

09-May-2019

IntelGenx Technologies Corp. (IGX.CA)

Q1 2019 Earnings Call

CORPORATE PARTICIPANTS

Stephen John Kilmer
Investor Relations, IntelGenx Technologies Corp.

Andre Godin
President and Chief Financial Officer, IntelGenx Technologies Corp.

Horst G. Zerbe
Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

OTHER PARTICIPANTS

Susan Lee
Research Assistant, Maxim Group

Patrick Tully
Managing General Partner, Endeavor Asset Management, L.P.

Douglas Loe
Analyst, Echelon Wealth Partners, Inc.

MANAGEMENT DISCUSSION SECTION

Operator: Good afternoon. My name is Carmen, and I will be your conference operator today. At this time, I would like to welcome everyone to the IntelGenx 2019 First Quarter Conference Call. All lines have been placed on mute to prevent any background noise. After the speakers' remarks, there will be a question-and-answer session. [Operator Instructions]

Thank you. I would now like to turn the call over to Mr. Stephen Kilmer, Investor Relations Please go ahead.

Stephen John Kilmer
Investor Relations, IntelGenx Technologies Corp.

Thank you. Good afternoon everyone. And thank you for joining us on today's call. Before we begin, I would like to remind you that all 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 maybe 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. The details on these risks and assumptions can be found in our filings with the U.S. and Canadian Securities Commissions.

I would now like to turn the call over to IntelGenx's CEO Dr. Horst Zerbe. Horst?

Horst G. Zerbe
Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yes, thank you, Steve. And good afternoon everyone. And thank you for joining us for the IntelGenx 2019 first quarter conference call. As you know due to the additional time needed to finalize here in audits and so on, this

call falls quite close to our Q4 discussion. Accordingly, there's a little less for us to update you on. That's not to say though that we haven't been busy.

On today's call, I will begin by providing a corporate update and discuss the progress we've made on our key pipeline projects. Following that Andre Godin will review our Q1 2019 financial results. I'm very pleased to say that he would be doing that in a different capacity this time, as he has just been appointed our President and Chief Financial Officer. Andre has already been integral to our success, and I look forward to continuing to work with him and support him in his newly standard role.

Let me start by providing a review of our activities surrounding the RIZAPORT new drug application or NDA. As we announced earlier, we received a Complete Response Letter from the U.S. Food and Drug Administration in early April. The comments that the agency may conduct CRL were specifically focused on the chemistry, manufacturing and control section, also referred to as CMC section of the application and did not request a new bioequivalent system. With reviews or comments listed in the CRL and have determined that the additional information requested in this CRL is either already available or can be generated in time to submit a response to the CRL in Q3 of 2019.

I wish to emphasize that across our executive management team timely and successful response to the CRL is top priority at IntelGenx. We're currently mapping out our response to each of the items and we remain committed to working closely with the agency to make this innovative product available to people suffering from migraines in the U.S. With respect to Europe, we are working closely with our partner Exeltis and finalizing the timeline for the site exchange, application, submission and approval. We're expecting a review time by the Spanish authorities of six months to nine months.

I will now provide an update on tadalafil. We recently entered into a definitive worldwide agreement with Aquestive Therapeutics for the co-commercialization of tadalafil oral films for the treatment of erectile dysfunction. The tadalafil film is fully bioequivalent with the brand product Cialis. Under the terms of the agreement IntelGenx and Aquestive will each grant to the other exclusive worldwide licenses to their respective intellectual property relating to tadalafil oral film formulation and manufacturing. Further on, the companies who jointly undertake further co-development and commercialization of tadalafil oral film products will equally share, equally meaning 50/50 net profits from worldwide product sales.

We strongly believe that this agreement maximizes the opportunity for both companies, basically for the following reason. The Aquestive product is further advanced than the IntelGenx product from a regulatory perspective, in that Aquestive had already submitted a 505(b)(2) NDA and received the Complete Response Letter in 2018. Both companies have agreed to jointly work on responding to that Complete Response Letter as quickly as possible.

