, and (ii) an Ameluz® price increase effective in January 2021, which further increased Ameluz® revenue by $0.7 million. The overall increase in Ameluz revenue was partially offset by a $0.2 million decrease in Xepi® revenue.

Operating Expenses

Cost of Revenues, Related Party

Cost of revenues, related party was $7.6 million and $4.0 million for the nine months ended September 30, 2021 and 2020, respectively, an increase of $3.6 million, or 89.6%. $2.5 million of such increase was driven by the increase in Ameluz® product revenue. Cost of Ameluz® is directly correlated to the selling price under the Ameluz LSA with Biofrontera Pharma GmbH. In addition, we received cost reimbursement from Pharma in 2020, which resulted in $1.1 million reduction in cost of revenues, related party during the nine months ended September 30, 2020.

Cost of Revenues, Other

Cost of revenues, other was $0.3 million and $0.6 million for the nine months ended September 30, 2021 and 2020, respectively. Decrease in cost of revenue, other was mainly driven by a $0.4 million provision in 2020 for Xepi® inventory obsolescence due to product expiring.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were $26.9 million and $13.6 million for the nine months ended September 30, 2021 and 2020, respectively, an increase of $13.4 million, or 98.7%. The increase was primarily driven by the legal settlement expenses recorded as of September 30, 2021 in the amount of $11.25 million. The increase

was further driven by a $1.7 million increase in headcount costs as a result of (i) resumed hiring in 2021 and (ii) higher commission expenses related to improved sales performance, and (iii) the impact of cost reimbursement received from Biofrontera Pharma GmbH which resulted in $0.1 million cost reduction during the nine months ended September 30, 2020. Marketing expense also increased by $1.2 million as we launched various marketing campaign for our licensed products. In addition, sales force travel and in-person trainings increased by $0.2 million. Such overall increase was partially offset by a decrease of $0.4 million in professional service expenses.

Selling, General and Administrative Expenses, Related Party

Selling, general and administrative expenses, related party were $0.5 million and $0.4 million for the nine months ended September 30, 2021 and 2020, respectively. Related party expense is based on costs incurred by Biofrontera AG plus 6% for services provided to us related to accounting consolidation, IT support and pharmacovigilance.

Restructuring Costs

Restructuring costs were $0.7 million and $0.9 million for the nine months ended September 30, 2021 and 2020 respectively, both of which related to facility exit costs.

Change in Fair Value of Contingent Consideration

Change in fair value of contingent consideration was an increase of $1.7 million and $0.2 million for the nine months ended September 30, 2021 and 2020, respectively. 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.

Interest Expense, net

Interest expense was $0.3 million and $2.1 million for the nine months ended September 30, 2021 and 2020, respectively. Interest expense during the nine months ended September 30, 2020 included $1.9 million incurred on the intercompany loan issued by Biofrontera AG. The intercompany loan was fully converted into shares of our common stock at the end of 2020. In addition, interest expense from the straight-line amortization of the contract asset related to start-up cost financing received from Maruho under the Share Purchase Agreement was $0.3 million during both of these periods.

Other Income, net

Other income, net was $0.4 million and $0.8 million for the nine months ended September 30, 2021 and 2020, respectively, both of which primarily related to reimbursed Share Purchase Agreement costs.

Net Income to Adjusted EBITDA Reconciliation for the three months and nine months ended September 30, 2021 and 2020

We define adjusted EBITDA as net income or loss from our statements of operations 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 cash flows as measures of 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 ("contingent consideration"). 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.

Cost reimbursement from Biofrontera Pharma GmbH: On August 27, 2020, we received $1.5 million cash consideration from Biofrontera Pharma GmbH to support our marketing effort to grow the sales of the licensed products we purchase from Biofrontera Pharma GmbH, Ameluz® and BF-RhodoLED® lamps. Of the $1.5 million, $1.2 million was recorded as a reduction of costs incurred during the three months ended September 30, 2021 and the remaining $0.3 million was recorded as a reduction to marketing expense incurred during the fourth quarter of 2020. This cash consideration is one-time and non-operating in nature. We believe that adjustment for this item more closely correlates with the reality of our operating performance.

