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IMMU - Q3 2017 Immunomedics Inc Earnings Call

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PRESENTATION

Operator

Good afternoon, ladies and gentlemen. Thank you for standing by. Welcome to Immunomedics, Inc. Third Quarter Fiscal 2017 Results Conference Call. As a reminder, this conference call is being recorded. Today is Wednesday, May 10, 2017.

Before we begin, I would like to remind everyone that during this call, the company will be making forward-looking statements made pursuant to the Private Securities Litigation Reform Act of 1995. Such statements may involve significant risks and uncertainties. Actual results could differ materially from those expressed or implied on this call. For factors that could cause such differences, please refer to the company's regulatory filings with the Securities and Exchange Commission, most recently, its annual report for the year ended June 30, 2016. The earnings report is available on the company's website at www.immunomedics.com.

With us on the call are Dr. Behzad Aghazadeh, Chairman of the Board of Immunomedics; and Michael Garone, Chief Financial Officer of the Company. Following their prepared remarks today, we will open up the call for questions.

At this time, I would like to turn the conference over to Dr. Aghazadeh. Please go ahead.

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

Thank you, operator. Good afternoon, everyone, and thank you for joining us. This was a milestone quarter for Immunomedics. We have taken a number of actions that ensure we have the financial flexibility, the appropriate organizational structure to bring IMMU-132, our Breakthrough Therapy candidate to triple-negative breast cancer to market on our own. Immunomedics has a clear strategic plan in place to become a recognized leader in the field of antibody-drug conjugates, which we believe will translate into significant value for the company. I will get into some specifics of the actions we've taken, but first Michael will share our financial results for the quarter.

Michael R. Garone - *Immunomedics, Inc. - Interim CEO, VP of Finance and CFO*

Thank you, Behzad. I'll begin with the third quarter (inaudible) results. Total revenues for the quarter were $1.3 million compared to $900,000 for the same quarter for the prior fiscal year, an increase of 44% due primarily to an increase in LeukoScan product sales.

Total cost and expenses for the quarter were $23.4 million compared to $15.5 million for the same quarter of last year, an increase of approximately 51% due primarily to an increase in general and administrative expenses, including a $5.9 million increase in legal and advisory fees associated with proxy contest, professional services in connection with the licensing agreement with Seattle Genetics, which was terminated subsequently and an increase in other corporate legal fees. These were partially offset by a decrease in research and development expenses.

We recognized a $28.3 million noncash expense during the quarter reflecting the increase in the fair value of warrant liabilities at March 31, 2017, resulting from the increase in price of our common stock during the period. We also recognized a $7.6 million noncash expense representing the excess of fair value of the Seattle Genetics warrant issued on February 10, 2017 over proceeds received from the issuance of common share -- of common stock and the warrants.

Interest expense related to the 4.75% convertible senior notes due 2020 was $1.4 million for both quarters ended March 31, 2017 and 2016, including the amortization of $200,000 of debt issuance costs in each quarter.

The company did not realize any income tax benefit in the quarter ended March 31, 2017 compared to a $1.9 million income tax benefit for the same quarter in fiscal 2016 from the sale of a portion of our New Jersey state tax net operating losses and R&D tax credits.

Net loss attributable to stockholders was $59.3 million or $0.55 per share for the third quarter of fiscal 2017 that compares to a net loss attributable to stockholders of $14 million or $0.15 per share for the same quarter in fiscal 2016, that's an increase of $45.3 million or approximately 324%. The increase was due primarily to the $28.3 million increase in the fair value of warrant liabilities, the $8.9 million increase in general and administrative expenses, the $7.6 million Seattle Genetics warrant-related expense and the nonrecurring $1.9 million income tax benefit received in fiscal 2016, and all that was offset partially by an $800,000 decrease in R&D expense.

Moving on now to the 9 months results. The 9-month period of fiscal 2017, total revenues were $2.4 million compared to $2.3 million for the same period in the prior fiscal year. That's an increase of approximately 4.4% due primarily to an increase in LeukoScan sales.

