THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

TH.TO - Theratechnologies Inc. - Special Call

EVENT DATE/TIME: MARCH 06, 2018 / 9:30PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

Christian Marsolais *Theratechnologies Inc. - Senior VP & Chief Medical Officer*

Denis Boucher *Theratechnologies Inc. - VP of Communications & Corporate Affairs*

Luc Tanguay *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Lyne Fortin *Theratechnologies Inc. - Senior VP & Chief Commercial Officer*

Philippe Dubuc *Theratechnologies Inc. - Senior VP & CFO*

CONFERENCE CALL PARTICIPANTS

Andre Uddin *Mackie Research Capital Corporation, Research Division - MD of Healthcare Research*

Douglas W. Loe *Echelon Wealth Partners Inc., Research Division - Healthcare and Biotechnology Analyst*

Endri Leno *National Bank Financial, Inc., Research Division - Associate*

Neil Maruoka *Canaccord Genuity Limited, Research Division - Analyts*

Prakash Gowd *CIBC Capital Markets, Research Division - Executive Director of Institutional Equity Research*

PRESENTATION

Operator

Good afternoon, ladies and gentlemen, and thank you for standing by. Welcome to Theratechnologies' analyst conference call. (Operator Instructions) I would like to remind everyone that this conference call is being recorded today, March 6, 2018, at 4:30 p.m. Eastern Time.

I would now like to turn the conference over to Denis Boucher. Mr. Boucher, please go ahead

---

Denis Boucher - *Theratechnologies Inc. - VP of Communications & Corporate Affairs*

Thank you, and welcome. Luc Tanguay, President and Chief Executive Officer of Theratechnologies will be the speaker on today's call. A Q&A period open exclusively to financial analysts will follow his presentation. Philippe Dubuc, Chief Financial Officer; Lyne Fortin, Chief Commercial Officer and, Christian Marsolais, Medical Officer, will be available to field questions of a more technical nature. Before Luc begins his remarks, I have been asked by Theratechnologies to read the following message regarding forward-looking statements.

I would like to remind everyone that Theratechnologies' remarks today contain forward-looking statements about its current and future plans, expectations and intentions, results, levels of activity, performance, goals or achievements or other future events or developments. In preparing these forward-looking statements, several assumptions were made by Theratechnologies, and there are risks that results actually obtained by the company will differ materially from those statements. As a consequence, the company cannot guarantee that any forward-looking statement will materialize, and you are cautioned not to place undue reliance on them.

Theratechnologies refers current and potential investors to the forward-looking information section of its press release issued today and to its annual information form dated February 6, 2018, and the Risk Factors section therein available at www.sedar.com under Theratechnologies' public filings. Forward-looking statements represent Theratechnologies' expectations as of March 6, 2018. Except as may be required by securities laws, Theratechnologies does not undertake any obligation to update any forward-looking statement whether as a result of new information, future events or otherwise.

I would now like to turn the conference over to Luc.

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Thank you, Denis. Good afternoon, everyone, and thank you for being on the call today. I am particularly pleased and proud that the U.S. Food and Drug Administration has approved ibalizumab or Trogarzo as it is now known by its commercial name. Trogarzo is indicated for use in combination with other antiretrovirals for the treatment of heavily treatment-experienced adults infected with multidrug resistant HIV-1 who are failing their current treatment regimen.

Today's announcement is great news for both Theratechnologies and for these vulnerable patients who are in dire need of a new treatment option to control multidrug resistant HIV. It took over 20 years of research and development to bring this FDA-designated breakthrough therapy to patients in need of a new mechanism of action to fight their HIV infection. Of course, it will not have been possible without our colleagues at TaiMed who demonstrated tremendous vision and commitment. We are honored to partner with them in making this product available to patients in the United States.

I also want to recognize the contribution of clinicians and patients who took part in the clinical trial process. And of course, I want to thank the people here at Theratechnologies who have worked so hard over the last 2 years to prepare the launch of Trogarzo. As you know, Trogarzo has quite an enviable pedigree. It's the first and only treatment in a new class of antiretrovirals called HIV-1 inhibitors. It's the first biologics for the treatment of HIV-1. It's also the first treatment for HIV-1 that does not require daily dosing. It's the first HIV-1 treatment with a new mechanism of action approved in more than 10 years. More precisely, it's the first humanized monoclonal antibody approved for the treatment of HIV-1 and works by binding to CD4 receptors on the host cells known as T-cells.

