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IntelGenx

Fourth Quarter 2019 Earnings Conference Call

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CORPORATE PARTICIPANTS

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CONFERENCE CALL PARTICIPANTS

Sean Lee, *H.C. Wainwright & Co.*

Christian Oquera, *First Berlin Equity Research*

Steven Silman, *Private Investor*

Neil Panesis, *TD Ameritrade*

Moe Sakajia, *Private Investor*

PRESENTATION

Operator

Welcome to the IntelGenx Fourth Quarter and Fiscal Year 2019 Results Conference Call.

At this time, all participants are in a listen-only mode. After the speaker's presentation, there will be a question-and answer-session. To ask a question during this session, you will need to press star, one on your telephone. Please be advised that today's conference is being recorded. If you require any further assistance, please press star, zero.

I would now like to hand the conference over to your speaker today, Stephen Kilmer, IntelGenx Investor Relations. Thank you, please go ahead.

Stephen Kilmer

Thank you. Good morning everyone, and thank you for joining us on today's call.

With me on the line are Dr. Horst Zerbe, IntelGenx's CEO, and Andre Godin, our President and CFO.

Before we begin, I would like to remind you all that amounts mentioned today are in U.S. dollars unless otherwise mentioned, and today's call may contain forward-looking information that represents our expectations as of today and, accordingly, are subject to change.

We do not undertake any obligation to update any forward-looking statements, except as may be required by U.S. and Canadian Securities laws. A number of assumptions were made by us in preparing these forward-looking statements, which are subject to risks, and results may differ materially. Details on these risk factors and assumptions can be found in our filings with the U.S. and Canadian Securities Commission.

I would now like to turn the call over to Dr. Zerbe. Horst?

Dr. Horst G. Zerbe

Thank you, Steve.

Good morning and thank you for joining us for the IntelGenx Fourth Quarter and Year End 2019 Conference Call.

On the call, I will provide a corporate update and discuss the progress we've made on our key pipeline projects. Following that, Andre will review our Q4 and full year 2019 financial results. Following that, we will open up the line for any questions.

First, an update on Rizaport; as of this morning, we have not received any communication from the FDA regarding our response to the complete response letter we received in 2019. The most recent communication occurred about one month ago, when we contacted FDA regarding the status, and we were informed that the application is still active review, and that FDA might get back to us with any additional questions.

As soon as we hear from the agency, we will inform investors about the response and any next steps. We do remain committed to working very closely with the FDA to make this and other (inaudible) product available to people suffering from migraines in the U.S.

We believe that Rizaport is an attractive therapeutic alternative for migraine patients, specifically for the 80% of migraine sufferers that experience migraine-related nausea. Rizaport is also attractive to patients suffering from dysphasia or difficulties swallowing.

Subsequent to year-end, we signed a binding term sheet with Orivas for the commercialization of Rizaport in Lithuania, Latvia, Estonia and Poland. Orivas has the right of first refusal for a predefined term to include the Republic of Belarus and/or the Republic of Ukraine, as well as any of Finland, Denmark, Sweden and Norway. This agreement further expands Rivaport's distribution in new markets.

Moving on to Tadalafil; as we earlier reported, a clinical trial protocol, or an irritation study requested by FDA, was submitted to FDA for review. We expect FDA's feedback and approval before the end of Q2 2020.

We conducted a successful kick-off meeting with Aquestive, our partner for this product, and achieved alignment with Aquestive on deal terms. All data and negotiation authority has been transferred to IntelGenx, so we have started an active outreach to potential partners in the U.S.

Moving on to cannabis-infused films; we are developing a cannabis-infused film in collaboration with our partner Tilray. As discussed on our last call, we collaborated with Tilray to select a cannabis-infused VersaFilm prototype for manufacturing scale-up, which began in October and has now been successfully completed.

We are currently in contact with the Cannabis Licensing Group at Health Canada, which is reviewing our application for a micro-processing license, and expect to receive that license sometime in April. That license will enable us to begin commercial production, with product sales expected to begin in Q3 of this year. Our Operations team is working closely with Tilray to coordinate launch preparations.

