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TH.TO - Q3 2018 Theratechnologies Inc Earnings Call

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CORPORATE PARTICIPANTS

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

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

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

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

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

CONFERENCE CALL PARTICIPANTS

Brian Corey Abrahams *RBC Capital Markets, LLC, Research Division - Senior Analyst*

Dewey Steadman *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

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

PRESENTATION

Operator

Good morning, ladies and gentlemen, and thank you for standing by. Welcome to Theratechnologies earnings call for the third quarter of 2018. (Operator Instructions)

I would like to remind everyone that this conference call is being recorded today, October 4, 2018, at 8:30 a.m. Eastern time.

And I would now like to turn the conference over to Mr. 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've 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 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 October 4, 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. - President, CEO & Non-Independent Director*

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

I know that many of you were anxiously awaiting the conference held this morning. Without further delay, I can tell you that we are very pleased with the numbers we are presenting this morning. Not only are the numbers positive, but they strongly demonstrate the impact of Trogarzo.

Indeed, in the full first quarter of commercial availability of Trogarzo, Theratechnologies is recording a positive EBITDA. Those results certainly held to give an appreciation for what Trogarzo already represent for Theratechnologies and what it will bring to the company when we reach peak sales in 3 to 5 years from now.

From the short-term perspective, the sales run rate of Trogarzo should surpass that of EGRIFTA by the end of the first year of commercialization, which is in line with I have been saying ever since we obtained commercial rights to the product, but this is now supported by what we have been witnessing, thus far, with Trogarzo.

Looking at the longer term, Trogarzo peak sales could be 5x or more than those of EGRIFTA, so we believe that such objectives are both achievable and realistic. Some may have thought that because Trogarzo is an exceptional lifesaving treatment that sales will reach their peak overnight. Of course, this is not in line with what I always tell to the investment community. It takes time for a new drug to gain momentum, and Trogarzo is no exception.

Building the market for a niche injectable product takes more than a few months. Many ingredients need to come together before sales can gather that momentum. This is what we have been focusing on for the last several months.

Among what needs to happen is patient access and reimbursement. On that front, I must say that I'm very impressed with the progress made by our market access team in the U.S. Today, we have over 195 out of 283 insured lives already covered. This is almost 70% of all insured lives in the U.S. In fact, 65% of commercially insured lives are covered. And Medicaid coverage is available in 48 states, representing 95% of Medicaid covered lives.

However, obtaining positive payer policy is only one step on the path to initiating patient on the treatment. Prescriptions need to be triaged and paperwork has to be processed by physician or support staff and our THERA patient support hub to ensure that patients are, in fact, eligible to public or private access. The patients finally has to determine between receiving the treatment at the physician's clinic, at an infusion center or at home.

When Trogarzo became available at the end of April, the time lapse between prescription and treatment initiation was 48 days. In a matter of just a few months, we managed to bring it down to 20.5 days. Of course, this is good news from a patient perspective, and we also know that it has a positive impact on sales as the longer it takes before treatment initiation, the greater probabilities are the prescription will be never filled.

Another ingredient is to bring our message to physicians. Our sales team in the U.S. has worked hard since April, visiting as many physician as possible. During the last quarter alone, our sales team made more than 5,000 physician visits. Physicians are receptive and interested in getting to know more about Trogarzo and how it could help their patients that are multidrug resistant.

All of this to say that Trogarzo is off to a good start. More importantly, it is of the start we had planned for. We will see how the sales curve resolves over the next few months, but our targets remains the same. And we still believe that Trogarzo will be, in terms of sales run rate, a bigger product than EGRIFTA by the end of the first 12 months on the market. That's why our level of enthusiasm and excitement for Trogarzo is high.

This is especially justifiable with the string of good news regarding Trogarzo that we received during our last quarter. One of them was the inclusion of Trogarzo in the treatment guidelines of the International Antiviral Society. The IAS is highly credible and reputable organization with a high level of influence among key HIV treating physicians.

In addition, 2 articles on Trogarzo were published in The New England Journal of Medicine, which, as you know, is probably the most highly recognized peer-reviewed medical publication in the world.

Such achievements will not only sustain growth in the U.S. It will also help in the preparation for the potential launch in Europe, which is the second most important market in the world.

