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PLX - Q2 2019 Protalix Biotherapeutics Inc Earnings Call

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

Alan Lada

PRESENTATION

Operator

Good morning, ladies and gentlemen, and welcome to the Protalix Second Quarter 2019 Financial Results and Corporate Conference Call.

(Operator Instructions) As a reminder, this conference is being recorded.

I would now like to turn the conference over to our host, Mr. Lada, investor relations. You may begin your conference.

Alan Lada

Thank you. Hello, everyone, and welcome to Protalix BioTherapeutics' Second Quarter Earnings Results and Corporate Update Conference Call.

With me today is Dror Bashan, Protalix' President and CEO.

A press release announcing the results is available on the Protalix website. Please take a moment to read the disclaimer about forward-looking statements in the press release. The earnings release and this teleconference include forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual future experiences to results -- 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 filings with the U.S. Securities and Exchange Commission. The Form 10-K we filed for fiscal year 2018 and Form 10-Q filed for the period ending June 30, 2019, include a detailed discussion of applicable risk factors.

I will now turn the call over to Mr. Dror Bashan.

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

Good morning and thank you for joining us today to review the company's second quarter and recent highlights. During the call this morning, I will provide a corporate update and review the company's financials before opening the lines for questions.

Before reviewing the events of the past quarter, I would like to take this opportunity to more formally introduce myself and explain why I've decided to lead the Protalix team. By way of background: I have worked within the pharma business for over 20 years, with experience in almost all verticals of the business. Most recently, I was Teva's Senior Vice President of Global Business Development, where I was involved in certain -- in creation of strategic alliances, I have supervised complex cross-company projects and oversaw acquisition and divestitures of certain assets.

I joined Protalix for many reasons. On a personal level, I'm excited for the challenge and opportunity and to work with the established and talented team management [has been]. Protalix is well known in Israel as a company with great science. They have successfully developed a drug to the

point of commercialization. However, to me the company's potential in the future is much more exciting. The data to date from our product for Fabry has been fantastic, fantastic. We clearly have a drug candidate with the potential to be much better than the current standard of care.

Protalix has a strong and promising relationship with Chiesi, which is our marketing partner for our product in Fabry, which I look forward to continuing and building on.

I recognize that the company has its challenges, and I plan to be thoughtful and diligent to deal with them to the best of my ability. To that end, I believe that there are resources out there that can utilize to bring much needed improvements to our capital structure. Overall, Protalix is a company with a promising future, and I'm happy that I was approached and joined Protalix to move the company in the positive direction.

Now let me please discuss the past quarter with the company.

Other than myself, we were also happy to announce that we will -- we are, we'll be bringing in Eyal Rubin, currently the CFO at BrainStorm Cell Therapeutics, as the CFO to replace Yossi. Eyal will introduce himself next quarter, but we feel that his skill set will complement well with my own and those of others as the company. We wish the best to Moshe and Yossi and thank them both for the many years of service to Protalix.

Moving now to our pipeline. Most importantly, as we have already announced, we have received communication from the FDA that we allow -- that we'll allow us to file the BLA for an accelerated approval for PRX-102. I am happy to report today that we have scheduled a pre-BLA meeting with the FDA in the fourth quarter, keeping us on track to apply for the BLA through the first quarter of 2020.

We were also happy to report in June the completion of enrollment in our BRIGHT study, in which patients are treated with 2 milligram of our product every 4 weeks. We expect to present the data from this study at the upcoming medical conference after completion. To date, almost all of the patients have continued on the 4 weeks treatment in an applicable extension study. And over 3 studies, we have -- currently have more than 55 patients on extension studies, which I believe to be a great sign that patients want to continue to be treated with our products. Our pivotal trial, the BALANCE trial, is 95% enrolled. And I'm confident that we'll be able to announce the completion of enrollment soon.

I will now review the financial position.

