Biofrontera Inc. Reports Strong Third Quarter 2026 Financial Results Driven by 30% Year-Over-Year Revenue Growth

WOBURN, Mass., Nov. 13, 2026 (GLOBE NEWSWIRE) — Biofrontera Inc. (NASDAQ: BFRI) (“Biofrontera” or the “Company”), a biopharmaceutical company specializing in the development and commercialization of photodynamic therapy (PDT) in dermatology, today reported financial results for the quarter ended September 30, 2026.

Third Quarter 2026 Highlights

- Net product revenue of $9.1 million, an increase of 29.8% compared to $7.0 million in the prior-year period.
- Gross margin of 74.4%, compared to 70.7% in the prior-year period, an improvement of approximately 370 basis points, reflecting the lower Ameluz® cost structure established following the closing of the strategic transaction with Biofrontera AG in October 2025 (the “Strategic Transaction”), partially offset by ITC Matter-related inventory write-downs and higher lamp and device costs.
- Net loss of $6.4 million, or $(0.42) per share, compared to a net loss of $6.6 million, or $(0.62) per share, in the prior-year period.
- Adjusted EBITDA of $(5.5) million, compared to $(6.0) million in the prior-year period.
- On September 9, 2026 FDA Approval of Ameluz on September for the treatment of Superficial Basal Cell Carcinoma (sBCC), making Ameluz plus Red-Light the first and only PDT approved for the treatment of cancerous skin tumors.
- US Customs and Border Protection ruled that the re-designed XL-C lamp did not violate the ITC order and could be imported for use in the US market.

Nine Months Ended September 30, 2026 Highlights

- Net product revenue of $31.2 million, an increase of 26.6% from $24.6 million in the prior-year period.
- Gross margin of 78.0%, compared to 67.7% in the prior-year period.
- Net loss of $11.8 million, or $(0.89) per share, compared to a net loss of $16.2 million, or $(1.67) per share, in the prior-year period.
- Adjusted EBITDA of $(9.3) million, compared to $(15.5) million in the prior-year period.

Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera, stated: “The third quarter was a pivotal one for Biofrontera. On September 9, the FDA approved Ameluz® PDT for the treatment of superficial basal cell carcinoma (sBCC), making it the first PDT approved in the United States for a cancerous skin tumor. Five days later, U.S. Customs and Border Protection ruled that our redesigned RhodoLED® XL-C is not subject to the ITC exclusion order, which allows us to again serve the customers who rely on our large-field lamp.

Revenue grew 30% in the quarter and 27% for the first nine months, and our gross margin continues to reflect the lower cost structure we put in place with the Strategic Transaction. The quarter also carried the legal and remediation costs of the ITC Matter, and with the XL-C now cleared our attention is on execution. We are preparing to begin commercializing Ameluz® for sBCC later in the fourth quarter and into the first quarter of 2027, and in October we submitted a supplemental New Drug Application to expand the Ameluz® label for actinic keratosis to the extremities, neck and trunk. Each of these indications is served by the lamps and the sales force we already have in place."

Third Quarter 2026 Financial Results

Net product revenue for the third quarter of 2026 was $9.1 million, an increase of $2.1 million, or 29.8%, from $7.0 million in the third quarter of 2025. The increase was primarily attributable to a 23.3% increase in Ameluz® unit volume resulting in an increase of $1.6 million and $0.3 million due to price and mix increase, with the balance reflecting higher device sales. The increase in unit volume was partially driven by accelerated order timing from certain customers in early July 2026 in anticipation of potential supply restrictions resulting from the limited exclusion order and cease and desist order issued by the U.S. International Trade Commission ("ITC") related to our RhodoLED® XL lamp, which took effect on July 6, 2026 (the "ITC Matter") and importantly, commercial execution where we have focused on increasing utilization with key accounts and bringing Ameluz to new dermatology customers. We believe that the accelerated ordering impacted the timing of orders rather than total demand. On September 14, 2026, U.S. Customs and Border Protection ("CBP") issued a ruling finding that our redesigned RhodoLED® XL-C is not subject to the exclusion order, and we began placing XL-C lamps during the 3rd quarter, enabling these customers to again purchase Ameluz®.