We believe that our cannabis-infused oral film will be an attractive alternative among the new formats of cannabis products that are now authorized for sale. We're looking forward to providing more details on this product closer to commercial launch.

Moving on to Montelukast; we were pleased to announce that Health Canada issued a new objection letter in response to our amended clinical trial application for the ongoing Montelukast VersaFilm Phase 2a, the so-called BUENA clinical trial, in patients with mild to moderate Alzheimer's disease. The CTA was based on additional efficacy testing of Montelukast in an Alzheimer's disease mouse model, conducted in collaboration with Professor Aigner's group at the Paracelsus Medical University in Salzburg.

This testing demonstrated that Montelukast dose dependency improves cognitive outcome; higher doses significantly increasing the mice's cognition in two behavioral tests. Health Canada's objection enables us to continue the BUENA trial at an increased daily dose. Unfortunately, the current COVID-19 situation will affect the enrolment under the amended protocol, because the target study population is considered a high risk group in terms of potential for infection with the virus.

We have therefore informed Health Canada that we are on a temporary recruitment hold. Realistically speaking, we believe that enrolment under the new amended protocol will commence by mid-June.

We continue to evaluate the trial's expansion to the United States via a potential R&D filing with the FDA. We expect the R&D to be filed sometime in the second quarter of 2020.

We were contacted by several shareholders who were concerned about the black box warning that the FDA has imposed on Montelukast containing products. We do not think that this will, in any way, affect the currently ongoing BUENA study, or the future product. The reason for that is that we're already mentioning those neuropsychiatric effects that the FDA is addressing in that black box warning in the informed consent form, and through investigators and through studies done.

Besides that, the incidence of these neuropsychiatric effects is extremely low, with an occurrence of less than 0.01%, meaning less than one in 10,000 patients.

Moving on to animal health; subsequent to year-end, we made our foray into the animal health market by signing a feasibility study agreement with a leading animal health industry player. We will be conducting a feasibility study on an undisclosed molecule for buccal absorption using our VetaFilm platform, and assuming successful feasibility, we will have exclusive rights to further develop, manufacture and supply the product.

This agreement demonstrates the versatility of our oral film technology and the potential for this delivery method to become more widely used in veterinary settings.

With that, I would like to now turn the call over to our President and CFO, Andre Godin, who will review our financial results. Andre?

Andre Godin

Thank you, Horst. Good afternoon, everyone.

Horst mentioned I'll take a few minutes to discuss the Company's financial performance for the fourth quarter and full year ended December 31, 2019.

The total revenue for the fourth quarter of 2019 amounted to $68,000 compared to $651,000 in the same period last year. The decrease is mainly attributable to a decrease in R&D revenue.

The operating cost and expenses were slightly lower this year, at $2.4 million for Q4 2019 versus $2.9 million for the corresponding three-month period of 2018. The decrease is mainly attributable to a $1.1 million decrease in R&D expenses; that is partially offset by a $671,000 increase in SG&A for the same period of last year.

For Q4 2019, the Company had an operating loss of $2.4 million compared to an operating loss of $2.2 million for 2018. Adjusted EBITDA was -$2.1 million for Q4 2019, compared to $2 million for the same period last year.

Net comprehensive loss was slightly below, at $2.7 million or $0.03 on a basic and diluted per share basis, versus $2.9 million last year or $0.03 as well per share for the period of 2018.

Now for the year, for the full calendar year and Fiscal Year; total revenue for the 12-month period of 2019 was $742,000 compared to $1.8 million last year. The decrease is mainly attributable to $1.5 million decrease in R&D revenue, partially offset by an increase of $372,000 in R&D milestone revenue.

Our operating costs and expenses for the 12-month period was about half a million lower than last year, at $10.3 million for the full year of 2019, versus $10.8 million for the corresponding 12-month period of 2018. The decrease is mainly due to $1.3 million increase in R&D, which is partially offset by an increase of $800,000 in SG&A.