When you also take into consideration its safety and efficacy profile, it's no wonder that Trogarzo was designated as a breakthrough therapy by the FDA. The Phase III clinical trial showed that 83% of patients taking Trogarzo's reached the FDA-defined primary endpoint of at least 0.5 log or 70% reduction in viral load. The mean reduction was 1.1 log 7 days after the first dose on Trogarzo as a functional monotherapy.

Following the optimization of the background regimen after day 7, the observed mean viral load reduction at 24 weeks reached 1.6 log. Furthermore, HIV was undetectable in 43% of patients previously dealing with an increasing and uncontrolled viral load. It's also important to mention that having viral load below detection levels is greatly beneficial from a public health standpoint. Indeed, it has been shown and recognized by the United States Centers for Disease Control that HIV cannot be transmitted if it is suppressed to undetectable level. Trogarzo also had a positive impact on T-cells count, which is critical to rebuilding a patients' immune system and a key goal of any antiretroviral therapy. As a reminder, the Biologics License Application for Trogarzo was accepted by the FDA on June 30, 2017, and Trogarzo was then evaluated under priority review.

We are pleased with the label approved by the FDA, which is, as I mentioned earlier, is to use Trogarzo in combination with other antiretrovirals in heavily treatment-experienced adults with multidrug resistant HIV-1 who are failing their current treatment regimen. Importantly, for physician and patients, the approved label states that Trogarzo has no drug-drug interaction and has not been associated with cross-resistance with other antiretrovirals. The most common adverse reaction observed were diarrhea, dizziness, nausea and rash. And each of them occur in less than 8% of patients.

The approved indication is in line with our expectation and will address a patient population of approximately 20,000 to 25,000 people in the U.S. Of those, 10,000 to 12,000 are in need of a new treatment option as their therapy is no longer effective at controlling their viral load, which is putting their health and ultimately their life at great risk. Of course, now that Trogarzo is approved in the U.S., our goal is to make it available to patients as quickly as we possibly can.

We estimate that Trogarzo will be available to patients within 6 weeks. In the meantime, we have a number of things to do. To start with, we will finalize packaging of the product already manufactured. This will be followed by filling the supply chain and making the product commercially available. In that regard, we are working with RxCrossroads and also with Option Care, Walgreens AllianceRx, Accredo and CuraScript, which altogether has the right expertise to handle the distribution of the first-ever infused HIV-1 treatment and ensure that patients have access to Trogarzo, either through home infusion, infusion centers or physician offices.

Also our entire sales team will take part in the launch meeting that will happen at the end of March. Until then, they will remain busy promoting EGRIFTA and booking appointments with physician to introduce Trogarzo in the coming weeks. They will be fully ready to promote Trogarzo after the launch meeting, during which in-depth training will take place.

We are also focusing on building payers acceptance for Trogarzo. Our dedicated managed market team is ready and will certainly be extremely active from now on and over the next 4 to 6 months to facilitate patient access. They will work in close collaboration with our THERA patient support call center, which will help patient having been prescribed Trogarzo. Based on the time we estimate it will take to have Trogarzo added to payers' formularies, we believe that access to the medicine for patient as well as sales will gradually pick up in the next 2 quarters and will gather much more momentum onward as the measures I just described are fully deployed.

Our ultimate goal is to ensure that all patients who need Trogarzo will be able to access it, both from an outreach and from a financial point of view. Treatment accessibility was not only a major priority, but also a major parameter in establishing the price of Trogarzo. In addition, we took into consideration the size of the patient population, the investments required to reach and support patients and physician as well as feedback from different stakeholders. We also needed to take into account that we want to continue the development program of Trogarzo, which include an intramuscular formulation requiring additional investments by both TaiMed and Theratechnologies.

Taking all of this into consideration, we set the wholesale acquisition cost or WAC at USD 118,000 per year. It should be remembered that the WAC does not reflect the actual net selling price. We estimate that our net selling price will be approximately 30% lower due to rebates to payers such as Medicaid and AIDS Drug Assistance Program or ADAP. We will also have programs to facilitate treatment access to patients who need Trogarzo such as a generous co-pay program that we have already established. Trogarzo will also be made available through our patient assistance program for those who are not insured, and we are also working with patient foundation. Finally, distribution fees also have to be deducted from the WAC, which explain why the average net selling price that we will record should be approximately 30% lower than the WAC.

