Biofrontera Inc. Reports First Quarter 2024 Financial Results and Provides a Business Update

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Biofrontera Inc., a biopharmaceutical company specializing in the commercialization of dermatologic products, reported financial results for the three months ended March 31, 2024 and provided a business update.

Conference call begins at 10:00 a.m. Eastern time on Thursday, May 16, 2024

WOBURN, MA / ACCESSWIRE / May 15, 2024 / Biofrontera Inc. (NASDAQ:BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatologic products, today reported financial results for the three months ended March 31, 2024 and provided a business update.

Highlights from the first quarter of 2024 and subsequent weeks included the following:

- Total revenues for the first quarter of 2024 were $7.9 million, a 9% decrease from the same period of the prior year primarily driven by reimbursement headwinds our customers experienced due to the Change Healthcare data breach
- Cash and cash equivalents were $3.8 million as of March 31, 2024, compared with $1.3 million on December 31, 2023
- The Company completed a private placement of preferred stock with healthcare focused institutional investors for gross proceeds of $8 million
- Met operational and commercial milestones to secure an additional $8 million through the exercise of warrants in connection with the private placement mentioned above
- Renegotiated the Ameluz® license and supply agreement (LSA) to reduce the transfer price of Ameluz® for 2024 and 2025 from 40 - 50% to 25%, stepping up to 35% by 2032 for Ameluz® prescribed in actinic keratosis and non-melanoma skin cancer indications;

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product costs associated with any acne indication will be 25% indefinitely

- In connection with the LSA amendment, the Company will take over the management and costs of US clinical trials relating to Ameluz on June 1st, 2024, allowing more direct control and cost management
- The Company anticipates that sales of its new RhodoLED XL® lamp will begin in the second quarter of 2024
- U.S. Food and Drug Administration (FDA) issued a "*no filing review issues identified*" letter regarding the supplementary New Drug Application submitted by our Ameluz licensor Biofrontera Bioscience GmbH to increase the maximally approved dosage from one to three tubes of Ameluz® per treatment. We expect a final decision from the FDA on or around October 4, 2024

Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera Inc., stated, "Although we are disappointed with the decrease in sales during the quarter compared to the same period in 2023, we believe general healthcare reimbursement issues affecting the entire industry were a major factor. Our team continues to work with insurers and medical providers to help minimize these challenges. As we have already announced, we have managed to make up the sales shortage and as of April 30th our 2024 YTD revenue growth is over 5%."

"We have focused much of our efforts over the last year on developing new accounts and in the first quarter of this year we placed 29 BF-RhodoLED® lamps, an increase of 123% over 1Q 2023, illustrating the need and demand we continue to experience. We are also looking forward to June 1, 2024, when under the amended LSA we will take control of all clinical trials relating to Ameluz® in the US, allowing for more effective cost management and direct oversight of trial efficiency. The reduced transfer price will allow us to finance R&D activities and continue our commercial growth trajectory," concluded Mr. Luebbert.

First Quarter Financial Results

Total revenues for the first quarter of 2024 were $7.9 million compared with $8.7 million for the first quarter of 2023. The decrease is due in part to healthcare reimbursement challenges caused by the Change Healthcare data breach that created cash challenges for the entire health care industry throughout the quarter.

Total operating expenses were $13.4 million for the first quarter of 2024 compared with $14.2 million for the first quarter of 2023. Cost of revenues was $4.1 million for the first quarter of 2024 compared with $4.6 million for the prior-year quarter, with the decline driven by lower sales. Selling, general and administrative expenses were $9.3 million for the first quarter of 2024 compared with $9.8 million for the first quarter of 2023. The decrease was primarily driven by a $1.1 million decrease in non-recurring legal costs and a decrease of sales and marketing expenses of $0.3 million. The decrease was primarily offset by a $0.7 million increase in fees and issuance costs as well as a small increase in personnel expenses.

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The net loss for the first quarter of 2024 was $10.4 million, or $(2.88) per share, compared with a net loss of $7.5 million, or $(5.60) per share, for the prior-year quarter. The change in net loss was driven by the revaluation of the B-3 Preferred Warrants, a non-cash adjustment, along with lower-than-expected sales.

Adjusted EBITDA for the first quarter of 2024 was negative $4.6 million compared with negative $4.1 million for the first quarter of 2023, reflecting lower revenues for the first quarter of 2024. 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.

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

Conference Call Details

Conference call: Thursday, May 16, 2024 at 10:00 AM ET
Toll Free: 1-877-877-1275 (U.S. toll-free)
International: 1-412-858-5202
Webcast: https://event.choruscall.com/mediaframe/webcast.html?webcastid=XHBE0SOB

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 a focus on photodynamic therapy (PDT) and topical antibiotics. The Company's licensed products are used for the treatment of actinic keratoses, which are pre-cancerous skin lesions, as well as impetigo, a bacterial skin infection. For more information, visit www.biofrontera-us.com and follow Biofrontera on LinkedIn and Twitter.