Total cost and expenses for the 9-month period were $54.9 million compared to $46.7 million for the same period in fiscal 2016, an increase of approximately 18% due primarily to an increase in general and administrative expenses, including a $7 million increase in legal and advisory fees associated with a proxy contest, professional services in connection with a now terminated licensing agreement with Seattle Genetics and a $1.4 million increase in legal fees. These are offset partially by a $1.7 million adjustment for deferred unearned executive bonuses and a decrease in R&D expenses.

We recognized a $35.6 million noncash expense during the period, reflecting an increase in the fair value of warrant liabilities from the increase of common stock price from the issuance dates of February 10, 2017 and October 11, 2016 through March 31, 2017. We also recognized a $7.6 million noncash expense representing the excess of fair value of the Seattle Genetics warrant issued on February 10, 2017 over the proceeds received from the issuance of common stock and the warrant.

Interest expense related to the 4.75% convertible notes due 2020 was $4.1 million for both periods ended March 31, 2017 and 2016, including the amortization of $500,000 debt issuance costs in each period. The company did not realize any income tax benefit for the 9-month period ended March compared to the $5.1 million income tax benefit for the same period of fiscal 2017 from the sale of a portion of our New Jersey State tax NOLs or R&D tax credits.

Net loss attributable to stockholders was $100 million or $0.97 per share for the 9-month period ending March 31, 2017 compared to a net loss attributable to stockholders of $43 million or $0.46 per share for the same period last fiscal year, that's an increase of $56.9 million or approximately 132% and the increase was due primarily to the $35.6 million increase in fair value of warrant liabilities, the $9 million increase in general and administrative expenses, the $7.6 million Seattle Genetics warrant-related expense and the nonrecurring $5.1 million income tax benefit received in fiscal 2016.

Cash, cash equivalents and marketable securities were $46 million as of March 31, 2017. Today, we closed on the previously announced $125 million private placement financing with institutional investors.

This financing, along with our current cash at hand, provides us with the capital necessary to fully support the development of IMMU-132 in metastatic triple-negative breast cancer, including the goal of biological license application with the FDA for accelerated approval; initiate the Phase III confirmatory trial in metastatic TNBC, which is a prerequisite for filing of BLA; continue large scale manufacturing of IMMU-132 and begin preparations to market IMMU-132 for metastatic TNBC patients in the United States. It will also be used to fund general corporate and operational

enhancement in the third quarter of calendar 2018, which the company believes is sufficient to obtain accelerated approval for IMMU-132 in metastatic TNBC subject to meeting all standards, completing the review and final determination by the FDA.

The completion of this financing gives us significant financial flexibility. It was highly gratifying to see the enthusiastic response from institutional investors in the market when given the opportunity to invest in the company. That summarizes our financial results for the quarter.

I'll now turn it back over to Behzad.

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

Thanks, Mike. Let me begin with what the new board has been working on since we were seated. We have conducted a thorough review of both Immunomedics and in particular IMMU-132, focusing on 3 areas: organizational, operational and clinical and regulatory preparedness. Each of these 3 areas was led by top tier independent consultants with specific levels of expertise.

While we respect Seattle Genetics as a leading organization in the field of ADCs and admire their accomplishments in this field, based on the multi-faceted review by our consultants, we have come to the conclusion that we can perhaps realize more value and better benefit patients by maintaining control of IMMU-132. Thus, we have decided to mutually terminate the exclusive global licensing agreement for IMMU-132 with Seattle Genetics. Seattle Genetics will maintain its existing equity investment in Immunomedics as well as the warrants, albeit with a shortened exercise period.

It is important to note that there will be no payments or expenses associated with the termination agreement on either side. Now please note that all of this is subject to court approval.

To fund the further development of 132, as mentioned by Mike earlier, we have raised a $125 million in gross profit through a convertible preferred stock offering with a strong group of institutional investors. I share the same sentiment as Mike in that the offering was extremely well received by the investors, which reflects the confidence in the long-term value of this company.