For the 12-month period of 2019, the Company had an operating loss of $9.6 million compared to an operating loss of $9 million for the comparable period in 2018. Adjusted EBITDA for the 12-month period ended December 31, 2019 was -$8.5 million compared to -$7.9 million for the 12-month period ended December 31, 2018.

Net comprehensive loss was $10.3 million or $0.11 per share for 2019, and compares to a comprehensive loss of $10.7 million or $0.14 per share for 2018.

As at December 31, the Company free cash and short-term investments totaled $1.9 million compared to $11 million as of December 31, 2018. As everybody knows, and subsequently to the year-end, we closed an offering for gross proceeds of CAD$8.2 million.

I will now turn the call back to Dr. Zerbe to conclude our remarks.

Dr. Horst G. Zerbe

Thanks, Andre.

In closing, I'm pleased with the progress IntelGenx has made since the beginning of 2019. Our efforts have positioned us to achieve important milestones in the coming months, including commercialization of our cannabis-infused VersaFilm, as well as reporting initial results from our BUENA clinical trial. We're looking forward to updating you on our continued progress.

I will now turn the call over for questions. I'd like to remind you that our forward-looking statements apply to both our prepared remarks and the following Q&A. Thank you.

Operator

At this time, I would like to remind everyone, in order to ask a question, please press star, then the number one on your telephone keypad. That's star, one on your telephone keypad to ask a question.

Our first question comes from Sean Lee from H.C. Wainwright. Your line is open, please go ahead.

Sean Lee

Good morning, Horst and Andre. Thank you for taking my question.

My first question is on the ongoing pandemic situation. You mentioned in your remarks that you expect the enrolment in the Alzheimer's disease study to be delayed. Is there any other effects on your other operations, in terms of manufacturing or pre-clinical development?

Dr. Horst G. Zerbe

Good morning, Sean, and thanks for the question.

The quick answer is no. We received an exemption from the Quebec government, from the current shutdown that is in effect all over the province. However, the exemption applies to companies that perform pharmaceutical production research and provide laboratory services. We fall into that category, and so therefore, we are continuing operations; however, at a reduced level. All our Admin staff works from home. In the lab, we have research and development work ongoing, to the extent necessary and possible, and we are conducting production activities in the back with our production staff.

We try to maintain operations, albeit by applying an abundance of caution and leaving everybody and anybody who is not essentially required here on the premises, at home.

Sean Lee

Great, that's nice to hear. My second question is on the Tadalafil clinical study. Do you already have the product ready to make, and just are waiting for the final from the FDA before you can start that study?

Dr. Horst G. Zerbe

I'm sorry, can you repeat the first part of, do we have already—what?

Sean Lee

The product already made, and you're just waiting for the FDA to sign off on the protocol before you're ready to start the study?

Dr. Horst G. Zerbe

Yes. We're waiting for the trial application to be approved by FDA. Following that, we can initiate the study. The CRO has been lined up.

Sean Lee

Excellent, so that's all ready to go then. My final question is on the balance sheet. Just wondering if you can provide a bit more color on the cash runway following the latest raise?

Dr. Horst G. Zerbe

Cash runway.

Andre Godin

I mean, as Horst mentioned, now we're obviously—even though things are moving in the back, and in the back there is quite a bit of cost savings, and also, I mean, all of the creditors are very understanding. I can talk about our bank loan, or rent and everything. We're getting a lot of breaks, financially, which is very helpful, considering the situation.

I don't see any issues for at least a good six months at minimum, in terms of cash burn. I mean, obviously that will depend also on our potential launch for our cannabis film, and potential status with Riza, whether we get approved or not and when. But for the time being, there is no concern cash-wise.

Sean Lee

Great to hear, that's all I have. Thanks again for taking my questions.

Andre Godin

Thank you.

Dr. Horst G. Zerbe

You're welcome, Sean.

Operator

Your next question comes from Christian Orquera from First Berlin. Your line is open.

