VIAVID
communications simplified.

IntelGenx Corp.

First Quarter 2020 Financial Results Conference Call

May 14, 2020

CORPORATE PARTICIPANTS

Stephen Kilmer, *Investor Relations*

Dr. Horst Zerbe, *Chief Executive Officer*

André Godin, *President & Chief Financial Officer*

CONFERENCE CALL PARTICIPANTS

Sean Kang, *H.C. Wainright*

Colin Taylor, *Private Investor*

Nathan Randall, *Private Investor*

Christian Orquera, *First Berlin*

Doug Bisler, *Shareholder*

David Berris, *Buckman Reed*

Stephen Silman, *Private Investor*

Tom Maglino, *Private Investor*

PRESENTATION

Operator

Welcome to IntelGenx Reports First Quarter 2020 Financial Results.

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 the session you will need to press star, one on your telephone. 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, Investor Relations. Thank you. Please go ahead, sir.

Stephen Kilmer

Thanks, Mike. Good afternoon, everyone, and thank you for joining us on today's call. With me on the line are Dr. Horst Zerbe, IntelGenx's CEO, and André Godin, our President and CFO.

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 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 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 Dr. Zerbe. Horst?

Dr. Horst Zerbe

Thank you, Steve. Good afternoon, everyone, and thank you for joining us for the IntelGenx's First Quarter 2020 Conference Call.

On today's call, I will provide a corporate update and discuss the progress we've made on our key pipeline projects. Following that, André will review our Q1 2020 financial results. Then we will open up the line for your questions.

Before I begin my update, one brief introductory comment. We received a number of questions by e-mail from shareholders, and we have attempted to include the responses or our responses in the update. For any remaining questions, we'd be happy to address those in the Q&A section.

Let me start with RIZAPORT. As discussed on our last call, we received a complete response letter from the FDA related to our RIZAPORT New Drug Application, NDA. The FDA did not request a new (inaudible) study. We have requested a meeting with the FDA to discuss and obtain clarification on new comments in the CRL and also to discuss our proposed responses plus to get this application approved as soon as possible.

Also, discussed on our last call was the signing of the binding term sheets with Orivas for the commercialization of RIZAPORT in Lithuania, Atria, Estonia and Poland. Orivas has the right of first refusal or a pre-defined term to include the Republic of Belarus and/or Republic of Ukraine as well as any of Finland, Denmark, Sweden and Norway.

We're currently working with Exeltis Healthcare, our (inaudible) report commercialization partner for Spain to accelerate the launch of the product in Spain. We had initially planned to supply product out of our manufacturing site in Canada, which would have required a quite time-consuming manufacturing site change. We're discussing with Exeltis to continue commercial production at the German contract manufacturing organization that was originally listed in the marketing authorization rather than at our manufacturing facility in Canada. This would allow Exeltis to launch the product already in the fourth quarter of 2020 and should also accelerate product launches in other European countries. Manufacturing for the U.S. and certain other markets will continue to be performed at our GMP Compliant Production facility in Montreal.

Moving on to Tadalafil. On April 30, 2020, we, meaning IntelGenx and Aquestive, received feedback from the FDA regarding the protocol design of the Irritation Study that FDA had requested in the CRL. This study will be jointly conducted by Aquestive and IntelGenx. Both companies met earlier this week to discuss the FDA's recommendations. We are comfortable to say that the changes are not major and will not have any significant impact on this study design.

We will be updating the protocol, evaluate some of the request to changes with the CRO, the Contract Research Organization that is and revise the protocol. Once the protocol is finalized by both IntelGenx and Aquestive, we will be sending the protocol to FDA for final approval, which should take one or two months, at this moment and because of the ongoing dialogue with FDA, we do not have a concrete time line as to when we would start to study.

Moving on to cannabis-infused films. We are still awaiting receipt of Health Canada's microprocessing license, which will enable us to begin commercial production of our cannabis-infuse VersaFilm. This delay, which is entirely due to the impact of the COVID-19 pandemic, should be temporary. We remain confident that our microprocessing application will be approved, such that we can begin commercial production and initiate product sales as soon as possible thereafter. We're looking forward to Health Canada's response to our application and to providing more details on the product closer to commercial launch.

Now some comments on Montelukast.

