

Immunotherapy Vaccine Proscavax in Phase 2/3 Clinical Studies Offering Hope in the Area of Prostate Cancer



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CEOCFO: *Mr. Kucharchuk, OncBioMune Pharma specializes in innovative cancer research. What is your approach?*

Mr. Kucharchuk: First of all, we started out in immunotherapy, which is kind of a new hot button item. We have been developing immunotherapy drugs since early 2000s. Now we are taking a broader approach by our planned acquisition of Vitel Laboratorios, S.A. de C.V. (“Vitel”) from Mexico City where we are in-licensing more drugs hoping to build a robust portfolio to attack cancer and other diseases.

CEOCFO: *Was it a deliberate decision to acquire or was it more opportunistic?*

Mr. Kucharchuk: It was a funny story. Our Chairman and CEO, Dr. Jonathan Head, Ph.D. ended up sitting next to the CEO of Vitel on a plane ride. As they spoke, they realized the possible synergies and decided to do more business together. So, I guess it was opportunistic, while keeping in mind that acquisitions were always part of our long term strategy.

CEOCFO: *Would you tell us what you are working on now?*

Mr. Kucharchuk: Our lead product now is Proscavax, a therapeutic prostate cancer vaccine. We are going into two Phase 2 studies. One will be at a prominent northeastern university cancer center. The other will be a Phase 2/3 in Mexico City with Vitel. In addition to that, with the merger we are working on several other in-license pieces of IP which are already revenue generating to help us minimize the money we will need to raise on Wall Street. We want to be revenue producing and not out to go take out any type of toxic financing.

CEOCFO: *What types of products are you evaluating?*

Mr. Kucharchuk: We are looking at anything from cancer to diarrhea.

CEOCFO: *What makes a product that you want to license in for revenue?*

Mr. Kucharchuk: We are open to many possibilities for near-term revenue products, but ideally will stay in the immunotherapy space as our primary focus of drug development. We prefer therapeutic vaccines that boost the immune system to fight any given particular disease without being totally individualized, which provides for much easier and less costly manufacturing.

CEOCFO: *Are there readily available products to do that today?*

Mr. Kucharchuk: Oh absolutely. We have talked to several companies and through our planned merger with Vitel we have in-licensed several drugs in Mexico and we are talking about many more. The reason for that is big pharma has kind of written off many newer products because if you do not produce at a west coast or northeast university, they seem to go overlooked or can be viewed as lacking value. So there are many products that are made by Middle America companies that are looking for help financially and also with knowledge of the FDA process. There are a lot of willing participants in our model.

CEOCFO: *How do you gain attention for newer products?*

Mr. Kucharchuk: We use our investor relations and put out press releases and there is a type of multimedia advertising. That is pretty much it. We have to wait for the results to come out and then make a big PR push.

CEOCFO: *What have you learned so far about Proscavax?*

Mr. Kucharchuk: We know two very key things. One, it's non-toxic with a strong safety profile and, two, it works. Most recently we learned that it seems to work in all stages of prostate cancer, which is paramount because there are no safe options for early-stage patients. We are excited to have it being evaluated as a treatment for relapsed/refractory patients in the Mexico trial and for the U.S. trial to be evaluating it as a front-line treatment. We know it will teach the immune system to keep fighting disease. With so many cancers, they say you are "cured" after you do your chemo, but they come back after remission so we are very optimistic that Proscavax will provide a meaningful clinical benefit across the therapeutic spectrum.

CEOCFO: *What is the competition in the prostate arena?*

Mr. Kucharchuk: They have some immunotherapies but we are pretty much the farthest along. There is a drug called Provenge, which is on the market, but it is a logistical nightmare. They have to take your T-cells, FedEx it to a location, then FedEx your individualized vaccine back. Where we benefit and where we are a game changer in this is ours is an off-the-shelf vaccine. We can mass produce it while some of these other immunotherapies are autologous and completely individualized, but ours works for all patients.

CEOCFO: *Do you see more attention being paid away from the personal and more towards something that can work for many people?*

Mr. Kucharchuk: Yes and no. The major players want something that will treat everybody because they know it is cost effective. If you hit the right cascade on somebody, you will cure them individually. I think for the economics of it, they are pushing towards something that is mass

producible but for the humanitarian, the individualized therapies will always be there, but they are just very costly.