Christian Orquera

Yes, thank you very much for taking my question. I have a few questions, if I may. The first question is regarding the cannabis product. You mentioned that you expect the license approximately in April, and this could lead to sales in about approximately Q3. Can you provide a bit more of color on if Tilray has already given any guidance about potential purchase or their initial stocking? What would be the procedure or probably timeline, how much it will take production and then that you can invoice and stuff like this? It would be good to have a bit more of details about that.

The second question is here also, how you see the market in Canada. Do you have the impression that, on the one side, the arrival of edibles has brought some dynamics to the market; what is your impression in how it's—the market, and if there's going to be any—what's your expectation of a potential impact of the COVID-19 on this market? Probably not that easy if that continues, to promote the product.

The second question is similarly on Rizaport; assuming an approval anytime soon. Can you give some more feedback, what type of preparation have you taken together with your partner for the commercialization, and what impact do you expect also in Gensco for the sales, to be able to promote the product, given the current crisis? I think in general, would be if you expect an impact on potential sales of these two products that are going to be launched in this year.

My third question is regarding financials. As a follow-up question on the previous one, can you give a bit more guidance about, how do you expect key positions like sales or R&D or cap ex to develop in 2020 compared to 2019? That would give us a better idea of how your potential burn rate would look compared to the previous year. Thank you very much.

Dr. Horst G. Zerbe

Okay. I will try to respond to your first two questions, and for the third one I'll turn over to Andre.

You start out with a couple of questions on our cannabis product. With respect to the status of our license, that was the first part of your question. We are currently in a very active dialogue with the Review Group at Health Canada, or the Review Group for Cannabis Licenses. They have completed a first part of the review, and are now reviewing the so-called evidence package, which deals with mostly security provisions on the premises, and things like that.

According to them, the review of the evidence package, and with that, the review of the entire application should be completed in early April, actually the first week of April. Then, according to the reviewer, it usually takes about two (phon) weeks to issue the license. Therefore, we incorporated the statement in our presentation that we expect the license to be issued by mid-April.

Now, moving on to the second part of your cannabis-related question that referred to our production activities; we are in the process of preparing ourselves to move forward with commercial production as soon as we have the license in our hands. The first step will be that we will order the API, the active ingredient, from Tilray. Tilray has explained to us that they have the material and are waiting to receive the request for shipment, but they can only ship once the license has been issued. We have all the other excipients that are required for processing in-house, so immediately upon receipt of the API—which is of course, controlled by Tilray, we can commence commercial production.

Then, we will ship the product, which then will be in its secondary packaging. Tilray will then apply the final labeling in accordance with the labeling provisions that were imposed by Health Canada, and then the product can go into the market.

We expect product to be—but again, I want to stress, we are not in control of the launch. Tilray is. But based on what we hear from them, we expect the product to be on the market in at least early Q3, or late Q2. Yes, late Q2. That's the best I can say with respect to the expected launch.

You then asked the question about the market. Again, there is not much experience available. What we believe is a great opportunity for us is the fact that there is no oral film on the market as yet, at least here in Canada. We have a great opportunity to be the first cannabis film on the market here in Canada, and I think that presents a great opportunity, but I can really not go beyond this more qualitative statement.

Moving on to Rizatriptan; I mentioned before in my introductory remarks that, as of this morning, we have not received anything from the agency, so I really don't know the status. I reached out to them about a month ago, and we are told that the application is, and I quote them, under active review, and that they would get back to us with any questions they might have, and we haven't heard from them ever since.

Gensco is waiting for the approval, and they are doing their part to get the product to market ASAP. We expect shipment of the first launch quantities in early Q3, in an August-September timeframe, and Gensco should then launch soon thereafter. That is under the assumption that we will receive approval over the next—whenever that may be the case.

What we do see is heightened interest in the product in a number of European markets that goes above and beyond just Spain. We have confirmed interest or existing agreements, at this point, in more than 20 countries in Europe. That's regarding the Riza.

