

Healthcare: Biotechnology
Analysis of Sales/Earnings

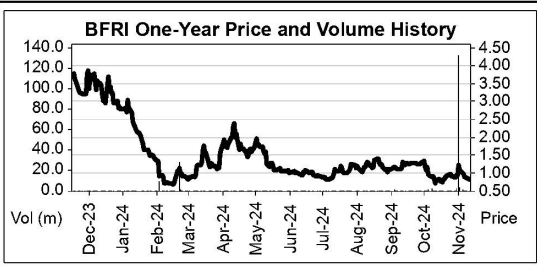
Estimates Changed

Biofrontera, Inc. | BFRI-\$0.83-NASDAQ | Buy

Stock Data					
52-Week Low - High	\$0.68-\$3.99				
Shares Out. (mil)	5.54				
Mkt. Cap.(mil)	\$5.22				
3-Mo. Avg. Vol.	2,491,628				
12-Mo.Price Target	\$16.00				
Cash (mil)	\$2.9				
Tot. Debt (mil)	\$0.0				

Rev (\$M)					
Yr Dec	— 2023—	— 2024E—		— 2025E—	
		Curr	Prev	Curr	Prev
1Q	8.7A	7.9A	7.9A	11.0E	--
2Q	5.8A	7.8A	7.8A	10.0E	--
3Q	8.9A	9.0A	11.0E	12.0E	--
4Q	10.6A	15.2E	14.2E	15.1E	--
YEAR	34.0A	39.9E	41.0E	48.1E	49.6E

EPS \$					
Yr Dec	— 2023—	— 2024E—		— 2025E—	
		Curr	Prev	Curr	Prev
1Q	(5.60)A	(2.88)A	(2.88)A	(0.21)E	--
2Q	(7.23)A	(0.05)A	(0.05)A	(0.32)E	--
3Q	(4.64)A	(0.98)A	(0.73)E	(0.15)E	--
4Q	1.66A	0.02E	(0.03)E	0.12E	--
YEAR	(13.02)A	(3.09)E	(3.07)E	(0.55)E	(0.47)E
P/E	NM	NM	NM	NM	NM


BFRI 3Q24: Hurricane Milton Impacted 3Q Revs, But 4Q Is Already Compensating

BFRI ended 3Q24 with cash of \$2.9M, enough funding into early 2025. 3Q24 sales were \$9M and we expect 17% YoY annual revenue growth for 2024. Ameluz's 3-tube/procedure sNDA was approved last month, the Phase 3 sBCC trial was highly successful (expecting early 2026 approval), and the recent launch of the new larger RhodoLED XL lamp is building momentum and fits well with Ameluz's recent sNDA approval. 3Q24's \$9M revenue (versus our \$11M) was due to hurricane interruptions and will instead bolster 4Q24 revenue.

- 3Q24 financial results.** BFRI recorded 3Q24 revenue of \$9M, up 1.5% YoY, and up 15% QoQ, but the YoY growth would have been 19% if shipments (namely 4,460 Ameluz units representing \$1.5M in revenue) were not delayed from September to October due to Hurricane Milton. 4Q and 1Q are BFRI's strongest quarters seasonally, as Ameluz is best received in less sunny weather, and we expect 4Q24 to substantially outperform each of the first three quarters of 2024. BFRI implemented an Ameluz price hike of 5% on October 1. We project a 68% and 43% QoQ and YoY increase in 4Q24 revenue, respectively, and revenue growth should continue to benefit from an improved competitive position for Ameluz, which is partly due to the commercial launch of the larger RhodoLED XL lamp last quarter and October's Ameluz sNDA approval. The bigger lamp will better utilize both the patient's and physician's time by treating a larger surface area at once. BFRI placed 57 BF-RhodoLED lamps and 4 RhodoLED XL lamps over 1H24, and then placed another 9 BF-RhodoLED and 35 RhodoLED XL in 3Q24, a favorable shift towards larger lamp sales. BFRI expects to be cash flow break-even around YE25/early 2026.
- Recent FDA approval of 3 Ameluz tubes per treatment.** After BFRI demonstrated the safety of using up to three tubes of Ameluz per actinic keratosis (AK) treatment, in early October the FDA approved BFRI's sNDA to expand the treatment's utility to treating larger surface areas at one time on the face and scalp. The supplemental approval also dovetails nicely with the larger treatment lamp that BFRI launched in 2Q24, the RhodoLED XL lamp, which can illuminate a surface area of 667cm² (23cm x 29cm), versus 96cm² (6cm x 16cm) for the original BF-RhodoLED lamp. In reality, dermatologists have been spreading Ameluz more thinly than they should over a broader area than is recommended on the Ameluz label in order to cover more AK lesions at once. The new approval should help them apply the correct amount which, given the markup they pass through to insurance on the tubes of Ameluz they buy, should increase both procedure profitability and effectiveness. Furthermore, the more liberal Ameluz approval also helps BFRI better compete against the competing Levulan Kerastick photodynamic therapy, given that the Kerastick procedure covers a greater surface area per treatment than the original BF-RhodoLED lamp used with one Ameluz tube. Ameluz treats the visible lesions plus those that cannot be seen because, unlike *(text continued on page 2)*

