CEO CFO

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Set on harnessing the immune system to prevent colon cancer recurrence, Vaccinogen now ready to repeat success from its first Phase 3 trial in a second and final Phase 3 clinical trial

Biotechnology
Oncology
(Private)

Dr. Michael G. Hanna, Ph.D.
Chairman & Chief Executive Officer

BIO:
Dr. Hanna is a co-founder of Vaccinogen, Inc., the discoverer and developer of Vaccinogen's lead product OncoVAX®, and a pioneer in the field of cancer vaccines. He also developed and obtained FDA approval for TICE BCG for treatment of carcinoma in situ ("CIS") bladder cancer which remains the standard of care and for prophylaxis of high risk superficial bladder cancer.

Dr. Hanna was director of the National Cancer Institute's, Frederick Cancer Research Center between 1975 and 1983 where he created a center of research excellence and managed over 2,000 technologists. Prior to founding Vaccinogen, Dr. Hanna previously served as Chairman and Chief Scientific Officer of Intracel Resources, an integrated biopharmaceutical company that developed cancer vaccines and immunotherapeutic and diagnostic products for both cancers and infectious diseases. Dr. Hanna also served as President and Chief Executive Officer of PerImmune, Inc. prior to its merger with Intracel in 1998. From 1985 to 1994, he was the Chief Operating Officer of Organon Teknika Biotechnology Research Institute and Senior Vice President of Organon Teknika Corporation, a subsidiary of Akzo Nobel, N.V., The Netherlands.

Dr. Hanna received a doctoral degree in experimental pathology and immunology from the University of Tennessee. He has over 225 publications to his credit, has 10 patents in immunotherapy and has been the recipient of numerous honors.

Company Profile:
Vaccinogen, Inc. is a cancer vaccine company developing OncoVAX®, a patient specific therapy to prevent the recurrence of colon cancer and potentially other solid tumors. Vaccinogen has developed a process that circumvents the extreme diversity of tumor cells by leveraging a patient's own live tumor cells to launch a broad immune response against cancer. OncoVAX has completed five dose and regimen finding clinical studies, including one Phase III trial with the optimum dose and regimen and will begin a pivotal phase III trial under an FDA Special Protocol Assessment (SPA) classification by the end of 2012.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Hanna, what was the vision when you founded the company and where are you today?
Dr. Hanna: It's been four decades since the United States declared a war on cancer yet the life sciences industry is still plagued by mostly unfulfilled hopes. The pharmaceutical industry continues to push *targeted* therapies for cancer despite decades of chemotherapy drugs with limited efficacy and barely tolerable toxicity. This approach has been based on *the false premise that all cancer cells are identical*, or homogeneous, and that a one-size-fits-all strategy could be aimed at a handful of cancer targets. However, there is now indisputable evidence from cancer genome DNA sequencing studies revealing the extreme genetic diversity, or heterogeneity, of cancer cells is far greater than previously imagined. While the pharma industry continues to advocate for more targeted therapies for smaller patient populations, the hundreds and thousands of cancer mutations revealed over the past few years makes this approach impractical. We cannot treat a heterogeneous disease with homogeneous drugs.

My vision for the company is to harness the one evolutionary approach that already exists to address this magnitude of cancer diversity – the immune system. The immune system constantly protects humans from a diverse array of deadly foreign pathogens, viruses and proteins. With the exception of safe drinking water, no other modality, not even antibiotics, has had such a major effect on mortality reduction and population growth.

Vaccinogen is in the final stages of clinical development of OncoVAX®, the first cancer vaccine that both prevents colon cancer recurrence and addresses the diversity of cancer cells. OncoVAX has completed five clinical studies, including one Phase

III trial. Results from this Phase III trial were published in The Lancet and showed OncoVAX cut the risk of recurrence by 61% in patients with Stage II colon cancer. This is significant considering that colon cancer recurrence has been considered mostly incurable.

We are now focused on initiating a second and final Phase III trial that, if successful, will enable us to apply to the FDA for marketing approval. If that goes well, we will have a product with a significant clinical benefit and commercial value.

CEOCFO: What have you discovered that others have not?
Dr. Hanna: There are two key differences with OncoVAX compared to other cancer vaccines, and this is the most interesting part for me as a scientist. The first is that OncoVAX embraces the now recognized and established fact of heterogeneity, or the genetic diversity, of cancer cells within a patient's primary tumor. The second is that OncoVAX is used the way vaccines are intended to be used – as a preventative measure rather than a late stage treatment. I'll explain.

Twenty-five years ago when I was director of the National Cancer Institutes Center in Frederick, Maryland, one of the investigators I worked with described a phenomenon of heterogeneity in tumors. In other words, this investigator described how cancer cells from the same tumor can be vastly different with respect to some characteristics. This was shocking at the time when common thinking in the scientific community believed that cancer was homogeneous. They believed that all breast cancer cells were the same, all lung cancers were the same, and so on. That heterogeneity as described in several papers was of interest but it was not taken very seriously because it was not widely proven and at the time was considered controversial. Consequently, many of the early cancer vaccine programs were based on a false premise of tumor homogeneity, where standard, off the shelf cancer antigens were used to treat patients with very diverse cancer cells. And these programs all failed.

When we were faced with making a decision regarding our cancer vaccine approach, we felt that the safest decision is to assume there is heterogeneity and that we need to work with the patient's own tumor because whatever heterogeneity exists, it would be in the primary tumor and the immune response would respond to all of the various antigenic differences of the patient's own cancer cells.