Cost of revenues was $2.3 million, compared to $2.0 million in the prior-year period, producing gross profit of $6.7 million and a gross margin of 74.4%, compared to gross profit of $4.9 million and a gross margin of 70.7% in the third quarter of 2025. The improvement was driven principally by the transition from the prior transfer pricing arrangement to a cost structure comprising Ameluz® direct cost plus a 12% earnout on net revenue, which reduced cost of Ameluz® despite a 23.3% increase in unit volume. This was partially offset by a $0.4 million increase in lamp and device costs, including $0.3 million of ITC Matter-related inventory write-downs.

Selling, general and administrative ("SG&A") expenses, including SG&A, related party, were $12.5 million, compared to $10.4 million in the prior-year quarter, an increase of $2.1 million, driven primarily by a $0.9 million increase in legal fees related to the ITC Matter, $0.7 million

of combined costs from lamp manufacturing and regulatory and product affairs, and a $0.5 million increase in direct sales expenses, mainly commissions on higher Ameluz® sales volume.

Research and development expenses were $0.5 million, compared to $0.9 million in the prior-year quarter, reflecting the substantial completion of clinical trials.

Patent remediation expense related to the ITC Matter was $0.3 million, compared to none in the prior-year quarter, reflecting a $0.2 million increase in the estimated remediation cost following the September 14, 2026 CBP ruling and a $0.1 million write-down of loaner and RhodoLED® XL lamps used in the remediation program.

Net loss for the third quarter was $6.4 million, or $(0.42) per share, compared to a net loss of $6.6 million, or $(0.62) per share, for the prior-year quarter. Adjusted EBITDA, a non-GAAP measure reconciled below, was $(5.5) million, compared to $(6.0) million in the prior-year period.

Nine Months Ended September 30, 2026 Financial Results

Net product revenue for the nine months ended September 30, 2026 was $31.2 million, an increase of $6.6 million, or 26.6%, from $24.6 million in the first nine months of 2025. The increase reflects Ameluz® unit volume growth of $5.5 million and a price impact of approximately $0.7 million and the remainder generally attributable to increases in device sales.

Cost of revenues was $6.8 million, compared to $8.0 million in the prior-year period, producing gross profit of $24.3 million and gross margin of 78.0%, compared to gross profit of $16.7 million and gross margin of 67.7% in the prior-year period. The improvement was driven principally by the same transition in Ameluz® cost structure described above.

SG&A expenses, including SG&A related party, were $33.2 million, compared to $29.6 million in the prior-year period, an increase of $3.5 million. The increase was primarily driven by $1.8 million of combined costs from manufacturing and regulatory and product affairs; $1.2 million of higher direct sales expenses, mainly sales commissions reflecting Ameluz® sales volume growth; and $0.8 million of higher sales support expenses, reflecting increased commercial activity. Other SG&A expenses, including stock-based compensation, depreciation and amortization, and bad debt, increased $0.3 million. These increases were partially offset by a $0.3 million decrease in selling, general and administrative expenses, related party, and a $0.2 million decrease in general and administrative costs.

Research and development expenses were $1.8 million, compared to $2.9 million, reflecting the substantial completion of clinical trials.

Patent remediation expense related to the ITC Matter was $0.7 million, compared to none in the prior-year period. Including inventory write-downs recorded in cost of revenues, the Company has recognized total charges of $1.1 million related to the ITC Matter through September 30, 2026, consisting of $0.6 million of accrued remediation costs and $0.5 million of inventory write-downs to net realizable value. Of the accrued remediation costs, $0.2 million was settled with inventory used in the remediation program and the remaining $0.4 million is paid or payable in cash.

Net loss was $11.8 million, or $(0.89) per share, compared to a net loss of $16.2 million, or $(1.67) per share, in the prior-year period. Adjusted EBITDA was $(9.3) million, compared to $(15.5) million in the prior-year period.

Please refer to the table below which presents a GAAP to non-GAAP reconciliation of Adjusted EBITDA for the third quarters and first nine months of 2026 and 2025.

Balance Sheet and Cash Flow

Cash and cash equivalents were $3.2 million as of September 30, 2026, compared to $6.4 million as of December 31, 2025. Cash used in operating activities for the nine months ended September 30, 2026 was $3.2 million, compared to $11.0 million in the prior-year period.

