CEOCFO Interviews & News!

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The vision for Carrington Laboratories has been totally changed as they are now focused on the delivery of vaccines and therapeutics nasally in a powder form

Healthcare
Biopharmaceuticals
(CARN-NASDAQ)

Carrington Laboratories, Inc.

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THE HONORABLE CARLTON E. TURNER

BIO:
Carlton E. Turner, Ph.D., D.Sc., is President and CEO of Carrington Laboratories, Inc., a publicly-held, biopharmaceutical operating company listed on NASDAQ and in the top 50 biotech companies (sales) in the U.S. He has over 30 years experience as an executive, policy maker, researcher, scientist, administrator and manager, as well as extensive experience with national and international law enforcement, intelligence and development agencies. He has negotiated agreements for the U.S. government with heads of states and ambassadors throughout the world, and was a member of the Presidential Mission to the United Nations in June 1987.

Prior to joining Carrington in 1994, he was President and CEO of Princeton Diagnostic Laboratories of America (PDLA), a publicly-held company listed on the American Stock Exchange.

Prior to joining PDLA in 1987, he was an assistant to President Reagan with cabinet rank (1981-1987) and was Director of the White House Drug Abuse Policy Office. The President assigned him the responsibility to rid the military of drugs. The drug testing was so successful, it is now used extensively in the private sector. He served on the South Florida Task Force chaired by Vice President Bush, with membership consisting of select cabinet members. He developed concept papers, coordinated the formation of and served on the board (with cabinet rank) of the National Narcotic Border Interdiction System, also chaired by Vice President Bush. Dr. Turner also assisted Mrs. Reagan in her prevention campaign, conceived and chaired her two "First Lady to First Lady" conferences at the White House and the United Nations. He also served as a consultant to President Bush's campaign and administration.

During his stay at the White House, Dr. Turner received the *Government Executive Magazine's* Manager of the Year Award (1986). He received this award based on the management and success of his portfolio which encompassed oversight, interaction and coordination of national and international drug strategy through 33 government agencies, which ranged from the Attorney General of the United States to the Head of the United States Information Agency.

Prior to joining the Reagan Administration, he was Director of the Research Institute of Pharmaceutical Sciences at the University of Mississippi (1980-1984). As a director, he was responsible for policies, research programs and ensuring funding from private sector sources, government sources and the legislature of Mississippi. As a researcher, Dr. Turner has published over 125 scientific papers, patents and chapters of books, ranging from analytical technology of natural products to psychiatry.

Company Profile:
Carrington Laboratories, Inc. is a publicly traded (NASDAQ – CARN), ISO 9001-certified, research-based, biopharmaceutical company whose core technology is based on naturally-occurring complex carbohydrate polymers. Carrington manufactures and markets drugs, professional wound and oral care products. All products, regardless of classification, are manufactured under FDA cGMP regulations for human drugs. Carrington also produces raw materials for sale and further manufacture, as well as select consumer products. Carrington's technology is protected by more than 130 patents in 26 countries. Select wound care products carry the CE mark, recognized by more than 20 countries around the world.

Carrington Laboratories has three, wholly-owned subsidiaries supporting its core business and technology. These sub-

sidiaries are responsible for the development of drug and vaccine delivery technologies, processing of raw materials and finished products, and the supply of plants.

DelSite Biotechnologies, Inc. was formed in 2001 to commercialize innovations discovered by scientists at Carrington. DelSite is developing its proprietary GelSite® technology designed to provide controlled release of peptide and protein-based vaccines or drugs. DelSite's unique polymer technology system GelVac™ is used to produce vaccines in dry powder form, free of preservatives, requiring no cold storage, and which do not require needles. DelSite is currently working on a vaccine for bird flu (H5N1). An Investigational New Drug application (IND) will be filed with the FDA later this year.

Sábila Industrial, S.A. provides the GelSite® polymer used in DelSite's research, Carrington branded products, and commercial raw materials. Sábila Industrial is cGMP compliant and an ISO-certified manufacturing facility located in Liberia, Costa Rica. Sábila Industrial also makes finished nutraceutical products for Korea, Japan, Hong Kong and other countries in the Pacific Rim.

Finca Sábila is Carrington's certified-organic farm located in Liberia, Costa Rica. Finca Sábila provides the plant material used by Sábila Industrial to make all of Carrington's and DelSite's raw materials.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Dr. Turner, what was your vision when you became CEO of Carrington Laboratories, and where are you today?

