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PLX - Q1 2019 Protalix Biotherapeutics Inc Earnings Call

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CORPORATE PARTICIPANTS

Moshe Manor *Protalix BioTherapeutics, Inc. - CEO, President & Director*

Yossi Maimon *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

CONFERENCE CALL PARTICIPANTS

Edward D. Marks *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Peter James Welford *Jefferies LLC, Research Division - Senior Equity Analyst*

PRESENTATION

Operator

Good day, ladies and gentlemen, and welcome to the Protalix First Quarter 2019 Financial Results and Corporate Conference Call. (Operator Instructions) As a reminder, this call will be recorded.

I would now like to introduce your host for today's conference, Yossi Maimon. Please go ahead.

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Thank you. Hello, everybody. Good morning. Welcome to Protalix BioTherapeutics 2019 First Quarter Earnings Result and Corporate Update Conference Call.

With me today is Moshe Manor, our President and CEO. A press release announcing the result is available on our website. I'd just like to take a moment -- ask you to take a moment and read the disclaimer about the forward-looking statements in the press release. The earning release and this teleconference includes some forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experience and results to differ materially from the statements made. Factors that could cause actual results to differ are described in the disclaimer and in our filing with our U.S. Securities and Exchange Commission.

I will now turn the call over to Mr. Moshe Manor.

Moshe Manor - *Protalix BioTherapeutics, Inc. - CEO, President & Director*

Thank you. Yossi. Good morning and thank you for joining us today to review the company's first quarter and recent highlights. During the call this morning, I'll provide a corporate update and then Yossi will review the company's financials before opening up the line for questions.

This will be a much briefer call than usual as we have been working hard to get pegunigalsidase alfa, or PRX-102, across the finish line, but there is no much news to discuss. We're happy to report that the BRIGHT study is currently one patient away from our enrollment target. From this study, we presented data on the 15th Annual WORLDSymposium showing the infusion of PRX-102 every 4 weeks results in the presence of continuous active enzyme throughout the entire infusion interval.

We are excited about this data as we believe that this potential -- potentially means that PRX-102 could be dosed monthly instead of biweekly like the current standard of care.

Through our BALANCE study, we are making progress in recruiting the final patient as well. We are currently in the process of screening and enrolling the final 11 patients to reach our enrollment target.

After patients complete the initial portion of the study, they may continue in our various extensive studies, staying on PRX-102 treatment while still being monitored. We currently have more than 40 patients who have wanted to continue on PRX-102 instead of going back to or starting an approved product. We consider this policy as this means that both patients and their physicians want to continue with the drug candidate after trying it in the clinic. It also enables us to generate long-term data on the product prior to launch.

We are happy -- also happy to report that we will be presenting 3 posters on PRX-102 during the 6th Update on Fabry Disease international conference being held in Prague, Czech Republic on May 26-28, 2019.

Finally, as we have discussed on earlier calls, we still plan to meet with the FDA during the second quarter in connection with the potential accelerated approval pathway. While the FDA minutes from this meeting are released, we will evaluate and communicate any changes to our approval pathway.

We're excited with the data reported so far from the BRIDGE study showing a significant improvement in kidney function among patients who were switched from Replagal to PRX-102.

In addition, based on characteristics for the BALANCE trial highlighting PRX-102 is less inhibited by preexisting neutralizing antibodies than Fabrazyme. This data supports our belief that PRX-102 will be the drug of choice for Fabry patients. The next 12 months are set out to be very busy and exciting period for us including the following potential catalysts: meet with the FDA in Type C meeting this quarter and have more clarity on the potential accelerated approval path.

Finally, the enrollment in both the BRIDGE, the BRIGHT and BALANCE study, report interim data from our BRIGHT study, report final data from the BRIDGE study, move PRX-106 into next development stage, either alone or through a collaboration. I will now turn the call back to Yossi, who will provide the financial overview.

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Thank you, Moshe. So for the quarter ended March 31, 2019, Protalix reported a net loss of $7.3 million or $0.05 per share, basic and diluted, compared to a net loss of $7.2 million or $0.05 per share, basic and diluted, for the same period of 2018.

Protalix reported total revenues of $10.4 million for the 3 months ended on March 31, 2019, compared to $6.7 million for the same period of 2018. The increase could be attributed to the recognition of $6.9 million of license revenue in the 3 months ended on March 31, 2019, compared to $2.2 million for the same period in 2018.

Research and development expenses were $11.7 million for the first 3 months of '19 compared to $7.3 million for the same period in '18. Selling, general and administrative expenses were $2.2 million for the first 3 months of '19 compared to $2.5 million for the same period of '18.

