



Press Releases

Biofrontera Inc. Reports Third Quarter and Nine-Month 2024 Financial Results and Provides Business Update

November 14, 2024 | 13 min read



	<ul style="list-style-type: none">Total revenues for the third quarter 2024 were \$9.0 million, an increase of 1.5% from Q3 2023. Revenue increase would have been 19% if shipments were not delayed due to Hurricane Milton.
	<ul style="list-style-type: none">Total revenues for the first 9 months were \$24.8 million, an increase of \$1.3 million, or 5.6% as compared to the same period last year. Without the impact of Hurricane Milton delaying shipments, the increase would have been 12%.
	<ul style="list-style-type: none">Ameluz® achieved record volume in September 2024.
	<ul style="list-style-type: none">Organization continues to prudently manage SG&A expenses in line with business needs with a reduction of 14% in the first 9 months of 2024 vs 2023.
	<ul style="list-style-type: none">Cash and cash equivalents were \$2.9 million as of September 30, 2024, compared with \$1.3 million on December 31, 2023.
	<ul style="list-style-type: none">RhodoLED XL launch continues to be successful with 39 installed since launch in late June 2024; additionally, 66 BF-RhodoLED lamps have been installed in the first three quarters of 2024.
	<ul style="list-style-type: none">On October 4 FDA approved sNDA to increase the maximally allowed dosage of Ameluz® from one tube to three tubes per treatment.
	<ul style="list-style-type: none">Preliminary results of Phase 3 sBCC study are highly statistically significant for all primary and secondary endpoints (p<0.0001). Ameluz-PDT achieved 75.9% histological clearance vs 19% with placebo.

WOBURN, Mass., Nov. 13, 2024 (GLOBE NEWSWIRE) -- Biofrontera Inc. (Nasdaq: BFRI) (“Biofrontera” or the “Company”), a biopharmaceutical company specializing in the development and commercialization of photodynamic therapy (PDT), today reported financial results for the three and nine months ended September 30, 2024 and provided a business update.

Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc., stated, “While we are pleased with the third quarter results, we faced challenges from Hurricane Milton that impacted our business and that of our customers in the areas affected. The hurricane delayed the shipment of 4,640 tubes of Ameluz, representing approximately \$1.5 million in revenue. All the tubes were shipped in October and will count towards Q4. As reported, this reduced our quarterly growth to 1.5% and year-to-date growth to 5.6%. Without this delay, quarterly growth would have been 19% and year-to-date growth 12%.”

“We have made some important progress across our business in 2024. We have seen very positive uptake of our products throughout the United States, illustrated by the number of lamps sold to dermatology offices. The transfer of clinical trial activities from Biofrontera AG to Biofrontera Inc. was seamless, with all trials progressing as planned. We continue to prepare our FDA filing for the approval of Ameluz for the treatment of sBCC, which we expect to submit in the 1st half of 2025. If that is the case, we anticipate approval in early 2026. Furthermore, on October 4th the FDA approved an increase in the maximally approved dosage from one to three tubes of Ameluz® per treatment. This approval allows for larger field treatment of mild to moderate actinic keratosis on the face and scalp with Ameluz®-PDT using the BF-RhodoLED® or the RhodoLED® XL lamp.





Third Quarter Financial Results

Total revenues for the third quarter of 2024 were \$9.0 million compared with \$8.9 million for the third quarter of 2023. This increase was driven by a \$0.6 million increase from sales of devices, offset by a net decrease in sales of Ameluz of \$0.5 million. The decline in Ameluz unit sales resulted from the delayed delivery of 4,640 units in October 2024, as Hurricane Milton caused office closures and shipping delays across the Southeast.

Total operating expenses were \$14.0 million for the third quarter of 2024 compared with \$13.5 million for the third quarter of 2023. Cost of revenues was \$4.9 million for the third quarter of 2024 compared with \$4.6 million for the prior-year quarter. This was driven by an increase of \$0.5 million due to higher COGS for lamp revenue, partially offset by a decrease of \$0.2 million due to the decrease in sales of Ameluz®.

Selling, general and administrative expenses were \$8.4 million for the third quarter of 2024 compared with \$8.6 million for the third quarter of 2023. The decrease was primarily driven by a \$0.5 million reduction in general business administration expenses, as well as a decrease of non-personnel sales and marketing expenses of \$0.2 million, and a \$0.3 million decrease in personnel costs due to change in headcount and reduced severance. This was offset by a \$0.8 million increase in legal expenses related to the competitor complaints at the International Trade Commission (ITC) and the US District Court for the District of Massachusetts.