In combination with our worldwide exclusive license to Lilly's dosing patent, this gives us an opportunity to launch this important product significantly sooner and that would have been the case had we continue to pursue our own application. In addition to our complementary technologies, we share a similar commercialization strategy with Aquestive for tadalafil oral films, making this an obvious and mutually beneficial collaboration.

We're looking forward to having Aquestive and IGXT jointly commercialize tadalafil oral film product in the United States while we jointly explore other potential benefits. We believe that this tadalafil agreement is a transformational event for IntelGenx. Given the synergy of our oral film technologies particularly pertaining to the development and commercialization to tadalafil oral films, we're pleased to collaborate with Aquestive. The launch of a partner tadalafil oral film in the U.S. has the potential to provide patients with access to this important product

much sooner. In addition, it will maximize the commercial opportunity for IntelGenx, Aquestive and our respective shareholders.

Moving on to cannabis-infused films, our joint project with our co-development partner Tilray. This is a very exciting project for us as it allows IntelGenx to be at the forefront of the new cannabis industry by developing much needed noncombustible cannabis film products for both the adult use that meaning recreational and the medical use market. We are actively working with Tilray on the formulation development of the product exploring various medical use and adult use film formulation prototypes. Our adult use cannabis film will comply with the upcoming Canadian regulations for edible cannabis products.

The amended Canadian cannabis regulations, which are expected to come into effect no later than October 17, 2019 would allow adult use consumers to purchase edible products in Canada. The market for cannabis is expected to see significant growth under the new Canadian legal regime both in terms of number of consumers and dollar value. In fact BDS Analytics recently projected legal cannabis market will grow to \$5.2 billion by 2024. This basically is a good problem to have. But one of the issues the industry is facing is making sure that supply will keep up with this growing demand.

So yesterday we were pleased to see Tilray announce its investment of \$32.6 million to increase its Canadian cannabis production and manufacturing footprint by over 200,000 square feet across three facilities thereby expanding its total production manufacturing footprint from 1.1 million to 1.3 million square feet worldwide. We look forward to updating investors with progress on our cannabis-infused films on future calls.

In addition to the Tilray partner cannabis-infused oral film, IntelGenx is currently finalizing a cannabis transdermal patch prototype. This cannabis containing transdermal patch has the potential to be therapeutically effective over an extended period of time in three days to seven days. One major advantage of transdermal delivery is the avoidance of first-pass metabolism which significantly affects blood levels of both THC and CBD when administered orally. Currently, we are actively looking for the right partner to co-develop and commercialize this new potential product.

Now move on to Montelukast. This is our major drug repurposing opportunity indicated for the treatment of certain degenerative diseases of the brain such as Alzheimer's. Montelukast addressable Alzheimer's disease market is roughly \$5 billion and is expected to grow significantly. We currently have 16 out of the targeted 70 subjects enrolled in our Phase 2a clinical trial of Montelukast VersaFilm. Another seven patients will be enrolled shortly pending successful completion of the screening process.

We have been monitoring the recruitment activities across our sites. And in an effort to expedite enrollment, we are working with the contract research organizations increase recruitment at all our participating sites. We're working to generate investor interest by sharing successful recruitment approaches – I'm sorry, let me correct with that. We're working to generate investigator interest by sharing successful recruitment approaches on the other sites and are increasing awareness of the trial, particularly among existing Alzheimer's disease advocacy group.

We've also been reviewing these existing sites with low enrollment and limited screening activity and looking at alternative site options where we believe an enrollment maybe higher. As a result of that Toronto Western Hospital is now no longer part of our Phase 2 study. While it isn't customary for a study sponsor to comment or provide status updates on individual trial sites, I think it's fair to point out that Toronto was the only city hosting more than one site and that Western Hospitals withdrawal from the study was by mutual consent. We expect an alternative site in Ontario outside of the Toronto region to be added soon.