As discussed on our last call, Health Canada issued a No Objection letter in response to our amended clinical trial application or our CTA for the ongoing Montelukast VersaFilm Phase IIA, the so-called BUENA clinical trial in patients with mild-to-moderate Alzheimer's disease. Health Canada's NOL enables us to continue the BUENA trial at an increased daily dose, which is based on additionally testing of Montelukast in Alzheimer's disease mouse model.

Now because when a target study population is considered to be a higher risk group for severe illness from COVID-19, we have informed Health Canada that the study is on a temporary recoupment (inaudible). We are closely monitoring the situation and will resume enrollment under our amended protocol as soon as practical. In the meantime, we will continue expansion to the United States via a potential IND filing with the FDA when that is appropriate.

Moving on now to animal health. As also reported during the first quarter, we entered the animal health space 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 a successful feasibility, we will have exclusive rights to further develop, manufacture and supply the product.

A few comments now on our Performance Improvement program. I have already addressed some of the program's components today, particularly the next steps for RIZAPORT program. Other components of this program are intended to generate near-term revenue, preserve the Company's resources, extend our cash runway and strengthen various parts of our business, including regulatory affairs and manufacturing operations.

We will continue to focus on partnering our current product pipeline, which includes 10 pharmaceutical oral (phon) film product candidates as well as pursuing potential oral thin film manufacturing opportunities. We will also pursue short-term revenue-generating opportunities by expanding our pipeline to include products that do not require regulatory approval, such as nutraceutical films and personal hygiene products, and we are already in active discussions with potential partners.

In order to preserve our resources and extend our cash runway, we've taken immediate measures to reduce our burn rate, including cutting 10% of employee headcount with the expectation that could increase to up to 15%, deferring 20% of compensation for Executive Officers, VPs and Board members, deferring 5% to 20% of compensation for all employees, and decreasing nonessential expenses in all areas of the business.

Finally, we implemented several organizational changes. André is now responsible for all business functions, including finance and business development. I am now overseeing our product development and manufacturing functions, including R&D, regulatory affairs, quality operations and production.

In addition, the Company's Board and Management is conducting a comprehensive review of all functions and reporting relationships with the goal of making sure we are optimally staffed and structured to support both our current business and the successful execution of key new initiatives.

These have been difficult but necessary decisions aimed at maintaining our financial stability during this uncertain time. Our Management and Team and Board—our Management Team and Board will continue to identify and consider other opportunities to better position the Company for future success.

Finally, some words on COVID-19. COVID-19 has severely impacted on our day-to-day operations and some immediate steps we implemented include people working from home, wherever possible, freezing all nonessential travel and switching to virtual sales and business meetings. COVID-19 also impacted on some business—on some development programs and mostly the BUENA study, and as I discussed before, subject (phon) recruitment for the BUENA study was put on hold. Also as discussed earlier, the issuance of the microprocessing license has been delayed.

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

André Godin

Thank you, Horst. Good afternoon, everyone. As Horst mentioned, I'll take a few minutes to discuss the Company's financial performance for the first quarter ended March 31, 2020.

So for the first quarter, the total revenue amounted to $202,000 compared to $416,000 in the same period last year. The decrease is mainly attributable to a decrease in R&D revenue of $214,000.

The operating costs and expenses were $2.4 million for Q1 2020 versus $2.7 million for the corresponding three-month period in 2019. The decrease in expenses is mainly attributable to a $10,000 decrease in R&D and $380,000 decrease in SG&A compared to the same period last year.

For Q1 this year, the Company had an operating loss of $2.2 million, a slight improvement compared to an operating loss of $2.3 million for the comparable period of 2019. Also, the Adjusted EBITDA was negative $1.9 million for Q1 compared to negative $2.1 million for the same period last year, an improvement of approximately $200,000.

The net comprehensive loss was $2.9 million or $0.03 on a basic and diluted per share basis for Q1 2020 compared to net comprehensive loss of $2.3 million or $0.03 as well for the comparable period of 2019.

As at March 31, 2020, the Company's cash and short-term investment was US$4.4 million compared to $1.9 million as at December 31, 2019.

Subsequent to the year, we closed an offering for gross proceeds of CA$8.2 million, which provides the Company with sufficient capital the end of this year. We are also looking at more alternatives to secure additional capital for 2021, including, among other things, short-term revenue opportunities.