For the quarter (sic) [6 months] ended June 30, 2019, Protalix reported a net loss of $15 million or $10 -- or $0.10 per share basic and diluted compared to the net -- to a net loss from continuing operations of $15.7 million or $0.11 per share basic and diluted for the same period in 2018. Protalix recorded total revenues of $22.7 million for the first 6 months of 2019 compared to $11.6 million for the same period of 2018. The increase can be attributed to the recognition of $15.7 million of license revenues in the 6 months ended in June 30, 2019, compared to the $5 million in the same period of 2018.

Research and development expenses were $25 million for the first 6 months of 2019 compared to $13.7 million for the same period of 2018. Selling and general and administrative expenses were $4.3 million for the first 3 months (sic) 6 months of 2019 compared to $4.7 million in the same period of 2018.

As of June 2019, we had $25.1 million of cash and cash equivalents, and as we have previously guided, our current cash position will take us into 2020. Given the current cash balance, we are within 12 months of cash leading to the growing-concern disclosures in the documents we have filed with SEC and our press release this morning. This should not come as a surprise to anyone. We are discussing and have started negotiation with relevant parties regarding ways to improve our capital position. I believe that this discussion will evolve and enable Protalix to continue its main effort through to 2022, beyond both of the potential accelerated approval which is expected, hopefully, if things go smoothly, end of 2020; and ultimately a U.S. approval after we have results of the BALANCE study, which we designed to analyze superiority of our products over Fabrazyme.

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

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question is from the line of Peter Welford with Jefferies.

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

A few, please. Firstly, just on the financials. Presumably the R&D run rate we see in 2Q is abnormally high. Perhaps if you just comment a little bit on that? And then what we should be thinking about for the R&D, I guess, for the second half of the year. Secondly, then just on the milestones. Can you confirm that the first milestone due from Chiesi would be the approval by the FDA? And then importantly, the -- an accelerated approval would still constitute that, to be able to receive that milestone; and that almost full approval is not required to trigger the milestone from Chiesi, i.e., I guess, on completion of the larger Phase III?

And then just finally then, obviously I appreciate you haven't had long within the company, but just looking at beyond 102 and some of the other assets obviously and technology within the company. I guess I'd love to hear your view on the potential avenues that you could pursue to, I guess, crystallize the value or bringing cash with some of those other assets and platforms you have within the company; and perhaps where you think potentially things could be improved over what was done in the past given obviously there were efforts already to try and pursue that avenue.

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

So the first question, I believe, is the R&D expenses. So first, thank you for that. You are correct. It was a number which is way higher than the former period last year, and there are 3 main reasons. First, during these 12 months, there were way more patients enrolled into the studies, so it adds a lot of cost. Two; many of the patients or a pretty significant portion of the patients went into extension studies that we also finance. And the third one, we buy Fabrazyme in the market at the full price, of course, and this is part of the clinical trials. With regard to the fact if we will for the second half of this year -- so I assume it will be more or less the same, at least for the first 2 reasons, maybe even a bit higher because we have more patients.

And second, with regard to the Fabrazyme purchases, this is it should be more or less the same, but it's a matter of a timing issue right now. But indeed we do need to further buy Fabrazyme, as the patients are -- once they are finished, they still have 2 years, each of them, on the BALANCE study. This is on the first question.

The second question and on the milestone. So it's not a done deal. We believe that approval is approval. So accelerated process is just a vehicle how to, hopefully, get an approval. So the first milestone from Chiesi should be upon approval of -- if indeed we receive it, of the accelerated approval path.

And the third one -- and can -- if you don't mind just to repeat the third question, please.

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

Yes. Sorry. Just with regards to the other assets within the company beyond 102 and the platform; and sort of your thinking, I guess, on those; and perhaps where you think perhaps management -- what happened in the past could be improved upon to try and crystalize the value of those assets within the company that clearly at the moment are basically just treading water.

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

So thank you for that. You're correct. And I don't like to use the excuse that I'm only 5 weeks in the company. I do believe that the technology and the infrastructure and knowledge and capabilities gained in Protalix along the years are significant and by the way of unique or uniqueness. And still for me to further evaluate the pipeline outlet -- assets, I believe that I need a bit more time before I will come and say what we plan to do with

it. We will take a couple of months to review the pipeline in detail; and refine or relook into the strategy going forward, where Protalix would be focused. And we'll take it from there. And of course, we will be open and share it with everybody.