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

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 loss to Adjusted EBITDA for the three months and nine months ended September 30, 2021 and 2021:

	Three months ended September 30,		Nine months ended September 30,	
	2021	**2020**	**2021**	**2020**
Net loss	**$ (16,012)**	**$ (2,985)**	**$ (23,208)**	**$ (10,801)**
Interest expense, net	86	744	255	2,113
Income tax expense	6	61	51	66
Depreciation and amortization	134	141	409	423
EBITDA	**(15,786)**	**(2,039)**	**(22,493)**	**(8,199)**
Change in fair value of contingent consideration	700	100	1,698	238
Cost reimbursement from Biofrontera Pharma GmbH	-	(1,188)	-	(1,188)
Legal settlement expenses	11,250	-	11,250	-
Adjusted EBITDA	**$ (3,836)**	**$ (3,127)**	**$ (9,545)**	**$ (9,149)**
Adjusted EBITDA margin	***-88.5%***	***-96.2%***	***-63.9%***	***-89.0%***

Adjusted EBITDA

Adjusted EBITDA decreased from ($3.1) million during the three months ended September 30, 2020 to ($3.8) million for the three months ended September 30, 2021. Our adjusted EBITDA margin improved from (96.2%) to (88.5%) during the same periods.

Adjusted EBITDA decreased from ($9.1) million during the nine months ended September 30, 2020 to ($9.5) million for the nine months ended September 30, 2021. Our adjusted EBITDA margin improved from (89.0%) to (63.9%) during the same periods.

Liquidity and Capital Resources

We devote a substantial portion of our cash resources to the commercialization of our licensed products, Ameluz®, the BF-RhodoLED® lamp and Xepi®. We have historically financed our operating and capital expenditures through cash proceeds generated from our product sales and proceeds received in connection with the Intercompany Revolving Loan Agreement with our parent, Biofrontera AG. On December 31, 2020, the Company agreed to convert the outstanding principal balance of the revolving debt in the amount of $47.0 million into an aggregate of 7,999,000 shares of our common stock at a price of $5.875 per share, which was based on our internal assessment and agreement with Biofrontera AG, our then parent, for an aggregate gross capital contribution of $47.0 million. On March 31, 2021, we entered into the Second Intercompany Revolving Loan Agreement with Biofrontera AG for $20.0 million of committed sources of funds for a two-year term. As of September 30, 2021, there was no loan principal balance outstanding under the Second Intercompany Revolving Loan.

Since inception, we have incurred losses and generated negative cash flows from operations. As of September 30, 2021, we had an accumulated deficit of $64.4 million, which is inclusive of a legal settlement liability of $11.25 million – see *Legal Proceedings section in Note 19* for further details, and cash and cash equivalents of $1.7 million.

On November 2, 2021, we completed an IPO, and issued and sold 3,600,000 Units, each consisting of (i) one Share and (ii) one Warrant entitling the holder to purchase one Share at an exercise price of $5.00 per Share. In addition, the underwriters exercised in full their option to purchase up to an additional 540,000 Warrants to cover over-allotments. The Units were sold at a price of $5.00 per Unit, and the Company estimates the net proceeds from the IPO to be $15.4 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by the Company.

On November 24 and November 26, 2021, investors exercised their warrants to purchase a total of 854,000 shares of common stock at an exercise price of $5.00 per share, resulting in estimated net proceeds of $3.9 million after deducting underwriting discounts and commission.

On November 29, 2021, we entered into a securities purchase agreement with a single institutional investor for the purchase of 2,857,143 shares of common stock (or common stock equivalents in lieu thereof) and warrants to purchase up to an aggregate of 2,857,143 shares of common stock, in a private placement. The combined purchase price for one share of common stock (or common stock equivalent) and a warrant to purchase one share of common stock is $5.25. The warrants have an exercise price of $5.25 per share, will be immediately exercisable, and will expire five years from the issuance date. The gross proceeds from the private placement offering are expected to be approximately $15.0 million. The private offering is expected to close on or about December 1, 2021, subject to the satisfaction of customary closing conditions.