Trogarzo brings new hope to patient who greatly need a new option to lower their viral load and for many, to bring it to undetectable levels. When we announced the partnership with TaiMed, I mentioned to analysts that Trogarzo could very well be a game changer for Theratechnologies. Today, I think it will also be a game changer for thousands of patients with multidrug resistant HIV-1 infections in the U.S. as they now have a new powerful tool to address their condition.

This is exactly in line with our corporate mission of meeting unmet medical needs to promote healthy living and improve quality of life among HIV patients. In conclusion, I can say at this time, that we are geared up for a successful launch. We have put a team in place, including an extended medical science liaison contingent, a larger sales force has been in place for more than 8 months and we have extended our patient support programs, which is ready to help patient initiate therapy. Finally, our team is ready to approach payer to ensure timely reimbursement.

Once again, I want to thank everybody that was involved in making such an important announcement possible. We are all very proud to be associated with making this crucial treatment advance available to patients, and we will make sure that they can benefit from it.

Thanks for being on the call today, and we will now take questions from the financial analysts.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from Andre Uddin from Mackie Research Capital.

Andre Uddin - *Mackie Research Capital Corporation, Research Division - MD of Healthcare Research*

Congratulations, Luc, Philippe, Christian and Lyne. Nice job on the approval. I just actually had one question. Luc seem to have answered everything. In terms of this week, there's a conference called CROI in Boston. And I was just wondering if there are any abstracts being presented there? And if you have any Carewell meetings going on there as well (inaudible) timing?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Okay. I'll ask Christian who's in the -- at CROI at this point in Boston in the winter storm there. So Christian, can you answer to that?

Christian Marsolais - *Theratechnologies Inc. - Senior VP & Chief Medical Officer*

Yes, absolutely. We're in Boston with the medical team. And of course, we had a number of meetings with physicians during CROI. I think that tomorrow will be a very busy meeting. And we also have a poster presentation on the resistance of the virus of the patients that were enrolled in the Phase III that really shows that Trogarzo worked independently of the resistance acquired by the -- all of the other drugs approved by the FDA, and this is what we'll be discussing tomorrow afternoon with the physicians on-site.

Andre Uddin - *Mackie Research Capital Corporation, Research Division - MD of Healthcare Research*

Okay. Is there any KOL meetings that you're hosting at all there?

Christian Marsolais - *Theratechnologies Inc. - Senior VP & Chief Medical Officer*

Yes, we have some. We have some during CROI, it seems like we cannot do any specific meeting because it's a scientific meeting. But we had one outside of CROI on Saturday, and we'll continue our medical activities right tomorrow (inaudible) in the field, and they will be starting to work on our medical plan.

Operator

Your next question comes from Neil Maruoka from Canaccord Genuity.

Neil Maruoka - *Canaccord Genuity Limited, Research Division - Analyts*

Congratulations on the approval. That's great news. Your -- the time lines to the launch, you expect to be able to launch this drug within 6 weeks. Certainly, the delay that the FDA imposed on the drug early in November maybe had a positive impact in terms of your ability to prepare for the launch. Can you comment on your discussion with insurers, where you sit now? How close you are with some of the major insurers and the percentage of covered lives that you expect to be able to gain in the near term? And also in terms of your readiness for your launch within 6 weeks, marketing materials, are there any other approvals that you need to be ready. And then, finally, just in terms of the preparation of your sales force, how much training do they need to undergo and -- or do you think that they'll be ready by the end of March?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Okay. I'll let Lyne to answer the -- your second and third question. It will answer to your first one. Neil, I don't think that the -- the fact that the -- we had a small delay in the approval process change the fact that we need 6 weeks or at the most, 6 weeks, to have the product available because once it's approved, we have to do the packaging, we have to print the box with the right numbers and so on. So this 6 weeks is definitely needed to -- and to fill the supply chain. So we definitely need that -- that 6-week period to bring the product to the market. So -- but in a way, and Lyne

will comment on that, it helped us of course on some part of probably marketing, get all the MSLs, the sales reps prepared and so on. So Lyne, can you answer to second and third question, please.

