**WSA:** Good day from Wall Street. This is Juan Costello, senior analyst with the Wall Street Analyzer. Joining us today is Dr. Bill Williams, president and CEO for BriaCell Therapeutics. The company trades on the TSX Venture, ticker symbol is BCC, and on the OTCQB, ticker BCTXF. Thanks for joining us today there, Dr. Williams, Bill.

**Dr. Bill Williams:** Thanks so much for having me.

**Juan Costello:** So starting off, please give us a history and overview there about BriaCell.

**Dr. Bill Williams:** Sure. Well, BriaCell was founded by a gentleman by the name of Chuck Wiseman. And Chuck has been in the cancer vaccine area for his entire career. He himself has treated over 250 patients with cancer vaccines that he's developed largely out of Saint Vincent Medical center in California, but before then, he was at MD Anderson. Chuck has developed BriaVax™, which is a breast cancer cell line that he derived from a patient with very aggressive metastatic breast cancer.

He used this cell line initially by itself, after radiation so it would not replicate, to vaccinate 14 patients who had breast cancer. And they did quite well. In fact, even though the study was done more than 10 years ago, one of those patients is still alive today. The median survival rate was about a year--half a year better than you'd expect in this population. But Chuck still wasn't satisfied with that level of efficacy that he got from this first generation vaccine. So he took the cell line and he transected it with a gene for a cytokine called GM-CSF.

GM-CSF is a very potent stimulator of immune responses especially in dendritic cells, which are the key cells for stimulating the immune response. And he took this engineered vaccine again using irradiation, and used in combination also with a pre-treatment with very low dose Cytoxan, which helps to get rid of suppressor T cells and then post-treatment with alpha interferon to boost the immune response, giving this locally into the side of inoculation.

So he used this regimen to treat four additional patients, and they all did quite well. Their median survival was close to three years. And one of them in particular, had a remarkable response with over 90% regression in the cancer. And then according to the protocol after five months or so of treatment, she had to come off study and the cancer recurred. She was treated again and she responded again. In fact, she went into pretty much a complete remission of brain metastases. So this was really quite a remarkable observation.

But, unfortunately, Chuck's funding dried up and he was unable to secure any funding to further develop BriaVax™ or BriaCell until a couple of years ago in 2014. He connected with a few people who understood the financial side of things in terms of raising money for a company. So along with Saeid Babaei, who's our chairman of the board, they engineered a reverse merger into a Canadian mining shell which had some money. He has done a couple of rounds of small financing since then to basically get things out of the deep freeze, get them manufactured and get us back into the clinic, which leads us to where we are today. We are on the verge of treating some patients again right now.

**WSA:** All right, so that brings us to the FDA clearance for the initiation for your Phase I trail, can you talk about BriVax.

**Dr. Bill Williams:** Sure, absolutely. So Chuck had things in the deep freezer for quite a while and it took awhile to get the cells out and then to find a GMP manufacturer who would be able to grow the vaccine up under the proper conditions and then generate enough so that we can start to treat patients again. This was done in collaboration with the GMP facility at University of California Davis under Gerhard Bauer, and they've done a very nice job in growing and characterizing BriaVax™.

So towards the end of last year, we took what Gerhard had grown and subjected it to a series of very stringent test, looking for any evidence of infectious agents, making sure that the vaccine was potent and that it secreted the GM-CSF that it needed to. And it passed all of those tests with flying colors. So all of this information was submitted to the FDA in January, and after the 30-day clock tick down, we knew that they were okay with us continuing to dose or starting to dose patients again with BriaVax™. And this was after also some communication back and forth with the FDA. So we are cleared now to start dosing yet again.

**WSA:** Great. And, so what are some of the key trends that you're seeing right now in the breast cancer space and how are you positioning the company to capitalize?

**Dr. Bill Williams:** So, I think that there's a lot of interest in immunotherapy. I mean, it's really remarkable what strides are being made with Opdivo and Keytruda and other immunotherapies like that, but they work in the generalized manner where they basically pretty much take the brakes off the immune system in general. And so it tends to be kind of, like, carpet-bombing when you're going after a cancer because there can be some collateral damage, there can be autoimmune disease. I think the vaccine approach is much more targeted. There are several different approaches to breast cancer vaccines right now.

There is peptide vaccine of HER2, there's whole protein HER2 vaccine and there are some viral vectors and some carbohydrate antigens that are being looked at. And these have shown some interesting results in terms of inducing immune responses. But we really haven't seen the kind of clinical responses we would like to see. The approach that Chuck took, the so-called GVAX approach,h has shown some promise in breast cancer. There's been one study of 20 patients where at six months, 55% derived clinical benefit, and that was 40% at one year.

So there was some benefit there but there was really only one patient with this other cell line, the SK-BR-3 cell line that was used, that actually had shrinkage of their tumor large enough to call it a partial response. Now, we've got one out of four who responded and it was pretty much a complete remission. And we think that we know the reason for that now, and that speaks to another bit of news we had recently. We had a patent submission for what we're calling BriaDx™ or the diagnostic arm of BriaCell. The way BriaDx™ works is that we try to identify patients up front who are the most likely to respond to BriaVax™.