BFRI Intraday Price: \$0.74 at 11:52AM ET

Important Disclosures & Regulation AC Certification(s) are located on pages 5 to 6 of this report.

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Biofrontera Inc. et al v. Sun Pharmaceutical et al

Sun Pharmaceutical's Exhibit 2078

EX2078, Page 1

- *(text continued from page 1)* Kerastick, Ameluz is applied to the entire area rather than just as spot treatments to each visible lesion, thereby delaying or removing the need for repeat visits to treat new lesions that appear thereafter. We also note that up to 60% of squamous cell carcinomas begin as untreated AK lesions, underscoring the importance of treating the entire affected area rather than only visible lesions. We believe that the new supplemental approval will increase Ameluz sales, as well as demand for the new RhodoLED XL lamp.
- **Successful sBCC trial top-line data.** Two weeks ago, BFRI reported successful results from its Phase 3 multi-center, double-blind, 2:1 randomized, and placebo-controlled trial that evaluated Ameluz-PDT versus placebo-PDT in 187 superficial basal cell carcinoma (sBCC) patients. Each patient received two treatments that were one to two weeks apart, and dosing was repeated after three months if needed. The primary endpoint was a composite of complete clinical and histological clearance of one preselected target sBCC lesion at 12 weeks after the start of the last PDT therapy. Clinical assessment means what the investigator can see, and histological assessment involves cutting out the entire region plus a margin around the prospectively defined lesion of interest, slicing it up completely, and examining it histologically. Although success required both clinical and histological clearance, we note that in about 10% of cases, investigators thought that some diseased tissue was left (i.e., clinical failure), but histological examination proved that assessment to be incorrect, with those patients failing the primary endpoint. The histological endpoint is the more important of the two for the patient and was higher than the compounded endpoint owing to this discrepancy. As for the primary endpoint, Ameluz-PDT achieved 65.5% success (95/145 patients) versus 4.8% success (2/42 patients) for placebo-PDT ($p < 0.0001$). Complete histological clearance occurred in 75.9% (110/145 patients) for Ameluz-PDT, versus 19.0% (8/42 patients) for placebo-PDT. Complete clinical clearance occurred in 83.4% (121/145 patients) for Ameluz-PDT, versus 21.4% (8/42 patients) for placebo-PDT. All other secondary endpoints achieved $p < 0.0001$, with 64.1% of Ameluz-PDT patients achieving total clearance of all sBCC lesions, versus only 4.8% placebo-PDT patients. Regarding overall treatment satisfaction and esthetic outcome, most Ameluz-PDT patients rated it as very good (64.3%) or good (22.2%). We expect BFRI to submit its supplemental NDA for approval in sBCC by mid-2025 for a likely early 2026 FDA approval, and note that Ameluz-PDT for sBCC would represent a novel, non-invasive option that may reduce scarring and repeat office visits to receive ionizing radiation, thus reducing patient burden and improving cosmetic outcome.
- **Clinical trial progress.** In 1H25, we expect a follow-up release of longer-term data from the already successful Phase 3 sBCC trial. There are now 106 of the 126 (84%) patients dosed in the moderate-to-severe acne trial, with data expected in 2H25, and 130 of the 165 (79%) patients dosed in the peripheral AK trial, with data expected in 2H25. We note that after the likely 2030 approval of Ameluz-PDT in acne, the procedure will have access to what should be an \$850M market at the time. Acne is the most common skin condition in the U.S., 20% of whom have severe acne, followed by AK. We note that in 2022, the market for generic Accutane (isotretinoin, also sold as Absorica, Amnesteem, Claravis, and Sotret) was \$800M, and that Ameluz-PDT would generate more revenue per patient, given its likely preferential use in severe acne.

