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Biofrontera Inc. (NASDAQ:BFRI) Q4 2023 Earnings Call Transcript

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Biofrontera Inc. isn't one of the 30 most popular stocks among hedge funds at the end of the third quarter (see the details here).

Operator: Welcome to the Biofrontera Incorporated Fourth Quarter 2023 Financial Results and Business Update Conference Call. All participants will be in listen-only mode. [Operator Instructions] Please note, this event is being recorded. I would now like to turn the conference over to Andrew Barwicki with Barwicki Investor Relations. Please go ahead.

Andrew Barwicki: Thank you. Good morning, and welcome to Biofrontera Incorporated's fourth quarter fiscal 2023 financial results and business update conference call. Please note that certain information discussed during today's call by management is covered under the safe harbor provisions of the Private Securities Litigation Reform Act. We caution listeners that Biofrontera's management will be making forward-looking statements and that actual results may differ materially from those stated or implied by these forward-looking statements due to risks and uncertainties associated with the company's business. All risks and uncertainties are detailed in and are qualified by the cautionary statements contained in Biofrontera's press release and SEC filings.

Quote Lookup
U.S. markets closed
US Europe Asia Rates
S&P Futures 5,680.00 -29.00 (-0.51%)
Dow Futures 41,224.00 -203.00 (-0.49%)
Nasdaq Fut... 20,097.75 -97.50 (-0.48%)
Russell 200... 2,011.90 -14.90 (-0.74%)
VIX 22.68 -1.92 (-7.80%)
Gold 3,253.40 +10.10 (+0.31%)

Also, this conference call contains time-sensitive information that is accurate only as of the date of the live broadcast, March 18, 2024. Biofrontera undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this conference call, except as required by law. During today's call, there will be reference to certain non-GAAP financial measures. Biofrontera believes these measures provide useful information for investors, yet should not be considered as a substitute for GAAP, nor should they be reviewed as a substitute for operating rules determined in accordance with GAAP. A reconciliation of non-GAAP to GAAP results is included in this Friday's press release. More specifically, management will be referencing adjusted EBITDA and non-GAAP financial measures 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.

With that said, I would like now to turn the call over to Hermann Luebbert, CEO, Chairman, and Founder of Biofrontera. Hermann?

Hermann Luebbert: Yes. Thank you, Andrew. And my thanks to everyone joining us this morning. On today's call, I'll provide an overview of our accomplishments and [patent] (ph) strategy that occurred during the second part of 2023 and how these changes help lay the groundwork for many value-driving initiatives in 2024 and beyond. Additionally, we have had some significant successes already in the first quarter of 2024 that I will touch upon. Fred Leffler, our CFO, will follow with a discussion on financial results, and then both of us will be available to answer questions after our prepared remarks. Starting with the business update, we have made tremendous progress across three critical areas, including: first, optimizing our customer-facing teams to provide the right support and services to our customers; second, controlling our cost structure and improving our balance sheet; and third, advancing R&D and assuming all clinical initiatives on Ameluz starting June 2024.

This tremendous progress has been realized by investors. Following the renegotiation of our license and supply agreement for Ameluz with dramatic deduction -- reductions in the transfer price we paid to Biofrontera Group in Germany, we very recently secured financing of $8 million and expect another tranche of $8 million in Q2. These proceeds will be used to finance our ongoing commercial organization and support the clinical activities for further Ameluz development, which, as mentioned, we will take over from the German

Biofrontera Group in June 2024. I would like to comment all our employees as we announced net revenue of $34.1 million, a record for Biofrontera, and a 19% increase for the year. While Ameluz makes up for most of our revenue, we are also proud to share that 123 BF-RhodoLED lamps were placed at physician offices during the year, compared to 66 placed in 2022, an increase of 86%, and the highest number we have ever installed in a single year.

