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Biofrontera Inc. (BFRI) Q4 2024 Earnings Call Transcript

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Biofrontera Inc. (NASDAQ:[BFRI](#)) Q4 2024 Earnings Conference Call March 21, 2025 10:00 AM ET

Company Participants

Andrew Barwicki - IR Representative
Hermann Luebbert - CEO, Chairman, and Founder
Fred Leffler - CFO

Conference Call Participants

Jonathan Aschoff - Roth Capital

Bruce Jackson - The Benchmark Company

Operator

Good morning and welcome to the Biofrontera Fourth Quarter and Fiscal 2024 Financial Results and Business Update Conference Call. All participants will be in listen-only mode. [Operator Instructions] After today's presentation, there will be an opportunity to ask questions. [Operator Instructions] Please note, this event is being recorded. I would now like to turn the conference over to Andrew Barwicki, Investor Relations Representative. Please go ahead.

Andrew Barwicki

Thank you. Good morning and welcome to Biofrontera Incorporated's fourth quarter and fiscal year 2024 financial results and business update conference call. Actual results may differ materially. 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 releases and SEC filings. Also, this conference call contains time-sensitive information that is accurate only as of the date of this live broadcast, March 21, 2025. 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 references 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 viewed as a substitute for operating results determined in accordance with GAAP. A reconciliation of non-GAAP to GAAP results is included in the press release we issued earlier today. More specifically, management will be referencing adjusted EBITDA, a non-GAAP financial measure defined as net income or loss, excluding interest income and expenses, income taxes, depreciation and amortization, and certain other non-recurring or non-cash items.

With that said, I would like 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 up this morning. On today's call, I'll provide an overview of our accomplishments throughout 2024 and how our initiatives and execution have resulted in a record sales year. 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.

I am pleased with \$37.3 million in sales in 2024. This represents an annual sales growth of 18.5% for Q4 and almost 10% for the entire year and is a record for our company. We strongly believe our past investments, business plan, and execution will allow us to achieve another record year in 2025.

The year included some further milestones that we are very pleased with. First and foremost, we placed 52 RhodoLED XL lamps in the first quarter -- fourth quarter alone and 100 between the launch in June 2024 and the end of 2024. Providing a larger PDT lamp to our customers is an important milestone in our overall strategy to extend the use of Ameluz PDT for treating mild to moderate actinic keratosis on the face and scalp and potentially further indications in the future that are currently in development.

The state-of-the-art red light emitting LED lamp is designed to revolutionize the photodynamic therapy of actinic keratosis aimed at enhancing the ease of use for healthcare providers by being highly maneuverable and capable of accommodating various patient treatment positions. It provides clinicians with the ability to illuminate a larger treatment area in a single session, which is particularly advantageous for treating extensive fields with multiple actinic keratosis lesions.

Second, we obtained FDA approval to use up to three tubes of Ameluz per treatment. Ameluz, a photosensitizing agent and porphyrin precursor, is FDA approved for use in combination with both RhodoLED lamp models and for lesion-directed and field-directed treatment of actinic keratosis of mild to moderate severity on the face and scalp. Treating larger fields is a second milestone in our overall strategy and complements the availability of a larger lamp.

Third, we achieved significant results in the Phase 3 study of Ameluz photodynamic therapy regarding the treatment of superficial basal cell carcinoma. We believe Ameluz has additional applications other than actinic keratosis, and we are committed to explore these opportunities. I can tell you that being able to treat actinic keratosis, which are precancerous lesions that may progress to squamous cell carcinoma, is a wonderful thing. But to expand beyond that to treating non-melanoma skin tumors, is very encouraging and exciting for all of us at Biofrontera. We expect to submit the new data to the FDA in the second half of this year.

Additionally, early in 2024, we successfully negotiated the restructuring of agreements with our former parent company Biofrontera AG, resulting in the transfer price of Ameluz being reduced from 50% to 25% for all purchases in '24 and '25. I strongly believe this was accomplished through the demonstration of our strong commitment towards promoting PDT in the USA and exploring the many open opportunities of this wonderful therapy. As part of the re-negotiated agreements, we took control of all clinical trials with Ameluz in the USA. This allows us to speed-up patient recruitment and the corresponding label expansions with the FDA. Just recently, we announced the recruitment of the final patient in our Phase 3 study for mild to moderate actinic keratosis on the trunk, neck, and extremities. The goal is to extend our current label, which is restricted to treatments of AK on the face and scalp, to the entire body. This represents another important cornerstone in our overall strategy, complementing the use of three tubes and the availability of the larger lamp.