Cash Flows

The following table summarizes our cash provided by and (used in) operating, investing and financing activities:

	Nine Months Ended September 30,	
(in thousands)	**2021**	**2020**
Net cash used in operating activities	$ (5,725)	$ (11,706)
Net cash used in investing activities	(2)	-
Net cash provided by (used in) financing activities	(638)	8,856
Net increase (decrease) in cash and restricted cash	$ (6,365)	$ (2,850)

Operating Activities

During the nine months ended September 30, 2021, operating activities used $5.7 million of cash, primarily resulting from our net loss of $23.2 million, adjusted for non-cash expense of $2.4 million as an offset and net cash provided by changes in our operating assets and liabilities of $15.1 million. The change in our operating assets and liabilities was primarily due to the legal settlement liability recorded as of September 30, 2021 in the amount of $11.25 million.

During the nine months ended September 30, 2020, operating activities used $11.7 million of cash, primarily resulting from our net loss of $10.8 million, adjusted for non-cash expense of $1.3 million as an offset and net cash used by changes in our operating assets and liabilities of $2.2 million.

Investing Activities

During the nine months ended September 30, 2021, net cash used in investing activities in the amount of $2,000 consisted of purchase of computer equipment.

Financing Activities

During the nine months ended September 30, 2021, cash used in financing activities was $0.6 million related to payments for deferred offering costs.

During the nine months ended September 30, 2020, cash provided by financing activities was $8.9 million, related to proceeds from the related party indebtedness and start-up cost financing related to the Cutanea acquisition.

Funding Requirements

We expect to continue to generate revenue from product sales. We also expect to continue to incur operating losses due to significant sales and marketing efforts as we seek to expand the commercialization of Ameluz® and Xepi® in the United States. In addition, we expect to incur additional expenses to add and improve operational, financial and information systems and personnel, including personnel to support our product commercialization efforts. We also 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 do not expect to incur significant costs related to capital expenditures.

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.

On March 31, 2021, we entered into the Second Intercompany Revolving Loan Agreement with Biofrontera AG for $20.0 million of committed sources of funds for a two-year term.

On November 2, 2021, we completed an IPO, and issued and sold 3,600,000 Units, each consisting of (i) one Share and (ii) one Warrant entitling the holder to purchase one Share at an exercise price of $5.00 per Share. In addition, the

underwriters exercised in full their option to purchase up to an additional 540,000 Warrants to cover over-allotments. The Units were sold at a price of $5.00 per Unit, and the Company estimates the net proceeds from the IPO to be $15.4 million, after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by the Company.

On November 24 and November 26, 2021, investors exercised their warrants to purchase a total of 854,000 shares of common stock at an exercise price of $5.00 per share, resulting in estimated net proceeds of $3.9 million after deducting underwriting discounts and commission.

On November 29, 2021, we entered into a securities purchase agreement with a single institutional investor for the purchase of 2,857,143 shares of common stock (or common stock equivalents in lieu thereof) and warrants to purchase up to an aggregate of 2,857,143 shares of common stock, in a private placement. The combined purchase price for one share of common stock (or common stock equivalent) and a warrant to purchase one share of common stock is $5.25. The warrants have an exercise price of $5.25 per share, will be immediately exercisable, and will expire five years from the issuance date. The gross proceeds from the private placement offering are expected to be approximately $15.0 million. The private offering is expected to close on or about December 1, 2021, subject to the satisfaction of customary closing conditions.

With the funds available under the Second Intercompany Revolving Loan Agreement, the net proceeds from the IPO, and the proceeds from the private placement offering, we will have sufficient funds to support the operating, investing, and financing activities of the Company through at least twelve months from the date of the issuance of the interim financial statements.

Impact of becoming a standalone company

We expect that our transition to operating as a standalone company will have a number of potentially significant effects on our results of operations.

Additional operating costs for becoming a standalone company — In the transition to becoming a public company and operating as a standalone entity, we will incur additional operating expenses that could be significant as a percentage of our net revenues, including costs associated with the financial reporting requirements of a standalone public company, such as salaries associated with building out our accounting department, legal fees, accounting and valuation services costs associated with preparing U.S. GAAP financial statements and external audit fees. *In addition*, we will incur additional operating expenses, including costs related to the build out of treasury and investor relations functions, additional non-executive board expenses, shareholder administration and insurance costs. In the short term, we expect general and administrative expenses to increase (both in absolute terms and as a percentage of net revenues) as a result of the costs associated with becoming a public company and operating as a standalone entity.

Additional costs to further business development and expansion – As we seek to expand the commercialization of Ameluz® and Xepi®, we expect to incur additional operating costs for significant sales and marketing efforts 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.