As previously announced earlier this week, we also intend to amend the convertible debenture in order to extend their maturity from June 2020 to June 2022.

Finally, we're monitoring all available government program to evaluate our eligibility and have identified a couple that might be applicable. We will keep shareholders updated in our future investor communications.

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

Dr. Horst Zerbe

Thanks, André. In closing, while we have had to make several changes in response to unforeseeable developments, our platform technology's value proposition remains the same. Nutraceutical oral film products provide tangible benefits for patients, such as improved efficacy, quicker onset of action. We use side effects and ease of administration, particularly for patients who have difficulties swallowing. We're determined to build a stronger and more nimble organization and are 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 (inaudible) and the following Q&A. Thank you.

Operator

At this time I would like to remind everyone, to ask a question, you will need to press star, one on your telephone. To withdraw your question, press the pound or hash key. Please standby while we compile the Q&A roster.

Your first question comes from Sean Kang from H.C. Wainright. Your line is open

Sean Kang

Hi. Tank you for taking my question. This is Sean for RK at H.C.W. So my first question is regarding the microprocessing licensing, you mentioned. So once after obtaining the license, how soon could you launch the product in Canada?

Dr. Horst Zerbe

Yes, thanks for the question, Sean. I cannot provide a clear answer to an exact launch date simply because that is not in our control. So I can tell you what we do control and how fast we can respond. We have obviously developed a formulation, which is approved by the partner, and we conducted scale-up trials, so as to be able to immediately commence commercial production once the microprocessing license has been obtained. When I say immediately, I mean, literally days after we have received the APIs.

Now a word on that. Tilray is telling us that they have the API on standby, they can only ship, under the law, once we have received the microprocessing license. So the process will unfold in the following way. We receive the microprocessing license. We will immediately inform Tilray. Tilray will ship the API, and we will immediately commence commercial manufacturing. Then we will ship and commercial manufacturing will approximately (inaudible) those first batches will approximately take two weeks, then we will ship the product to Tilray for secondary packaging. We only do primary packaging, and so from there on the process is under Tilray's control. We expect that a launch will occur in Q3, but I say that with caution because, as I said, we're not controlling that.

Sean Kang

I see. That's helpful. One last question is, did I hear this correctly, did you say your current cash run rate is expected to the end of this year?

Dr. Horst Zerbe

Yes. I turn over to André.

André Godin

Yes. Yes. Obviously, like Horst mentioned, we've done some salary deferrals. Obviously, we've been very focused on specific projects. So we're managing very tight, and we should be able to make it till the end of the year.

Sean Kang

I see. Thank you. That's all for now. Thank you.

André Godin

You're welcome.

Operator

Your next question comes from Colin Taylor, Private Investor. Your line is open.

Colin Taylor

Hi. Thanks for taking my question. Thanks for taking the time out of your day. I've been an investor with IntelGenx for a couple of years now. My question for you guys is market capitalization. Do you feel that the market capitalization that IntelGenx currently has is justified among the investors? Thank you.

Dr. Horst Zerbe

André, I suppose that's a question for you, right?

André Godin

Yes, yes. Obviously, we're not happy about the market capitalization right now. I think that many companies have taken a hit because of this COVID-19 virus, and biotech has been hit quite a bit and so far, we're not commercializing any product, so we could be viewed as biotech. I think that we're all working very hard to make this share price go up, and I think that by doing what we did recently with our new strategic program, focusing on short-term revenue opportunity as well as obviously continuing our main program. That should definitely provide the Company with short-term revenue and address these this issue that we have with our share price. But I think that we're all really focused at IntelGenx and it is probably one of our main objectives to get to where we should be. We're definitely undervalued. I don't know it's a cliche, but for us, it's really pretty accurate to say that with our share price at this time.

Colin Taylor

Thank you. Just one last question. Would you guys—with the Board, and has it been discussed that any plans for potential buyouts or looking to sell the business in the future to resemble a market capitalization that fits the Board and the shareholders ultimate belief in its value? Thank you.

Dr. Horst Zerbe

That's not a consideration right now. We had requests in the past, not recently, but in the past, we did. We continue to believe strongly in the value of this Company and continue to work very hard on getting our pipeline programs to the market, which will have an impact on the valuation, and while we don't have a clear exit strategy at this point, if any of that came up, it could only happen at that point in time, not at this point with this market cap.