We now have the financial resources to proceed with the final selection of a CRO to launch the confirmatory Phase III study in metastatic triple-negative breast cancer with the expectation of first patient enrolled in the late third quarter of this year as well as executing on a manufacturing plant to build commercial inventory in preparation for potential launch in the U.S. in 2018.

Based on our expert consultant review of the clinical data and regulatory correspondence, we believe that the data generated to date and the ongoing 100-patient Phase II study of IMMU-132 in the third-line setting of triple-negative breast cancer, which was fully enrolled in December 2016, can provide the basis for accelerated approval subject to review by the FDA.

On behalf of the entire board, I would like to take this opportunity to acknowledge the efforts of Cynthia Sullivan and Dr. David Goldenberg for bringing IMMU-132 to this critical point. I'm grateful to both for their contributions to the company and I look forward to working with David in his capacity as a director moving forward.

In summary, we are absolutely committed to bring IMMU-132 to the U.S. market ourselves. To that end, our immediate goals are to begin enrolling in the triple-negative setting in the Phase III confirmatory trial in the third quarter of calendar 2017, and, subject to FDA input on the acceptance of the CMC filing plan, to submit a BLA to the FDA during the late fourth quarter of '17 or the first quarter of 2018. Going forward, we will be evaluating strategic opportunities with regional partners for IMMU-132 and plan for further development beyond triple-negative.

We are pleased to announce a significant development that provided us new level of clarity regarding the progress that has been made at Immunomedics. Looking ahead, the board will also continue to focus on driving value for our stakeholders, beyond 132 by looking at broader partnership opportunities for the pipeline. We intend to maximize value for the company's shareholders in the foreseeable future. We will be providing regular updates as appropriate in the coming months as we navigate the regulatory development plan.

This concludes our prepared remarks. We will now open up for questions. Operator?

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Our first question come from the line of Boris Peaker from Cowen.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Great. Behzad, just was wondering, my first question is, can you give more color on the tasks needed to complete prior to filing BLA, specifically what do you need to do to start enrolling the confirmatory Phase III in addition to selecting CRO? How many patients do you think you need to have enrolled prior to actually following BLA -- filing the BLA and other outstanding CMC steps that must still be completed prior to BLA filing?

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

Sure. Thanks for it and I'll take a crack at it and I'll hand it over to Mike also. So it has been a couple of interesting months, and I appreciate your comments earlier. In terms of with respect to what needs to be done for the submission, there are 2 work streams that we're working on, one is with respect to CMC, we've developed detailed work plans that need to be presented to the FDA for sign off. There is a critical series of activities around validation of the antibody where we need FDA input on whether that needs to occur prior to submission or can potentially occur concurrent with the review period and that will then define the CMC filing plan. With respect to clinical activities, while we certainly again need input from the FDA and there is a request of Type B meeting, we believe that time lines that we have communicated should be able to accommodate most scenarios that the FDA would want us to explore and essentially represent in the filing. In terms of what we need for the start of the Phase III confirmatory trial, it really is signing the paperwork with the CRO. There is no additional input as we see it required from the FDA.

Boris Peaker - *Cowen and Company, LLC, Research Division - MD and Senior Research Analyst*

Great. And my second question is, you recently presented updated data or the Immunomedics, the company recently presented updated data for both advanced urothelial carcinoma as well as advanced small-cell lung cancer and so I'm just curious based on the data to date, do you plan on making substantial investments in either of these indications? And if so, what are those investments and the associated studies?

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

Yes, Boris, the focus of the board and all our regulatory has been principally on the triple-negative setting. While we are obviously aware and have followed the progress in the other indications, we have not formulated a specific plan beyond continuing what we are doing today. So the budget does accommodate further developments in those settings, but at a pace that is not too far off from the pace that we've been running at. Now having said that, we are pretty far along in the urothelial setting already in terms of number of patients. So there is not a dramatic increase in the spend associated with getting perhaps additional data that we might need for additional regulatory conversations. In the lung setting, there would be more patient data required and again those are still ongoing, but at a clip that is not really dramatically impacting the budget.