VALUATION

Our 12-month price target of \$16 is based on a DCF analysis using a 10% discount rate that is applied to all cash flows and the terminal value, which is based on a 5x multiple of our projected 2031 operating income of \$70 million. We arrive at this valuation by projecting future U.S. revenue from Ameluz in treating AK. Our initial valuation excludes potential commercial upside from any potential future programs, given BFRI's clear focus on its two currently approved drugs, and therefore commercial success from other programs would serve as potential upside to our valuation.

Factors that could impede the achievement of our target price include, but are not limited to: (1) failure and/or setbacks of pipeline candidates in clinical studies; (2) failure of pipeline candidates to gain regulatory approval; (3) departure of key personnel; and (4) smaller than projected commercial opportunity due to changes in market size, competitive landscape, and drug pricing and reimbursement.

RISKS

Clinical risk. BFRI's clinical staged products could fail to deliver statistically significant results in clinical trials, substantially reducing the value of BFRI's product candidates and therefore our price target.

Regulatory risk. Even if successful in the clinic, BFRI's products could fail to be approved by domestic and/or foreign regulatory bodies, which would reduce BFRI's value and therefore our price target.

Financing risk. BFRI will need additional capital to fund its operations, and such financing may not occur, or it could be substantially dilutive to existing investors.

Competitive risk. For any current or future approved BFRI products, they may not be well adopted in a competitive marketplace, which would adversely affect BFRI's value and therefore our price target.

High stock price volatility. This issue is common among small-cap biotechnology companies with relatively low trading volumes.

COMPANY DESCRIPTION

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.