Colin Taylor

Okay. Thank you and continue the good work guys and appreciate taking the call.

Dr. Horst Zerbe

Thank you.

Operator

Your next question comes from Nathan Randall (phon), Private Investor.

Nathan Randall

Good afternoon. Thanks for taking my call. Questions pertaining to Tadalafil and RIZAPORT, two questions. Can you explain why did you even enter into a partnership with Aquestive? You could have applied and gotten approval potentially by now, had you applied on your own. What is the benefit of going into a CRL and wasting so much time in the whole process?

Dr. Horst Zerbe

If we look back at the evolution of (inaudible) and the reasons for the decision to partner with Aquestive. At the point when we were ready for filing a 505(b)(2), we realized that our competitor Aquestive, was further advanced with their application. So the situation that we had in front of ourselves, there was the following: we were behind in the FDA review process, even though we had the advantage of having a license from Lilly that would have enabled us to launch a product prior to expiry of the relevant patents. So the underlying idea was to combine the best of two worlds, which is to use a further advanced application, which undoubtedly Aquestive's application at that time was and to apply our license to that combined effort. So that would have given us the chance to be quickly in the market and at the same time to not have to face competition, which would have undoubtedly a negative effect on pricing. That was the underlying thinking.

Now things do not all the time develop as expected and so we had a complete response data with the Aquestive application, so now joint application as well. So we are as where we are now. But as I just explained, these were the underlying reasons, and I continue to think that they made a lot of sense because to the day, there's not going to be a competing film product. That remains a valuable advantage once the product gets to market.

Nathan Randall

But wouldn't that change immediately after your product really exclusivity goes away?

Dr. Horst Zerbe

No, because there is no other film application pending. We know that. So generic tablets have been on the market for quite some time. So the only relevant competition for us really would have been a film. And with this, cooperation, we remain the only film product on the market, once the product hits the market.

Operator

Your next question comes from Christian Orquera from First Berlin.

Christian Orquera

Yes. Thanks for taking my questions. I have a few questions if I may.

The first question is regarding the cannabis-infused film. Can you provide an update what is currently the situation of the retail cannabis consumption distribution channels in Canada in scope of the current pandemic?

Second question would be on RIZAPORT. Can you provide a bit more of light on what could have been the reason that the FDA raised questions that were beyond the previous questions from the CRL from 2019?

Then I have a question on the opioid dependence CRL, which you are preparing together with Par. Could you could you please provide some guidance when could be the potential filing, which was planned to take place in this year, if anything has changed on that side?

My last question on the Tadalafil and Aquestive. It sounds like you are in quite close contact with Aquestive on preparing the response letter. Can you provide some more background what could be the potential timeline? Can we still expect that that may take place in the second half of this year? Thank you very much.

Dr. Horst Zerbe

Yes. Okay. So I'll try to respond to these four questions. The first question, it is not quite clear to me what your question is. You were asking about the distribution channel for cannabis (inaudible). Could you specify a little more what exactly the question is? That was not quite clear to me.

Christian Orquera

Oh sure. I'm just wondering based on the pandemic and probably once you have the possibility to go to the market together with your partner Tilray. I'm trying to have a feeling about how the market is looking if retail shops are opening. In some countries, much of the retail shops are closed. I'm just wondering how the possibility will be to distribute the product to the consumers?

André Godin

Horst, do you want me to respond to this?

Dr. Horst Zerbe

Yes, go ahead. Go ahead.

André Godin

Yes. Yes. So cannabis. I mean, obviously, in Canada, like everywhere in the world, we've been dealing with that that virus, and the Government of Canada has initially in March obviously closed a lot of business except for what was essential. So obviously, grocery stores and pharmacies and like pharmaceutical companies and cannabis as well as liquor stores were considered essentials. What we have seen so far since the beginning of the pandemic is increased sales in the cannabis distribution network across Canada. So the sales have gone up since COVID-19 has entered the country. So we don't see—and until we reported the latest quarter, I think it was yesterday or few days ago, and the revenue are obviously quite up from last year. I'm not saying it's all because of that but a short answer is that revenue from cannabis derived products have increased quite a bit since the beginning of the COVID-19. So we don't see any issues with our product, not at all.

Christian Orquera

Excellent. Thanks. Okay.