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

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you Horst. Good afternoon, everyone. As Horst mentioned just a few minutes to discuss the company's financial performance for 2019 first quarter ended March 31, 2019. But before I start I would like to take this important opportunity to thank Horst and IntelGenx's Board for this additional vote of confidence in appointing me President, CFO of IntelGenx.

Now, let's talk about financial performance of Q1. Total revenue for the first quarter were increased by 74% to \$416,000 compared to \$239,000 for the same period last year. The increase is mainly attributable to an increase in R&D milestones and revenue of \$372,000 which was offset by a decrease in R&D revenue of \$195,000. The operating cost and expenses were \$2.7 million for Q1 versus \$2.3 million for last year equivalent three month period. The increase is mainly attributable to increase in SG&A expenses of \$424,000 and also R&D expense of \$63,000 compared to the same period last year.

For Q1 2019, the company had an operating loss of \$2.3 million compared to an operating loss of \$2 million last year. Adjusted EBITDA was negative \$2.1 million compared to negative \$1.8 million for the same period last year. The net comprehensive loss was \$2.3 million or \$0.03 on a basic and diluted per share basis for both the three month period ended March 31, 2019 and 2018. As at March 31, 2019, the company had cash and short-term investments totaled \$8.6 million or approximately CAD 11.5 million.

On that, I will turn the call back to Dr. Zerbe to conclude our remarks.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Thanks, Andre. I would like to close by acknowledging the support of our Board of Directors, for their guidance, for shareholders for sticking with us and most importantly the ongoing hard work and dedication of our staff. A heartfelt thank you to all of them.

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

QUESTION AND ANSWER SECTION

Operator: [Operator Instructions] Your first question comes from the line of Jason McCarthy with Maxim Group.

Susan Lee

Research Assistant, Maxim Group

Q

Hi. This is Susan Lee calling on behalf of Jason McCarthy. Thanks for taking my question. Congrats Andre and congrats on your last quarter. My first question is why did you guys choose Aquestive for a partner? Hello?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah. It's Horst. Thanks for the question.

Susan Lee

Research Assistant, Maxim Group

Q

Hi.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

There are a couple of reasons that prompted us to do that. One is a very obvious one. We wanted to provide patients with the opportunity to obtain access to the product as soon as possible. Now Aquestive product was further advanced than ours. As I previously mentioned, they had submitted a 505(b)(2) NDA for the year earlier than we would have been able to do so, and they had actually received a Complete Response Letter in October of 2018. So a market introduction was inside. However, they were blocked from early market entry by the fact that they didn't have a license to any orange book patents. So protecting CRS tablets and that's where we came in, we as we had announced earlier, we have a worldwide license to that respective patent that allows us to enter the market sooner. And so now you put two together, there's a product that is advanced much further branch than ours. And here we have leverage to enter the market much sooner. So that made it very logical to form an alliance. And so already in 2017 – late 2017, we started talking to them about this path to the market, took a little longer than we expected, but here we are now.

Susan Lee

Research Assistant, Maxim Group

Q

Great. Thank you for answering that. And also I was wondering why you guys included RIZAPORT in their agreement?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

I'm sorry, I missed the...

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Why RIZAPORT was included in the agreement?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah. To be frank and open, we wanted to avoid after having just entered into a partnership with them to potentially be in court with them, because the work on at least some similar products, their manufacturing technology is quite comparable and we couldn't exclude that there could have been a potential, let me put it that vaguely, a potential IP collision. And so, therefore, we included RIZAPORT in a deal that make sure that there will not be any litigation...

Susan Lee

Research Assistant, Maxim Group

Q

Right, right.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

... over RIZAPORT. That is the main reason. We didn't see any active interference, but we couldn't on the other hand definitively exclude it.

Susan Lee

Research Assistant, Maxim Group

Q

Got it.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

And just to add on what Horst just said, it would prevent them to launch any RIZAPORT program or products in the future, because now they can't do it with that agreement. So we're avoiding competition to that as well.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah.