I'm very pleased with the fact that we are several months ahead of our initial game plan for Europe. We submitted the application for marketing authorization in Europe on August 28 after having received confirmation that the pediatric investigation plan was not going to be required prior to signing. Then a few days later, we received confirmation from the EMA that the application was valid and that the accelerated assessment procedure had started on September 13. The accelerated assessment procedure means that the review time is shortened by 60 days. In other words, it will take 150 review days to which a few weeks will be added to answer question that the EMA may submit as part of the normal review process. Of course, we are actively working on our infrastructure or pricing or regulatory and/or reimbursement strategies in preparation for a launch in Europe.

Now let's talk about EGRIFTA. Since the beginning of the fiscal year, EGRIFTA has shown sustained growth from one quarter to the next, while last quarter was no exception, with a 15% growth in sales compared to the same quarter last year and almost 13% growth for the 9-month period this year compared to last year. Looking ahead, we are also working on our launch plan for the F4 formulation of EGRIFTA in the U.S. We think that the F4 formulation is a perfect opportunity to sustain growth and even reenergize the EGRIFTA brand. After all, it offers several advantages over the original formulation currently in the market. From a patient perspective, the main advantages are certainly the fact that it does not require refrigeration and that the reconstitution will be much simpler.

Moreover, the reduction in the volume of injection could lead to less sight reaction, and the smaller needle size could be better tolerated. From our perspective, the F4 formulation will generate an even better gross margin, as the cost of goods will be significantly lower.

The FDA confirmed that the target date for the decision on the F4 is November 3 of this year. If a positive decision is given by the FDA, our goal is to launch the F4 at an appropriate time in 2019, while taking into consideration that we need a smooth transition to manage our inventories well. Until then, we will remain active promoting EGRIFTA, which should end the year with 10% to 15% growth compared to last year. Needless to say, that while Trogarzo was bound to become a much bigger revenue generator, EGRIFTA will still generate significant revenue and provide important cash flow.

I hope that you are all excited as we are here about the third quarter results and as to how the future is shaping for Theratechnologies.

On that note, I will now let Philippe present our result for the third quarter, and I'll come back after for a few closing remarks. Philippe?

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

Thank you, Luc. Good morning, everyone. I know it seems I keep repeating myself. I'm pleased to report that we, again, recorded our best quarter ever in terms of sales.

Quarter-over-quarter sales grew 58%, which is a result of growth in sales for both Trogarzo and EGRIFTA.

Consolidated revenue for the third quarter of 2018 increased to more than $17.7 million from $11.2 million in the same quarter of last year.

Net sales of EGRIFTA reached $12.9 million compared to $11.2 million in the same quarter last year, which represents an increase of 15%. For the 9-month period ended August 31, sales reached $34.2 million compared to $30.3 million for the same period last year, representing growth of 13%.

In terms of U.S. dollars, net EGRIFTA sales grew 13%, reaching almost $10 million in Q3 and by 16% for the 9-month period to reach $26.5 million.

Units sold by pharmacies, which are less susceptible to inventory fluctuations, also grew by 15% in the last quarter.

As for Trogarzo, as Luc just mentioned, this was the first full quarter of sales, and we recorded revenues of $4.9 million. This is compared to just over $1 million in sales for the second quarter that mostly constituted inventory buildup. We've now been selling Trogarzo for 5 months, and we've determined that our initial gross to net assumptions were somewhat conservative. Given the current and anticipated patient mix as well as co-pay usage and delivery mode chosen by patients, we concluded that a 25% reduction from wholesale acquisition cost, or WAC, was appropriate going forward.

With such revenues and expenses remaining stable, we were able to generate a positive EBITDA of $2,735,000 in Q3 2018 compared to negative EBITDA of about $2 million in Q3 of last year. This is quite impressive, as we are only beginning to feel the impact of Trogarzo, and it certainly bodes well for future quarters.

Cost of sales increased significantly in the third quarter compared to last year to $6 million from $2.6 million. Most of that increase is due to sales of Trogarzo, which currently carry a 62% cost of sales.

