Biofrontera

Experts in photodynamic therapy

Conference call script

for the 9-month period ended 30 June 2018

Conference call on November 16, 2018

Pamela Keck

Good morning and welcome to Biofrontera's third quarter and nine months ended September 30, 2018 earnings conference call.

Before we begin the call, I have to go through some household items first.

Earlier this morning, we issued a press release announcing our financial results for the nine months ended September 30, 2018. We would like to remind everyone that we will only be summarizing results in today's call. Biofrontera's earnings report for the reporting period ended September 30, 2018, the corresponding news release and our annual report on Form 20F have been filed on EDGAR and are also available in the investors section of our website www.biofrontera.com. We encourage you to review the documents in their entirety. Please note that certain information discussed on the call today is covered under the Safe Harbor provisions of the Private Securities Litigation Reform Act. We caution listeners that during this call, Biofrontera's management will be making forward looking statements. Actual results could differ materially from those stated or implied by these forward-looking statements due to risks and uncertainties associated with the Company's business. These forward-looking statements are subject to a number of risks, detailed in, and qualified by the cautionary statements contained in, Biofrontera's press releases and SEC filings, including its annual report on Form 20F and subsequent filings. This conference call contains time sensitive information that is accurate only as of the date of this live broadcast, November 16, 2018. Biofrontera undertakes no obligation to revise or update any forward-looking statements to reflect events or circumstances after the date of this conference call.

With that, I would now like to turn the call over to Dr. Hermann Lübbert.

Dr. Hermann Lübbert, CEO

Thank you, Pamela. And thank you everyone for joining us this morning for Biofrontera's third quarter 2018 earnings conference call. Today I am accompanied by Christoph Dünwald, our CCO, and Pamela Keck, our Head of IR. I will provide you with a brief summary of our updates in both the U.S. and Europe during the reporting period, and discuss the financial results of the first 9 months of 2018. After that, Christoph Dünwald will provide an update on our commercial progress.

Over the course of 2018, we have made great strides in our business strategy. We have outperformed our expectations for the reporting period January through September. Driven by the improved competitive

positioning and market potential of Ameluz in the U.S. and Europe, we nearly doubled our total revenue year-over-year to about 14.6 million euro. Even better, our pure product sales increased by over 130%.

In the U.S., our direct sales force continues to successfully grow Ameluz into a household name for photodynamic therapy supported by the recently improved reimbursement rates under a product specific J-code and procedural CPT-codes. The renewed growth in the EU has been driven by Ameluz's label expansions into basal cell carcinoma last year and even more so by the regulatory approval and commercialization of Ameluz in combination with daylight photodynamic therapy this year, which significantly improved the reimbursement and competitiveness of Ameluz. It seems our global strategy is paying off.

Looking to the future, we believe that we have the opportunity to significantly expand the reach of Ameluz with our ongoing studies for treatment of BCC in the U.S. as well as the treatment of actinic keratosis on the extremities, trunk and neck. But before we elaborate on our recent successes and upcoming milestones, I would like to review the financials.

For the first nine months ended September 30, 2018, we reported total revenue of about 14.6 million euro compared to approximately 7.3 million euro for the same period in 2017. This represents a 98% increase year-over-year. Looking at our pure product sales revenue, we saw a 131% increase compared to last year.

Revenue in the U.S. improved by 204% to about 10.2 million euro in the reporting period compared to 3.4 million last year. As I already mentioned, the main reasons for the successful sales development in the U.S. are the significant improvement in reimbursement with the revised CPT-codes and the product- specific J-code. And in September, we saw a significant increase in sales caused by an anticipatory effect through the expected 5.6% increase in the list price of Ameluz as of October 1.

Revenue in Germany amounted to about 2.1 million euro for the first nine months of 2018 compared to 1.7 million euro in 2017, a 24% growth year-over-year. This growth was mostly due to the summer months, following European approval for daylight PDT in March.

Our revenue in the remainder of Europe increased by 73% to about 2.1 million euro for the first nine months of 2018 compared to 1.2 million euro in 2017. The increase in sales in Europe overall is also mainly due to the introduction of daylight-PDT.