CEOCFO: *Would you tell us more about how you are integrating the acquisition?*

Mr. Kucharchuk: It definitely will change because we will go from a clinical stage biotech to a revenue producing clinical stage biotech. Vitel already has a sales force and all the infrastructure in Mexico, but we will have to bring on more capital to help run and scale. I am an MBA, but I do not have international accounting skills, so we will have to bring on some controllers and integrate our computer systems for transparency and accuracy to keep up with our SEC filings. That will be one hurdle, but it is very invigorating because we positioned on the cusp of becoming an international biotech. With that comes access to capital and more strategic partnership opportunities, as well as the ability to go after larger pharmaceuticals that are coming off of patent and larger companies that are trying to divest those assets.

CEOCFO: *Is there any concern about the current administration and Mexico or is that not applicable?*

Mr. Kucharchuk: There is always concern when an administration comes in or when an administration leaves. Since ours is unique to Mexico and we are worried about Mexican imports, I do not know if they will have problems with us exporting product to Mexico and importing revenues back so we will see what happens.

CEOCFO: *Is the medical community paying attention to what you are doing?*

Mr. Kucharchuk: I believe so. We have presented at many scientific conferences and are regularly approached by certain media outlets to provide updates on progress with Proscavax. We also are seeing more interest from the investment community than ever before. The two communities kind of fuel each other. I have been here for ten years and I have raised every dollar we raised for this company. We are not getting the door slammed in our face anymore. Institutional investors are letting us in and talking to us and telling us what we are doing right and wrong as a relatively new public company. We have hit Wall Street and done these big meetings and each year more and more people want to meet with us. Being from Baton Rouge, Louisiana and not a major institution or a biotech hub like Boston presented challenges because people didn't know who we were a few years ago. As the story progresses and each time we go up to Wall Street, we meet with more and more people, making it certainly feel like the momentum is building for our company.

CEOCFO: *What is in the pipeline?*

Mr. Kucharchuk: After we get Proscavax off into its Phase 2/3 in Mexico and Phase 2 at the northeastern institution, we are going to go to OvcaVa, which is an ovarian cancer vaccine that is built upon our platform technology just like Proscavax is for prostate cancer. The beauty of our platform is that we can just insert a different antigen specific for a particular cancer and our adjuvant should work of pretty much all solid tumors; at least that's our contention at this moment with some clinical and laboratory evidence supporting it.

CEOCFO: *How do you decide?*

Mr. Kucharchuk: We are looking at unmet markets right now. For example, we can go and do a breast cancer therapy, but for that

indication it is really based on competition and the market landscape. There are already so many established drugs for breast cancer that it is hard to break in and we see other areas of greater unmet medical need. Our model involves drug development for diseases, such as ovarian, prostate or pancreatic cancer where today's drugs are relatively ineffective or patients have to deal with horrible side effects, where we hope that we could start helping people right away. Our decisions are underscored by our goal to be successful and build corporate value by leaving behind a legacy of helping people that didn't have many options before our treatments were developed.

CEOCFO: *Why pay attention to OncBioMune Pharmaceuticals?*

Mr. Kucharchuk: I think that we are a great growth story and opportunity for a value investor. We aren't exactly reinventing the wheel here, but we are taking a path less traveled compared to peers. As we develop our novel prostate cancer treatment in two mid-stage trials, we are acquiring a revenue-generating company that, based upon preliminary sales figures, could lead to millions of dollars in cash flow, which minimizes shareholders' risk of dilution. The fact is that Proscavax right now has the potential to one day treat some 200,000 new prostate cancer patients annually. It can be used as a stand-alone therapy or in combination with other drugs at any stage of disease. No other drug can do that for prostate cancer. Obviously, that is a tremendous competitive edge for us should Proscavax make it through the approval stage. Through an abbreviated approval process in Mexico, Proscavax could be commercialized in about two years should the clinical trial there meet its endpoints. Plus, with the Vitel acquisition, we will have pipeline assets for years to come. Obviously I am biased, but I don't know of another biotech our size that offers so much near-term potential. I'm very proud of what we're building at OncBioMune.