Biofrontera, Inc.																							Jonathan Aschoff, Ph.D. (646) 616-2795			
Income Statement																							jaschoff@roth.com			
Fiscal Year ends December																										
(in \$000, except per share items)																										
	2020A	2021A	2022A	1Q23	2Q23	3Q23	4Q23	2023A	1Q24A	2Q24A	3Q24A	4Q24E	2024E	1Q25E	2Q25E	3Q25E	4Q25E	2025E	2026E	2027E	2028E	2029E	2030E	2031E		
Net product revenue	18,787	24,043	28,541	8,715	5,830	8,879	10,581	34,005	7,901	7,831	9,012	15,161	39,905	11,000	10,000	12,000	15,120	48,120	59,799	75,573	97,099	119,644	144,904	167,866		
Related party revenue	62	57	133	18	18	17	13	66	11	8			19													
Total Revenue	18,849	24,100	28,674	8,733	5,848	8,896	10,594	34,071	7,912	7,839	9,012	15,161	39,924	11,000	10,000	12,000	15,120	48,120	59,799	75,573	97,099	119,644	144,904	167,866		
Cost of revenue	9,066	12,742	15,185	2,888	4,598	4,590	5,368	17,444	4,116	4,342	4,977	5,306	18,641	2,750	2,500	3,000	3,780	12,030	17,940	22,672	29,130	35,893	46,369	53,717		
Gross Profit	9,783	11,358	13,489	4,135	2,960	4,306	5,226	16,627	3,796	3,497	4,135	9,855	21,283	8,250	7,500	9,000	11,340	36,090	41,859	52,901	67,969	83,751	98,534	114,149		
SG&A	18,117	37,197	35,870	9,827	11,559	8,726	9,015	39,127	9,246	7,947	8,426	8,510	34,129	8,595	8,681	8,768	8,856	34,901	35,250	35,955	36,674	37,407	38,155	38,918		
Restructuring costs	1,132	1,464	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-	-		
R&D	-	-	-	-	-	-	77	77	17	621	669	1,238	2,545	1,300	1,365	1,433	1,504	5,601	5,825	6,990	7,340	7,707	5,395	5,125		
Total Operating Expenses	19,389	39,659	35,870	9,827	11,559	8,726	9,092	39,204	9,263	8,568	9,095	9,748	36,674	9,895	10,046	10,201	10,360	40,502	41,075	42,945	44,013	45,114	43,550	44,043		
Operating Income	(9,606)	(28,301)	(22,381)	(5,692)	(8,599)	(4,420)	(3,866)	(22,577)	(5,467)	(5,071)	(4,960)	107	(15,391)	(1,645)	(2,546)	(1,201)	979	(4,412)	784	9,956	23,956	38,637	54,984	70,105		
Interest expense (net)	(2,869)	(344)	(195)	(35)	(79)	(142)	724	468	(1,407)	(596)	8		(1,995)					-	100	150	225	450	900	1,350		
Bargain purchase gain/Chg fair val cont consid & warrant liab	-	(9,702)	21,935	(1,713)	(1,207)	(1,814)	6,651	1,917	(3,426)	5,424	(682)		1,316					-	-	-	-	-	-	-		
Other income	1,552	689	33	(33)	62	35	11	75	(136)	6	(32)		(162)					-	-	-	-	-	-	-		
Net income (pretax)	(10,923)	(37,657)	(608)	(7,473)	(9,823)	(6,341)	3,520	(20,117)	(10,436)	(237)	(5,666)	107	(16,232)	(1,645)	(2,546)	(1,201)	979	(4,412)	884	10,106	24,181	39,087	55,884	71,455		
Income tax expense (benefit)	64	56	32	5	14	1	(6)	14	1	20	3		24					-	-	-	5,078	8,208	11,736	15,006		
Net income	(10,987)	(37,713)	(640)	(7,478)	(9,837)	(6,342)	3,526	(20,131)	(10,437)	(257)	(5,669)	107	(16,256)	(1,645)	(2,546)	(1,201)	979	(4,412)	884	10,106	19,103	30,879	44,149	56,450		
EPS basic	(9,589.35)	(85.63)	(0.61)	(5.60)	(7.23)	(4.64)	1.66	(13.02)	(2.88)	(0.05)	(0.98)	0.02	(3.09)	(0.21)	(0.32)	(0.15)	0.12	(0.35)	0.10	1.13	2.04	3.13	4.27	5.20		
EPS diluted	(9,589.35)	(85.63)	(0.61)	(5.60)	(7.23)	(4.64)	1.66	(13.02)	(2.88)	(0.05)	(0.98)	0.02	(3.09)	(0.21)	(0.32)	(0.15)	0.12	(0.35)	0.09	0.34	0.63	1.01	1.42	1.79		
Basic shares outstanding	1	440	1,057	1,335	1,361	1,367	2,123	1,546	3,624	5,091	5,774	6,555	5,261	7,866	7,945	8,025	8,105	7,985	8,510	8,936	9,382	9,851	10,344	10,861		
Diluted shares outstanding	1	440	1,057	1,335	1,361	1,367	2,123	1,546	3,624	5,091	5,774	6,555	5,261	7,866	7,945	8,025	8,105	7,985	29,238	29,663	30,110	30,579	31,072	31,589		

Source: SEC filings, company press releases, and ROTH Capital Partners

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Each box on the Rating and Price Target History chart above represents a date on which an analyst made a change to a rating or price target, except for the first box, which may only represent the first note written during the past three years. **Distribution Ratings/IB Services** shows the number of companies in each rating category from which Roth or an affiliate received compensation for investment banking services in the past 12 month.

Distribution of IB Services Firmwide

Rating	Count	Percent	IB Serv./Past 12 Mos. as of 11/14/2024	
			Count	Percent
Buy [B]	347	73.21	105	30.26
Neutral [N]	78	16.46	6	7.69
Sell [S]	2	0.42	0	0
Under Review [UR]	47	9.92	1	2.13

Our rating system attempts to incorporate industry, company and/or overall market risk and volatility. Consequently, at any given point in time, our investment rating on a stock and its implied price movement may not correspond to the stated 12-month price target.

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Buy: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return of at least 10% over the next 12 months.

Neutral: A rating, which at the time it is instituted and or reiterated, that indicates an expectation of a total return between negative 10% and 10% over the next 12 months.

Sell: A rating, which at the time it is instituted and or reiterated, that indicates an expectation that the price will depreciate by more than 10% over the next 12 months.

Under Review [UR]: A rating, which at the time it is instituted and or reiterated, indicates the temporary removal of the prior rating, price target and estimates for the security. Prior rating, price target and estimates should no longer be relied upon for UR-rated securities.

Not Covered [NC]: ROTH Capital does not publish research or have an opinion about this security.

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