Dr. Horst Zerbe

Okay. Before I get to the RIZAPORT question, you asked about Par and potential filing timeline. The situation there is the following: We are working on a first-to-file opportunity that we cannot disclose the molecule. That is confidential, very obviously, since a first-to-file opportunity. The brand product is not yet on the market, but is expected to be on the market anytime soon. As soon as that is the case, we will conduct a biostudy. So filing of the NDA could happen or will happen as soon as the results of the pivotal biostudy are available and provided that, that result is passing, which could be the case later this year or early next year. But that is really speculative since the reference part (phon) is not even out, we cannot really predict with any accuracy how the situation is unfolding.

On the Tadalafil timeline, as I mentioned, we received comments from the FDA on the study design. The study that FDA requests or requested in the complete response data is a safety study, and more specifically, a mucosal irritation study. We are in contact with the CRO. As soon as we have a response from FDA on the final details of the protocol, the study can be conducted. There is certainly a possibility that the study will be completed later this year, and that we can respond to the complete response letter in Q4 of this year. But again, since the study is not yet available, there is no certainty to that, but that is certainly the plan.

Finally, on RIZA, you require more details on the complete response. Typically, and no company does that. We do not provide any details on the—well from the complete response letter. Qualitatively speaking, the FDA did not comment on the responses that we provided previously. They came up with, and very unexpectedly, that really caught us by surprise by comments that were totally unrelated to the responses that we supplied in August of last year. So therefore, it is really important for us to conduct the meeting with FDA, which should take place within the next four weeks, at least under the current rules. Once we have that meeting, we will know more specifically what FDA requires, and we can then provide further details.

Christian Orquera

Excellent. Thank you very much.

Dr. Horst Zerbe

You're welcome.

Operator

Your next question comes from Doug Bisler (phon), Shareholder.

Doug Bisler

Hello, I've been a stockholder for, I guess it's been over 15 years, and I remained a stockholder over the years because of what I view a very promising pipeline. Unfortunately, it seems like the Company continues to find it very difficult to get these film products over the finish line. In particular, the RIZAPORT, the four CRLS, I find amazing that through all the negotiations and conversations that the Company has with the FDA that it ought to be almost a checklist that as long as the Company has met these requirements because there's never been any—the four CRLs that the Company has received, there's never been a problem with the bioequivalence of the film strip.

So there's these other things that you would think would be minor in getting across the finish line. So I wonder if you could just address, just—and you kind of—in listening to the last caller, I guess you're prohibited or not willing to disclose, but it just seems like that we should be farther along after four CRLs that we should be further along in getting this film strip approved. It's been very frustrating to watch this. Could you give any more color or disclose any more information that would give us some hope that we'll eventually get this over the finish line?

Dr. Horst Zerbe

Yes. Doug, thanks for the question. Let me be honest, I'm not proud of how this project was handled. I mean, I'm probably stating the obvious and stating anything to the contrary would not be truthful. So we're not proud of that. However, not all the blame has to go on us. First of all, to correct you slightly, these were three CRLS, not four, but three is bad enough. But keep in mind that the reason why the product was rejected the first time was entirely out of our control. It was solely because the API supplier, Apotex, at that time had received an import ban from the FDA, which was certainly not something that we could be blamed for. The items that remain and that we need to address are, with no exception, all in the area of chemistry manufacturing and controls. So we are still not be able to satisfy the FDA in all aspects of the manufacturing procedure, which if you recall, had been transferred from the initial European CMO to interject. We had to re-establish all that.

So while we're confident that we are in full control of the process. Now that certainly had resulted in some hiccup. So let me summarize it that way, FDA has comments on chemistry manufacturing and controls, the so-called CMC section. They remain satisfied with the clinical performance of the product or bipolancy performance of the product, and that is what we need to address. Now we want to know specifically what FDA expects from us, which is why we applied for that meeting. We hope and actually are confident that this will clearly be the last complete response that we will receive from them.

Operator

Your next question comes from David Berris from Buckman Reed.

David Berris

Good afternoon gentlemen. Thank you for the updates today. My question concerns around your cash burn. I heard you mentioned you—with the recent move you've made, you anticipate having enough cash to last through the end of the year. However, what concerns me has been the dilution to current shareholders over the last couple of years with the warrants, with the private placements and now lowering the convertible price on your debentures to $0.50 a share, that obviously would mean more

shares. At what level of revenue would it take for you to not have to access the capital markets anymore, and would you anticipate the approval of either RIZAPORT or the cannabis film, accomplishing those revenue levels, so we wouldn't have to dilute current shareholders anymore?