Over the last three or four years there has been a major improvement in the technology of sequencing the DNA. Because of the improvement in technical capabilities in which sequencing can be completed rapidly and accurately, scientists have rediscovered that tumors are indeed heterogeneous, both within the tumor and between the different tumors. Once that heterogeneity concept was established and validated at the molecular level, our assumption twenty-five years ago suddenly had a great deal of credibility and it was a paradigm shift in the antigen discovery aspect of cancer vaccine development.

Vaccinogen has been in stealth mode over the past few years and is therefore widely unknown. However, we are on the front lines of a recent reinvigoration of cancer vaccines. After decades of trials and tribulations, the first cancer vaccine was finally approved last year, and the next wave of cancer vaccines in development continue to improve upon past approaches. OncoVAX represents a new paradigm for cancer treatment that has a very strong possibility of being successful and it will mean a great deal to the patients who would normally recur after surgery.
- Dr. Michael G. Hanna

The other thing we decided was vaccines do not work well against advanced disease; they work prophylactically to prevent disease. Consider small pox, measles, and polio. We provide vaccines before infection to prevent future infection. However, for cancer vaccines, so many programs were designed to treat late stage disease perhaps too much and too late for an immune response to overcome. In our case with OncoVAX, we worked with patients who have had surgery that got rid of the tumor in the colon. We use that tumor to develop a vaccine regimen of four inoculations to prevent the recurrence of colon cancer.

CEOCFO: What is Vaccinogen doing today?
Dr. Hanna: We are getting ready to begin the pivotal Phase III clinical trial required by the FDA for registration of OncoVAX for the prevention of recurrence of colon cancer following surgical resection of Stage II colon cancer. A special protocol assessment (SPA) has been granted by the FDA, which means that the Agency has accepted our trial design and clinical endpoints. Our key initiatives going forward will be to enroll approximately 600 patients into the trial.

CEOCFO: Has the medical community paid attention or is it still wait and see?
Dr. Hanna: They are paying attention in the sense that the consensus now from a technical point of view is that there is validity in patient specific immunotherapy and our approach of using the primary tumor as the source of the vaccine. There is also a major unmet need for these patients. Surgery is the gold standard for patients with Stage II colon cancer, however up to 30% of patients recur. And once they recur, there is no cure. In addition, OncoVAX works very well with existing clinical practice. Patients with Stage II colon cancer undergo surgery as standard practice. We are using the tumor sample from that procedure to create a vaccine that can be administered within 35 days. Considering the medical need to prevent colon cancer recurrence and the additive nature of OncoVAX to existing clinical practice, we think it will be embraced by the medical community.

CEOCFO: What is the timetable on that?
Dr. Hanna: If we start the pivotal Phase 3 trial this year, we anticipate an interim analysis of data by mid 2015.

CEOCFO: Do you have the trial in place or are you looking for partnerships to get that moving ahead?
Dr. Hanna: We are working on that now and have some partnerships. We are about to appoint our clinical research organization partner to conduct the trial. We hope to be starting to accrue patients by the end of the year. We also have the opportunity to generate near term revenues from licensing agreements for distribution of OncoVAX in certain territories as well as additional cancer indications.

CEOCFO: What else is going on at Vaccinogen?
Dr. Hanna: We have plans to expand this approach to more advanced Stage III colon cancer, combining our product OncoVAX with the standard of care chemotherapy and seeing if we can improve, in this combo approach, the outcome of recurrence-free survival. We are also looking at the possibility of using it in other types of solid cancers such as renal cancer, a recurrent ovarian cancer, and possibly melanoma.

CEOCFO: What is the market opportunity?
Dr. Hanna: It is very large. It is a product which would have wide acceptance because of the lack of competitive treatments. There are about 120,000 patients diagnosed with colon cancer in the United States per year; about 40% of them are Stage II. In Europe there is about 160,000 and 40% of them are Stage II. The opportunity is well over 100,000 patients total between Europe and the United States, which would make for a very large market opportunity in this market alone.

CEOCFO: What is ahead for the company and why should people pay attention now?
Dr. Hanna: Vaccinogen has been in stealth mode over the past few years and is therefore widely unknown. However, we are on the front lines of a recent reinvigoration of cancer vaccines. After decades of trials and tribulations, the first cancer vaccine was finally approved last year, and the next wave of cancer vaccines in development continue to improve upon past approaches. OncoVAX represents a new paradigm for cancer treatment that has a very strong possibility of being successful and it will mean a great deal to the patients who would normally recur after surgery. I think it would have a very strong health economic benefit because today when patients recur, the treatment costs are very high. The drugs that they use now are very expensive; if the patient does not recur you will not need those drugs. It has benefit in terms of healthcare costs and benefits in terms of recurrent-free survival in the patient.

CEOCFO: How do you personally deal with the frustration of knowing you have something that is potentially life-saving and yet has such a long and arduous process to into use?
Dr. Hanna: I feel once you take on a responsibility and you commit to it, you finish the job. I consider it a responsibility. Vaccinogen benefited from the new molecular genetics data that validated the heterogeneity of cancer and thereby validated the OncoVAX approach. This is direct data from the best in the molecular biology laboratories in the world so nobody can argue this. By knowing the biology of the disease, our approach is well founded and it has helped us to gain support from recent investors. I am encouraged by our early clinical data and I am confident that we have the right approach and the right clinical trial to move into final stage of development before seeking FDA approval.

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