Biofrontera Inc. Reports Record Fiscal Year 2023 Financial Results and Provides a Business Update

Conference call begins at 10:00 a.m. Eastern time on Monday, March 18, 2024

WOBURN, MA / ACCESSWIRE / March 15, 2024 / Biofrontera, Inc. (NASDAQ:BFRI) (the "Company"), a biopharmaceutical company specializing in the commercialization of dermatological products, today reported financial results for the three and twelve months ended December 31, 2023.

Highlights from 2023 and subsequent weeks include:

- Record total revenues of $34.1M reported for 2023, an increase of 19% over total revenues for 2022 of $28.7M.
- Total operating expenses for the year were $56.7 million compared with $47.3 million for 2022. Approximately, $2.0M of this increase was driven by one-time legal expenses.
- Achieved 4% increase in revenues for fourth quarter 2023 compared with 2022 despite more than doubling sales in third quarter.
- Restructured organization to align with business needs including expanding medical and reimbursement teams, contributing to 8% decrease in operating expenses for fourth quarter 2023 compared to 2022.
- Initiated a comprehensive strategic account strategy leading to deeper partnerships and multiple annual contracts.
- Submitted sNDA to increase maximum use to 3 tubes of Ameluz® in the treatment of actinic keratosis (AK) on the face and scalp with photodynamic therapy (PDT) using the RhodoLED® XL lamp with PDUFA date of October 4, 2024.
- Completed patient enrollment in Phase 3 clinical study evaluating Ameluz®-PDT with BF-RhodoLED® lamp for the treatment of superficial basal cell carcinoma (sBCC).
- Received approval from the FDA, through our partner Biofrontera Biosciences GmbH, for an improved formulation of Ameluz® without propylene glycol.
- Acquired patents and entered into an R&D agreement to develop a new, low-cost portable photodynamic therapy lamp for use with Ameluz®.
- Announced first patient dosing in Phase 3 multicenter clinical study of safety and efficacy of Ameluz® and RhodoLED® XL for treatment of AK on the extremities, neck and trunk.

"I am pleased to announce 2023 was a record year for revenues," said Hermann Luebbert, Chief Executive Officer and Chairman of Biofrontera. "Our strategy as I took over as CEO in 2023 was to focus on holistic sales and marketing that included continuing to have a strong sales organization and strengthening our medical and reimbursement capabilities so we can

provide dermatologists with the most effective support. Our sales growth reflects the strength and commitment of our organization and the partnerships we have.

“We have also made progress in key areas in the early part of 2024 to position ourselves for future success. The restructuring of our LSA agreement with our supplier, Biofrontera GmbH, to reduce the transfer price of Ameluz to 25% for 2024 and 2025 will allow us to manage our costs more closely, Transferring the management of US clinical trials in-house will lead to greater efficiency and efficacy of these activities, potentially leading to earlier FDA approvals for future indications. We also believe the cost improvements and reallocation of spend made over the last year will allow us to continue to grow while improving the value for our investors.”

“We had a strong 2023. We achieved a record high revenue number and sales volume, placed a record number of RhodoLED lamps, cleaned up our balance sheet, and continued to optimize our cost structure. The renegotiation of the LSA and securing of additional capital have been transformational events to our goal toward break even,” added Fred Leffler, Chief Financial Officer of Biofrontera.

Fourth Quarter Financial Results

Total revenues for the fourth quarter of 2023 were $10.6 million, an increase of $0.5 million, or ~4%, compared with $10.1 million for the fourth quarter of 2022. This growth reflects the continued adoption of Ameluz but was impacted more than anticipated by strong buy-in prior to the price increase at the beginning of the quarter.

Total operating expenses were $14.5 million for the fourth quarter of 2023 compared with $15.8 million for the fourth quarter of 2022. Cost of revenues was $5.4 million for the fourth quarter of 2023 compared with $5.3 million for the prior-year quarter, driven by higher Ameluz product revenue. Selling, general and administrative expenses were $9.1 million for the fourth quarter of 2023 compared with $10.2 million for the fourth quarter of 2022, with the decrease primarily driven by lower personnel costs.

The net income for the fourth quarter of 2023 improved by $6.3 million to $3.5 million, or $1.65 per share, from a net loss of $2.8 million, or $(2.16) per share, for the prior-year quarter, with all per-share figures on a split-adjusted basis.

Adjusted EBITDA for the fourth quarter of 2023 was negative $3.2 million compared with negative $4.4 million for the fourth quarter of 2022, reflecting higher revenues partially and decreased Selling, general, and administrative expenses. Adjusted EBITDA, a non-GAAP financial measure, 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. We look at this customary metric to better assess and understand the performance of the business. Please refer to the table below for a reconciliation of GAAP to non-GAAP

financial measures.

Full Year Financial Results

Total revenues for 2023 were $34.1 million compared with $28.7 million for 2022, an increase of approximately 19%, primarily driven by a higher volume of Ameluz sales and a higher average Ameluz selling price.