Revenues from other regions in the reporting period amounted to about 0.2 million euro compared to the previous year of 1.1 million euro. In 2017, this revenue mostly consisted of revenues from a preclinical research collaboration that was completed on March 31st.

Gross profit increased 83% to 11.7 million euro in the first nine months of 2018 from 6.4 million euro in 2017. Gross margin decreased to 81% from 88% for the same period in the previous year. The reason for the decrease was a significant reduction in revenues from development projects, which were not offset by any cost of sales in the prior-year period.

Research and development expenses remained almost flat at about 3.2 million euro in the first nine months compared to the same period last year. Research and development costs primarily include costs for clinical studies as well as regulatory expenses, such as fees for maintaining and extending our regulatory approvals.

General and administrative expenses were about 7.3 million euro in the reporting period and doubled year-over-year from about 3.6 million euro in 2017. The increase is mainly due to higher legal and consulting costs as well as administrative costs in the U.S. compared to the previous-year period.

Sales and marketing expenses increased less than one percent to about 12.7 million euro in the first nine months of 2018 from 12.6 million euro in the previous year. Sales costs include the costs for our direct sales force in Germany, Spain, Great Britain and the U.S. as well as marketing expenses. The increased sales activities in the USA are reflected in both the sales costs and administrative costs in the USA.

For the first nine months of 2018, we reported a net loss of about 12.7 million euro, or 28 cents per share. In the same period in 2017, we saw a net loss of approximately 13.7 million euro, or 38 cents per share.

Cash and cash equivalents on the balance sheet were about 21.1 million euro as of September 30, 2018, compared to 11.1 million euro as of December 31, 2017.

Finally, as already announced in October, we have raised our revenue guidance for the full year 2018 from 16 to 20 million euro to 19 to 22 million euro. We are, however, maintaining our forecast for the consolidated net loss at 15 to 16 million euro for 2018 due to continuously high costs from ongoing legal disputes, which offset the higher revenue contribution.

With the financials complete, let me turn the call over to Christoph to highlight our commercial progress in the U.S. and Europe.

Christoph Dünwald, COO

Thank you, Hermann.

Since 2017 we have been on a role and have been doubling our product sales! And during the third quarter of 2018, we have consistently followed this trend! We expect to successfully close out 2018 and, as Hermann just mentioned, recently raised our sales forecast.

While we still had to struggle with new unexpected problems regarding reimbursement in the U.S. in July and August, we experienced our first real momentum of exponential growth in September. The month of September 2018 was the most successful month in Biofrontera's history from a sales perspective. We were able to sell 22,000 tubes in just one month. What is particularly pleasing about this sales record is that all sales teams globally contributed to the success. Of course, sales in our largest market, the U.S., are overly high - but Europe is also continuing its dynamic growth.

In the U.S., we are continuing to execute our growth strategy. Initially, our team had been focusing on the low hanging fruit – dermatologists who are already familiar with photodynamic therapy. Having established our products with total sales in excess of $20 million in the first two years since launch has worked out well and we should now be able to attract new customers to the PDT market. In the US, only 3% of diagnosed actinic keratosis patients are treated with PDT. This has to and will change.

Our sales team of 37 employees currently covers around 85% of the USA. We enjoy a very low turnover of employees and assume that in the medium term a total of around 50 sales employees will be sufficient to efficiently penetrate the dermatology market in the USA. The team is supported by 7 additional employees in the scientific side and 3 reimbursement specialists.

As experts in photodynamic therapy, our experienced team continues to educate U.S. dermatologists about the high efficacy of Ameluz for actinic keratosis and to train personnel in dermatology offices how to use our products.

Our growing business success in the USA validates the performance of our sales team and the efficient collaboration across all areas of our company.

Over 900 US customers have ordered and used Ameluz on patients since we launched the product. More interestingly, however, the average order size from repeat customers doubled during the third quarter

compared to previous quarters. Some of that is certainly due to the strong September when we announced price increase of 5.6% as of October 1. However, we also see the increasing order sizes as a sign of the successful establishment of Ameluz with our customers. Nobody stocks up on a product, if they are not convinced of it.

