THOMSON REUTERS STREETEVENTS

EDITED TRANSCRIPT

TH.TO - Q1 2018 Theratechnologies Inc Earnings Call

EVENT DATE/TIME: APRIL 05, 2018 / 12:30PM GMT

THOMSON REUTERS

CORPORATE PARTICIPANTS

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

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

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

PRESENTATION

Operator

Good morning, ladies and gentlemen, and thank you for standing by. Welcome to Theratechnologies' earnings conference call for the first quarter of 2018. (Operator Instructions) I would like to remind everyone that this conference call is being recorded today, Thursday, April 5, at 8:30 a.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. Mr. Luc Tanguay, President and Chief Executive Officer of Theratechnologies; as well as Mr. Philippe Dubuc, Senior Vice President and Chief Financial Officer, will be the speakers on today's call. A Q&A period open exclusively to financial analysts will follow their presentation.

Before Mr. Tanguay 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 refer current and potential investors to the forward-looking information section of its press release issued this morning 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 April 5, 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*

Okay. Thank you, Denis. Good morning, everyone, and thank you for being with us today.

I'm pretty sure that not so long ago, I spoke to the vast majority of people in the call today. Although it seems like months have already gone by given the level of activity here, it's only a month ago that we received the much-anticipated approval of Trogarzo by the Food and Drug Administration in the U.S.

In essence, the approval cannot have come at a better time. Indeed, it was announced as the 25th Conference on Retroviruses and other Opportunistic Infection, known as CROI, was taking place in Boston. CROI is among the most important medical conferences on HIV.

As we were presenting a poster session on Trogarzo, we received a great deal of attention, and we fielded questions from specialists from around the world. This was a great opportunity to communicate the fact that Trogarzo had been approved for the treatment of patients with multidrug resistant HIV.

Furthermore, we were able to underline some unique features of Trogarzo, such as being the first monoclonal antibody used in the treatment of HIV, the first HIV treatment with a new mechanism of action approved in more than 10 years and the first non-daily treatment for HIV.

We are also quite pleased with the indication approved by the FDA. In fact, the indication reflects the patient population of 20,000 to 25,000 that we have been talking about ever since our Investor Day in March 2017.

Getting the approval was one thing. We are now concentrating on making sure that we have product available to physicians and patients. I can tell you that the first commercial vials are being packaged by TaiMed, supplier in the U.S., and as soon as they are ready, the vial will be shipped to our distributor to fill our supply chain.

Our target for the commercialization -- commercial availability of Trogarzo remains around the end of April. Based on the level of activity at our call center THERA patient support, I can also tell you that things are shaping up quite well.

Of course, as I mentioned during the analyst call on approval day, we expect sales to gather momentum, as we obtain reimbursement from public and private payers. But I'm very pleased with the reports I'm getting from our managed market team.

There is definitely enthusiasm for the product. In fact, shortly after the approval and even before any active promotion, we started receiving requests for enrollment forms from across the U.S. Enrollment forms are used by physicians to prepare prescriptions for patients. And as of today, we have provided forms to close to 200 clinics, and we have then -- have received some prescription at our call centers.

While this is already impressive, we expect that we should see even more movement as our complete U.S. team of sales, representative, medical science liaison and reimbursement professionals receive a compressive training last week here in Montréal.

So as such, the product has been officially launched since Monday of this week, and a full contingent of representatives is now calling on 5,000 physicians. This means that we should start seeing even more traction in the coming weeks and months.

As far as reimbursement is concerned, we are already seeing positive developments. In fact, the reimbursement of Trogarzo was quickly approved on an individual basis for some patients.

On top of this, some payers have already developed their reimbursement policy, which is quite encouraging as it's extremely rare for plans to have medical policy developed this soon after approvals. Consequently, we will start to record and to report sales revenue from Trogarzo in our second quarter.

It's a very exciting time for Trogarzo and also for Theratechnologies. That does not mean that we will lose sight of the importance of EGRIFTA for our business.