Operator

And your next question is from the line of Rag -- Ram Selvaraju with H.C.

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

This is Edward on for Ram. You went into a little more detail about the BALANCE and the BRIGHT studies, and I appreciate and commend you for being so close to finishing enrollment. And I was just wondering if you can provide a little more granularity on when the final top line data might be available for BALANCE and BRIGHT?

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

So on the BALANCE study we hope to finalize enrollment soon, which I don't want to commit to a certain date. As you know, it is designed as follows. It is 2 years to -- hopefully, to meet superiority over Fabrazyme, and this will be 2 years from last patients in. This is the end of the dosing. Then there is data cleaning. It takes some time, so I assume it will take additional 4 or 5 months after. I mean please don't catch me if it's 1 month plus or minus. As part of this BALANCE trial, after 1 year, there is an interim analysis which is supposed to serve for the European submission, which will be a non-inferiority over other drugs. Again, 1 year submission for the Europe, a non-inferiority one; and 2 years, hopefully, to show superiority over Fabrazyme, 2 years dosing, this is for the U.S. as agreed with the FDA, of course. And this is the protocol and end points appropriately.

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

Okay. And then we're looking at the BRIGHT trial. I'm just wondering how significant this data might be in terms of the commercial outlook for 102 as you're moving forward?

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

So for the BRIGHT, the last patient -- last treated was July 2020 actually. So this will -- it still will be 2020. We assume that, around 12 months later, there will be top line data, which takes us to the end of 2020. And please understand that the -- under the accelerated approval path, the BRIGHT study is not included. And I hope this answers what you asked, but please...

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

No, no, that does. And moving on to the BRIDGE trial, I'm just wondering if any feedback has been received from the FDA concerning the suitability of some of the data just along with the prior clinical results from the Phase I/II studies that would support maybe initial approval of 102 or whether it's really the BRIGHT study coming out next year that will be the main driver for...

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

Yes, yes. So the BRIDGE study, we have, I believe, I think, 16 patients that will be included within this BLA application under the accelerated approval path. It is considered at least a safety data. I don't want to promise over biomarker or preliminary efficacy, but right now it's -- will be part of the accelerated approval or the BLA submission as safety data.

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

Perfect. I just wanted to make sure that, that was going to be a part of everything. And then...

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

Yes. And please understand. You can understand that the BRIDGE is the 1 milligram and the BRIGHT is the 2 milligrams, and 2 milligrams is not part of it.

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

Okay. And appreciating that you are new to the company, my final question is more on the competitive landscape. And so starting with just enzyme replacement therapies, is there still a view that Fabry disease cannot be kind of supplanted by drugs like migalastat or lucerastat? Or are enzyme replacement therapies really going to be the standard of care going forward? And then looking at also gene therapies, just thinking about the preclinical programs that are still ways away from commercialization, is there a concern regarding any of the persistence for some of these lentiviral constructs? And then when we look at something like AVROBIO's, their AVR-RD-01, what was the -- or how key was the vector drop in some of the peripheral blood that was seen in these early-stage clinical data?

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

So you wanted to refer first to the -- to migalastat and lucerastat. Or you prefer that I will discuss the gene therapy by AVROBIO.

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

Whatever order you prefer.

Dror Bashan - *Protalix BioTherapeutics, Inc. - President, CEO & Director*

It doesn't matter. So migalastat, as far as we understand, cannot address all Fabry patient. I understand it is a matter of amenable mutation, and we understand it's around 30%. Lucerastat is still in development and safety and efficacy need to be further developed; and so we will see the outcomes, of course. As for AVROBIO, first, it's very interesting, of course. And it's not a matter of a concern or not. If it works, it's good for the patients, so it's okay. It still needs to be shown for longer duration and many more patients, so time will tell. We saw what they have published recently, and let's see it holds going forward. And anything else on earlier programs is difficult for me to refer because they are very early. So nobody will know how to tell the future, of course.

Anyone else, please?

Operator

And ladies and gentlemen, this concludes today's conference. [Thank you very much] for your participation. Have a wonderful day. You may all disconnect.