Lyne Fortin - *Theratechnologies Inc. - Senior VP & Chief Commercial Officer*

Yes, obviously. So we've been very busy in the past year interacting with payers, to your second question, with our managed market team. And we did clinical presentation with the help of our medical science liaison to really share information about the unmet medical need when it comes to treating HIV for a multidrug resistant HIV infection. And highlighting to them that there is a proportion of their HIV-covered life that will need a new treatment options. And they can certainly appreciate that this is an important new mechanism of action that is needed to help control the disease progression, help keep the viral load under control, bring back the virus to undetectable phase. So there's an appreciation for the value. They understand to interacting with us on the clinical side what the need is for those patients. So we are very confident. And we've been interacting with national and regional payers from both the commercial side and also the government side. And we're all ready to engage with the CMS agreement and continue to work with them to ensure as broad access as possible, as early as possible.

Neil Maruoka - *Canaccord Genuity Limited, Research Division - Analyts*

Can you quantify in terms of covered lives or how close you are with some of the major insurers?

Lyne Fortin - *Theratechnologies Inc. - Senior VP & Chief Commercial Officer*

Well, we've interacted with, say, over 80% of the covered lives in the U.S. through the plans that we have interacted with at this point in time. Now with the approval, we will turn our attention on interacting with them on specifically talking about Trogarzo and working with them so that they can develop payer policy that will open up access and have the right criteria for authorizing the reimbursement of this drug. So all the legwork has been done covering the vast majority of HIV-covered lives in both commercial and government setting, as I said.

Neil Maruoka - *Canaccord Genuity Limited, Research Division - Analyts*

Okay.

Lyne Fortin - *Theratechnologies Inc. - Senior VP & Chief Commercial Officer*

On the training for our sales force. Yes, obviously, we use the additional time to perfect the training so they have had extensive training on understanding multidrug resistant infection, the current HIV treatment options and most recently, we have shared with them information so that they can prepare ahead of the launch meeting with all the information they need on Trogarzo itself and its clinical program and be fully prepared to come at the end of March to be certified to actually promote it right after the meeting. So we've really done the extensive preparation with all of our sales force at this point in time to be ready.

Operator

(Operator Instructions) Your next question comes from Doug Loe from Echelon Wealth Partners.

Douglas W. Loe - *Echelon Wealth Partners Inc., Research Division - Healthcare and Biotechnology Analyst*

My congratulations, gentlemen, as well. I think I know the answer to this question, but I'll ask it anyway. Your time lines to launch are sort of quite aggressive by conventional standards and I assume that's because the TaiMed or WuXi PharmaTech already has commercial batches ready for sales

as TaiMed has confirmed itself in its own investor presentation. Can you just sort of confirm for me that there really -- there aren't any lingering manufacturing risk elements to your time lines to launch?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

You're right, Doug. The TaiMed, as you know, has been audited by the FDA and they were audited during -- when they processed with batches of this drug. So it's already manufactured. It's -- what we need to do now is just to package it, import it to the U.S. Some of it is already in the U.S., and to package it and then fill the supply chain. So we need to send it to our main distributor and then they have to sell it or to send it to the 4 companies I mentioned previously to make sure that this will be available for patients. So it's just a question of the mechanic here to make sure that we are able to fill correctly the supply chain.

Douglas W. Loe - *Echelon Wealth Partners Inc., Research Division - Healthcare and Biotechnology Analyst*

That's perfect. And then just a quick follow-up question here, and this might be more relevant for TaiMed, but if you have any insights on this. I mean, TaiMed has long had an IM ibalizumab formulation in development that it expected to submit data for claims extension. Any update from them that they conveyed to you on time lines on that, which they have said themselves could be in a position to be approved sometime early 2019?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

I think I mentioned that the focus of the last few quarters were on the approval of ibalizumab with the current formulation. So I think now that it's -- this is behind us, on our side, we'll get prepared for the launch, and Christian and the people at TaiMed will start to discuss the game plan for the intramuscular. We already had some discussions, but really, the focus in the last few quarters were really on making the drug approved.

Operator

Your next question comes from Prakash Gowd from CIBC.