Dr. Turner: "I became CEO in 1995 after serving on the board from 1989. The vision was to focus on drug development and to be successful in the development of drugs beneficial in the treatment of diseases that are difficult to treat. We first looked at ulcerative colitis; however, two Phase III trials were not successful. Based on research, the vision has evolved. Our focus is now on a platform drug delivery system for proteins and peptides, as well as vaccines and therapeutics. We have been very successful in developing the platform. We may be a few years behind others in drug delivery, but we are going to totally change the way vaccines and therapeutics are delivered. Our nasal powder delivery form for both vaccines and therapeutics is exciting."

"Our technology is very simple. It is comprised of a naturally-occurring polymer. The polymer GelSite® is in a class of compound called pectin, but is unique and not like pectins from fruit. GelSite® has the unique ability to bind to and stabilize proteins and peptides. Many new drugs under development are proteins or peptides. DelSite's technology can deliver vaccines and therapeutics utilizing a nasal powder delivery technology. DelSite's powder formulation does not require preservatives, cold storage, or needles. We currently have a vaccine that has been stable for thirty months at room temperature. Our platform technology is not limited to nasal powders, but can deliver through different routes of administration: injectable, oral, suppository, topical, or vaginal. GelSite® polymer will deliver anywhere you have calcium in a body fluid. Calcium is key to our delivery system, as we use the calcium molecule to help deliver therapeutics over time."

- Carlton E. Turner, Ph.D., D.Sc.

CEOCFO: Would that be through your DelSite Biotechnologies, Inc. subsidiary?

Dr. Turner: "Yes. In 2001, we decided to refocus our vision from pure drug development to the development of a delivery platform for vaccines and drugs. To do this, we set up the DelSite Biotechnologies, Inc. subsidiary, with a dedicated staff, location and corporate structure. DelSite has been very successful in the last few years."

CEOCFO: What is the technology?

Dr. Turner: "Our technology is very simple. It is comprised of a naturally-occurring polymer. The polymer GelSite® is in a class of compound called pectin, but is unique and not like pectins from fruit. GelSite® has the unique ability to bind to and stabilize proteins and peptides. Many new drugs under development are proteins or peptides. DelSite's technology can deliver vaccines and therapeutics utilizing a nasal powder delivery technology. DelSite's powder formulation does not require preservatives, cold storage, or needles. We currently have a vaccine that has been stable for thirty months at room temperature. Our platform technology is not limited to nasal powders, but can deliver through different routes of administration: injectable, oral, suppository, topical, or vaginal. GelSite® polymer will deliver anywhere you have calcium in a body fluid. Calcium is key to our delivery system, as we use the calcium molecule to help deliver therapeutics over time."

CEOCFO: Is it a one-size-fits-all?

Dr. Turner: "I would not say that it is a one-size-fits-all. This is a linear polymer, with a negative charge, and it has an affinity for a compound with a different charge, sort of like a magnet. During the formulation process, when GelSite® comes in contact with proteins or peptides, it stabilizes and protects the integrity of the target protein or peptide. One of the problems with current vaccines, such as the flu vaccine, is the short shelf life. The flu vaccine administered last fall, say in October, expired in June of 2007. Therefore, to stockpile vaccines, there needs to be a way to stabilize them for a longer period of time. Based on stability data at room temperature, we have a system that will accomplish this goal. Does this mean GelSite® can be used to deliver every vaccine known to man? No, but we do have five companies looking at GelSite® to deliver different vaccines. These include one for dysentery; another for a peptide as an HIV vaccine; one for a cancer therapy; and, yet another for the sublingual delivery of vaccine in the developing world. Finally, there is one for nasal delivery of therapeutics. We are

also working with the National Institute of Health to modify one of our polymers to become an antigen for typhoid fever. With the National Cancer Institute, we are working to develop a needle-free nasal delivery system for the human papillomavirus (HPV). Our nasal powder delivery platform allows for a powder to be stored at room temperature and distributed over a temperature range. It also will allow delivery of certain vaccines in the developing world where current vaccines are not delivered. These are places of need where no cold storage system and no infrastructure to medically deliver vaccines are available; whereas, in the developed world, systems are in place to support cold distribution, medical facilities and professionals to deliver the needed services."

CEOCFO: What is next; is there a timetable and what should people be looking at?