Quite the contrary, EGRIFTA is and will be a key element in our strategic plan, as it generates solid cash flow to sustain our operations and has proven to be a pivotal tool in our development. Indeed, it enabled us to sign the agreement with TaiMed.

As we build the Trogarzo franchise in the U.S., it's certain that we will remain committed to continue growing EGRIFTA sales. On that front, I'm quite pleased with what I have been seeing ever since we expanded our sales force in the U.S.

In simple terms, EGRIFTA is benefiting from our investment in Trogarzo. The impact of our larger sales force combined to additional marketing activities has been translating into sales increases compared to last year.

The new F4 formulation could also eventually support sales growth. On that front, the necessary bioequivalence study has now been completed. Result obtained show bioequivalence to the current 1 milligram formulation. And as a result, we expect to submit the supplemental new drug application, or sNDA, to the FDA in the third quarter of 2018 as previously mentioned.

On the financial front, Philippe will give you all the details in a moment, but I can already tell you that we had our best first quarter ever in terms of revenues. Of course, you will not be surprised that our expenses were also higher compared to the same quarter last year, but they were, in fact, slightly lower than in Q4 2017. And this is in line with what we have previously alluded to in terms of expenses reaching a plateau.

This goes to show that we have been managing expenses closely even as we were preparing to launch Trogarzo in the U.S. and speeding up our proprietary work in Europe. As a matter fact, in a few days from now, we will be meeting with representatives from rapporteur and co-rapporteur countries assigned to review our file.

As you may recall, the 2 countries are the Netherlands and Italy. This technical meeting will be very, very helpful to finalize our regulatory strategy and to ensure that we can file in Europe as soon as we possibly can.

So that being said, it's still too early to provide the potential timeline for filing in Europe, but we will have a much more precise idea once the meeting with the rapporteurs has taken place.

So on that note, I will let Philippe present our results for the first quarter 2018, and I will come back after. Philippe?

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

Thank you, Luc, and good morning, everyone.

As Luc mentioned a minute ago, this was our best first quarter ever in terms of revenues. In U.S. dollars, we saw 18% growth compared to the same quarter last year. In Canadian dollars, net sales of EGRIFTA came in at $10.2 million compared to $9 million last year, representing 13% growth.

Increased revenues were recorded due to higher unit sales and prices. The revenue increase was somewhat offset by higher discounts in patients' assistance costs as well as unfavorable exchange rate fluctuation.

We expect that our expanded sales force will continue to have a positive impact on EGRIFTA sales in the coming quarters, as our 35 sales representatives will call on more than 5,000 key physicians in the field of HIV.

Nevertheless, the investment made towards the launch of Trogarzo obviously had an impact on our bottom line. In Q1 2018, we recorded a negative EBITDA of $2,021,000 compared to a positive EBITDA of $725,000 during the first quarter of 2017.

In Q1 of this year, cost of sales, which includes cost of goods sold, production-related costs and royalties to EMD Serono, was $2.1 million or approximately $100,000 more than in Q1 2017. In more detail, cost of goods were up slightly, increasing to $1.2 million in Q1 2018 from $1.1 million last year.

As for royalties, they reached $1.1 million in Q1 2018 compared to slightly less than $800,000 for the same period last year. Due to the reversal of a loss provision taken in Q4 2017, production costs in Q1 2018 were actually favorable in the amount of $160,000. This compares to an expense of $178,000 in Q1 of last year.

As for research and development expenses, we also recorded an increase in Q1 2018 when compared to Q1 of last year. More precisely, it increased to $2.4 million from $2 million last year. Notably, R&D expenses were down by almost $600,000 from Q4 2017. The increase in spending compared to last year was, of course, related in great part to the anticipated launch of Trogarzo.

The same can be said regarding selling and market development expenses. Indeed, they were up to about $6.7 million in Q1 2018 compared to $3.8 million in Q1 last year. But again, they were down compared to Q4 2017 when they were close to $8 million. The increase compared to last year is largely due to the expansion of the sales force, which started to occur in Q2 of last year and was fully implemented in Q3.