For the financial question, I will turn over to Andre.

Andre Godin

Regarding the cap ex or the spending for 2020, we haven't given any guidance, but what I can say, there are potentially two products launched that would, in fact, reduce the burn rate. There is also the—which would impact the burn rate. What could also negatively impact the burn rate is the Montelukast trial that will resume at some point in 2020, but we don't know, because of the COVID-19 situation, when we will be in a position to resume the trial, especially because of the population in this trial are mostly at risk.

We're expecting to have a lower burn rate than last year, but then again, that will depend on market launch for our two products, and when much of that will resume. But in all, I believe that we'll… We're obviously very, very—managing our money very tightly, very closely. That's why we expect not having—not the same level of burn rate as 2019.

Christian Orquera

Okay, understand. Thank you.

Perhaps a follow-up question on Rizaport; is there any update on the process in the registration, the filing for transfer of the manufacturing side? Can you update if there's any news of that type?

Dr. Horst G. Zerbe

Yes. We're currently pursuing two alternative strategies. One is as you correctly mentioned, the transfer of the manufacturing from the initial European manufacturer to our operation here. That requires the completion of validation batches, which we are producing over the next four to six weeks. Once we have the results from those validation data, they will be submitted to the Spanish Authority to satisfy their information demands for the site change.

Alternatively, we are pursuing a strategy that which we try to reactivate the contract manufacturer that is listed in the initial application, to step in for the manufacturing of, initially, the Spanish, and subsequently, European supplies. We believe that that strategy can accelerate the launch of the product in Europe, simply because of the fact that that company or that manufacturer has already been approved by the Spanish Authority and by European authorities as the licensed manufacturer.

Then, whichever strategy gets us quicker to the market is the one that we will eventually implement. At this point, we're pursuing both in parallel.

Christian Orquera

Okay, that helps. Great. Okay, thanks.

Dr. Horst G. Zerbe

You're welcome.

Operator

Your next question comes from Steven Silman (phon), a private investor. Your line is open.

Steven Silman

Good morning, Dr. Zerbe.

Dr. Horst G. Zerbe

Good morning.

Steven Silman

IntelGenx is a microcap company. It's cash-strapped. We just heard that we have six months of cash, which means that the Company is in a parlor (phon) situation in the sense that you will have to come back to the market in some form at a time when markets are very weak.

You received—so you raised funds recently, at a very low price, a price which, for long-standing shareholders like myself, was a little distressing.

My question for you is this: in these circumstances, was it really appropriate for you to be awarded a pay raise shortly after the cash was raised, before the complete response letter was received from the FDA? My concern is that the optics of this are extremely poor; it fuels the arguments of those who say that what this Company does is raise cash and then use that cash to pay higher salaries and bonus to Executives. You are the largest shareholder in the Company, and I have to say that, if I were in your position, I would have said—I would not have saw the pay rise, simply because we're all in this together, you and your shareholders, and you should be acting in moderation in those circumstances.

What do you have to say about that?

Dr. Horst G. Zerbe

Honestly, I'm a little reluctant to discuss my personal remuneration in public, but I want to say this, two comments on this.

The first one is, we are, of course, very aware of the impression that any pay raise or other remuneration like bonus payments or so might convey to the public. I can tell you, mostly Andre and myself, but more generally speaking amongst the Executive group, we are in discussions about how to signal to the public

and to our investors that we are aware of the need to manage our finances very tightly, and that that might include any monies that are being paid to Executive Management.

What you don't know because you don't see it is that we have already foregone certain payments that we were entitled to as a sign, in this case to the Board, that we are assuming responsibility for the financial situation. I'd like to leave it at that point, Andre, unless you want to add…

Andre Godin

Yes.

Dr. Horst G. Zerbe

…any comments about how we manage our finances, also from a salary standpoint.

