

Q&A with Kirk Look, CA, CFO, Oncolytics Biotech® Inc. with their REOLYSIN® product being the First Virus to show Statistically Significant Overall Survival Benefits in Metastatic Breast Cancer**Kirk Look, CA, CFO****Oncolytics Biotech® Inc.**
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CEOCFO Magazine**CEOCFO: Mr. Look, you joined Oncolytics Biotech® Inc. in 2003 as Controller and assumed the role of CFO in 2012. What attracted you to Oncolytics and what is your role today? Has it expanded beyond the average CFO role?****Mr. Look:** Originally, I was attracted to the idea of helping people with cancer and the idea of using a virus to treat the disease. I felt it was a novel concept. At the time I thought it was also a good opportunity to advance my career by stepping away from my role at a large accounting firm and step into a senior role with a different company. I never expected the CFO opportunity to happen at Oncolytics, but I was fortunate to be appointed in 2012. I am not

sure I would describe my role as CFO as beyond average, but it is somewhat different in the biotech sector, as we have been operating since inception without any revenue, and our only real source of cash coming from Public Markets in Canada and the US, which has presented us with some unique hurdles and challenges. It has required us to run a lean operation that is sensitive to changes in the capital markets, as well as changes in the operating environment.

CEOCFO: Would you give us a brief look at Oncolytics, its origins and its purpose? Why the focus on cancer?**Mr. Look:** Oncolytics is focused solely on REOLYSIN®, a product coming out of the work Dr. Matt Coffey did at the University of Calgary in the late 1990's. Based on his early research, Dr. Coffey surmised that the reovirus, from which REOLYSIN is derived, would replicate in cancer cells and create cell death and he was ultimately successful with proving his theory in mouse models. With some advice from friends and family, Dr. Coffey had the foresight to apply for a patent, and he ultimately started a private company in an effort to fund the patent application. That private company ultimately became Oncolytics Biotech and REOLYSIN now has the potential to treat metastatic breast cancer.**CEOCFO: Before we discuss REOLYSIN, it seems to be the only product in your pipeline. Is that a deliberate strategy and will that be the same going forward?****Mr. Look:** The company was founded on the one product, but REOLYSIN has been studied in many different cancer indications. We became a company with a single product, but we have tested it now in more than 10 different indications and in combination with over six different approved cancer therapies. While we are currently a single product company, we have a multi-indication pipeline and a product that that could potentially impact many different indications and hundreds of thousands of cancer patients. Looking forward we are likely to stay focused on REOLYSIN in the near term. With the advent of immunotherapies, including the immune checkpoint inhibitors and the targeted therapies such as IMiDS, future development opportunities for REOLYSIN alone are not at all limiting.

CEOCFO: *There are so many different approaches to treating cancer today. Where did the idea for using a virus come from and why has it shown success in killing cancer cells? Is it that the virus actually kills the cancer cell or activates the immune system to do so, as in an immunotherapy?*

Mr. Look: The idea came out of the work that Dr. Coffey did when he hypothesized that the reovirus' mechanism of action was lytic, meaning that it can replicate in cancer cells and kill them. What we've realized over the last several years is that the virus has a two-stage mechanism of action. While it does have lytic activity that kills the cell, this is a necessary first step that creates an immune response. An innate immune response that up regulates NK, or natural killer cells, that in turn creates an adaptive response wherein the body's immune system learns to fight on its own. We believe that the patient's immune system recognizes the virus and the body's natural killer cells attack in an effort to rid the body of the infection, and that this innate response leads to the maturation of the body's T-cells, which then teaches the body to recognize the tumor as being part of the viral infection, leading to what appears to be a better overall survival outcome.

CEOCFO: *One of the main problems with some cancers is getting the immune system to respond to them.*

Mr. Look: The virus is very eloquent because it is naturally recurring and it is quite benign. The long-term success is coming from the situation where the virus is able to replicate in cancer cells, waking the immune system to recognize that the tumor is an infection. This causes the immune system to respond the way it should and starts to rid the body of the infection.

"We have the first virus to show statistically significant survival benefits in metastatic breast cancer and we believe that this market is over 150,000 patients every year in the US alone. That's a lot of lives we can impact. From a financial perspective, when pricing at conservative levels of a branded cytotoxic drug, that makes this a multi-billion dollar opportunity in breast cancer alone, for just this one region." - Kirk Look, CA, CFO

CEOCFO: *What are the cancer targets for REOLYSIN? Why were they selected and what advantage does REOLYSIN offer in treatment?*

Mr. Look: We started off with what we like to describe as a "basket" concept, where we tried it in many different cancer indications, as we tried it in lung, colorectal, breast, pancreatic cancer and ovarian, brain and prostate. In addition, we treated with different combinations, such as with taxane, paclitaxel, radiation, and most recently with KEYTRUDA®, a check point inhibitor and Revlimid® and Imnovid®, which are immunomodulatory drugs, or IMiD's. Through these clinical studies and the resulting clinical data, we have seen some significant survival data coming out of the breast cancer study, which is where we decided to move forward and focus our efforts at this time. We have also seen some interesting early stage results with immune checkpoint inhibitors and we are looking to move forward with that in the near future. Then we have seen some anecdotal responses; not statistically significant, but meaningful results coming out of colorectal, as well as some elements of the lung studies and the pancreatic cancer studies that we have run that will also refine our studies.