G&A expenses reached $1.5 million in Q1 2018 compared to $1.2 million last year, reflecting the general development of the business, including the preparation of our European entry strategy.

Finance costs amounted to $195,000 compared to $2.3 million for the same quarter last year. The fair value of the warrant liability does not affect our reporting anymore, as all warrants have now been exercised. As a result, we recorded a net loss of $2.6 million or $0.04 per share in Q1 2018 compared to a net loss of $2.2 million or $0.03 per share last year.

Operating activities in Q1 2018 generated a negative cash flow of about $1.1 million compared to a positive one of $2.5 million in Q1 2017. Operations led to a negative impact of $2.6 million, which was offset by changes in operating assets and liabilities, which generated over $1.5 million.

The exchange rate from American to Canadian dollars positively impacted our cash balance. As a result, the company retained a strong cash position at the end of its first quarter of 2018 with $32.5 million in cash and equivalents compared to $33 million at the end of our last fiscal year.

And given the cash flow generated by EGRIFTA alone and the fact that we should start recording sales of Trogarzo in our second quarter, we currently have a comfortable cash position that gives us enough room to aggressively pursue the European filing for Trogarzo as well as to continue to look for other opportunities that would be a great fit for our company.

So on that note, I will turn it back over to Luc, who has some closing remarks.

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

Thanks, Philippe. It's fair to say that our company has never been in a better position. This was our best first quarter ever in terms of revenues, and EGRIFTA sales are still growing and generating significant gross margin.

Trogarzo is now approved, and we can feel a high level of interest from physicians, patients and importantly, from payers. It's only a matter of a week before we start recording revenues from Trogarzo, and of course, sales will pick up momentum as reimbursement is being confirmed by more and more private and public payers.

To that end, our managed market team is very active and will continue to be over the next 6 months. Definitely, things are going in the right direction. While this is happening, we're also ensuring to move the European file as fast as we can. This is a significant market, and we want to be there in the shortest timeframe possible.

Finally, from a cash point of view, we still have $32 million in liquidities, which is a great position to be in. We are at the pivotal point in our history, and I invite you to stay with us for what could be a very exciting journey.

So on that, we -- I want to thank you all 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 the line of Prakash Gowd from CIBC.

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

I just had a couple of questions. First on reimbursement for Trogarzo. You mentioned that you've already received some prescriptions at your THERA patient support call centers. And it sounds like you're probably trying to get some exception authorization for these patients. Can you quantify at all how many prescriptions we're speaking about here? And then what it really entails to get the exception authorization and the likelihood of success?

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

We prefer not to. And same thing in the future, maybe not provide exactly how many prescription we receive. What you have to understand, Prakash, is that we just launched actually the product. In fact, this week, we were in training the whole week last week. So no promotion has been done before Monday of this week. So even without that, we have sent over 200 or close to 200 enrollment forms to clinics. So there is interest for the product from those physicians and clinics, and we already received some prescriptions. So I imagine it's between 0 and 200. But the point is that even at so early in the process, it's very rare to see this kind of process and even having some insurance company approve on an individual basis those prescription or reimbursement for those patients. So all that put together, I think it shows that there is interest from physicians, from patients and also by the insurance company. And I think it will be a very -- it won't be fair -- a fair guideline if I was telling you what is the number. But we are very excited about the fact that this -- we have this kind of interest so early in the process. I don't know, Lyne, if you want to add on the (inaudible).

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

Yes, Prakash, I just wanted to add that, actually, you are right. The exception process is what is working now until the coverage criteria are loaded in the payer system. But I must say that the exception process is working very well, and that entails the physician justifying the medical necessity of getting Trogarzo to their patients. So this is what led to the approval of patients already into that process.

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

Okay. So Lyne, just a follow-up on that then. For the market access team and in their discussions with payers, are the payers sticking very much to the label requirements for Trogarzo? Or are they requiring any additional steps or administrative hurdles?