Total liabilities were $21.7 million as of September 30, 2026, compared to $18.1 million at December 31, 2025. The Company’s outstanding indebtedness as of September 30, 2026 consisted of $4.7 million of convertible notes, net, maturing in November 2027. The Company has no bank or other term debt.

Conference Call

Biofrontera will host a conference call and webcast on Friday, November 13, 2026 at 10:00 a.m., Eastern Time. Participants may dial 1-877-877-1275 (U.S./Canada toll-free), 1-866-605-3852 (Canada toll-free), or 1-412-858-5202 (international).

About Biofrontera Inc.

Biofrontera Inc. is a U.S.-based biopharmaceutical company commercializing a portfolio of pharmaceutical products for the treatment of dermatological conditions with photodynamic therapy (PDT). The Company’s products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions, and, following FDA approval in September 2026, superficial basal cell carcinoma, and are in development for additional indications. For more information, visit www.biofrontera-us.com and follow Biofrontera on LinkedIn and X.

Use of Non-GAAP Financial Measures

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.

We exclude the change in fair value of warrant liabilities and the change in fair value of investment, related party, because these items are non-cash. We exclude patent remediation expense and ITC-related inventory write-downs because they relate to a discrete adverse legal and regulatory matter that is not indicative of the Company's ongoing operating performance. We exclude stock-based compensation, which is non-cash, because the subjective assumptions and variety of award types involved can cause this expense to vary significantly, and its exclusion allows for more meaningful comparisons of our operating results to peer companies.

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, and we believe that, when viewed with GAAP financial information, this presentation provides investors with useful information regarding financial and business trends related to our results of operations and a more meaningful understanding of our ongoing operating performance.

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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. All statements, other than statements of historical facts, in this press release, including statements regarding our strategy, future operations, regulatory process, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth, are forward-looking statements. The words "believe", "anticipate",

“intend”, “expect”, “target”, “goal”, “estimate”, “plan”, “assume”, “may”, “will”, “predict”, “project”, “would”, “could” and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. You should read this press release and any documents referenced herein completely and with the understanding that our actual future results may be materially different from what we expect. While we have based these forward-looking statements on our current expectations and projections about future events, we may not actually achieve the plans, intentions or expectations disclosed in or implied by our forward-looking statements, and you should not place undue reliance on our forward-looking statements.

These forward-looking statements are subject to risks, uncertainties and assumptions about us and accordingly, 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 ability to achieve and sustain profitability; our ability to compete effectively in selling our products; our ability to expand, manage and maintain our direct sales and marketing efforts, including our ability to obtain the financing to develop our marketing strategy, if needed; changes in our relationship with our manufacturing partners and the possible impact of tariffs; our ability to manufacture our products; our ability to adequately protect our intellectual property and operate the business without infringing upon the intellectual property rights of others; our actual financial results may vary significantly from forecasts and from period to period; our estimates regarding anticipated operating losses, future revenues, capital requirements and our needs for additional financing; market risks regarding consolidation and group purchasing organizations (“GPOs”) in the healthcare industry; the willingness of healthcare providers to purchase our products if coverage, reimbursement and pricing from third-party payors for our products, or procedures using our products significantly declines; our ability to market, commercialize, achieve market acceptance for and sell our products; the fact that product quality issues or product defects may harm our business; any claims brought against the Company, including but not limited to product liability claims, claims of patent infringement, or claims challenging the validity of our intellectual property; our ability to maintain compliance with The Nasdaq Stock Market, LLC continued listing standards; our ability to comply with the requirements of being a public company; the progress, timing and completion of research, development and preclinical studies and clinical trials for our products; our ability to obtain and maintain the regulatory approvals necessary for the marketing of our products in the United States; 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. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. Any forward-looking statements speak only as of the date on which they are made, and we undertake no obligation to publicly update or revise any forward-looking statements to reflect events or

circumstances that may arise after the date of this press release, except as required by applicable law. Investors should evaluate any statements made by us in light of these important factors.