Operator

Our next question comes from the line of Matthew Andrews from Jefferies.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

Behzad and Michael, can you talk about when we may get the next meaningful update on the TNBC data set? You presented 85 patients' worth of data earlier this year. When can we expect to see some sort of a meaningful update?

Michael R. Garone - *Immunomedics, Inc. - Interim CEO, VP of Finance and CFO*

Matthew, it is Mike. Thanks for that question. We anticipate we're going to have a full set of data before the fall. Naturally our focus is to have the information to the FDA in support of the BLA. However, we're going to be evaluating our options and considering the appropriate venue to share the data with you in a timely matter.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

So would that be the next time we get any sort of commentary relative to the concordance between your independent third-party lab doing the blinded reviews and what -- what the scan assessments were by the investigator sites?

Michael R. Garone - *Immunomedics, Inc. - Interim CEO, VP of Finance and CFO*

Yes. I am not -- really not in a position to talk about the details that we're going to be providing in the future. But we know that it's a topic that folks are interested in. Our focus is on getting that information to the FDA and filing the BLA, but we will be evaluating the opportunities to communicate and get you the data that's meaningful in a timely way.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

And when do you expect the last patient to complete the second confirmatory scan? Is that a Q2 event? Has it happened yet?

Michael R. Garone - *Immunomedics, Inc. - Interim CEO, VP of Finance and CFO*

I think that that's going to happen mid this year, third quarter probably, and we'll be in a position then to start collecting the data -- or having the data for the FDA.

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

And Matthew, on the confirmatory scan, if the patient is going through response on the first scan, then the second one obviously 6 to 8 weeks thereafter, so you can kind of figure out the time lines, what that could look like. But not every patient responds on the first scan and sometimes on the second or third scan, you get the response and so the confirmatory scan would come essentially thereafter. But beyond just the response rate, we're obviously also collecting the duration and trying to finalize the PFS benefit. So if you just go through the time lines, the last patient was -- got the first treatment in mid-January. We will talk about midyear when they would be essentially 6 months out and that's probably a reasonable time frame as to thinking about when the data collection would occur and then subject to scrubbing it and whatnot, it would become available sometime thereafter. And that's obviously independent of the confirmatory reads by third party, perhaps not for the very last patient, because obviously, we couldn't send it for confirmation until the patient's data is in, but the [triple] processes are in parallels and not necessarily entirely joint. So some information might come available ahead of that.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

And then I know this is a bit far afield, you have a lot to do with starting the Phase III and filing the BLA, but can you give us some initial thoughts on, how are you thinking or board's thinking about sizing the sales force in the U.S. with the focus of launching this later next year or '19 depending

on time lines? How big a sales force? And then also timing of when you may bring them on-board and ramping up regulatory and any marketing staff you may want to bring on-board?

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

So I'll take a crack at that. The question has been asked and at a very high level, we have some broad-based perspective. It's not that different to some of the other recently launched targeted oncology companies in terms of size of sales force, but it's really premature for us to get into exactly what we're thinking and sort of the budgeting that would go into that. Suffice it to say from a capital raising standpoint, we factor in some level of spend to prepare for that. The sales force will probably, much like most other players, not really come into play until we are very close to the approval. The layer above that in terms of the management and infrastructure that we need to put in place would occur probably in the early part of next year, call it first quarter end of that. But as I think we also mentioned, there's certainly a plan to replace the CEO role, which we're now in the market for and that's certainly going to be a function and area of focus for that individual. To some extent, people that I have discussed who might come in, at least phenotype of that is that, that really has not been able to be defined until essentially last Friday morning when we announced that the assets -- the agreement with Seattle was terminated because that now defines the kind of CEO we're looking for and certainly will be a commercially-oriented individual with the expectation that we will be filing and hopefully have approval in 12 to 18 months from now. And that person will certainly have the responsibility to find the team and tying the sequence of events that end up to having the sales force in place.