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

Well, it is very early because, as I mentioned, the exception process is what's working now until the established payer policy. But I can say that the payer policies that are in development right now are looking very positive and aligned with the FDA approved indication. So we are very enthusiastic about the responsiveness of the payers on that front for the patients who are in the difficult situation of needing Trogarzo.

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

Okay. That's great. That's a good sign. Then just on EGRIFTA. Can you talk a little bit about your expectations for the momentum to continue throughout the course of this year? Or are you potentially expecting maybe sales to plateau a bit as the sales force priority now shifts to Trogarzo?

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

No, we -- it's a very good question, Prakash. We're still in line with our guidance on sales of Trogarzo. We believe that we will have between 10% to 15% growth in EGRIFTA this year. And to make sure that the whole sales force would not shift solely on Trogarzo, we make sure that the incentive plan will cover both EGRIFTA and Trogarzo. So it's very important for us to continue the growth of EGRIFTA. Of course, we won't have the same growth in Trogarzo. But it's a product that generates good gross margin, and it's a very important asset for us. So we're still seeing some growth in EGRIFTA for the rest of the year. We don't think we're going to get the plateau this year. Yes.

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

And if I can add as well is that promoting Trogarzo is opening up new doors for EGRIFTA as well, because ID specialists who are interested in treating HIV may not have been so interested in talking about the co-morbidity conditions associated with HIV care. But now having our representative present Trogarzo is opening up those new avenues to discuss EGRIFTA in physicians who may have not been that accessible in the past.

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

Okay. That's great. And for the -- for EGRIFTA sales, you mentioned that the growth was offset by increased discounting and slightly negative changes in payer mix. Now is this kind of a onetime thing? Or is this something you're likely to see going forward, the discounts and payer mix changes?

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

In fact, Prakash, it was partially offset discount -- offset, I believe. It's just that our gross to net has diminished maybe by 1 or 2 points because we're getting more and more Medicaid patients where the discount is high -- the rebates is higher. So it's just that we're getting more patient. Our patient base is growing. And some patient are coming from Medicaid, and this is normal. I think it just is not that big of a change. Maybe a couple of points -- basis points. Yes.

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

Last question. Just on the F4 formulation. You're filing the sNDA Q3. I know it's early, but in terms of commercial strategy, is it -- would it be your goal to transition all of the business to the F4 formulation in the bounds of patent expiry?

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

We're going to -- once we know how it's going with the FDA in the, let's say, in the second half of this year, we're going to prepare our transition plan for the F4. We think the F4 will capture more -- most of the business. At this point, I would say that we intend to keep the current presentation on the back half, that could be for Canada or for some patients that would not like to transit to the new formulation. But most of our business will probably be on the F4 eventually, yes.

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

We will have actual plans to make that very attractive in terms of the 1 vial reconstitution instead of 2, the no refrigeration, the smaller needle size. So there's a lot of good commercial, promotional spend that we will be using to leverage that new formulation.

Operator

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

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

Just a quick one from me for Trogarzo. I was wondering if you can please provide, what do you expect the public/private payer mix composition to be when it's all said and done? And then as perhaps a follow-up a little bit to that, I mean, what -- or when do you expect Medicare, Medicaid approval or inclusion to come?

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

In general, Medicaid, Medicare and private, we expect to have more and more approved between 3 to 6 months. That is our target. As our -- as I mentioned in my speech, we already have some -- that has put Trogarzo on their policy, both from private and public payers at this point. So it's already started, but we're going to get momentum between 3 to 6 months. That's where we think we're going to have the most of them for that part. In terms of proportion, we believe that -- what's the percentage, Lyne, maybe 1/3 each from that?

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

Yes, probably 1/3 each commercial, Medicare and Medicaid and ADAP.

Operator

There are no further questions at this time. Mr. Boucher, I turn the call back over to you.

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

Well, thank you. On behalf of everyone here, I would like to thank you for being on the call today. Have a great day.

Operator

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