As most of you know by now, the CPT codes, which defines the payment the physician receives for PDT, were revised at the beginning of the year. Ameluz now has a significant reimbursement advantage over traditional cryotherapy - the historically preferred treatment for actinic keratosis. PDT with Ameluz has thus become even more attractive for dermatologists. Highly effective, excellent cosmetic result and attractively reimbursed - we see this as a great opportunity to gain a higher share of the entire AK market.

Now to Europe: We are very satisfied with the sales growth of 45% in the first nine months for Europe as a whole. Motivated by our potential, we naturally want to maintain this growth momentum.

The European approval for the daylight PDT, which we received in March, finally allows us to compete with topical drugs. The approval for daylight therapy was equivalent to an entire new product launch. In Germany, our most important European market, prescriptions for Ameluz more than doubled during the summer months of June and July alone, compared to the same period last year.

We also recorded strong growth in Spain following the launch of Ameluz with daylight PDT. In the first 9 months of 2018, we already achieved the same total sales as in the entire previous year.

In addition, we continue to advance the use of Ameluz in the treatment of basal cell carcinoma and field cancerization in Europe. These approvals have not only expanded the market opportunities for Ameluz, but have also enabled the sale of Ameluz to hospitals where many European dermatologists practice.

In the UK, we used the second and third quarters to expand our sales team. A great deal of work has gone into the administrative steps with individual hospitals in order to list Ameluz there so we are able to sell there in the future. We see a large percentage growth in Great Britain, albeit from a very low base, and are confident that we will be able to generate significant sales growth here very soon.

As mentioned before, we have taken the strong sales growth in the third quarter as an opportunity to raise our sales forecast for the year as a whole. We are now in the peak season for PDT in all markets and are making every effort to close 2018 extremely successfully. A further doubling of product sales is our declared goal.

And now, let me hand the call back to Hermann for an update on the clinical front and closing remarks.

Dr. Hermann Lübbert, CEO

Thank you, Christoph.

Let me give you a brief summary of our current phase III trials and add some final remarks.

In July, we completed patient enrollment for our phase III trial of Ameluz examining the safety and efficacy of PDT for the treatment of actinic keratosis on the extremities, trunk and neck. Our goal for this study is to enable patients to receive treatment of actinic keratoses and field cancerization on the entire body. Patients with actinic keratosis on the face or scalp oftentimes have other severely affected areas. We anticipate results from this trial in the first quarter of 2019. If approved, Ameluz would be the only PDT drug in Europe and the U.S. that could be used to treat actinic keratosis of all degrees of severity on the extremities, trunk and neck, which will further increase our competitive advantage over existing PDT drugs.

In September, after consultation with the FDA, we initiated patient recruitment in our U.S. phase III evaluating Ameluz and our BF-RhodoLED for the treatment of superficial basal cell carcinoma. We expect to announce results from the study in the first half of 2020, followed by a potential FDA submission for the label expansion. Following successful FDA approval, Ameluz would be the only drug in the U.S. for the treatment of superficial BCC through photodynamic therapy. There are more than 4 million BCC treatments performed each year in the U.S. The approval would allow us to finally offer patients and physicians a treatment option for superficial BCC with high efficacy and excellent cosmetic results. While still a few years away, this label expansion will serve as another pillar to our growth.

Thus far, we have had a very successful 2018 and expect to continue to execute on our strategic growth initiatives.

Operationally, we have built a strong U.S. commercial infrastructure. We expect our sales force to drive continued adoption of Ameluz. We have consistently outperformed in the U.S. and re-ignited revenue growth in the EU.

Clinically, we have continued to increase the indications for Ameluz and have a number of ongoing trials which will continue to support Ameluz's growth in the long term.

In summary, we are doing exactly what we said we'd do: executing our overarching strategy of expanding the positioning and market potential of Ameluz by increasing our sales efforts and adding indications to the label.

Looking ahead, we intend to keep this trend going and expect to close out the year with a strong finish, as the winter months tend to be seasonally strong for PDT treatments. We remain focused on successful execution of our strategy in both the U.S. and Europe. With that, I would like to reiterate our deepest thanks to our employees, shareholders and board of directors for their contributions.

And now, I would like to open the call for questions. Operator?