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Biofrontera Inc. (BFRI) Q2 2024 Earnings Call Transcript

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Q2: 2024-08-14 Earnings Summary

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Press Release

10-Q

EPS of -\$1.08 **misses by \$0.73** | Revenue of \$7.84M (34.05% Y/Y) **misses by \$367.50K**

Biofrontera Inc. (NASDAQ:[BFRI](#)) Q2 2024 Earnings Conference Call August 15, 2024 10:00 AM ET

Company Participants

Andrew Barwicki - Barwicki Investor Relations
Hermann Luebbert - CEO, Chairman and Founder
Fred Leffler - CFO

Conference Call Participants

Jonathan Aschoff - ROTH MKM
Bruce Jackson - The Benchmark Company

Operator

Good day, and welcome to the Biofrontera Inc. Second Quarter 2024 Financial Results and Business Update Conference Call. All participants will be in a listen-only mode. [Operator Instructions] Please note, this event is being recorded.

I would now like to turn the conference over to Andrew Barwicki. Please go ahead.

Andrew Barwicki

Thank you. Good morning, and welcome to Biofrontera's Second Quarter Fiscal Year 2024 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 releases and SEC filings.

Also, this conference call contains time-sensitive information that is accurate only as of the date of this live broadcast, August 15, 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 references to certain non-GAAP financial measures. Biofrontera believes that 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 this week's press release.

More specifically, management will be referencing adjusted EBITDA, a non-GAAP financial measure 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'm pleased now to turn the call over to Hermann Luebbert, CEO, Chairman and Founder of Biofrontera. Hermann?

Hermann Luebbert

Yes. Thank you, Ambu, and my thanks to everyone joining us this morning. On today's call, I'll provide an overview of our accomplishments during the second quarter and first half of 2024. Fred Leffler, our CFO, will follow with a discussion on financial results, and then both of us will be happy to answer questions after our prepared remarks.

Starting with the business update. We have made tremendous progress across three critical areas, including, one, first and foremost, our sales report. Increasing sales during the second quarter and first half of the year has been accomplished, we grew our sales by 34% for the quarter. In Q2, we managed to compensate the negative influence of the reimbursement challenges stemming from the change health care cybersecurity event and the consecutive sales decline in Q1 achieving a little over 8% growth compared to 2023 for the half year.

Two, managing our total operating expenses. For example, during the second quarter of 2024, total operating expenses were \$12.9 million compared to \$14.5 million in the second quarter of last year. Another example relates to our SG&A expenses, where in Q2 this year, the SG&A was \$7.9 million compared to \$11.6 million last year. Three, strengthening our balance sheet by paying down all outstanding debt in the second quarter.

[Audit Start]

I believe these three simple yet significant accomplishments on the commercial side of the company, have enhanced our day-to-day operations and put us in a position for long-term growth. Together with the rise of gross \$8 million in May from exercised warrants, the company is in a stable financial condition.

The second quarter was also a very anticipated time for us as we began to sell the FDA-approved RhodoLED XL. Keep in mind, sales only began on June 10, which is the end of the quarter, but we feel very optimistic about the potential as we continue rolling it out and making it available to all our customers. It is important to understand the benefits for doctors and patients as we look to increase sales.

The BF-RhodoLED XL lamp is designed to facilitate the treatment of extended photo damaged thin areas with actinic keratosis which may require several illuminations with the original small BF-RhodoLED lamp. While Ameluz makes upmost of our revenue, we are also proud to announce that in addition to the initial RhodoLED XL lamp sales, 57 of the original BF-RhodoLED lamps were placed at physician offices during the first half of the year compared to 52 in the same period last 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 new and existing customers.

Although we are very pleased with some reductions in costs such as SG&A and total operating expenses, we continue to invest in our commercial and support teams by increasing sales force focused organization to invest in marketing, strategic accounts, medical and reimbursement support. We believe this approach will increase Ameluz purchases by the doctor's offices, which then need unproblematic patient treatment and reimbursement to make this process financially viable for them.