Critical Accounting Policies and Significant Judgments and Estimates

Our unaudited interim financial statements and the related notes included elsewhere in this Quarterly Report on Form 10-Q are prepared in accordance with GAAP. The preparation of our financial statements requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements, as well as the reported amounts of revenue generated and expenses incurred during the reporting periods, as well as related disclosures. Our estimates are based on our historical experience and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying value of assets and liabilities and the amounts of revenue and expenses that are not readily apparent from other sources.

Actual results may differ from these estimates under different assumptions or conditions, and any such differences may be material.

There have been no material changes to our critical accounting policies and estimates as compared to the critical accounting policies and estimates as described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations — Critical Accounting Policies and Significant Judgments and Estimates" in our Final Prospectus, except as noted in Note 2 – Summary of Significant Accounting Policies of the notes to our unaudited interim financial statements included elsewhere in this Quarterly Report on Form 10-Q.

Recently issued accounting pronouncements

A description of recently issued accounting pronouncements that may potentially impact our financial position and results of operations is disclosed in *Note 2—Summary of Significant Accounting Policies of the notes* to our financial statements included in this Quarterly Report on Form 10-Q.

Contractual Obligations and Commitments

During the three months ended September 30, 2021, there were no material changes to our contractual obligations and commitments from those described under the heading "Management's Discussion and Analysis of Financial Condition and Results of Operations – Contractual Obligations and Commitments" in our Final Prospectus.

On November 29, 2021, the Company entered into a settlement and release agreement with the respect to previously mentioned litigation in *Legal Proceedings section in Note 19*. 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 1-year constant maturity Treasury yield and agreed to pay in three installments, as follows:

- On the 25th day following the entry into the settlement agreement, the Company will pay 50% of the aggregate amount it owes;
- On the 365th day following the entry into the settlement agreement, the Company will pay 25% of the aggregate amount it owes; and
- On the 730th day following entry into the settlement, the Company will pay 25% of the aggregate amount it owes.

As of September 30, 2021, we recorded a legal settlement liability in the amount of $11.25 million.

Off-balance Sheet Arrangements

Besides the contractual obligations and commitments as discussed above, we did not have during the periods presented, and we do not currently have, any other off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Emerging Growth Company Status

The Jumpstart Our Business Startups Act of 2012 permits an "emerging growth company" such as us to take advantage of an extended transition period to comply with new or revised accounting standards applicable to public companies until those standards would otherwise apply to private companies. We have elected to take advantage of such extended transition period, which means that when an accounting standard is issued or revised and it has different application dates for public or private companies, we will adopt the new or revised standard at the time private companies adopt the new or revised standard and will do so until such time that we either (i) irrevocably elect to "opt out" of such extended transition period or (ii) no longer qualify as an emerging growth company.

Quantitative and Qualitative Disclosures About Market Risk.

As a "smaller reporting company," we are not required to provide the information required by this item.

Controls and Procedures.

We maintain a system of disclosure controls and procedures, as defined in Rule 13a-15(e) or Rule 15d-15(e) under the Securities Exchange Act of 1934, as amended (the "Exchange Act"), which is designed to provide reasonable assurance that information required to be disclosed in our reports filed pursuant to the Exchange Act is accumulated and communicated to management in a timely manner. Management recognizes that any disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their objectives. Because there are inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud have been or will be detected.

Evaluation of Disclosure Controls and Procedures

Our management, with the participation of our Chief Executive Officer and Corporate Controller, evaluated, as of the end of the period covered by this Quarterly Report on 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 Corporate Controller concluded that, as of September 30, 2021, our disclosure controls and procedures were not effective at the reasonable assurance level.

Material Weakness

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, 2020 and December 31, 2019, we identified a material weakness in our internal control over financial reporting. The material weakness we identified 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 a third-party service provider was not sufficiently precise to identify an error. 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.

While we have taken steps to enhance our internal control environment and continue to address the underlying cause of the material weakness by the creation of additional controls including those designed to strengthen our review and validation of the work product from third-party service providers, the steps we have taken to date, and that we are continuing to implement, may not be sufficient to remediate this material weakness or to avoid the identification of material weaknesses in the future. We will monitor the effectiveness of our remediation plan and will make changes we determine to be appropriate.

We are still in process of remediating this material weakness as of September 30, 2021. 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.