As of March 31, 2019, we had $30.4 million of cash and cash equivalents.

As we have previously guided, our current cash position will take us into 2020. Again, depending on how the discussions with the FDA will proceed, our cash position could potentially take us through filing of accelerated approval. Such approval -- potential approval would trigger a milestone payment from Chiesi.

With that now, I will now turn the call back to the operator who will open up the call for questions from the audience. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) And our first question comes from the line of Raghuram Selvaraju with H.C. Wainwright

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

This is Edward Marks on for Ram. Just a few questions really quick. I might have missed this in your prepared remarks but when you're talking about the BRIDGE data, I was wondering when that might become available?

Moshe Manor - *Protalix BioTherapeutics, Inc. - CEO, President & Director*

Again you're talking about the BRIDGE data?

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Yes.

Moshe Manor - *Protalix BioTherapeutics, Inc. - CEO, President & Director*

Yes, the BRIDGE data will around mid -- so end of 2019.

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Okay. And then for taliglucerase alfa, just wondering how many patients in Brazil are currently receiving that therapy?

Moshe Manor - *Protalix BioTherapeutics, Inc. - CEO, President & Director*

Actually in Brazil, we have over 130 patients in -- that was using the -- our product that -- which represents around -- I would say, around 20% share of the market.

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Okay. And then my final question. Just wondering if any internal decisions have been made on some of the next steps for clinical testing for OPR -- OPRX-106? Sorry.

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Again your question, Ram, I'm not sure I followed.

Edward D. Marks - *H.C. Wainwright & Co, LLC, Research Division - Research Analyst*

Just wondering if you've made any clinical testing decisions for OPRX-106?

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Well, as Moshe said, I think that we're coming closer to decide whether we're doing it on our own or collaboration. So not yet.

Operator

And our last question comes from the line of Peter Welford with Jefferies.

Peter James Welford - *Jefferies LLC, Research Division - Senior Equity Analyst*

Couple of financial ones and then just one on 102. So just with regards to the financials, I wonder if you could disclose what the sales were in -- to Brazil relative to Pfizer during the quarter. Just for modeling purposes. And also, could you give us a bit of an understanding on the change in the balance sheet for operating leases that was done as well during the quarter? And then just secondly then with regards to 102. And just to be clear obviously the open-label follow-up is still ongoing. Is it possible or rather is it possible to give us any flavor in terms of off those 40 how many patients have now passed shall we say 6 months, 12 months, 2 years? I'm saying with regards to the data that I think you'll have to be able to give to FDA when you enter the meeting in 2Q, what's the sort of split of that 40 patients, if possible, you can give us in terms of duration of therapy?

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Okay, Peter. So I'll start. In terms of product revenues, we will have more color in the queue, but I can already share that we have shipped (inaudible) to Pfizer in the amount of $1.4 million approximately, and we have shipped product vials to Brazil in the amount of $2.2-almost million dollars in the first quarter of '18. As for the open-label, we -- I guess you mean the extension studies for the BRIDGE and some patients (inaudible). I guess that we have different durations for the different trials. We don't -- I don't have the exact timing for each but we have patients that have been on the drug and on the extension for well over a year as the enrollment has been slower. Obviously, the flip side of it is we have patients that have been on the drug for a very long time now on any of the 3 different studies. I think that we will, in the future, in addition to the final results from the BRIDGE study, I guess we will find the right venue to maybe share some interim data from the BRIGHT study as we have more patients that will conclude 12 months. I think that as opposed to the study in the BRIDGE, where we share data after 6 months, I think that in the BRIGHT study, I think it will make more sense to have more data on patients that have concluded at least 12 months given the nature of the study and what would you expect. I think that we will be in a position to share some interim data in the second half of 2019.

Peter James Welford - *Jefferies LLC, Research Division - Senior Equity Analyst*

That's great. Sorry, with regards to the operating leases, the changes in that, just the equivalent of IFRS 16, just recognizing the leases that you've had in the past, now just recognizing them on the balance sheet but it's existing contracts.

Yossi Maimon - *Protalix BioTherapeutics, Inc. - CFO, VP, Treasurer & Secretary*

Correct. It's basically recognizing them along the way and it's both for the up-front and the reimbursement that we're getting and according to new revenue recognition rules, we're recognizing them at some pace and those will continue until approval.

Operator

And that does conclude today's question-and-answer session. Ladies and gentlemen, thank you for participating in today's conference. This does conclude today's program, and everybody may disconnect. Have a great day.
