CEO CFO

IMMUNE DESIGN

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Employing Advanced, Leading Edge Methods to Precisely Control the Activation and Context of Antigen by Dendritic Cells to Shape the Desired Adaptive Immune Response, Immune Design Corp is moving forward the Field of Therapeutic Vaccines for Infectious and Malignant Disease

Biotechnology
Vaccines
(Private)

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Dr. Carlos Paya, M.D., Ph.D.
President and CEO

BIO:
Carlos Paya joined Immune Design Corp in May 2011 as President and Chief Executive Officer. He previously served as President of Elan Corporation and led the biotechnology company's commercial, marketing, clinical, research and development teams from 2008 to 2011. Before joining Elan, Dr. Paya was at Eli Lilly & Company as Vice President, Lilly Research Laboratories where he led various therapeutic areas encompassing discovery, clinical development, and the Diabetes and Endocrine franchise. Prior to this, Dr. Paya was Professor of Medicine, Immunology, and Pathology, and Vice Dean of the Clinical Investigation Program at the Mayo Clinic in Rochester, Minnesota. He received his MD and PhD degrees from the University of Madrid and underwent postdoctoral training at the Institute Pasteur, Paris, France.

Company Profile:
Immune Design Corp (IDC) is a privately held biotechnology company based in Seattle, Washington and formed in 2008 to bring together some of the world's leaders in the field of molecular immunology to develop therapeutic vaccines for the treatment of infectious and malignant disease. The company employs advanced and leading edge methods to precisely control the activation and context of antigen presentation by dendritic cells in order to shape the desired adaptive immune response. This goal is accomplished through the application of two proprietary technology platforms that activate the immune system by distinct mechanisms.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Dr. Paya, I know that Immune Design is leading the breakthrough into therapeutic vaccines, what are you doing more specifically?
Dr. Paya: We are taking the immune system of patients that are afflicted with chronic disease, like cancer, and infectious diseases and are upgrading and enhancing it using novel technologies so that the patient can fight off the cancer or chronic infectious disease with their own immune system without requiring any specific drug.

CEOCFO: What are the technology and the concept that you have chosen?

Dr. Paya: The technology we have are tools whereby we activate immune cells that are already present in the patient but by themselves are weak and cannot effectively clear the cancer or infectious disease process. By activating them in a very selective way, we are trying to make those cells more efficient to proliferate and kill the tumor and the infectious disease.

CEOCFO: How are you getting them activated and what would they be doing after activation?
Dr. Paya: For example one of the tools is a very novel vector discovered by Dr. David Baltimore. It is a vector that has the ability to go inside the most important cell in the immune system called the dendritic cell, which is the cell that everyone uses in human or animals to start presenting to the immune system foreign antigens. What happens is that this vector will encode genes of interest that we want the immune system to be aware of. That is one of the reasons why this would be ideal to apply to cancer, where patients have cancer but the immune system is not seeing those tumor cells and by incorporating the antigens that those tumor cells carry within this vector into the dendritic cells, now the immune system of a patient with cancer will hopefully start seeing those tumor cells and the immune system will ultimately control the cancer. That is one of the tools. It is very selective delivery of tumor antigens to dendritic cells in humans.

The other tool a TLR4 agonist, is used when a patient has an immune system that is not effective. This is a molecule that will activate all the den-

dritic cells to then trigger the CD4 T-cell which is the one that ultimately will provide help to the CD8 T-cell, which is in charge of clearing up the viral infection or the cancer. By applying one or the other tool, both of which go through the dendritic cells, we are able to either induce de novo, an immune process, or strengthen an existing but weak immune process. Sometimes a combination of both of them provides a very synergistic effect, which makes the vaccine even more powerful.

CEOCFO: Would it be a different combination for each cancer or would this work across the board?

Dr. Paya: The technology is a platform and therefore it could work across the board. It has the ability to include in that vector a number of antigens. You could envision putting inside the vector a tumor antigen for melanoma and a tumor antigen for lung cancer if they were to be different. You could use the same vector for those types of patients to have one or the other cancer. Sometimes cancers share the same antigen, so if you are clever and you put an antigen that is expressed in a number of tumors, you could apply the initial vaccine to treat a number of tumors, which is what we are trying to do with our first product opportunity.

CEOCFO: Where are you in the development process?

Dr. Paya: For the first technology, which is the vector that targets dendritic cells, we are in the pre IND stage with the goal of going to Phase 1 in the clinic late next year. The other tool that activates the CD4 T-cells, which is a toll receptor TLR-4, is already in the clinic and has been tested in some infectious diseases like influenza.

CEOCFO: How far will your current funding take Immune Design?

Dr. Paya: The current funding takes us for a year and a half.

CEOCFO: Are you doing partnerships, joint ventures or collaborations; what is the strategy?

Dr. Paya: The strategy is to use our second technology to create a pipeline of products with partners. We already have a very good partnership with MedImmune / AstraZeneca, where MedImmune is using our TLR4 Agonist as an adjuvant of vaccines and they have selected three different infectious diseases to make a vaccine. That is an example of what we are doing. We have a second collaboration with another pharma company, called Sanofi, where we are testing the roll of this TLR4 Agonist in the field of allergies. These are ongoing right now. We are having discussions with additional pharma companies who potentially could use the TLR4 Agonist in other vaccines.

CEOCFO: It sounds like there is quite a bit of interest from the medical community.

Dr. Paya: Yes. It is a very hot field. The vaccine world is moving from just making antibodies against a pathogen to trying to come up with more effective vaccines that also trigger a cellular immune response. There is a lot of interest in our technologies, and they could really move forward the field of therapeutic vaccines.

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CEOCFO: You have been CEO for about eighteen months, how has the company grown and changed under your leadership?

Dr. Paya: What attracted me to this company was the technology, as it has the potential to shape the immune system in a way that no one has been able to do before. The world of immunotherapy has been recognized for many years, but no one has really come up with a way to boost the immune system to effectively treat disease (separate from using it to prevent disease via prophylactic vaccines). During the last year, the company has focused solely on a therapeutic vaccine for cancer and one for infectious diseases, has reduced its cash burn through this focus, and has engaged on new collaborations (Sanofi in allergy) and others under discussion. We are now poised to advance to the clinic and demonstrate the uniqueness of these technologies in boosting a powerful, selective and long lasting immune upregulation against the antigens selected.

CEOCFO: Are there any particular challenges you see as you move forward, is it just time to get everything done?

Dr. Paya: I think that separate and in addition to everything that everyone talks about, such as funding, we are a cutting-edge company. As you know cutting-edge can work and not work, so I think it is high risk and high reward. Minimal resources are required to the right clinical studies. The Phase 1 studies that are planned and on the way will really tell us whether these technologies are going to be as powerful as they look in animals. Therefore, that is a challenge. It could be a binary result, whether they work well or they are no different than others. So far so good and we are very excited.

CEOCFO: Why should investors and people in your industry pay attention to Immune Design?

Dr. Paya: The field of cancer immunotherapy is exploding. The recent approvals of drugs like YERVOY is telling us that the immune system can be a wonderful way to treat cancer versus the alternative of chemotherapy. An investor that is looking at getting into the field of cancer immunotherapy, which has experienced twenty-five years of recurring failures, will now see the field is becoming a reality using tools like ours. Therefore, it is going to be an attraction by a large pharma and others that want to get into this field. Secondly, if someone is looking for cutting-edge technology in the field of vaccines in general, not just cancer, but also chronic infectious diseases then we have both of those tools to win in the therapeutic vaccine field. It is not just a drug or an antibody, this could be the next generation vaccines and we are there and people will be open to that.