Total operating expenses were $56.7 million for 2023 compared with $47.3 million for 2022. Cost of revenues increased to $17.4 million for 2023 from $15.2 million in 2022 primarily driven by increased Ameluz sales volume. Selling, general and administrative expenses for 2023 were $39.1 million compared with $35.9 million for 2022, an increase of about 9% compared with the prior year, primarily driven by personnel-related expenses and higher legal expenses.

The net loss for 2023 was $20.1 million, or $(13.02) per diluted share, compared with a net loss of $0.6 million, or $(0.61) per share, for 2022.

Adjusted EBITDA was negative $19.5 million for 2023 compared with negative $18.1 million for 2022. The decrease was primarily driven by the commercial team expansion that took place in the first quarter of 2023. Again, please refer to the table below for a reconciliation of GAAP to non-GAAP financial measures.

Conference Call Details

Conference call: Monday, March 18, 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=r1jr13zC

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, as amended to date. 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 conducted by our licensing partners, and educational outreach efforts. 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, the impact of any extraordinary external events; any changes in the Company’s relationship with its licensors; the ability of the Company’s licensors to fulfill their obligations to the Company in a timely manner; the Company’s ability to achieve and sustain profitability; whether global disruptions in supply chains will impact the Company’s ability to obtain and distribute its licensed products; changes in the practices of healthcare providers, including any changes to the coverage, reimbursement and pricing for procedures using the Company’s licensed products; the uncertainties inherent in the initiation and conduct of clinical trials; availability and timing of data from clinical trials; whether results of earlier clinical trials or trials of Ameluz® in combination with BF-RhodoLED® in different disease indications or product applications will be indicative of the results of ongoing or future trials; uncertainties associated with regulatory review of clinical trials and applications for marketing approvals; whether the market opportunity for Ameluz® in combination with BF-RhodoLED® is consistent with the Company’s expectations; the Company’s ability to comply with public company requirements; the Company’s ability to regain compliance with Nasdaq continued listing standards, the Company’s ability to retain and hire key personnel; the sufficiency of cash resources and need for additional financing 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 plan 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.
CONSOLIDATED BALANCE SHEETS

(***In thousands, except par value and share amounts***)

	December 31,	
	2023	**2022**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 1,343	$ 17,208
Investment, related party	78	10,548
Accounts receivable, net	5,162	3,748
Other receivables, related party	–	3,658
Inventories, net	10,908	7,168
Prepaid expenses and other current assets	425	810
Other assets, related party	5,159	–
Total current assets	**23,075**	**43,140**
Other receivables long term, related party	–	2,813
Property and equipment, net	134	204
Operating lease right-of-use assets	1,612	1,375
Intangible asset, net	2,629	3,032
Other assets	482	320
Total assets	**$ 27,932**	**$ 50,884**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	3,308	1,278
Accounts payable, related parties, net	5,698	1,312
Accounts payable	5,698	1,312
Acquisition contract liabilities, net	–	6,942
Operating lease liabilities	691	498
Accrued expenses and other current liabilities	4,487	10,864
Short term debt	3,904	–
Total current liabilities	**18,088**	**20,894**
Long-term liabilities:		
Acquisition contract liabilities, net	–	2,400
Warrant liabilities	4,210	2,843
Operating lease liabilities, non-current	804	848
Other liabilities	37	21
Total liabilities	**23,139**	**27,006**
Commitments and contingencies	–	–
Stockholders' equity:		
Preferred Stock, $0.001 par value, 20,000,000 shares authorized, zero shares issued and outstanding as of December 31, 2023 and 2022	–	–

Common Stock, $0.001 par value, 15,000,000 shares authorized; 1,517,628 and 1,334,950 shares issued and outstanding as of December 31, 2023 and 2022	2	1
Additional paid-in capital	104,441	103,396
Accumulated deficit	(99,650)	(79,519)
Total stockholders' equity	**4,793**	**23,878**
Total liabilities and stockholders' equity	**$ 27,932**	**$ 50,884**

BIOFRONTERA INC.

CONSOLIDATED STATEMENTS OF OPERATIONS

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

	Three Months Ended December 31,		For the Year Ended December 31,	
	2023	**2022**	**2023**	**2022**
Products revenues, net	$ 10,582	10,074	$ 34,005	$ 28,541
Revenues, related party	13	70	66	133
Total revenues, net	**10,595**	**10,144**	**34,071**	**28,674**
Operating expenses				
Cost of revenues, related party	4,975	5,114	16,789	14,618
Cost of revenues, other	394	142	655	567
Selling, general and administrative	9,101	10,087	38,975	35,137
Selling, general and administrative, related party	(41)	121	152	733
Research and development	33	–	77	–
Change in fair value of contingent consideration	–	300	100	(3,800)
Total operating expenses	**14,462**	**15,764**	**56,748**	**47,255**
Loss from operations	**(3,867)**	**(5,620)**	**(22,677)**	**(18,581)**
Other income (expense)				
Change in fair value of warrant liabilities	4,455	1,121	6,456	19,017
Warrant inducement expense	(1,045)	–	(1,045)	(2,629)
Excess of warrant fair value over offering proceeds	(2,272)	–	(2,272)	–
Change in fair value of investment, related party	(786)	1,747	(7,421)	1,747
Gain on legal settlement	7,385	–	7,385	–
Interest expense, net	(211)	(35)	(468)	(195)
Other income (expense), net	(140)	3	(75)	33
Total other income (expense)	**7,386**	**2,836**	**2,560**	**17,973**
Loss before income taxes	**3,519**	**(2,784)**	**(20,117)**	**(608)**
Income tax expense	(6)	1	14	32
Net income (loss)	**$ 3,525**	**(2,785)**	**$ (20,131)**	**$ (640)**
Income (loss) per common share:				
Basic and diluted	$ 1.65	$ (2.13)	$ (13.02)	$ (0.61)