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

	September 30, 2026 (Unaudited)	December 31, 2025
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,218	$ 6,392
Investment, related party	12	9
Accounts receivable, net	4,787	7,291
Inventories	1,733	1,426
Prepaid expenses and other current assets	1,111	2,279
Other assets, related party	242	686
Total current assets	**11,103**	**18,083**
Inventories, long term	2,565	3,729
Property and equipment, net	2,112	2,158
Operating lease right-of-use assets	2,707	1,584
Intangible assets, net	2,528	2,650
Other assets	451	360
Total assets	**$ 21,466**	**$ 28,564**
LIABILITIES AND STOCKHOLDERS' (DEFICIT) EQUITY		
Current liabilities:		
Accounts payable	6,896	1,855
Accounts payable, related parties, net	731	4,811
Operating lease liabilities	463	332
Accrued expenses and other current liabilities	6,147	4,897
Total current liabilities	**14,237**	**11,895**
Long-term liabilities:		
Convertible notes payable, net	4,749	4,589
Warrant liabilities	395	351
Operating lease liabilities, non-current	2,322	1,240
Other liabilities	6	9
Total liabilities	**21,709**	**18,084**
Commitments and contingencies		
Stockholders' (deficit) equity:		

Convertible Preferred Stock, $0.001 par value, 20,000,000 shares authorized; 759 and 2,050 Series B-2; 6,498 and 6,593 Series B-3; 8,390 and 10,719 Series C; and 3,019 and 3,019 Series D shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	–	–
Common stock, $0.001 par value, 70,000,000 shares authorized; 17,949,000 and 11,648,323 shares issued and outstanding as of September 30, 2026 and December 31, 2025, respectively	18	12
Additional paid-in capital	139,463	138,413
Accumulated deficit	(139,724)	(127,945)
Total stockholders' (deficit) equity	**(243)**	**10,480**
Total liabilities and stockholders' (deficit) equity	**$ 21,466**	**$ 28,564**

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,	
	2026	**2025**	**2026**	**2025**
Product revenues, net	**$ 9,070**	**$ 6,988**	**$ 31,157**	**$ 24,605**
Operating expenses				
Cost of revenues, related party	2,164	1,922	6,180	7,377
Cost of revenues, other	157	123	667	578
Selling, general and administrative	12,461	10,047	33,083	29,229
Selling, general and administrative, related party	29	320	72	396
Patent remediation expense	306	–	698	–
Research and development	450	854	1,798	2,932
Total operating expenses	**15,567**	**13,266**	**42,498**	**40,512**
Loss from operations	**(6,497)**	**(6,278)**	**(11,341)**	**(15,907)**
Other income (expense)				
Change in fair value of warrant liabilities	132	(285)	(44)	417
Change in fair value of investment, related party	4	1	4	3
Interest expense, net	(128)	(111)	(379)	(331)
Other income (expense), net	70	30	8	(333)
Total other income (expense)	**78**	**(365)**	**(411)**	**(244)**
Loss before income taxes	**(6,419)**	**(6,643)**	**(11,752)**	**(16,151)**

Income tax expense	4	6	27	25
Net loss	**$ (6,423)**	**$ (6,649)**	**$ (11,779)**	**$ (16,176)**
Loss per common share:				
Basic and diluted	$ (0.42)	$ (0.62)	$ (0.89)	$ (1.67)
Weighted-average common shares outstanding:				
Basic and diluted	15,280,526	10,776,739	13,309,031	9,674,378

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,	
	2026	**2025**	**2026**	**2025**
Net loss	**$ (6,423)**	**$ (6,649)**	**$ (11,779)**	**$ (16,176)**
Interest expense, net	128	111	379	331
Income tax expense	4	6	27	25
Depreciation and amortization	59	25	179	76
EBITDA	**(6,232)**	**(6,507)**	**(11,194)**	**(15,744)**
Change in fair value of warrant liabilities	(132)	285	44	(417)
Change in fair value of investment, related party	(4)	(1)	(4)	(3)
ITC-related inventory write-downs	317	–	375	–
Patent remediation expense	306	–	698	–
Stock-based compensation	224	236	829	662 [(1)]
Adjusted EBITDA	**$ (5,521)**	**$ (5,987)**	**$ (9,252)**	**$ (15,502)**
Adjusted EBITDA margin	***-60.9 %***	***-85.7 %***	***-29.7 %***	***-63.0 %***

[(1)] Stock-based compensation for the nine months ended September 30, 2025 included in the Adjusted EBITDA reconciliation above has been revised from $0.4 million, as previously reported, to $0.7 million to correct the amount presented in the prior-period reconciliation. The revision affects only this non-GAAP measure and had no effect on the Company's condensed consolidated financial statements.