As you know, we used a portion of the note offering, which closed on June 19, to pay a sum of $23.85 million to EMD Serono as a final payment of our obligation. This represented a saving of more than USD 4 million, as the amount still owed under the original agreement was over USD 28 million. This transaction also put an end to royalty payments to EMD Serono, which were included in our cost of sales. This amount will be replaced by an amortization, a noncash item, related to the intangible asset created as a result of this transaction.

Research and development expenses were down from our third quarter of last year, more precisely, a decrease to $2.8 million compared to almost $3.1 million in the same quarter last year. Several factors contributed to the lowering of R&D expenses, including lower cost associated with our 2 Phase 4 clinical trials, which are no longer required by the FDA.

Selling and market development expenses amounted to close to $6.8 million in the last quarter. This is yet another area where expenses have stabilized, as $7.1 million was spent in the same quarter last year.

General and administrative expenses during our last quarter were on the rise compared to the same quarter last year. In Q3 of this year, they amounted to almost $2 million compared to $1.3 million for the same quarter last year. This is mainly due to professional fees associated with business development initiatives related to our preparatory work in Europe and other projects.

In the third quarter of 2018, finance cost increased to $1.6 million compared to $80,000 for the same quarter last year. This is mostly explained by 3 factors namely: $866,000 in interest on the debenture; a $375,000 loss on the repurchase of our obligation to Serono; and the increase -- an accretion charge of $352,000, which was mainly associated to the convertible notes issued in June of this year.

Taking into account all of the above and the early payment of the long-term obligation to EMD Serono, we ended the quarter with $66.5 million in cash on our balance sheet. This put -- this puts the company in a very comfortable position with a good cash balance and activities generating positive EBITDA. As you can attest from our balance sheet, the launch of Trogarzo has not had a significant impact on our working capital position. Inventory levels have increased marginally from Q2 to Q3, while accounts receivable and accounts payable have gone up in tandem. We are confident this situation will remain for the foreseeable future.

And finally, we recorded a net profit of $367,000 for the quarter, a figure that was helped by our operating performance and a $1.5 million tax recovery related to the accounting treatment of the convertible debentures.

On that note, let me turn it back to Luc, who has some closing remarks.

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

Thank you, Philippe. I certainly hope that you can appreciate just how much progress has been made at Theratechnologies in the last few years and even more in the last few months. There is a lot left to be done, but EGRIFTA, Trogarzo and Theratechnologies are most definitely on the right track.

EGRIFTA keeps on delivering good growth, and a positive decision from the FDA on the F4 could give it an additional push forward.

Trogarzo show -- showed a good progress in Q3. Sales almost reached $5 million. And we have succeeded in quickly obtaining payers inclusion for almost all Medicaid patients and almost 2/3 of commercially insured lives. This is unprecedented, and it showed the true value of our product. In fact, I just want to mention again that we have 195 out of 283 million insured lives already covered.

In addition, physician are receptive and confirm that they have patient that will eventually benefit from Trogarzo.

Furthermore, patients being prescribed Trogarzo are initiated on treatment in less than half the time it took just 4 months ago.

At the same time, we are ahead of schedule in Europe. Our application for marketing authorization is currently being reviewed under the accelerated assessment procedure, which means that we could get a decision around mid-2019.

Finally, the company is standing in a solid cash position, and it shows -- is now generating cash after only one full quarter of Trogarzo sales, which, of course, gives you an appreciation for how much leverage this product holds.

Before turning to questions from analysts, I want to take this opportunity to thank Lyne Fortin for her contribution over the last 5 years. As you know, Lyne announced last week that she would retire from Theratechnologies by the end of the year. Her knowledge and experience were instrumental in helping the company to be ready for the relaunch of EGRIFTA and the launch of Trogarzo. She'll remain on board until the end of the year to ensure a smooth transition and to make sure that her files are well addressed until she start a new phase in her life, so we all wish her the best.

I want to thank you all for being on the call today, and we will now take questions from financial analysts.

QUESTIONS AND ANSWERS

Operator

(Operator Instructions) Your first question comes from the line of Dewey Steadman from Canaccord Genuity.