Although the RhodoLED XL lamp began selling at the end of the quarter, which we sell the minimal, it is important to understand the benefits for patients as we look to increase sales. The RhodoLED XL is for the treatment of extended photo damaged thin areas with actinic keratosis. To eliminate restrictions on reimbursement for the use of more than one tube of Ameluz in a single treatment, a three tube Phase 1 safety study was completed, and the data was submitted to the FDA and accepted for review. We expect that FDA approval for including 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.

As previously announced, 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. First stretches with this formulation have now reached the market. The formulation will improve tolerability for some of our patients while also reducing the generation of impurities over time, which may result in an extended shelf life.

Between all our patents currently granted by the U.S. patent office, PDT with Ameluz and BF-RhodoLED is currently protected until 2040. A patent application for the new formulation is still pending and may extend the protection of our products until 2043 or even further.

A transforming event for our company was the successful renegotiation of our license and supply agreement for Ameluz and RhodoLED lamps in February. According to the agreement, we purchase Ameluz and the lamps from the German Biofrontera Pharma and upon arrival in the United States, we pay a percentage of our anticipated net sales price for Ameluz and the actual cost of manufacturing plus 10% for the lamps.

The cost of Ameluz has in the new LSA being reduced to almost half of what we have paid thus far. This will become effective when we order new batches, which we did not have to do in the first half of this year, due to an over stacking situation by the end of 2023. However, we will need to purchase more Ameluz in the second half of the year. Only then will the beneficial effects of the new LSA become effective lowering our cost of Ameluz from about 50% to 25% of our net sales price for all orders in 2024 and 2025.

On June 1, we transferred all clinical research with Ameluz from Biofrontera Bioscience to our wholly owned German subsidiary, Biofrontera Discovery. While all our clinical products are performed at centers in the U.S. The price will nevertheless be organized and managed out of the Biofrontera Discovery. We are planning to complete all ongoing trials and in parallel decide on new trials based on maximum commercial benefit for Biofrontera Inc.

Three ongoing trials are close to completion. The last patient in the one-year follow-up period for a Phase III trial for superficial basal cell carcinoma will be complete in November or December. This time point provides the data required for FDA approval for this new indication for Ameluz. Enrollment in the Phase III study for actinic keratosis on the extremities neck and trunk and a Phase II trial for moderate to severe acne is expected around the turn of the year. Currently, the extremity study is 69% enrolled. The acne is at 78%.

As the cost savings due to the renegotiated LSA has not started, but we consume the cost of the clinical trials since June, we will, for a few months, have an increased run rate until the reduced cost of goods balances dissolved towards the end of the year.

With that, I'll turn the call over to Fred to walk through the financial details of the second quarter and first half.

Fred Leffler

Thank you, Hermann, and it's great to be talking to everyone again. I'll start with our strong second quarter 2024 results. Total revenues for the second quarter of 2024 were \$7.8 compared with \$5.8 million for the second quarter of 2023, which is a 34% increase year-over-year. The increase is due in part to a catch-up from lower sales in the first quarter driven by reimbursement challenges stemming from the change health care, cybersecurity events, but also due to our effort to increase productivity of the sales force.

[Audit Ends]

Total operating expenses were \$12.9 million for the second quarter of 2024 compared with \$14.5 million for the second quarter of 2023. Cost of revenues was \$4.3 million for the second quarter of 2024 compared with \$2.9 million for the prior year quarter. The increase was driven by increased sales and the volume associated with that.

Selling, general and administrative expenses were \$7.9 million for the second quarter of 2024 compared with \$11.5 million for the second quarter of 2023. The decrease was due to our continued efforts to control costs and lower legal expenses compared to the same period in 2023.

The net loss for the second quarter of 2024 was \$257,000 and compared with a net loss of \$9.8 million for the prior year quarter. The decrease in the net loss is attributed to lower selling, general and administrative costs as well as changes in non-cash P&L items, including the fair value of warrants and investments in related parties.