The growing number of lamps in the field reflects both first-time installations and additional lamps among dermatology practices already familiar with Ameluz PDT, facilitating growth through existing and new customers. More specifically, of the 123 installations, 61 sites already had at least one of our lamps in place and bought a further lamp to provide more Ameluz PDT to their patients. The remaining 62 offices are now set up to start Ameluz BF-RhodoLED PDT. Lamp placements are a leading indicator for future growth, and we are delighted with the increasing recognition of Ameluz PDT as an effective and patient-friendly treatment for actinic keratosis and in the future also other diseases. During 2023, we have reduced our cost structure and invested a proportion of the cost savings in our commercial and support teams.

We are continuing to optimize our customer-facing strategy by shifting resources from a sales force-focused organization to invest in marketing, strategic accounts, medical and reimbursement support. Increasing efforts in sales force training will further help our territory managers to be more efficient. By doing so, we are continuing to develop a team that supports all stakeholders within our customer organizations. We believe this approach will be better suited to supporting our growth in the buy-and-bill PDT market and bringing new customers into PDT. To explain, buy-and-bill relates to Ameluz purchases by the doctors' offices, which then need unproblematic patient treatment and reimbursement to make this process financially viable to the office.

In December, we settled arbitration regarding a dispute around our acquisition of the Xepi asset. This allowed us to remove significant liabilities from our balance sheet, which Fred will discuss in a moment. Now, turning to new developments, research and development and patents. We expect two significant commercial developments for 2024 that will favorably impact our business. We are planning to launch the larger RhodoLED XL lamp for the treatment of extended photodamaged skin areas with AK in Q2 of this year. While this allows illumination of a larger skin area, a three-tube safety study was completed and the data was submitted to and accepted by the FDA for review. We expect to include the use of up to three tubes per treatment into the Ameluz

label during Q4 of 2024.

In combination with the launch of the XL lamp, this will allow PDT of larger skin areas constituting a crucial requirement for our further growth. The U.S. Food and Drug Administration, the FDA, has approved a new formulation of Ameluz lacking propylene glycol for the treatment of actinic keratosis. We expect that production of this formulation will begin in 2024 and help improve tolerability for some of our patients, while also reducing the generation of impurities over time, which may result in an extended shelf life. The U.S. Patent and Trademark Office, the USPTO, granted a new patent related to a photodynamic therapy, or PDT, protocol that is expected to be less painful, but similarly effective to conventional PDT. Between all our patents currently granted by the U.S. Patent Office, PDT with Ameluz and RhodoLED is currently protected until 2040.

A close-up image of a pharmaceutical product with microscope and lab equipment in the background.

Further patents are still pending and may extend the protection of our products until 2043 or even further. In 2024, we purchased -- no, in 2023, sorry, we purchased two additional patents for low-cost portable photodynamic therapy lamps for use with Ameluz, and we started development of these lamps. The planning process for building a prototype is nearing completion, and we expect to begin looking at next steps in the near future. We are also pleased to announce that the first patient has been dosed in a Phase 3 randomized, double-blind, vehicle-controlled multicenter clinical study to evaluate the safety and efficacy of Ameluz and RhodoLED XL in the field-directed treatment of actinic keratosis on the extremities, the neck and the trunk. This is significant

opportunity for our company as many patients suffer from AK not only on their face and scalp, but also on various exposed areas of the body.

The last two months have seen transformational developments for our company with the successful renegotiation of our LSA, our license and supply agreement, for Ameluz and RhodoLED lamps with Biofrontera Group in Germany, and the subsequent securing of up to $16 million in financing. According to the amended LSA, we have reduced our Ameluz transfer price. It is the price we pay to our licensor from 50% of our revenues up to $30 million and 40% from $30 million to $50 million to a flat 25% for '24 and '25. This amount will then step up to 30% in 2026 and stepwise up to 35% in subsequent years. This structure, however, applies only to actinic keratosis and non-melanoma skin cancers, while we have secured a flat 25% indefinitely for any acne-related indications.