The net loss for the third quarter of 2024 was \$5.7 million, compared with a net loss of \$6.3 million for the prior-year quarter. Adjusted EBITDA for the third quarter of 2024 was negative \$4.6 million compared with negative \$3.9 million for the third quarter of 2023, reflecting our selling, general, and administrative costs. We look at Adjusted EBITDA, a non-GAAP financial measure, as a better indication of ongoing operations and this measurement is defined as net income or loss excluding interest income and expense, income taxes, depreciation and amortization, and certain other non-recurring or non-cash items. The primary driver of the lower Adjusted EBITDA was increased R&D spend since we took over clinical operations for Ameluz as of June 2024.

Please refer to the table below which presents a GAAP to non-GAAP reconciliation of Adjusted EBITDA for the third quarters of 2024 and 2023.

Nine Month Financial Results

Total YTD revenues were \$24.7, an increase of \$1.3 million, or 5.6% as compared to the same period last year. This increase was driven by a higher unit sales price for Ameluz® and a revenue increase in device sales due to the commercial launch of the RhodoLED XL. After a revenue decline of 9% in Q1 followed by 8% growth for the first half of the year, we would now have seen year-over-year growth of approximately 12% without the impact of the shipping delays caused by Hurricane Milton.

Total operating expenses were \$40.2 million for the nine months ended September 30, 2024 compared with \$42.3 million to the same period last year. Cost of revenues increased from the prior year to \$13.3 million for the nine months ended September 30, 2024, compared to \$12.1 million for the same period last year. Selling, general and administrative expenses decreased to \$25.6 million compared to \$29.9 million in the prior year. Specifically, this decrease entails \$1.7 million in legal costs for the settlement with Biofrontera AG in April 2023, \$1.3 million of non-personnel sales and marketing expenses due to a lower level of marketing activities in general, \$0.6 million in general business administration, and \$0.6 million in personnel expenses, partially offset by legal costs relating to the complaints filed by our competitor.

Adjusted EBITDA was negative \$13.9 million for the nine months ended September 30, 2024 compared with negative \$15.8 million for the same period last year, primarily driven by the lower SG&A costs mentioned above.

Conference Call Details

Conference call: Thursday, **November 14, 2024 at 10:00 AM Eastern Time**

Toll Free: 1-877-877-1275 (U.S. toll-free)

International: 1-412-858-5202

Webcast: <https://event.choruscall.com/mediaframe/webcast.html?webcastid=OvxLI2Kz>

About Biofrontera Inc.

Biofrontera Inc. is a U.S.-based biopharmaceutical company specializing in the treatment of dermatological conditions with a focus on PDT. The Company commercializes the drug-device combination Ameluz® with the RhodoLED® lamp series for PDT of Actinic Keratosis (AK), pre-cancerous skin lesions which may progress to invasive skin cancers². The Company performs clinical trials to extend the use of the products to treat non-melanoma skin cancers and moderate to severe acne. For more information, visit www.biofrontera-us.com and follow Biofrontera on [LinkedIn](#) and [Twitter](#).

1 - <https://www.skincancer.org/skin-cancer-information/actinic-keratosis/>

Contacts Investor Relations

Andrew Barwicki



Forward-Looking Statements

Certain statements in this press release may constitute “forward-looking statements” within the meaning of the United States Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, statements relating to the Company’s revenue guidance, business and marketing strategy, revenue growth, sales force productivity, growth strategy, liquidity and cash flow, potential to expand the label of Ameluz®, available market opportunities for Ameluz®, ongoing clinical trials, educational outreach efforts, and other statements that are not historical facts. The words “intends,” “may,” “will,” “plans,” “expects,” “anticipates,” “projects,” “predicts,” “estimates,” “aims,” “believes,” “hopes,” “potential”, “target”, “goal”, “assume”, “would”, “could” or similar words are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. We have based these forward-looking statements on our current expectations and projections about future events; nevertheless, actual results or events could differ materially from the plans, intentions and expectations disclosed in, or implied by, the forward-looking statements we make. These risks and uncertainties, many of which are beyond our control, 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 the Company’s licensors to establish and maintain relationships with contract manufacturers that are able to supply the Company with enough of the licensed products to meet our demand; the ability of our licensors or their manufacturing partners to supply the licensed products that we market in sufficient quantities and at acceptable quality and cost levels, and to fully comply with current good manufacturing practice or other applicable manufacturing regulations; the ability of our licensors to successfully defend or enforce patents related to our licensed products; the availability of insurance coverage and medical expense reimbursement for our licensed products; the impact of legislative and regulatory changes; competition from other pharmaceutical and medical device companies and existing treatments, such as simple curettage and cryotherapy; the Company’s ability to achieve and sustain profitability; the Company’s ability to obtain additional financing as needed to implement its growth strategy; the Company’s ability to retain and hire key personnel; and other factors that may be disclosed in the Company’s filings with the Securities and Exchange Commission (“SEC”), which can be obtained on the SEC website at www.sec.gov. Readers are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date on which they are made and reflect management’s current estimates, projections, expectations and beliefs. The Company does not undertake to update any such forward-looking statements and expressly disclaims any duty to update the information contained in this press release, except as required by law.