André Godin

Yes. So I can answer that. Yes.

Dr. Horst Zerbe

Yes, sorry. Go ahead.

André Godin

I mean, obviously, we've been very cautious about our spending over the last month or so, and then we'll continue towards the remaining of the year, and in order to make it to the end of the year without having to raise further capital, especially at this level, which is totally ridiculous. We're looking at different source, non-dilutive source, like term loans and government assistance. Obviously, there's a lot of subsidies that are available for us. So, that's basically to answer the potential cash burn that we currently have. But in order to cover our full cash burn, I would say we probably need anywhere between $10 million and $12 million of revenue.

To answer your questions, your question regarding whether both cannabis and migraine, the RIZAPORT films could accomplish that. I mean, based on our projections and based on our discussion with our partners, we could anticipate to reach this level of revenue with these two programs. But it depends when, obviously, we launch both products. Cannabis is obviously the ones that should happen in the near future. RIZAPORT, because of the CRL, it's been pushed out a little bit. But if we were to launch both products tomorrow, we'd probably be okay to cover the cash burn. But the reality is that they won't be launched tomorrow. But one of them will be launched soon. We're expecting, obviously, this cannabis microprocessing license to be approved very shortly.

David Berris

Thank you very much.

Operator

As a reminder, to ask a question, press star, one.

Your next question comes from the line of Stephen Silman (phon), Private Investor.

Stephen Silman

Good afternoon Dr. Zerbe. Can you hear me?

Dr. Horst Zerbe

Yes.

Stephen Silman

My question is about corporate governance, and it may be that the Board reviews that you referred to will cover this. The modern trend is for publicly traded companies not to have the same individual as both Chairman of the Board and CEO, and this is for a very good reason. The chain of command in a company is that the executives are accountable to the Board, and the Board is accountable to the shareholders. If the same person is Chairman and CEO, then there is a potential for conflict of interest because the balance of power in the company is vested in one person who is effectively, I won't say accountable to no one, but he has limited accountability. And that's a particular risk, whereas in this case—sorry it's a particular risk in this case, where the person is also the largest shareholder.

Now I believe that IntelGenx needs to separate the roles of CEO and Chairman. My question to you, Dr. Zerbe, is, is this a question that the Board has given any thought to, and is this something that you yourself would contemplate, namely standing down as Chairman in favor of an independent non-executive Chairman?

Dr. Horst Zerbe

Thanks for the question. You can rest assured that the Board is considering and has been considering this question very, very cautiously. Whenever a situation at the Board level and in Board discussions comes up where a potential conflict of interest might arise, I will immediately step back and our lead Independent Director, Bernie Budro, takes over. The Board is extremely cautious about not allowing any conflict of interest to occur. So well, that basically is the response to that. We have repeatedly discussed that situation; we have not made a definitive decision. The situation of me remaining Chair of the Board and CEO will not perpetuate itself forever. There will be an end to that, the Board is clear about that, but we have not made any decisions as to an exact timing. But we are really conscious about that, and I don't think anybody can say that or accuse us that any decisions have ever been taken that could be viewed as a conflict of interest.

Operator

Your next question comes from Tom Maglino (phon)from Private Investor.

Tom Maglino

Yes. Thank you for taking my question. The first question I have is regarding RIZAPORT and the European manufacturing. Is this an interim step? Or is it your intent to continue producing this product in Germany? And also, how will that cut into the margins for this project? The last part of that is, for over a year, we've been hearing that the approval of the Canadian facility was imminent. What prompted this sudden change and what prompted this delay? I also have a question about Montelukast and cannabis, but I think maybe we'll take it one step at a time here.

Dr. Horst Zerbe

Yes. Okay. So let me respond to RIZA. First of all, the CMO in Germany will only handle initially the Spanish supply, but then certain other European countries as well. At this point, we do not, and the reason is simply that this will accelerate the launch. We want the product on the market. In Europe, the situation is, the product is approved, and the site change, which necessitates generation of new stability data and so on and so forth, just requires a little too much time. So we decided to stay with the CMO that was already or that is already listed in the approved MA.