Weighted-average common shares outstanding:				
Basic and diluted	2,140,400	1,290,467	1,546,297	1,056,988

BIOFRONTERA INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(In Thousands)

	Years ended December 31,	
	2023	**2022**
Cash Flows From Operating Activities:		
Net loss	$ (20,131)	$ (640)
Adjustments to reconcile net loss to cash flows used in operations		
Gain on legal settlement	(7,385)	–
Depreciation	86	101
Amortization of right-of-use assets	560	653
Amortization of acquired intangible assets	418	418
Change in fair value of investment, related party	7,421	(1,747)
Change in fair value of contingent consideration	100	(3,800)
Change in fair value of warrant liabilities	(6,456)	(19,017)
Warrant inducement expense	1,045	2,629
Excess of warrant fair value over offering proceeds	2,272	–
Stock-based compensation	1,045	1,852
Provision for inventory obsolescence	–	100
Provision for doubtful accounts	122	106
Non-cash interest expense	402	358
Changes in operating assets and liabilities:		
Accounts receivable	(1,536)	(70)
Other receivables, related party	6,470	4,990
Prepaid expenses and other assets	174	4,154
Other assets, related party	(5,159)	–
Inventories	(3,750)	(2,810)
Accounts payable and related party payables	6,415	912
Operating lease liabilities	(657)	(781)
Accrued expenses and other liabilities	(6,351)	(3,607)
Cash flows used in operating activities	**(24,895)**	**(16,199)**
Cash flows from investing activities		
Purchases of investment, related party	–	(5,118)
Sales of investment, related party	624	–
Purchases of property and equipment	(5)	(38)
Cash flows provided by (used in) investing activities	**619**	**(5,156)**

Cash flows from financing activities		
Proceeds from line of credit	21,448	–
Proceeds from short term debt	3,800	–
Principal payments short term debt, net	(21,344)	
Proceeds from issuance of common stock and warrants	4,507	9,391
Proceeds from exercise of warrants	–	4,630
Cash flows provided by financing activities	**8,411**	**14,021**
Net decrease in cash and cash equivalents	**(15,865)**	**(7,334)**
Cash, cash equivalents and restricted cash, at the beginning of the year	**17,408**	**24,742**
Cash, cash equivalents and restricted cash, at the end of the year	**$ 1,543**	**$ 17,408**
Supplemental disclosure of cash flow information		
Interest paid	$ 125	$ 1
Interest paid, related party	$ 22	$ –
Income tax paid, net	$ 15	$ 32
Supplemental non-cash investing and financing activities		
Release of start-up cost financing obligation as part of legal settlement	$ (7,300)	$ –
Release of contingent consideration obligation as part of legal settlement	$ (2,500)	$ –
Transfer of investment as part of legal settlement	$ 2,415	$ –
Addition of right-of-use assets in exchange for operating lease liabilities	$ 800	$ 234
Conversion of warrant liability to equity in connection with exercise of warrants	$ –	$ 6,840
Issuance of common shares in exchange for investment, related party	$ –	$ 3,683

BIOFRONTERA INC.

ADJUSTED EBITDA

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

	Three months ended December 31,		Twelve months ended December 31,	
	2023	**2022**	**2023**	**2022**
Net income (loss)	**$ 3,525**	**$ (2,785)**	**$ (20,131)**	**$ (640)**
Interest expense, net	212	35	468	195
Income tax expense	(6)	1	14	32
Depreciation and amortization	125	126	504	519
EBITDA	**3,856**	**(2,623)**	**(19,145)**	**106**
Gain on legal settlement	**(7,385)**	**–**	**(7,385)**	–
Change in fair value of contingent consideration	–	300	100	(3,800)
Change in fair value of warrant liabilities	(4,455)	(1,121)	(6,456)	(19,017)
Warrant inducement expense	1,045	–	1,045	2,629
Excess of warrant fair value of warrant liabilities	2,272	–	2,272	–

Change in fair value of investment, related party	786	(1,747)	7,421	(1,747)
Legal settlement expenses	–	381	1,225	870
Stock-based compensation	228	383	1,045	1,852
Expensed issuance costs	422	–	422	1,045
Adjusted EBITDA	**$ (3,231)**	**$ (4,427)**	**$ (19,456)**	**$ (18,062)**
Adjusted EBITDA margin	***-30.5* %**	***-43.6* %**	***-57.1* %**	**-63.0 %**

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SOURCE: Biofrontera Inc.

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