Andre Godin

Yes, I think that there's obviously some information that will be released in the proxy that will demonstrate that, like Horst said, that we have basically demonstrated, because of the financial situation, because of the COVID-19 situation. But as of now, it's not public knowledge, but you will see that we forfeit the bonus payments, we forfeit some money that we were entitled to, so that will demonstrate, I guess, and show how the Executives here are aware of the situation and are doing something about it.

In terms of the cash situation, it's always—and sometimes it's not easy because the market situation right now, as you know, is quite difficult. But having said that, I am already pursuing several non-dilutive options, and hopefully some of them or one of them could be successful, so that at least we don't have to wait. We could refinance some debt. We could maybe solidify our balance sheet, with non-dilutive or much less dilutive instruments, and not having to wait for three, four, five, six months to do so. Even though, the market should be, in general, better, it's always when you have cash in the bank that you should look to get more. But since the stock price is quite low, then obviously, equity is not an option.

Other options are being contemplated, and hopefully we'll be able to solidify our balance sheet in the short and near-term, and not depend on the market situation because nobody knows when this thing will end. It's prudent to do it this way.

Operator

Your next question comes from Neil Panesis (phon) from TD Ameritrade. Your line is open.

Neil Panesis

Thank you very much, good morning. I believe my question was already answered; it would have been posed to Mr. Godin. Andre, regarding the cash burn rate, the only thing I could possibly add is, would you care to or are able to comment on your average cash burn rate, quarter-per-quarter over the past fiscal year?

Andre Godin

Comment? Yes. I mean, our cash burn rate was roughly $2 million to $3 million per quarter over the last past—I mean, it went down towards the end of the year. One of the reasons for that is that there was, as

we said earlier, there was no bonus paid this year, nobody. Also, the Montelukast trial being put on hold, so that helps saving a little bit of money.

We're trying to keep our spending at the minimum, and that's always been the case over the last year or so. But we have a large infrastructure, we have a large manufacturing facility, so we need—and we're a GMP facility as you know, so that's quite costly. Even though we're trying to be cautious about spending our money, we have quite a bit of fixed costs that we have to maintain, and hopefully—and we've been operating the plant for most of 2019, for the mission batches, different programs, obviously Montelukast, producing the drug for the BUENA trial. Our fixed costs and variable costs that are directly related to our operations have gone up.

It is money well-spent because we need to submit all these products to FDA to get them approved in European Union, and in the case of cannabis, to Health Canada. But hopefully, we're expecting to launch product in 2020, as you know, so that will basically, more or less sustain fixed costs, then we'll be able, now, to generate revenue. That's why we're expecting, in 2020, to reduce our cash burn.

Neil Panesis

Thank you very much and all the best to all of us.

Andre Godin

Thank you.

Dr. Horst G. Zerbe

Thank you.

Operator

Your next question comes from Moe Sakajia (phon), private investor. Your line is open.

Moe Sakajia

Hi guys, I have a quick question regarding Rizaport. Are you planning on contacting the FDA in the next day or two, since you contacted them a month ago, way before the due date, and to see what's the status on that?

Dr. Horst G. Zerbe

We have already, but we haven't received a response yet, and we will continue to reach out.

Moe Sakajia

Yes, but you indicated recently that you contacted them a month ago.

Dr. Horst G. Zerbe

Yes.

Moe Sakajia

What I'm saying, if you don't hear from them in the next day or two, would you plan on contacting them, let's say, sometime early next week if you haven't heard anything by then?

Dr. Horst G. Zerbe

Oh, it could be as early as today that we will reach out to them.

Moe Sakajia

That'll be great. Okay, thank you folks.

Dr. Horst G. Zerbe

You're welcome.

Andre Godin

Thank you.

Operator

There are no further questions at this time. I will turn the call back over to Dr. Zerbe for closing remarks.

Dr. Horst G. Zerbe

Okay, that concludes the year end 2019 conference call.

Again, thank you all very much for your continued support, and a big thank you to staff here at IntelGenx for their confidence and hard work.

Thank you very much again, and goodbye.

Operator

This concludes today's conference call. Thank you for participating. You may now disconnect.