Dewey Steadman - *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

On Trogarzo, I know you've mentioned in the past that docs usually experiment with Trogarzo on their worst patient, so you're seeing one script from a whole bunch of doc. But have docs now moved to second patient and from third patient in their practices, yet? And if not, what do you think of potential timing for that?

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

We haven't. We still have a lot of prescriptions that are done by one physician. As of today, we have close to 85% of our prescription that are done by different physicians. So in a way, it's a very good news because the product is not concentrated in the hand of just few physician. We'll see over the next few months. I think it takes few months before the physician look at the count and all the parameters of a patient, so we'll see. But we think that if we have result comparable to the Phase III clinical trial that it's going to be a clear message to those physician for a second and a third patient being put on the drug.

Dewey Steadman - *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

And then the lag between the script and the actual administration at 48 days down to 20.5 days, how well do you think you can go with that? And what's really driving that lag? Is it just a prior authorization process? Or is there else something structural that need to be addressed there?

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

Yes. We're pretty much there, but we think that a realistic lapse of time is around, let's say, between 13 and 17 days. That will be the quite optimal in terms of treatment for those patients before to be initiated.

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

And if I can add, because it's a paradigm shift in using an IV infusion, sometimes, physician think of using it in their office and change their minds, perform infusions once they understand the implication. Or sometime, the payer might dictate going to a third-party infusion center and then hospital. So this is, obviously, taking time to sort out the -- all the options, but we've covered all of those. So at the end of the day, the time it takes to find the best option is what delays it a bit time.

Dewey Steadman - *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

Great. And then just a boring modeling question. The $1.6 million in amortization that you recorded this quarter, is that a good run rate going forward?

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

Yes. Well, that was for 2.5 months. So going forward, we'll have 3 months' quarter, so it's -- it'll be just a bit higher.

Operator

Your next question comes from the line of Brian Abrahams from RBC Capital Markets.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

I'm curious if you have a sense of the types of patients who are starting on Trogarzo treatment. Is this -- are they legacy kind of long-term HIV-infected patients, patients who are maybe not adherent to the oral meds? And do you have any sense of whether -- the degree to which you're seeing pent-up demand from folks who are waiting for a better option like this versus patients maybe who are being newly identified as potential candidates for therapy?

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

Very difficult, Brian because, as you know, information on patient is very confidential. And even us, we don't know it, the name of the patients for example, and of course, the profile. So the only thing we know is where it's coming from, which state and stuff like that. But it's very limited what can be transmitted to us in terms of information.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

Okay. That makes sense. And do you have any visibility at this point yet on compliance or persistence maybe? The proportion of patients who have started early post-launch who are staying on therapy, number of doses that you're seeing being missed or skipped, how high or low is that?

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

I think, in terms of compliance and drop rate, it's very low, if none. What we know is that some patient that -- for which we have a referral maybe do not go through the whole process, but it's very low in terms -- it's the -- in the single digits, yes.

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

And we have the similar experience in clinical trials as well as in expanded access program. And as it was mentioned before, we have -- because this program was a bit longer than a standard drug development program, we know that some patients from the Phase II had been on treatment for up to 8 or 9 weeks.

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

And we've been conditioning -- the majority of the EAP patients are now on commercial products.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

What proportion of your revenues -- I guess, what proportion of new starts during this past quarter were from EAP transitions versus patients new to therapy?

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

I know, in the last month, it's 100% from new patient because, as I mentioned, all the EAP patients has been transferred to the commercial program. So in the last month -- on the last full quarter maybe, what, 20%, maybe, less than that. It's minimal. All the new patients are coming from -- they are all new patient, in fact, yes.

Brian Corey Abrahams - *RBC Capital Markets, LLC, Research Division - Senior Analyst*

That -- that's really helpful. One last one for me and then I'll hop back in the queue. Wondering if you could maybe quantify the quarter-over-quarter inventory change that is embedded in the Trogarzo sales number.

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

Quarter-over-quarter, it's minimal, actually. It's probably $0.5 million at most.

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

We have to assume we won't keep a lot of inventory, so it's going mostly directly from TaiMed [to all these]. Yes.

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*

First one, a little bit of color you can provide on Trogarzo sales, how did they progress during the quarter? And how do you see that trend into Q3?

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

Sorry, I missed the beginning of your question. That trend of what?