Susan Lee

Research Assistant, Maxim Group

Q

Got it. Got it. Okay. That makes sense. Okay. And lastly what is your timeline for the U.S. launch?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

You mean for which product, you ask me both about rizatriptan and – I'm sure you're referring to tadalafil, right?

Susan Lee

Research Assistant, Maxim Group

Q

Yes.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah. I can't be sure at this moment. As we speak the companies are forming a joint project team that will assess or complete the assessment of the Complete Response Letter once our people here have complete insight into that. We have a good idea, but not final detailed information, will we be able to determine how much time do we need. There is a good chance that – we expect that much I can say to respond to the Complete Response Later this year. When exactly at this point I can't tell yet, but I'm sure, we will be able to communicate [indiscernible] (00:22:41).

Susan Lee

Research Assistant, Maxim Group

All right. Well, thank you. Thank you.

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

You're welcome.

A

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Operator: Your next question comes from the line of Doug Loe with Echelon Wealth.

Douglas Loe

Analyst, Echelon Wealth Partners, Inc.

Yeah. Thanks very much and good afternoon gentlemen. Not to beat to the death here, but I was just sort of following up on your new partnership with Aquestive. Just wanted to sort of pin down what your responsibility is on the commercialization and just general activities around development of that product will be operationally going forward? Will you have any manufacturing responsibilities? Will your facilities in [indiscernible] (00:23:19) sort of be subjected to FDA audits as part of the process? Is there any potential for adapting future next-generations thin film formulations, the VersaFilm sort of – along that theme just any feedback would be helpful.

Q

And then, secondly just on Montelukast, I mean I'm sure you've been following the Alzheimer's disease clinical activities by some of your beta amyloid targeted peers and the challenges that they've had developing antibody therapies in that realm is I'm sure you probably know there's – it's actually a pretty rich literature on how the leukotriene pathways are relevant to cognition. I was just sort of wondering if you know any of your scientific team have been participating in recent scientific conferences and presented any of the Montelukast data that you and peers have generated so far. Just sort of – what sort of feedback there has been from key opinion leaders and just how relevant leukotriene antagonist could be in mitigating cognizant deficit disorders and just any sort of scientific insights you might have in that theme as well. And I'll leave it there. Thanks.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yeah, thanks Doug for the question. So, going back to the – responding to the first part, tadalafil obviously we will not be involved in the manufacturing. There's a simple reason for that. The Aquestive has been named in the application as the manufacturing site. The entire process validation has been performed there. If we had any – or would obtain any manufacturing rights that would involve a manufacturing site change that wouldn't make much

A

sense at all. So, manufacturing rests with Aquestive only. Above and beyond that this is intended to be a true partnership.

In other words Aquestive and IntelGenx will jointly contribute to the marketing efforts. And while Aquestive will be the marketing entity, we will be involved both financially and if you will directionally. The same applies to whatever remains in terms of work to be performed to respond to the Complete Response Letter that is also going to be a true partnership effort. And as I mentioned before, a joint project team has been formed that will manage this partnership effort.

With respect to your Montelukast related question, of course – are we reaching out, are we trying to make noise and are we trying to let the world know that we are becoming a player in that attractive markets or for example, we presented at the last two ADPD conferences in both cases together with our external consultant Ludwig Aigner, who as we have mentioned before had developed this animal model and conducted animal experiments that initiated our interest in this project. So we're also reaching out to players. I think it's fair to say that that we have established contacts with many, if not all relevant players, institutional players in the U.S. in the Alzheimer's field and we also have regular interaction with Canada's governing Alzheimer's body that so-called C5R Group. And we're planning to actually further intensity that effort. Does that mostly address your questions Doug?