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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. These statements include, but are not limited to, statements relating to the Company's revenue guidance, business and marketing strategy, revenue growth, development and expansion of the Company's sales force and commercial infrastructure, 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 effect of the COVID-19 global pandemic; 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.

(Tables follow)

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

	March 31, 2024	December 31, 2023
	(Unaudited)	
ASSETS		
Current assets:		
Cash and cash equivalents	$ 3,817	$ 1,343
Investment, related party	23	78
Accounts receivable, net	3,520	5,162
Other receivables, related party	171	-
Inventories, net	6,905	10,908
Prepaid expenses and other current assets	560	425
Other assets, related party	5,159	5,159
Total current assets	**20,155**	**23,075**
Property and equipment, net	120	134
Operating lease right-of-use assets	1,416	1,612
Intangible asset, net	2,556	2,629
Other assets	328	482
Total assets	**$ 24,575**	**$ 27,932**
LIABILITIES, MEZZANINE EQUITY AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	2,717	3,308

Accounts payable, related parties	4,044	5,698
Operating lease liabilities	690	691
Accrued expenses and other current liabilities	4,230	4,487
Short term debt	2,355	3,904
Total current liabilities	**14,036**	**18,088**
Long-term liabilities:		
Warrant liabilities	11,731	4,210
Operating lease liabilities, non-current	621	804
Other liabilities	33	37
Total liabilities	**26,421**	**23,139**
Commitments and contingencies (Note 17)	-	-
Mezzanine equity:		
Series B-1 Convertible Preferred Stock, $0.001 par value, 6,586 share authorized, 4,806 and zero shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	3,570	-
Series B-2 Convertible Preferred Stock, $0.001 par value, 6,586 shares authorized, zero shares issued and outstanding as of March 31, 2024 and	-	-

December 31, 2023 Series B-3 Convertible Preferred Stock, $0.001 par value, 8,000 shares authorized, zero shares issued and outstanding as of March 31, 2024 and December 31, 2023	-	-
Stockholders' equity:		
Preferred Stock, $0.001 par value, 19,978,828 shares authorized, zero shares issued and outstanding as of March 31, 2024 and December 31, 2023	-	-
Common Stock, $0.001 par value, 15,000,000 shares authorized; 5,089,413 and 1,517,628 shares issued and outstanding as of March 31, 2024 and December 31, 2023	5	2
Additional paid-in capital	104,666	104,441
Accumulated deficit	(110,087)	(99,650)
Total stockholders' equity	**(5,416)**	**4,793**
Total liabilities, mezzanine equity and stockholders' equity	**$ 24,575**	**$ 27,932**

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

	Three Months Ended March 31,	
	2024	2023
Products revenues, net	$ 7,901	$ 8,715
Revenues, related party	11	18
Total revenues, net	**7,912**	**8,733**
Operating expenses		
Cost of revenues, related party	3,946	4,547
Cost of revenues	170	51
Selling, general and administrative	9,250	9,800
Selling, general and administrative, related party	(4)	27
Research and development	17	-
Change in fair value of contingent consideration	-	(200)
Total operating expenses	**13,379**	**14,225**
Loss from operations	**(5,467)**	**(5,492)**
Other income (expense)		
Change in fair value of warrant liabilities	(3,429)	1,028
Change in fair value of investment, related party	3	(2,941)
Loss on debt extinguishment	(316)	-

Interest expense, net		(1,407)		(35)	
Other income (expense), net		180		(33)	
Total other income (expense)		**(4,969)**		**(1,981)**	
Loss before income taxes		**(10,436)**		**(7,473)**	
Income tax expense		1		5	
Net loss	**$**	**(10,437)**	**$**	**(7,478)**	
Loss per common share:					
Basic and diluted	$	(2.88)	$	(5.60)	
Weighted-average common shares outstanding:					
Basic and diluted		3,623,593		1,334,950	

BIOFRONTERA INC.

GAAP TO NON-GAAP ADJUSTED EBITDA RECONCILIATION

(*In thousands, except per share amounts and number of shares*)

(Unaudited)

	Three Months Ended March 31,	
	2024	2023
Net loss	**$ (10,437)**	**$ (7,478)**
Interest expense, net	1,407	35
Income tax expenses	1	5
Depreciation and amortization	128	127
EBITDA	**(8,901)**	**(7,311)**
Loss on debt extinguishment	316	-
Change in fair value of contingent consideration	-	(200)
Change in fair value of warrant liabilities	3,429	(1,028)
Change in fair value of investment, related party	(3)	2,941
Legal settlement expenses	-	1,118
Stock based compensation	228	351
Expensed issuance costs	354	-
Adjusted EBITDA	**$ (4,577)**	**$ (4,129)**
Adjusted EBITDA margin	-57.9 %	-47.3 %

SOURCE: Biofrontera Inc.

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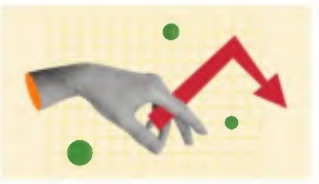
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