As a last building block for this label extension, FDA has requested a Phase 1 pharmacokinetics study with 16 patients which started in January and is currently recruiting. More long-term, we are aiming at getting Ameluz approved for the treatment of moderate to severe acne. Our ongoing Phase 2 study in this indication is close to completing patient recruitment. The further development plan will be discussed with the FDA once the data of this study become available.

Based on our recent successes, our continued improvements of sales force effectiveness, positive customer feedback, and the heightened level of customer engagement, we are excited about how 2025 is shaping up for the company.

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. It's my pleasure to be here today and provide you an overview of our 2024 financial performance. I'll start off with the fourth quarter 2024 results. Total revenues for the fourth quarter of 2024 were \$12.6 million, an increase of \$2.0 million or 18.5% compared with the \$10.6 million in revenue for the fourth quarter of 2023. This growth reflects the continued adoption of Ameluz, the launch of the Rhodo XL lamps, and a price increase in Q4 of 2024.

Total operating expenses were \$14.3 million for the fourth quarter of 2024 compared with \$14.5 million for the fourth quarter of 2023. Cost of revenues was \$5.3 million for the fourth quarter of 2024 compared with \$5.4 million for the prior year quarter. This reflects the lower transfer pricing Hermann mentioned a moment ago.

Selling general and administrative expenses were \$8.2 million for the fourth quarter of 2024 compared with \$9.1 million for the fourth quarter of 2023. The net loss for the fourth quarter of 2024 was \$1.4 million, or \$0.19 per share, versus a net income of \$3.5 million, or \$1.65 per share for the prior year quarter, with all share figures on a split-adjusted basis. This change was driven by a gain from a legal settlement recognized in Q4 of 2023.

Adjusted EBITDA for the fourth quarter of 2024 was negative \$1.4 million compared with negative \$3.2 million for the fourth quarter of 2023, 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, expenses, income taxes, depreciation, and amortization and certain other non-recurring or non-cash items. I'll refer you to the table in the press release we issued earlier today for reconciliation.

I will now summarize our full year 2024 results. Total revenues for 2024 were \$37.3 million compared with \$34.1 million for 2023, an increase of approximately 9.5% and was primarily driven by higher volume, a higher average selling price of Ameluz and the launch of the RhodoLED XL lamps.

Total operating expenses were \$54.5 million for 2024 compared with \$56.7 million for 2023. Cost of revenues increased to \$18.6 million for 2024 from \$17.4 million in 2023. And this increase was due to sales, but offset by the lower transfer prices that impacted Q4 2024 cost of goods sold.

Selling general and administrative expenses for 2024 decreased \$5.3 million or 13.5% compared to 2023. This was primarily driven by a \$3 million reduction in general and administrative expenses primarily attributable to a decrease in external legal expenses and expenses related to financing activities. The decrease was further driven by more strategic investment of promotional spend, which resulted in savings in general sales and marketing of about \$1.8 million.

The net loss for 2024 was \$17.8 million or \$3.22 per diluted share compared with a net loss of \$20.1 million or \$13.02 per share for 2023. Adjusted EBITDA was negative \$15.3 million for 2024, compared with negative \$19.5 million for 2023. The decrease was primarily driven by an increase in gross profits due to the increased sales and the reduction in transfer price and a decrease in SG&A expenses. Again, I'll refer you to the table in the news release earlier today for a reconciliation of GAAP to non-GAAP financial measures.

Turning to our balance sheet, as of December 31st, 2024, we had cash and cash equivalents of \$5.9 million compared with \$1.3 million as of December 31, 2023. This is due to our strong growth and additional capital raised in the fourth quarter. Our inventory balance as of December 31, 2024 was \$6.6 million compared to \$10.9 million for -- on December 31st, 2023. We believe we've gotten our inventory level to an adequate level and expect inventory to be around -- to maintain around this level. During the year ended December 31st, 2024, net cash provided by financing activities was \$14.8 million, which consisted of proceeds of \$7.7 million net of capitalized issuance costs, from the issuance of preferred stock and warrants, \$7.4 million from the exercise of warrants for preferred stock, plus \$4.1 million net of issuance costs received from the issuance of convertible notes. This was offset by repayments of \$4.3 million for our short-term debt.