Susan Lee

Research Assistant, Maxim Group

Q

Yeah no that's good. I just wondered within – well yeah you addressed those just kind of interested in how the beta amyloid hypothesis might be resonating within the scientific community as it relates to some of the new mechanistic stuff that Montelukast is clearly implying from some of the day that you've reported so, yeah you've hit that nicely. Thanks very much Horst.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah. You're welcome Doug.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Thank you, Doug.

Operator: Your next question comes from the line of Patrick Tully with Endeavor Asset Management.

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Q

Congratulations Andre. Couple of quick questions. So just to be clear, a question was using your own sales force to market tadalafil?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

That is correct Pat. First, thanks for the question. But that is correct. Aquestive has over the past – or well over a year put together its own sales and marketing organization. They are already marketing one product and they will market this product with their own sales force.

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. A couple...

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

To a great extent that much, I can – let's say, well to a great extent also media marketing – electronic marketing involved.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. A couple of other questions. Can you just elaborate a little bit on the transdermal patch and is it an FDA or Health Canada pathway or is there a recreational pathway that's faster for the cannabis transdermal patch that you see? I'm just trying to get a sense as to how far away that would be.

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

The transdermal patch will clearly be a product for medical use.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay.

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

So it will be Health Canada and hopefully subsequently FDA product. It will require full pharmaceutical approval.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. Andre in terms – on the Annual General Meeting slideshow you talked about strengthening the balance sheet. Can you elaborate on that and just tell us what actions you are looking at in that regard?

Q

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Yeah. I mean that's obviously our mandate or my mandate to strengthen the balance sheet. There is obviously a few options means one very obvious is to sign new partners. And with potential upfront payments, also I mean let's not forget that there's a potential this year – there could be a potential this year of launching three new products. So bringing revenue to the company also strengthen the balance sheet. There is a possibility also to do some capital raise at some point down the line, but obviously, we need the right condition to do so, and try to use instrument that are less dilutive than raising equity and so potential partnerships as well. I mean all of these different options could help strengthen our balance sheet.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. So I'd get our convertible offering is also on the table potentially down the road?

Q

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

That would be our preferred way to finance our growth and expansion as opposed to equity.

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Q

Okay. Lastly can you just talk – there's been a lot of debate about how you receive revenue from Tilray and the timing – when you expect to start see that flowing in on the cannabis recreational product. Can you just talk about the mechanism there, like do they pay you after the retailer sells some products or when they receive the product or how that works?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Yeah. So obviously the agreement with Tilray as is comprised, like manufacturing revenue as well as royalty revenue. So basically what we would do obviously we will get purchase orders from Tilray way ahead of obviously the launch time, because we need time to basically make the film and package the film and deliver the film, at which point we will invoice Tilray for the amount that we ship them. So it would be manufacturing revenue that would be top line revenue. And we would obviously have the cost associated to that inventory shipments in the cost of goods. And later on in the process after we sell to the retailer, then we would get the high single digit royalty from them. So it's – and that would be obviously top and bottom line because there is no costs related to that, so that would be pure profit. But it would be after they basically sell at the retail level. So we would be further out.

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Q

Okay. So you could potentially start to see manufacturing revenue as early as August, September timeframe, or is that is that too optimistic?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

It's a little bit optimistic. It could be possible that we start manufacturing around that period or maybe a little bit later. But I mean those manufacturing revenue will be recorded only upon invoicing Tilray. So August, September I think is a little bit too early. It would be...

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Q

Okay. So you could be producing product in August and September but not get paid until the fourth quarter?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Yes. But, at the same time, we need to have a final formulation and we need to have the raw material provided by Tilray. So, my expectation, I mean it is possible, but I think that Q4 is most likely to be reflected manufacturing revenue. But...

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay.

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

...at the same time, I mean this is something that we will be coordinating with Tilray and make sure that whenever they decide to launch, they have the inventory accordingly.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay, very good. Congratulations again.