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

Of sales -- of Trogarzo sales during Q2. And do you see that trend that progress? How do you see it going into Q3?

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

As you know, Endri, we don't provide the guidance. But as I mentioned, of course, it's progressing. There's growth. As Philippe mentioned, we had slightly above $1 million in sales in the last quarter. It was just one month, but most of it was inventory building. So this quarter, we have close to $5 million in sales. And what I mentioned in terms of trend is we really believe and that since the beginning that Trogarzo will be a bigger product than EGRIFTA within a year of being on the market.

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

Okay. And next one, I mean, is it possible to share how many patients are currently on Trogarzo? Are you willing to share the information?

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

We provided you with some numbers last time because we didn't have sales and we needed to give you an idea on where we stand in terms of activities. But the number of patients is very volatile for us, very difficult to calculate exactly the number patient because some of them are coming directly into our hub and others are going directly -- not going into our hub, for example, Kaiser. We don't see any patients coming from Kaiser through our hub, so it's very difficult to give a proper number. I think the best figures, what we see is the number of our sales, and that's why now we're going to talk about sales figure and -- which has amounted for the last quarter to $5 million.

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

Great. Next question. You mentioned that 65% of the private lives now have access to Trogarzo. And where do you see this number stabilizing at and in what time frame?

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

What was our goal on that, Lyne?

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

Our goal is to get to 80%, plus. And we think that within the next few months, we should be getting there.

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

Great. And one more question on Trogarzo. On preparation for European commercial activities, I mean, you -- how much are you budgeting for it, I mean, if you can share that? And when do you expect the majority of this cost to start incurring? This is primarily for the -- on the commercial end of things there.

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

For the next quarter, the level of commercial activities will stay pretty much the same. We are working at the moment on our budget for next year. We should be able to provide you with some figures later on. But at this point, I think you should take the same amount that we had in Q3. You should be close to what is going to happen in Q4 in terms of expenses at the commercial level.

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

I think you were asking Europe, Endri.

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

For Europe, for Europe, for Europe.

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

Europe, we're able in the final talks with the board as to how best we're going to implement our strategy over there. We'll probably be in a position to update you in the next couple of months on how, where and how much it's going to cost in the next, I would say, 2 to 3 months.

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

And just one question, primarily for Lyne. I guess, what is the decision to retire from Theratech? And are you just retiring? Are you going somewhere else? And how is the search for a successor going?

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

Well, I can tell that at this stage in my career and the last 5 years being at Thera were highly rewarding. It's time for me to leave the full-time commercial operations. And I will be probably looking for more advisory roles in the future, but I'm leaving the full-time workforce, to say. And I will be on, as I told Luc, until a successor is appointed, so that I can transition the file in an orderly fashion. So that's my personal plan and professional one.

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

And in terms of looking for a successor, we are already in the process to look for one.

Operator

Your next question comes from the line of Dewey Steadman from Canaccord Genuity.

Dewey Steadman - *Canaccord Genuity Limited, Research Division - Senior Specialty Pharma Analyst*

I don't know if Christian is there, but I just wanted to get your thoughts on the TaiMed pipeline, as holding the right of first refusal for many of the product on their pipeline. What's most interesting there? And what could fit best into a larger Thera portfolio over time?

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

In the pipeline, what they have at the moment is they have more than one compound, but the one which seems to be the most interesting one is the 365, which is a modified version of Trogarzo. In terms of the in vitro and modeling, so far, looks like this work -- could work in patient that would be resistant to Trogarzo and would have a different PK profile, so it could be administered most likely on a monthly basis. It's a bit too early to say if it could be administer as a subcu presentation, but it's something that we should probably learn in the coming year. But it looks very interesting. And if it's the profile that we're expecting, it's certainly a drug that could be used in much earlier in HIV, like, potentially first line or also potentially as prevention. And it's a very interesting compound.

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

And in terms of agreement we have with them, as you know, we have a right of first refusal and first negotiation on the 365.

Operator

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

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

Thank you very much. As there are no additional questions at this time, we will conclude this morning's earnings conference call. On behalf of everyone here at Theratechnologies, I want to thank you for being on the call today, and I wish you a very good day. Thank you.

Operator

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