And this is based on extremely interesting observation made by Markus Lacher, our head of R&D. Marcus is a brilliant scientist in his own right, having founded T cell therapeutics and been

involved with multiple other biotech companies over the years. Markus had the very good idea of looking at what's called the HLA type of the patients who were treated with BriaVax™ and the HLA type of BriaVax™ as well. So HLA typing is used – it should be very familiar to people because it's used for things like kidney transplants where you have to match the HLA type of the patient with the transplant; otherwise, they'll reject it.

And that's because this HLA molecules were at the very beginning of any immune response. The way they work is that– let's say you have a virus, the virus comes into a so-called antigen-presenting cells and they'll chew that virus up. The proteins of the virus get chewed up into short little pieces called peptides. And those peptides actually bind directly to these HLA molecules just like a hotdog sitting into a hotdog bun. And then that hotdog in the bun kind of goes on the surface of the antigen-presenting cell where it's recognized by T cells who have very specific T cell receptors that, you know, may or may not recognize that particular peptide antigen in the HLA molecule. And if it does recognize it, then, that T cell starts to grow and proliferate and be activated and secretes all these cytokines that basically kick-start the immune response. So –

**WSA:** Bill, we call that ketchup?

**Dr. Bill Williams:** Yes. Yes, right. That's right. You know, a little spicy mustard there too if you got a good immune response to really spice things up, but absolutely. So what Markus observed is that the patients who responded so well to BriaVax™ matched the HLA type at two different HLA loci with the BriaVax™ and – whereas the other patients matched with only one and one of them didn't match at all. So the hypothesis is that BriaVax™ itself is acting as an antigen-presenting cell stimulating the T cells of the immune system to kick-start an immune response against the cancerous cells. So we think that this is a really interesting observation and we really want to, now, as we get back into the clinic and confirm the observation and then try to extend it as best as we can.

**WSA:** Great. What are some of the factors that you feel make the company unique from some of the other players in the sector?

**Dr. Bill Williams:** So I think that there's a couple of things. One is our unique mechanism of action, which I was just discussing and the fact that we hope to have a companion diagnostic if we can confirm our early results. But I think the other thing that really makes us standout from other companies who are in this field is that we're starting with something that works clinically already. And we're really trying to just figure out how to get it to work best and how to target the patients optimally. It's a little bit different than other approaches where there may be good, you know, animal model data, for example, that looks promising. But as we all know, in the oncology field today, it's really easy to cure mice of cancer, not so easy for people. And so the fact that we're starting with something that's already had, at least one very remarkable clinical success, I think really increases our odds of success greatly compared to approaches where there's only animal data or in vitro data to support the study.

**WSA:** And what are the main goals and milestones moving forward over the next six to 12 months that you're hoping to accomplish?

**Dr. Bill Williams:** Right. Well, at this point, we are open again to recruiting. We have one clinical site open and we'll be opening a couple more in the coming months. We want to recruit nine patients. Our goal is to have nine in by the end of September so that we can get an initial take on the safety and a little bit of efficacy with BriaVax™ in-patients with recurrent invasive or metastatic breast cancer. And we are targeting the end of September because our first radiologic assessment is three to four months after the initial vaccination starts.

So we're hoping to have data on our first nine patients by the end of this year or certainly by the first quarter of 2018. The other key thing that we're going to be doing over the next few months is, along with our current protocol, which uses the BriaVax™ with the regimen I described earlier with pre-dose cyclophosphamide and then post-dose local alpha interferon injections, we're going to be developing a rollover protocol. Now, my background is that I came here from Incyte Corporation and was very involved in the development of ruxolitinib and baricitinib, and also, epacadostat. Epacadostat is an immunotherapy that's been developed by Incyte with very promising results.

In fact, Incyte's valuation, which is pretty big company right now, is probably 20% or maybe even 30% driven from epacadostat projections. Epacadostat is an immune checkpoint inhibitor. It did not work as monotherapy but when combined with either a Yervoy or with Keytruda, it markedly boosted response rates to those therapies. So with my background and that kind of information, knowing that we have something that already works is a monotherapy, the potential for combination therapy with one of the checkpoint inhibitors seems to be tremendous.

So, for the benefit of the patients, we're going to be developing a rollover protocol so that patients who don't respond to BriaVax™ monotherapy will be eligible to get combination therapy with a checkpoint inhibitor. And we've been talking to some of the different large pharma companies to establish some sort of collaboration. In fact, this discussion is still ongoing. So, while we don't have a partner for clinical development picked out yet, we still are going to go ahead with this one way or the other because, of course, Yervoy and Opdivo with Keytruda were all available commercially now. So one way or another, we are going to afford our patients this opportunity to have combination therapy with the checkpoint inhibitor.