Q

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

If I could just add to that Pat, it's Horst. I just mentioned that Tilray added to their manufacturing footprint, which is basically great news. But keep in mind that the effect of that in terms of improved supply will not be available immediately. That'll come with a delay of probably a year if not more, probably two years. And so, we have to expect – that's unfortunately out of IntelGenx control. We have to expect to have to deal with this apparent shortage of API for a little longer. So I don't want – while we are very excited about that program, I don't want to create in any unrealistic expectations that as soon as the [ph] RECs (00:37:26) come into play we can produce massive amount. We might be able to do that but the shortage of API will persist for another a short while.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. So I mean you're going to have some products in the beginning but you just don't know how much?

Q

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yeah.

A

Patrick Tully

Managing General Partner, Endeavor Asset Management, L.P.

Okay. All right. Thank you.

Q

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

You're welcome.

A

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Thanks, Pat.

Operator: Your next question comes from the line of [ph] Fati Benadine (00:38:05), private investor.

Q

Yeah. Hi. Good afternoon, gentlemen and congratulations Andre on the new position.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Q

Thank you. My first question is in regards to the RIZAPORT resubmission, you had stated that you plan on resubmitting before the end of Q3 of this year. Now could you touch or shed some light whether it's more towards the beginning of Q3 or is it towards the end?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Honestly speaking it is impossible for us to nail down a specific date. There are yet a number of experiments to be conducted. And as it is with experiments, you just have no assurance at the frontend regarding the outcome. So we have to leave it vague and cannot narrow it down any further as much as I would like to, but that would not be honest.

A

Q

Okay. Okay.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

But the important point here is that FDA asked very specific questions, without going into any details, we had a certain stability program for which FDA asked us to determine the root cause and then provide a solution. And I'm very happy to say that we have been able – clearly able to identify the root cause. And so, we now have a strategy in place as to how to solve that problem, all that will happen within Q3. But I can't be any more specific.

A

Q

Okay. But it is safe to say that you will be resubmitting in Q3 correct and not later?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

That is correct. Yes.

A

Q

Okay. My next question is in regards to the balance – cash on hand which you stated as \$8.6 million as of March. Now, is it safe to say Andre that we have a clear runway through Q1 of 2020 with the current cash on hand?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Yes. That's safe to say that we – as the actual burn, we should be able to be say for 9 to 12 months.

Q

Okay.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

But it always depend also on opportunities or it might change, but on the current burn rate, yes.

Q

Okay. Okay. That's fair. And the other question is in regards to the company going to a path that's cash flow status. Do you see this happening by end of this year, and I'm focusing more unlike Q4 being your first cash flow positive quarter?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

I think, this year, I don't see that happening this year. And being cash flow positive in Q4, then we would need to launch early in the quarter or at least in the middle of the quarter both – I mean cannabis tadalafil and RIZAPORT which is – it's likely to happen. So I think that by next year, we will be cash flow positive at some point, but it will depend on the timeline for the tadalafil launch, RIZAPORT launch and cannabis launch. If we have a full 12 months let's say of cannabis film and potentially tadalafil and at some point we had RIZAPORT, I think that by sometimes during the year we should be becoming cash flow positive.

Q

Okay. And just one question about the cannabis, with the October 17 legalization date, as Pat had mentioned, do you see possible accounting of profit from the cannabis launch this year?

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

I mean, I think, we've kind of covered that, but it is – let's put it this way, it is possible you know.

Q

Okay.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

But we don't know – at the end of the day, Tilray is responsible for the launch. But we're going to support Tilray obviously we work with them, they're our partner. So, whenever they need to launch and I know that they want to make a big buzz with our film. So, they like the delivery and everything. So, the sooner they order, the sooner we deliver and the sooner we can book revenue on the top line of our P&L.

Q

Okay, all right. My next question is in regards to the Suboxone, with your recent collaboration with Aquestive Therapeutics, does this have any effect on the [ph] top line (00:43:58) or Suboxone at all?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

First of all, generally speaking we are not at liberty to discuss whatever we do with our partner at all.