As far as our margin, at this point, we cannot be very specific. You have to understand our revenue stream from the Spanish commercialization is twofold. There is a manufacturing revenue component and then there is a licensing component. The licensing component will be untouched. That remains the same

whether the product is manufactured here or in Europe. There may be an impact on the manufacturing component. That depends on the pricing that we will be able to agree upon with the German CMO. We provided our Spanish partner with a certain transfer price and that transfer price assumes certain manufacturing cost from us. Now it all depends on whether the price that we get from the CFO matches our manufacturing cost. So what the situation there is, there could be no impact, there could be some impact. We do not expect the impact on our manufacturing revenue to be extremely significant. Well, that's on RIZA pricing. I'm sorry, what was the second question that you had?

Tom Maglino

Yes. It was, is this a permanent move? Or is it just a stop gap measure? I mean, at some point, will this be brought back to your facility in Canada for this? I understand it will only be for the Spanish manufacturing, but at some point, will it be transferred back or will it always be in Germany as the plan is now? By the way, I agree with you completely, let's get it sold, and if it means taking it to Germany, that's fine, but let's get it on the market somewhere. I'm not questioning that decision. I was just wondering what the long-term plan was on that.

Dr. Horst Zerbe

Long term, the way we see it now, we may leave it in Europe, and we actually plan to involve that German CMO in the supply for other European countries as well.

Tom Maglino

Okay. I think that takes care of that one. Regarding the cannabis strips, thank you very much for explaining the progression from you to Tilray into the market. My question is, at what point in time would you actually start seeing any revenue? Does it happen when you start shipping to Tilray? Do we have to wait until they're actually sold in the marketplace? At what point will there be revenue from this product?

André Godin

You want me to answer that, Horst?

Dr. Horst Zerbe

Okay. You may add to that. You may comment right away André. Go ahead.

André Godin

Yes. I mean the revenue, I mean, it's in twofold, like most, if not all, our programs. So as soon as we ship the product to Tilray, so as soon as the manufacturing is done and ready to ship, and we ship it to them, then we obviously record our manufacturing revenue, which will happen as soon as the product is manufactured. Then the second source of revenue was a royalty on their net sales. So that would come probably like every month based on how much the product is selling. So it's always going to be in twofold. The manufacturing revenues coming in right away and then the royalty coming in, whether it's 30 days or 45 days later, but it's going to be an ongoing royalty we'll be probably getting on a regular basis as opposed to manufacturing revenue, which will happen when we ship an order.

Tom Maglino

Understood. Thank you very much André. That makes sense. So we can expect to see revenue on this year, in 2020, you're hoping?

André Godin

Yes. Exactly.

Tom Maglino

How does this move—going back to Spain for a moment. How does this move to Germany affect the expansion that you recently did? I guess, it was about a year or so ago where you took over more square footage. Are we still holding that square footage? Is it utilized? Will it be laying fallow?

André Godin

As a matter of fact, the involvement of the German CMO provides quite a bit of relief because we are in the process of manufacturing submission batches, which are full-scale batches, for a number of our pipeline products. These products are fighting for production time, and so transferring the Spanish supplies to the CMO gives us relief to accelerate the manufacturing activities for our other pipeline products.

Tom Maglino

So that space is definitely being utilized at this time. I didn't understand that, thank you. And my last question is of Montelukast, which is a very simple one. As you're aware, the FDA recently issued a warning about Montelukast, regarding suicidal thoughts and tendencies, and I wondered if that impacted the study in any way or your outlook on you treating it for dementia in any way?

André Godin

Not at all. Of course, we know about this black box. But keep in mind, the incidence of this side effect is extremely low, 0.01% of patients. If you only look at the frequency, it's not extremely relevant and certainly not for the patient population that we are dealing with. So short answer, it's not affecting our Montelukast program at all.

Operator

That was our last question. At this time I will turn the call back over to Dr. Horst Zerbe for closing remarks.

Dr. Horst Zerbe

Okay. Since there are no more questions. This now concludes the call. Again, I thank everybody on the call, our shareholders very much for their continued support, and I wish you a nice evening. Thanks. Goodbye.

Operator

Ladies and gentlemen, this concludes today's conference call. Thank you for participating. You may now disconnect.