Adjusted EBITDA for the second quarter of 2024 was negative \$4.7 million compared with negative \$7.9 million for the second quarter of 2023, reflecting our lower selling, general and administrative costs. As Andrew mentioned, we look at adjusted EBITDA as a non-GAAP financial measure as a better indication of ongoing operations and the measurement is defined as net income or loss excluding interest income, 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 or 10-Q we issued yesterday for a reconciliation of GAAP to non-GAAP financial measures.

Now I'll summarize our first half 2024 results. Total revenues were \$15.8 million for the first half of 2024 compared with \$14.6 million for the first half of 2023. This 8% increase was primarily driven by continued penetration and adoption of PDT within the AK markets. Total operating expenses were \$26.3 million for the first half of 2024 compared with \$28.8 million for the first half of 2023. Cost of revenues increased from the prior year to \$8.5 million for the first six months of 2024 compared to \$7.5 million for the first half of 2023, again, due to our increased volume.

Selling, general and administrative expenses decreased to \$17.2 million from \$21.4 million in the prior year, again, primarily as we see benefits of continued cost control efforts and lower legal expenses compared to the first half of 2023. The net loss for the first half of 2024 was \$10.7 million compared with a net loss of \$17.3 million for the first half of 2023.

Adjusted EBITDA was negative \$9.3 million for the first half of 2024 compared with negative \$11.9 million for the first half of 2023. Again, please refer to the table in our 10-Q for a reconciliation between GAAP and non-GAAP financial measures.

Okay. Now turning to our balance sheet as of June 30, 2024. We had cash and cash equivalents of \$4.4 million compared with \$1.3 million as of December 31, 2023. We have been focusing on account receivable collections and improving our production process, along with the expected summer seasonality of our business, we have reduced our AR from \$5.2 million as of December 31, 2023, to \$3.5 million as of June 30 of 2024.

As of July 10, we have extinguished our short-term debt obligation as well. We are continuing to burn through our inventory that Hermann mentioned a moment ago and we expect to have sold through this excess inventory in the next few months. As I mentioned before, we will hold safety stock but at a lower amount, which is within typical industry standards.

Following an Ameluz recall in the first quarter, which was outside of our responsibility, we have received the three batches of replacement inventory in July from our supplier at no cost to us. In May, our stockholders approved an increase -- to increase our authorized common shares to \$35 million. Upon the stockholder approval, the redemption rights and preferred liquidation rights were eliminated for the Series B preferred and any remaining B1 preferred stock and any remaining B1 preferred stock automatically converted to Series B2 preferred stock.

As a result, of these changes to the rights and preferences all Series B convertible preferred stock was reclassified from mezzanine to permanent equity. On May 13 and 14, 2024, 7,998 preferred warrants were exercised to purchase shares of the company's B3 convertible preferred stock from which net proceeds were \$7.4 million. As a result of the Series B convertible preferred stock reclass to permanent equity, along with the warrant exercise, our shareholders' equity increased to \$10.9 million as of June 30, 2024.

[Audit Start]

Finally, I would like to comment on our capital structure and walk you through what management considers to be the fully diluted common share total. As of August 12, we had 5.5 million common shares outstanding. The B1 and B3 convertible preferred shares could convert to 17.7 million common shares. Our warrants, if exercised, would equate to 2.3 million common shares. I will note that of these warrants, 77,000 warrant shares are significantly out of the money with a strike price of \$100. The more recent warrants all have a strike price of \$3.55 and equate to 2.2 million common shares if exercised.

Finally, common shares converted by awards under our Omnibus plan totaled 1.8 million common shares if all awards are realized and exercised. As such, management believes our fully diluted common is approximately 27.3 million shares.

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] The first question comes from Jonathan Aschoff with ROTH. Please go ahead.

Jonathan Aschoff

Thank you. Good morning, guys. I was curious if I could just drill down on a quarter for sales of each type of land the second quarter and so far in this quarter. Can you give me 4 numbers, each type of lamp, how many you placed second quarter and so far in the third quarter?