**WSA:** Sure. So, perhaps you can walk us through your background experience, Dr. Williams, as well as the other key management team.

**Dr. Bill Williams:** Sure. So my background, as I mentioned, I come from Incyte Corporation to BriaCell. I was there for 11 years as the head of Exploratory Development. I took multiple molecules into the clinic and saw them through some of them post registration, proof of concept studies in numerous different indications. Before that, I was at GlaxoSmithKline where I started in clinical pharmacology. I then eventually became vice-president in clinical pharmacology and experimental medicine, ran the experimental medicine group in the U.S. for some time and also worked on a number of different molecules that got into the post-approval phase and I also worked with some people on lapatinib.

I worked on Bexxar, which is a lymphoma treatment. I worked on ibandronate and many others. Before that, I was at University of Pennsylvania. My clinical training is rheumatology and

immunology. I performed bench research on molecular immunology at the University of Pennsylvania in the rheumatology division there. So that's pretty much my background. Now, I already mentioned Chuck Wiseman, who's our scientific founder. I also mentioned Markus Lacher who's our head of R&D. Markus is really one of the key people in the company whose insights have given rise to BriaDx™ and we're going to continue with that. Markus is a brilliant scientist. He's been in biotech for 20 years and has been in several different biotech companies including starting T cell sciences by himself.

We also have our Chairman of the Board, Saeid Babaei who has been the CEO of several different biotech companies which have been very successful. And he's based up in Toronto. Rahoul Sharan is another board member who is based up in Vancouver where our corporate headquarters is. And he has many, many years of financing startup company experience.

And then a good friend of mine, Martin Schmieg, who's been in biotech for 35 years, he's been CEO and CFO of multiple companies including siRNA therapeutics and engineered their sale to Merck for 1.3 billion. So we have some really good talent in the company and we're going to use that talent to develop BriaVax™ and push it forward.

**WSA:** Certainly. And, so, as far as investors in the financial community are concerned, what are some of your key drivers that you wish perhaps they better understood about the company?

**Dr. Bill Williams:** In terms of the key drivers for value, I think it really is tied up in the BriaVax™ right now, which has, I think, tremendous promise to deliver clinical benefit to patients with breast cancer. We've looked at what the market size would be for BriaVax™ and we can see that there's close to 3 million patients with breast cancer just in the U.S. And if you do the math and figure out how many have metastatic breast cancer, it's close to 500,000.

And then if you look at those and see which have progressed the second line, which is where we are with our development, then that's closed to 100,000. And if you then assume that BriaDx™ works and that we can predict which patients are the most likely to respond and by doing this HLA typing, for example, and you need to double match like our excellent responder had, that's about 20,000 patients. So, if we do as well as I think we will, I think we'll probably get very good penetration into that patient population.

But even assuming we only have 25% penetration, that's still gives us about 5,000 patients per year to treat. And with very conservative estimates that we only have six months of treatment and then charge prices comparable to the other recently approved immunotherapies, our revenue stream even from this most conservative scenario is about a quarter of a billion dollars per year. If we are able to expand that by either moving into first line or by combining with immunotherapies and broadening our patient-base which would go up three-fold we estimate, then it's really easily a billion dollar a year drug by itself.

At the same time, we are going to be further developing BriaVax™ and coming up with third and fourth generations of BriaVax™, that will allow us to treat more patients by putting in different HLA molecules and allowing further use of the vaccine in more patients. So I think there's a lot of positive drivers, but I really think the main driver is the experience of the team right now, the

good expertise that we have and the fact that we are very, very committed to doing something good for these people who are suffering with metastatic breast cancer.

**WSA:** Well, great. And, so, once again, joining us today is Dr. Bill Williams, president and CEO for BriaCell Therapeutics which trades on the TSX Venture, ticker symbol, BCT, and on OTCQB, ticker symbol: BCTXF. Currently trading at 15 cents a share U.S., market cap is about 10 million U.S. And before we conclude here, Dr. Williams, to recap some of your key points. Why do you believe investors should consider the company as a good investment opportunity today?

**Dr. Bill Williams:** I think this derives from the science and the clinical information that we have to date. The fact that we are back in the clinic now after, you know, Chuck was unable to get funding for so many years, but we are back in the clinic now. We have a very skilled team with a lot of expertise both on the scientific medical clinical development and financial side. And we are poised to deliver significant value in the relatively short term as we start to get patients into our study and start to get what we hope will be some very positive data.

Well, of course, you have to always make the disclaimer. You never know what's going to happen in clinical development. But certainly, we have a reason to be optimistic that BriaVax™ will deliver on its promise for patients with late stage breast cancer.

**WSA:** Well, we certainly look forward and continue to track the company's growth and report on your upcoming progress. And we'd like to thank you for taking the time to join us today, Dr. Williams, and update our investor audience on BriaCell. It's always great having you guys on.

**Dr. Bill Williams:** Well, it's been a pleasure speaking with you and thanks so much for having us.