As part of this amendment, Biofrontera Inc. is taking over all clinical trials as of June 1, 2024. The additional cost is expected to be only a portion of the savings from the reduced transfer price. This arrangement allows us to more effectively run these trials and control their costs. Finally, we have secured sufficient funding for the company through two separate deals. In November 2023, we closed on additional financing of $4.5 million, and in February of this year, we closed on a private placement of up to $16 million that is expected to be paid in two tranches. We have received $8 million and expect to meet the requirements to secure the additional $8 million tranche in either May or June 2024. We look forward to providing updates on all these programs and more on our first quarter 2024 call.

With that, I'll turn the call over to Fred to walk through the financial details of the fourth quarter and full year. Fred?

Fred Leffler: Thank you, Hermann. And it is great to be talking -- excuse me, talking with everyone again. I will start with our fourth quarter 2023 results. Total revenue for the fourth quarter of 2023 were $10.6 million, an increase of $0.5 million or about 4% compared with $10.1 million for the fourth quarter of 2022. This reflects the continued adoption of Ameluz, but was impacted by -- impacted more than anticipated by a buy in prior to a 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 were $5.4 million for the fourth quarter of 2023 compared with $5.3 million for the prior-year quarter [Technical Difficulty] compared with $10.2 million for the fourth quarter of 2022, with the decrease

primarily driven by lower personnel costs.

Net income for the fourth quarter of 2023 was $3.5 million or $1.65 per share compared with a net loss of $2.8 million or a loss of $2.16 per share for the prior-year quarter, with all share -- 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 offset by increased SG&A costs. 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. I'll refer you to the table in the news release we issued on Friday, March 15 for a reconciliation of GAAP to this non-GAAP financial measure.

Now turning to our full year 2023 results. Total revenues for 2023 were $34.4 million compared to $28.7 million for 2022, a growth of approximately 19%. The increase was primarily driven by higher volume of Ameluz sales due to a restructured discount program, higher adoption of Ameluz by dermatologists 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 from the prior year to $17.4 million for 2023 from $15.2 million in 2022 primarily driven by increased Ameluz 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, driven by personnel-related expenses and higher legal expenses.

The net loss for 2023 was $20.1 million or $13.02 per share compared with a net loss of $0.6 million or $0.61 per share for the fiscal year 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 second quarter of 2023. Again, please refer to the table in news release on Friday, March 15 for a reconciliation of GAAP to non-GAAP financial measures. Now turning to our balance sheet as of December 31, 2023, we had cash and cash equivalents of $1.3 million compared with $17.2 million as of December 31, 2022. Our investment in related parties is $0.1 million compared with $10.5 million as of December 31, 2022.

This is due to the increase -- or the decrease in share price of the investment and the fact that we used a large portion of the shares to settle an arbitration dispute. As a result, we eliminated liabilities of approximately $9.8 million and

recorded a gain of approximately $7.4 million. I have talked about our increasing inventory in 2023 quite a bit, and as of today, we have received and paid for all orders. Our inventory balance as of December 31, 2023 is $10.9 million compared to $7.2 million on hand as of December 31, 2022. I would like to clarify this amount a bit. We also have an asset for replacement inventory of $5.2 million as well. This is due to a voluntary recall of three batches of Ameluz from our supplier of which we were notified of the issue in February of 2024.

The batches will be replaced at no cost to us and we expect to receive those batches over the summer months. This will not impact our ability to fulfill orders in the meantime. So, we are now in a position to sell off our inventory over 2024 and achieve a reasonable safety stock which improves our working capital position. We are still not anticipating on making any inventory purchases for until at least the second half of 2024. And as a result, we will continue to manage our working capital very closely. Finally, we entered into a bridge loan for $4 million at the end of December of 2023 in order to finance the company through the most recent capital raise that Hermann mentioned earlier. We will pay down this loan through early July of 2024 and do not expect to need such a facility in the near future.

Based on multiple positive indicators for the year, we expect two-digit growth in revenue compared to 2023 and expect to be cash flow positive within approximately 12 to 18 months depending on our spend associated -- with our additional spend associated with the U.S. clinical studies. So, with that overview of our business and recent financial performance, Hermann and I are now ready to take questions from our covering analysts. Operator?

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