Matthew J. Andrews - *Jefferies LLC, Research Division - Equity Analyst*

Got it. And just how critical is the new CEO, the phenotype you mentioned that they actually have oncology or hematology experience? Is that a must-have? Or is commercial experience sufficient?

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

So, I think we probably think about oncology and solid tumor as opposed to hematology is -- whether it's specific oncology experience is totally important, but we're looking for someone who is going to be a leader of an organization that I think is going to become among the names that will become a household biotech. So specific oncology expertise is important, whether it's the only determinant is probably subject to what the search provides and what the other candidates have to offer.

Operator

Our next question comes from the line of Nick Abbott from Wells Fargo.

Nicholas M. Abbott - *Wells Fargo Securities, LLC, Research Division - Associate Analyst*

It's Nick in for Jim this afternoon. Just going back to CMC, so can you just help me understand what the risk is if potential filing might be delayed by, I don't want to say CMC issue, but just the need to complete the CMC? I'm trying to understand if there are 3 suppliers of the antibody, the SN-38 and then somebody does the conjugation chemistry till the finish. And so all of those or any of those have commercial scale and who is supplying the material for the Phase III trial that you're planning? And I have a follow-up.

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

So I'll do the easy one, which is who is providing material for the Phase III that's Immunomedics, moving on from that one. I think with respect to the CMC, as best we can tell, the key steps involved that are subject to input from the FDA have to do with validation and when there's validation at the single component level, meaning the antibody versus the linker versus the toxin and then there's validation of the entire construct. What we need input on in the very near term is whether we need to have completed the validation steps prior to submitting the accelerated approval

package. If that is in fact the case, it just takes a certain amount of time to do those steps. We're going to start those essentially immediately now that we have the asset back and we have the financial means to do it. But it just takes time to complete it and we won't be in a position to file by the end of this year. If on the other hand, the FDA agrees with the proposed plan, which is to complete the validation concurrent with the review of the application, we might well be able to submit all the other modules for CMC and non-CMC clinical, preclinical, et cetera, hopefully by end of this year and supplement that package with validation information as it becomes available during the course of the review. And all of that -- the clarity for that is subject to a meeting with the FDA that has been requested and we should have hopefully clarity, but without that input, it's very hard for us to really nail down any better than where we've sort of developed the time line.

Nicholas M. Abbott - *Wells Fargo Securities, LLC, Research Division - Associate Analyst*

Okay. And then in terms of an ex-U. S. partner, is there anything you can salvage from the prior partnership discussions that gives us some leads to follow up on? Or you going to start de novo?

Behzad Aghazadeh - *Immunomedics, Inc. - Chairman*

Yes. I think I probably wouldn't use the word, 'salvage'. I think their level of interest has been strong since the announcement came out. I've received a number of inquiries and I think the company has received -- Mike has received a number of inquiries as well. Our focus is really on getting the task at hand done and done well. If, along the way, a partnership that is attractive to us comes along for ex-U. S. Right now, ex-U. S is -- there's a lot of geographies there, the regions that we might be interested in keeping, the regions that we might be interested in partnering and we are open to all sorts of conversations. But certainly, I don't think it's going to be a situation of salvaging, it's more whether it's something that we believe we need to do given the strength that we find ourselves in now.

Operator

At this time, I would like to hand the conference back over to Michael Garone for his closing remarks.

Michael R. Garone - *Immunomedics, Inc. - Interim CEO, VP of Finance and CFO*

Thank you. Well, we thank you all very much for joining us this afternoon. On behalf of the entire management team, I would also like to thank you for your continued support and interest in Immunomedics. Thank you.

Operator

That does conclude today's conference call. You may now disconnect. Thank you and have a great day.