CEOCFO: *At this point are you looking at this as an adjuvant or a stand alone?*

Mr. Look: We definitely see it as a treatment that needs to work in combination with something. What the virus requires is some kind of stressor event in order to fully replicate, but also to better penetrate the tumor. Then we also believe that what the virus does on the immune side of things can really help impact what some of these immunotherapies are doing and what they are seeing. Then possibly expand their reach into the indications they are successful in to broaden the patient base, or possibly expand into indications that right now do not seem to work for the immunotherapies, because a patient's tumor is considered immunologically cold, so we can turn the tumor environment immunologically hot and therefore lending itself to better results for these other immunotherapies.

CEOCFO: *Would you tell us about the safety profile for REOLYSIN and are there any potential side effects that might affect your progress with the therapy?*

Mr. Look: Our safety profile is quite benign. We have treated over 1,000 patients to date, primarily intravenously and what we have found is the side effect profile frankly mimics a viral infection. That would include flu like symptoms such as a fever. What is interesting about the side effect profile is that it does not change the toxicity profile that the patients realize on treatment. What that means is that the addition of REOLYSIN does not negatively affect the toxicity profile of chemotherapy or other immunotherapy treatments. We are showing that we can impact survival and in the same breath we are not forcing the patients to pay a toxicology penalty by the addition of the virus, so it appears to be quite benign.

CEOCFO: *Would you tell us about the delivery system for REOLYSIN? Is it proprietary and is it necessary for the successful treatment of cancer?*

Mr. Look: Our delivery is actually quite simple. We are able to treat patients intravenously, so the administration is typically done in conjunction with the other drug that we are working with. REOLYSIN is not modified, it is not pathogenic, it is treated like a BSL2 (Bio Safety Level 2), which is similar to a blood product in the clinic, so there is no special

handling required and there is no need to bleach hoods or use negative pressure rooms to use the virus. Therefore, it makes it quite easy from a delivery standpoint.

CEOCFO: *Oncolytics announced first patient treated in MUK eleven study and a successful end-of-Phase 2 meeting with the FDA for REOLYSIN in metastatic breast cancer. Where are you in clinical trials and could you share some of your results?*

Mr. Look: We are really focused in two areas right now. First and foremost, metastatic breast cancer. More specifically, HR+/HER2- metastatic breast cancer, which represents over 70% of metastatic breast cancer patients. We presented statistically significant metastatic breast cancer results from our randomized phase 2 study, IND213, which was run by the Canadian Cancer Trials Group (CCTG), in early in 2017. When looking at the overall population of the study, or the intention to treat group, we increased median overall survival from 10.4 months in the control arm (paclitaxel, the current standard of care) to 17.4 months in the test arm (paclitaxel plus REOLYSIN). We then ran subset analysis in conjunction with CCTG and our statistical group Cytel out of Harvard which demonstrated an almost doubling of overall survival in patients with HR+/HER2- metastatic breast cancer. In that group, the control arm had median overall survival of 10.8 months and the test arm was almost 21 months, so we were almost doubling survival in that group. What is interesting about this group of patients is that they do not have access to immunotherapies, as nothing has shown to work in that area. We are looking at a patient population where REOLYSIN could be the first immunotherapy to extend overall survival to this group of patients with metastatic breast cancer. The hope is to provide them with a meaningful survival improvement. We have tied our clinical focus to our mechanism of action, so we talked about the lysis and we have talked about the innate and adaptive immune responses. We are going to take advantage of the breast data and we are currently designing and obtaining key regulatory approvals and achieving regulatory milestones to commence a global phase 3 registration study in metastatic breast cancer that will focus on HR+/HER2- patients with the goal of initiating enrollment in Q3 2018. Our goal is to replicate the phase 2 data and ultimately obtain an approval. We were able to leverage this data to obtain fast-track designation from the FDA back in May and we received favorable advice from them in our end of phase 2 meeting. Our next step is to gain favorable feedback from the European Medicines Agency (EMA) and then file for a Special Protocol Assessment, or SPA and expect to have clarity on that in the first or second quarter of 2018. The other element and near-term focus is the Celgene collaboration, and that takes advantage of that innate immune response. What we find interesting is that Celgene is combining REOLYSIN with their products Revlimid and Imnovid in order to take advantage of the ability of REOLYSIN to attract NK or natural killer cells to the tumor micro environment, which is what Revlimid requires to work. In this study, as patient's response to Revlimid starts to level off, Celgene is adding REOLYSIN to these patients to see if NK cells are attracted to the micro tumor environment, and pick-up the response again. Ultimately, they are looking to extend Revlimid sales by using REOLYSIN. Finally, we are looking to enter into collaborations around immune checkpoint inhibitors with Large Pharma and are considering a variety of indications and basket study concepts, but this is very much a future development once our phase 3 study is up and running in 2018.