Q

Okay.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

I cannot comment specifically. But let me say this, we make sure with every single partnership that we're entering into, there is no collision with any existing partners that much I can say.

Q

Okay. All right. And just two more questions. One of them is in regards to the Alzheimer's study. Is there a possibility that you will be releasing any preliminary data from the patients that have been dosed in this year?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

That is the plan. We are working towards performing a what we call midway evaluation on a minimum of 10 patients who at that point in time have undergone six months treatment. Based on the current enrollment status, we will have that many or possibly more patients around October that will have completed six months treatment. So the answer is yes it is. We have to plan, to do a preliminary evaluation of the still blinded data that's important to point out sometime in the October timeframe.

Q

Okay. And my last question Horst is in regards to the VetaFilm that you recently have been focusing on. Is there any like timeframe to when you might actually – like I don't want to say like launch it, because it's too early. But

are there any like companies that have showed interest, are there any possible partnerships in the VetaFilm sector that you guys are working on currently.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

That's...

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Oh I'm sorry.

Q

Yeah for the veterinary film.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yeah, yeah the animal health product you mean. Yeah.

Q

Yes.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

The short answer is yes. Our Business Development person, Dana is in active discussions with a number of animal health companies. And one case in particular is very advanced. So we see a reasonably good chance that that effort may or could lead to a partnered project.

Q

All right. And the timeframe for the approval process for the veterinary product, is it similar to the human medicine product?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Yes.

Q

Okay.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yes. The review process is very similar to human. Okay.

A

Q

Okay. All right gentlemen. Thank you so much for taking my questions and have a great afternoon.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

You're welcome.

A

Operator: Our last question comes from [ph] Prashanth Rao (00:47:42), private investor.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Hello.

A

Q

Hi, good afternoon sorry. Hello.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yeah [ph] Prashanth (00:48:01) yeah. Good afternoon.

A

Q

Hi. Very good afternoon. Thanks for taking my call. Andre congratulations on your new position.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Q

A quick question insofar as RIZAPORT, I understand you negotiated RIZAPORT into the whole agreement to ensure we don't have any litigation going forward if they do decide to. Now we also are giving away the

manufacturing rights to tadalafil, will that mean that we will not have any revenue from manufacturing, will there be a cost of manufacturing which Aquestive will be charging us?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Manufacturing revenue for which product you mean tadalafil?

A

Q

Tadalafil?

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yeah. But that is obvious and that has not even anything to do with RIZAPORT. The simple reason is that it is – Aquestive NDA that we're dealing with their site, it's the only site listed in the application as the manufacturing site for legally or from a regulatory perspective even if we wanted we wouldn't have [indiscernible] (00:49:22) or the option to manufacture here. You're making your point though and or you're raising a good point, [ph] Prashanth (00:49:31). The point is that Aquestive has brought up with us the idea of at least for certain products [indiscernible] (00:49:47) each other as the backup manufacturer. And we don't have any deep discussions or any advanced discussions on that. But that could be way, way in the future become a possibility.

A

Q

Oh that's a great way to look at it. Thank you very much. That was my only question. And as I said at the AGM hopefully everybody does well and the company does miracles for us.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Yeah. We're very confident.

A

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

That's what we're working on, [ph] Prashanth (00:50:21).

A

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

Thanks, [ph] Prashanth (00:50:22).

A

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

Thank you.

A

Q

Thanks very much. Have a great day guys.

Andre Godin

President and Chief Financial Officer, IntelGenx Technologies Corp.

A

Thank you.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

A

Thank you.

Operator: And there are no further questions at this time. I will now turn the conference back over to Horst Zerbe for any closing remarks.

Horst G. Zerbe

Chairman, President, Chief Executive Officer & Founder, IntelGenx Technologies Corp.

While there's not much more to say other than thank you very much for your continued interest in the company and the trust you're putting into us here. And with that again thank you very much. And good bye.

Operator: This does conclude today's conference call. You may now disconnect.

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