Hermann Luebbert

In the second quarter, we placed 57 of the original lamps, and we placed in the last weeks of June, we shipped four of the XL lamps. We haven't published anything on the third quarter.

Jonathan Aschoff

That's no problem. Thank you. What would be the price hike percentage on October 1?

Fred Leffler

Price increase for Ameluz will be 5%.

Jonathan Aschoff

Got it. Thank you. And by the way, for the acne and the AK extremity trial, do you still expect to publicly release data when you originally said in mid-'25 and second half '25, respectively, for acne and AK. Is that still holding?

Hermann Luebbert

Yes, it will be second half of 25% for both of them.

Jonathan Aschoff

Okay. That's very helpful. So when will the royalty savings from the renegotiated LSA become higher than the costs of the trials. When does that whole LSA redo turn positive for you?

Fred Leffler

Yes. So that's obviously attached to our ordering of inventory, which we will start to do in the fourth quarter of 2024. And then depending on when the shipments come in and everything either late Q1 or early Q2, we'll sort of flip and have more savings than we spent on the clinical trials.

Jonathan Aschoff

Okay. And lastly, is there any update on the timing of that low-cost portable lamp development? Or even what has just happened irrespective of timing?

Hermann Luebbert

Well, we are nearing a first prototype and after that, we have to go into a more formal development according to the design control rules of the FDA.

Jonathan Aschoff

All right. That's all I had. Thank you very much.

Operator

The next question comes from Bruce Jackson with Benchmark Company. Please go ahead.

Bruce Jackson

Hi, good morning. And thank you for taking my questions. I wanted to look at the sales numbers for the quarter in a little bit more detail. Generally, the second quarter is seasonally a little bit weaker than the rest of them. And I'm kind of curious to know with the ordering patterns, how much of the results in the quarter were a rebound because of the change health incident? And how much of that is organic growth? And then the second part of that question would be, looking forward, how do you expect the rest of the year Q1 play out in terms of seasonality?

Hermann Luebbert

Most of the rebound we had in April. So we can consider the May and June already more or less a normal month. And in all three months, we had significant growth compared to last year. So I would -- if I had to guess, I would think that this is really a guess. We can't give you any real numbers on this. But at most, half is a rebound effect.

Bruce Jackson

Okay. And then in terms of the R&D spend going forward, is that going to -- what's the run rate on the R&D expense going to be, do you think, for the next couple of quarters?

[Audit Ends]

Fred Leffler

Yes. Hermann, I can take that. So we're expecting to spend a couple -- so we took over clinical trials on June 1, as Hermann mentioned. And as far as the run rate here, we were expecting two points spending about million or so this year in R&D spend.

Bruce Jackson

So that's for the entire year?

Fred Leffler

That is correct.

Bruce Jackson

From June 1. So then we'd be looking at -- okay, I got it.

Fred Leffler

Yes, we have, I would say, maybe \$1 million each quarter. I think as of right now, we believe it's going to be used, but that does depend on the recruiting and if there are a pop there, et cetera. So -- but we do think that it's -- over the next six months, it will be somewhere in that ballpark.

Bruce Jackson

Okay. And then you mentioned the data from the AK and the acne trials -- sorry, the extremity and the acne trials in the second half with the basal cell carcinoma, are you going to be releasing data on that as well?

Hermann Luebbert

Yes. We will release -- we expect to be able to release data from the clinical trial -- clinical part of the BCC trial still this year and then the follow-up part in the first half of next year.

Bruce Jackson

Okay. All right, great. That's it for me. Thank you.

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

Operator**Hermann Luebbert**

Yes. Thank you, operator. The second quarter and first half of the year has been a thriving and very encouraging time for us with a significant growth in our revenues. I would like all of you to participate in this call, and I would also take the opportunity to thank all our employees for the tremendous effort that went into this process. We look forward to speaking with you then when we report our third quarter 2024 results. Thank you, and have a nice day.

Operator

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

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