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

	September 30, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 2,873	\$ 1,343
Investment, related party	8	78
Accounts receivable, net	4,874	5,162
Inventories, net	6,526	10,908
Prepaid expenses and other current assets	350	425
Assets held for sale	2,300	-
Other assets, related party	-	5,159
Total current assets	16,931	23,075
Property and equipment, net	82	134



Intangible asset, net			39			2,629	
Other assets			383			482	
Total assets			\$ 18,516			\$ 27,932	
LIABILITIES AND STOCKHOLDERS' EQUITY							
Current liabilities:							
Accounts payable			2,027			3,308	
Accounts payable, related parties			3,680			5,698	
Operating lease liabilities			670			691	
Accrued expenses and other current liabilities			4,655			4,487	
Short term debt			-			3,904	
Total current liabilities			11,032			18,088	
Long-term liabilities:							
Warrant liabilities			1,601			4,210	
Operating lease liabilities, non-current			324			804	
Other liabilities			29			37	
Total liabilities			12,986			23,139	
Commitments and contingencies							
Stockholders' equity:							
Series B Convertible Preferred stock, \$0.001 par value, 20,000,000 shares authorized, no Series B-1, 4,695 Series B-2 and 7,093 Series B-3 shares issued and outstanding as of September 30, 2024 and no shares issued and outstanding as of December 31, 2023			-			-	
Common stock, \$0.001 par value, 35,000,000 shares authorized; 6,529,792 and 1,517,628 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively			7			2	
Additional paid-in capital			121,536			104,441	
Accumulated deficit			(116,013)			(99,650)	
Total stockholders' equity			5,530			4,793	



Total liabilities and stockholders' equity	\$	18,516	\$	27,932
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BIOFRONTERA INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts and number of shares)
(Unaudited)

	Three Months Ended September 30,				Nine Months Ended September 30,			
	2024		2023		2024		2023	
Product revenues, net	\$	9,012	\$	8,879	\$	24,744	\$	23,423
Revenues, related party		-		17		18		52
Total revenues, net		9,012		8,896		24,762		23,475
Operating expenses								
Cost of revenues, related party		4,801		4,495		12,839		11,814
Cost of revenues, other		76		95		496		262
Selling, general and administrative		8,425		8,619		25,589		29,874
Selling, general and administrative, related party		1		74		30		193
Research and development		669		33		1,306		44
Change in fair value of contingent consideration		-		200		-		100
Total operating expenses		13,972		13,516		40,260		42,287
Loss from operations		(4,960)		(4,620)		(15,498)		(18,812)
Other income (expense)								
Change in fair value of warrants		(680)		598		1,329		2,001
Change in fair value of investment, related party		(2)		(2,212)		(12)		(6,635)



Interest income																
(expense), net			8			(142	)			(1,995	)			(256	)	
Other income																
(expense), net			(32	)		35				154				65		
Total other expense			(706	)		(1,721	)			(840	)			(4,825	)	
Loss before income taxes			(5,666	)		(6,341	)			(16,338	)			(23,637	)	
Income tax expense			3			1				25				20		
Net loss		\$	(5,669	)		\$	(6,342	)		\$	(16,363	)		\$	(23,657	)
Loss per common share:																
Basic and diluted		\$	(0.98	)		\$	(4.64	)		\$	(3.39	)		\$	(17.57	)
Weighted-average common shares outstanding:																
Basic and diluted			5,773,993			1,366,842				4,833,091				1,346,264		

BIOFRONTERA INC.
GAAP TO NON-GAAP ADJUSTED EBITDA RECONCILIATION
(In thousands, except per share amounts and number of shares)
(Unaudited)

		Three Months Ended September 30,								Nine Months Ended September 30,								
		2024					2023				2024					2023		
		\$	(5,669	)		\$	(6,342	)			\$	(16,363	)			\$	(23,657	)
Net loss																		
Interest expense, net			(8	)			142					1,995					256	
Income tax expenses			3				1					25					20	
Depreciation and amortization			129				251					387					769	
EBITDA			(5,545	)			(5,948	)				(13,956	)				(22,612	)
Loss on debt extinguishment			-				-					316					-	
Change in fair value of contingent consideration			-				200					-					100	
Change in fair value of warrant liabilities			680				(598	)				(1,329	)				(2,001	)
Change in fair value of investment, related party			2				2,212					12					6,635	



Stock based compensation			288			207			720			817				
Expensed issuance costs			-			-			354			-				
Adjusted EBITDA		\$	(4,575	)		\$	(3,927	)		\$	(13,883	)		\$	(15,836	)
Adjusted EBITDA margin			-50.8	%			-44.1	%			-56.1	%			-67.5	%



- Massachusetts
- Earnings



"I do believe that Dr. Vince Clinical Research operates like a well-oiled machine, and their conduct of our study was instrumental in helping us achieve our goals."