CEOCFO: *Would you tell us about your licensing agreement with Adlai Nortye? How did that agreement come about and what does it accomplish for you?*

Mr. Look: Adlai Nortye is a Chinese biotech company and we are really excited about this licensing agreement, which is one of our more significant transactions entered into in Oncolytics' history. It is an \$86.6 million licensing agreement that allows Adlai to develop and commercialize REOLYSIN in China, Hong Kong, Macaw, Singapore, Taiwan and South Korea. In return we receive upfront licensing and milestone payments along with potentially a double-digit royalty if they are successful and obtain approval in these regions. What is significant for us is that we were able to connect \$21.2 million of these payments to actions and activities that are under our control and we have connected them to our phase 3 metastatic breast cancer program. Therefore, we feel confident that we can realize a great deal of these milestones. In addition, Adlai was interested in becoming a strategic investor in our company and is prepared to invest in Oncolytics at a premium to market as we progress through our global metastatic breast cancer trial. For us, it is an excellent opportunity to develop a group of countries that are unique and really are not a part of our internal skill set. We have been able to enter into this transaction, take advantage of their skill sets and in doing so have expanded REOLYSIN into a potential global product.

CEOCFO: *Where is Oncolytics today with regard to funding to move your programs forward? Are you looking for investors or partners to continue your growth?*

Mr. Look: With the recent Adlai deal, we have been able to reduce our funding needs for the phase 3 study. However, we do continue to look for other partners and investors. Our objective on the business development side is to look for similar licensing opportunities in Japan and Europe. We believe this can be a significant source of non-dilutive funding, while keeping North America open for future co-development opportunities. Japan and Europe are similar to China for us in that they are very specialized markets that require a strong partner to properly develop. As for investors, we are looking to

gain access to the US capital markets, and we hope to attract strong fundamentally US based investors by delivering on our corporate goals and objectives, while we look to relist on the Nasdaq.

CEOCFO: *Is there a great emphasis on attending conferences and investor forums?*

Mr. Look: Absolutely! We use scientific conferences to help us validate our technology, where the science is presented in front of our peers and it gets analyzed and queried, questioned and challenged, so that is important to us. Then on the IR side the conferences and forums are extremely important because we do want to reach out to as many investors as we can and cast a wide net. We want to talk to as many groups as we can, create relationships with as many groups as we can and create enthusiasm and excitement around REOLYSIN and the opportunities ahead for Oncolytics.

CEOCFO: *There are other biotech's developing viruses to treat cancer. What sets REOLYSIN apart?*

Mr. Look: Aside from being the only late stage intravenously (IV) delivered virus with randomized survival data, which is very strategically important, the other things setting us apart from other viruses being developed to treat cancer is that REOLYSIN is not genetically modified and is a non-GMO virus. This is very important, as we do not need special handling in the clinic and it lends itself to being manufactured quite easily at scale. Whereas a lot of our competitors' viruses tend to be genetically modified in some way, and as a result of that they become less stable as a virus, which makes it more difficult to manufacture and tends to require special handling in the clinic. Our competitors must administer their drug intratumorally, but are trying to get into IV systemic administration with mixed success. However, no one has been as successful at that kind of delivery as Oncolytics. Most importantly, from a patient's and clinician's perspective, we are the only ones who have shown a survival benefit. Everyone else's clinical success has been centered around a proxy to survival, so progression free survival or around a response rate, but to date that is not equated to a survival impact, whereas we believe the breast cancer data shows that REOLYSIN does impact survival.

CEOCFO: *In closing, why should potential partners and/or investors consider Oncolytics? Why is Oncolytics a special company?*

Mr. Look: First and foremost, we have the first virus to show statistically significant survival benefits in metastatic breast cancer and we believe that this market is over 150,000 patients every year in the US alone. That's a lot of lives we can impact. From a financial perspective, when pricing at conservative levels of a branded cytotoxic drug, that makes this a multi-billion dollar opportunity in breast cancer alone, for just this one region. REOLYSIN is safe, there is no toxicology penalty when it is included in current therapy, which is critically important. We can deliver REOLYSIN systemically through IV, where our competitors are trying to move into the IV delivery realm, but tend to be limited to intratumoral injections. We can already manufacture REOLYSIN at a commercial scale and it is very similar to vaccine productions, so it is done very inexpensively. In fact, the vialling of REOLYSIN costs more than the drug itself. We have patent protection, we have composition of matter that we believe can be extended to 2033 to allow us ample opportunity to move forward, gain approval and get into the market. There is extensive opportunity at Oncolytics.