Prakash Gowd - *CIBC Capital Markets, Research Division - Executive Director of Institutional Equity Research*

Congratulations, everybody. I'm very happy for you. It's been a long road. Most of the questions have been answered, but just a few little ones. Just getting back to the issue of reimbursement coverage. I know you talked about gradual pick up over the next 2 quarters. Can you kind of give me the -- some guidance on when you think an optimal reimbursement situation would be -- sort of a time line for that, would end of 2018 be a reasonable assumption?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

So, usually, what -- when we discuss with our managed market team, they estimate that it's going to take before -- or between 4 to 6 months before we reach an optimal level of reimbursement. So it doesn't mean that we won't have reimbursement before that, but we need to sit with every insurer and put this drug on their formulary. And I don't know, Lyne, if you want to add something to that.

Lyne Fortin - *Theratechnologies Inc. - Senior VP & Chief Commercial Officer*

No. It's exactly -- so we've met with them ahead of the approval so that they understood the need and the value. Now we will interact specifically for them to develop payer policy and this is what can take up to 6 months. But nevertheless, as Luc explained, patients would be able to get reimbursement through the prior authorization process and we'll start now interacting with them directly on setting the right process for getting

the drug reimbursed while they're building their payer policy and formulary view, which they all have different time lines, but we are very aware what these are for the major payers that were -- will be involved.

Prakash Gowd - *CIBC Capital Markets, Research Division - Executive Director of Institutional Equity Research*

Okay, great. Then maybe a question maybe for Philippe. Now that you've got the approval, looking forward on the different expense items, what sort of increase could you be potentially expecting in the next 12 months?

Philippe Dubuc - *Theratechnologies Inc. - Senior VP & CFO*

Well, actually, if you look at our fourth quarter expenses, that's the structure that we need going forward. And so what we've budgeted for this year is pretty close to Q4 times 4. So there's not a big bolus of expenses. We have the set up that we need.

Prakash Gowd - *CIBC Capital Markets, Research Division - Executive Director of Institutional Equity Research*

Perfect. And then lastly, maybe you...

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Maybe just to add on what Philippe just mentioned. Maybe the only thing that could increase a little bit our spending next -- or this year is all the activities for the European market. But as far as the U.S. is concerned, as Philippe mentioned, we reached the proper level.

Prakash Gowd - *CIBC Capital Markets, Research Division - Executive Director of Institutional Equity Research*

Okay. And that was my last question, just on the European filing. Any update on that? I know you've been busy with the U.S. approval?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

We -- as I mentioned, we already have been attributed rapporteur and co-rapporteur. And we'll have a meeting with the authorities in the coming months. I think it's -- what's the date exactly, Christian?

Christian Marsolais - *Theratechnologies Inc. - Senior VP & Chief Medical Officer*

It will be -- it's at the end of the third week of April that we will meet with the rapporteur and co-rapporteur. But that's really the, what we call, the kind of the regulatory issue, to present what will be included in the dossier core submission.

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

Yes. So we're online on our game plan on that.

Operator

(Operator Instructions) Your next question comes from Endri Leno from National Bank.

Endri Leno - *National Bank Financial, Inc., Research Division - Associate*

Congratulations on the approval. And vast majority of my questions have already been answered, but just a quick one, perhaps for Philippe, on the spending. Do you expect any increases in working capital over the next year?

Philippe Dubuc - *Theratechnologies Inc. - Senior VP & CFO*

Nothing, major, Endri. It's pretty much will continue as we have in 2017 or at least at the end of 2017.

Endri Leno - *National Bank Financial, Inc., Research Division - Associate*

Okay, great. And the next question is more for Health Canada. When do you expect to submit or have you had any meetings with them at all or if you have any background?

Luc Tanguay - *Theratechnologies Inc. - CEO, President and Non-Independent Director*

At this point, we don't have any specific plan for Canada. We definitely want to get the decision from the FDA before to do anything in Canada, and not to jeopardize anything we're doing in the U.S. So I think in the coming months, we'll sit and see what is the game plan for the Canadian market, if we decide to go ahead with Canada.

Operator

We have no further questions at this time. I would like to turn the call back over to Mr. Denis Boucher.

Denis Boucher - *Theratechnologies Inc. - VP of Communications & Corporate Affairs*

Well, thank you very much. Thanks for being on the call today. We wish you a very pleasant evening. See you soon.

Operator

This concludes today's conference call. You may now disconnect.