MEDICAL DIRECTOR, CLINICAL SCIENCE
JANUARY 2025



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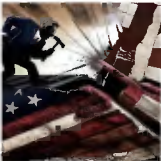


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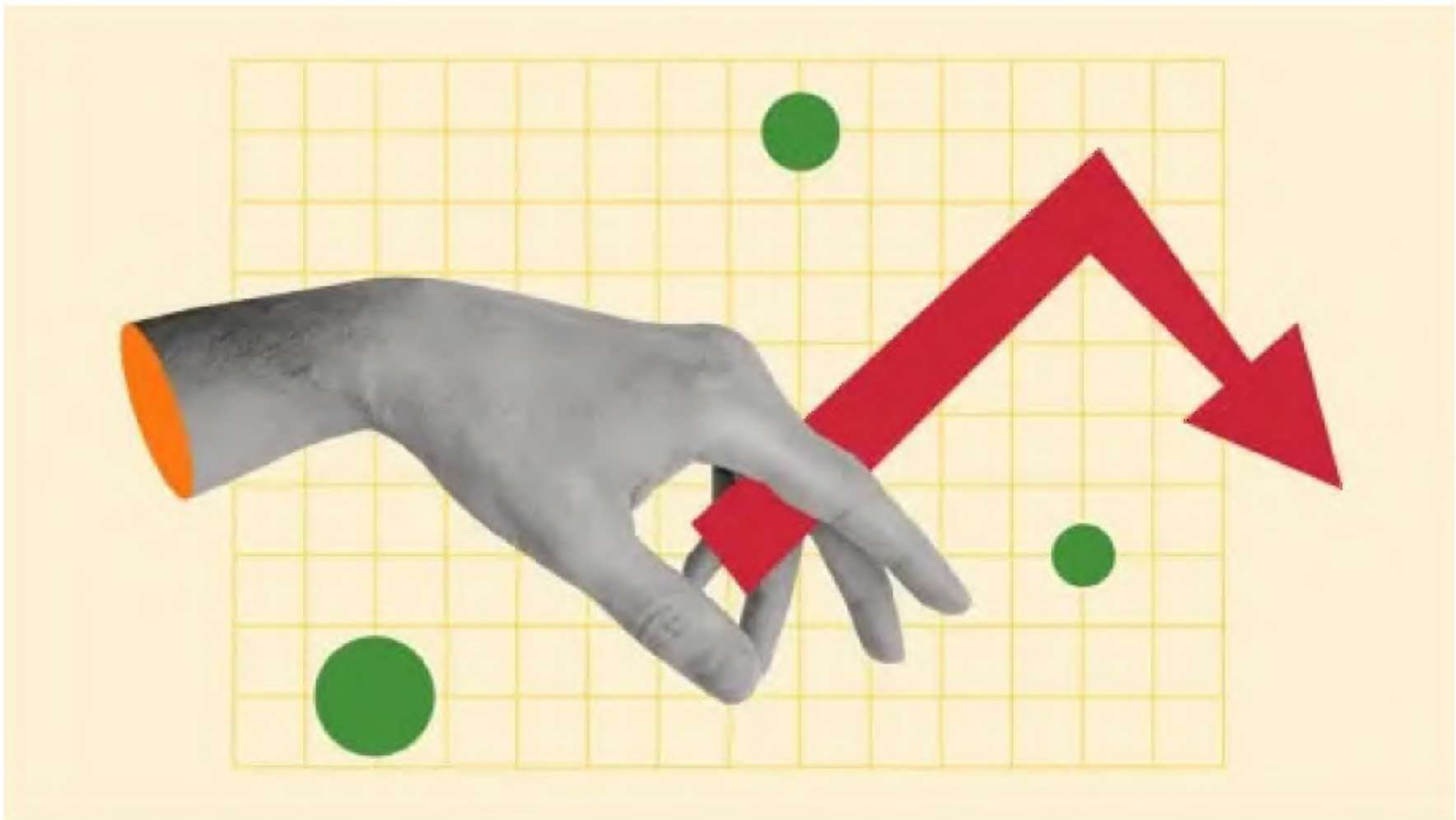
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