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?

Question-and-Answer Session

Operator

[Operator Instructions] Our first question today is from Jonathan Aschoff with Roth Capital. Please go ahead.

Jonathan Aschoff

Thank you. Good morning, Hermann and Fred. I was curious, what was the 4Q '24 Ameluz unit growth year-over-year?

Fred Leffler

Hermann, do you want me to take that one?

Hermann Luebbert

Yep, if you have the number in front of you, yes please.

Fred Leffler

Yeah, approximately 2%.

Jonathan Aschoff

2%, thank you. Was there any sales force addition or attrition over 2024?

Fred Leffler

As far as number of...

Jonathan Aschoff

Number of sales people, purely numbers.

Fred Leffler

Yeah, commercial, no, it was -- it held approximately constant.

Jonathan Aschoff

Okay, And lastly, what's the acne enrollment number? Maybe I missed that in your call. And are you still comfortable with the data timing you gave last?

Hermann Luebbert

Yeah, the enrollment number is 116. However, as the data look right now, we may be able to conclude that trial a bit earlier.

Jonathan Aschoff

Okay, so with 116 or maybe a few more?

Hermann Luebbert

Maybe a few more.

Jonathan Aschoff

All right. And okay, so clearly the data timing, I guess, if that number is going to be lower, should still be safe, right?

Hermann Luebbert

Yes.

Jonathan Aschoff

Thank you very much.

Operator

[Operator Instructions] The next question is from Bruce Jackson with The Benchmark Company. Please go ahead.

Bruce Jackson

Hi, good morning and thanks for taking my questions. Moving over to the income statement, now that you've got the more advantageous transfer pricing, how do you think that could impact gross margins in 2025?

Fred Leffler

Yeah. So, we have a transfer price of 25% through 2025. And so while Q4 -- we saw the impact of that in Q4, that was, as I mentioned, we had higher sales in Q4, higher revenues, and yet the cost of goods sold was slightly down. So, Q4 had a slight mix of that, but for 2025, it's going to be almost exclusively at the lower 25% transfer price.

Bruce Jackson

Okay, great. And then you mentioned that there was a price increase in the fourth quarter. Can you tell us how much of a price increase there was in percentage terms? And then also, did it have any effect on forward buying?

Fred Leffler

Yes. So that was a 5% price increase. So, our tube of Ameluz is [\$363] (ph). And there was -- certain customers, we do see customers do a bit of a buy-in before price increases. So that bit was reflected in Q3.

Bruce Jackson

Okay. Okay. Then last income statement question for me, the SG&A and the R&D equipment kind of coming down a little bit, is that going to continue to trend that way in 2025?

Fred Leffler

For the SG&A piece of it, we're expecting to hold approximately steady. We've adjusted some of the cost structure, like, the headcount and things like that to what we believe is an appropriate level. So, no adjustments on the commercial SG&A or anything like that. I'll pass it over to Hermann to speak about R&D, if that was part of your question.

Hermann Luebbert

Yeah, it's the same about R&D. It's going to be stable compared to the last couple months.

Bruce Jackson

Okay. Okay, great. That's it for me. Thank you very much.

Hermann Luebbert

Thank you.

Fred Leffler

Thank you.

Operator

This concludes our question-and-answer session. I would like to turn the conference back over to Hermann Luebbert for any closing remarks.

Hermann Luebbert

Yeah. Thank you to everyone for your participation today. We are pleased with the sales growth we had in 2024, and as we plan for the future, we are putting a great deal of emphasis on becoming cash flow positive and managing our expenses without sacrificing sales. Although we reached record sales annually of \$37.3 million in 2024, which is more than double from the \$18 million in 2020, we continue to make changes and pivot at times to improve our sales and marketing effort. Every day, our sales team gets new clients, which is a victory for the customer-facing strategy we previously implemented. We look forward to speaking with you again when we report our first quarter 2025 results. Thank you and have a nice day.

Operator

The conference has now concluded. Thank you for attending today's presentation. You may now disconnect.

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