Dr. Turner: "The most interesting event to everyone is the program geared to developing a vaccine for the H5N1 bird flu. This has been under development for a few years. We have done the Phase I safety study of the GelSite® polymer in humans. From this clinical, we have shown that our device will deliver 95% plus of the product to the proper site in the nasal cavity. We have secured a source of the H5N1 antigen, which will be shipped to us on or about July 9th of this year (2007). We will initiate toxicology (TOX) studies using a protocol agreed to by the FDA. Once TOX studies are completed later this year, we plan to file an investigative new drug (IND) application with the FDA to initiate a Phase I clinical in man using a bird flu (H5N1) vaccine. Vaccines are biologics and are regulated differently than drugs. With a drug, you do a Phase I, Phase II and a Phase III, and if everything works well, you file for a New Drug Application (NDA) and hopefully get permission to market the drug. Since there is so much experience with influenza vaccines, the system is different. A Phase I and a Phase II are required and if successful, you are allowed to go to market. Carrington nor DelSite is going to become a manufacturer of vaccines. We will license our technology to those that have the infrastructure and expertise to manufacture and deliver vaccines."

CEOCFO: You have a couple of other segments of Carrington; will you tell us about those?

Dr. Turner: "Years ago we needed a location in a warm climate to produce our natural product. The location needed to be free from political turmoil found in some countries, so we chose the stable democracy of Costa Rica. We have two subsidiaries there, one is Sábila Industrial, S.A., which is an ISO certified bulk pharmaceutical manufacturing facility operated under FDA Good Manufacturing Procedures (cGMP) and located in a duty free trade zone. To replace this facility would take about a $20 million. It provides all the raw materials used in DelSite's research, Carrington's products, as well as raw materials sold to other companies. It also produces nutraceutical products that are shipped to Hong Kong, Korea, Japan and other parts of the Pacific Rim. The other subsidiary in Costa Rica is an organic certified farm, Finca Sábila, which is not located in the duty-free zone. Finca Sábila is certified organic by an agency in Costa Rica and is recognized by Costa Rica, the United States Department of Agriculture (USDA) as well as the European Union (EU). These are the subsidiaries actively involved in developing Carrington research and core business and they do a good job in their respective areas."

CEOCFO: What is the financial picture for Carrington?

Dr. Turner: "The financial picture is not that pretty. We have been burning a lot of cash with DelSite. Since 2002, we have invested $39.6 million in DelSite. We are through the Phase I safety in man with the GelSite® polymer. To do the Phase I safety with the H5N1 (bird flu) vaccine, we have recently raised $8 million. Our financial situation is not as strong as I would like, so we are looking at ways to financially restructure the company. Our number-one goal now is getting the Phase I safety in man with the H5N1 vaccine completed. Number two is dealing with the financial situation and getting long-term stability. Number three is to grow the core business back to double-digit, annual growth."

CEOCFO: There are other development delivery technologies available, why should people focus on Carrington as opposed to some of the others?

Dr. Turner: "There are several resources and I will list them for you. 1. We have a nasal powder delivery system, which requires no preservatives. Some parents think preservatives create neurological problems with their kids and want preservatives eliminated. 2. Our system eliminates needles and the requirement of cold storage and cold distribution systems. 3. Our technology provides stability of vaccine antigens. We are at 30 months' stability with a room temperature influenza vaccine made with our polymer. 4. There are never any organic solvents used in the production of the GelSite® polymer. The GelSite® polymer is a water-soluble component, a natural product, a GRAS (generally regarded as safe) compound and recognized by the FDA as such. 5. DelSite can make the polymer in kilo quantities in an ISO-certified and GMP facility. Most companies this size do not have a production facility. One kilo of the GelSite® polymer can be used to make eight to twenty million vaccine doses. 6. The GelSite® polymer binds to, protects and stabilizes proteins and peptides. Many new vaccines and therapeutics are being developed from these classes of compounds."

CEOCFO: Why should potential investors look at Carrington Laboratories now?

Dr. Turner: "My stock is very low right now. It has been as high as $50.00 and below $1.00. It is about $1.30 now. Our outstanding shares are 10.9 million. We just raised $8 million. Carrington, in the recent issue of the *MedAdNews*, is number 75 in sales for biotech companies, number 55 in number of employees and number 94 in the amount of research funding. If Carrington had put the $39.6 million spent on DelSite into the core business, we would have had a very profitable business. In the past, we developed wound care products for commercialization. Now, with DelSite, we are looking at a platform technology to be licensed for an upfront fee, milestones and royalty payments on each unit sold. Additionally, we will provide the polymer to our partners for a fee. The stock is suppressed right now, but we are a company people should take time to look at. In all my investments, I dig, I look and then I make

my own decisions. I would sincerely hope your readers would do the same."

CEOCFO: Do you have any final thoughts for our readers and what should they remember about Carrington Laboratories?

Dr. Turner: "Two things are significant for Carrington Laboratories. One is that we have created a delivery platform for vaccines and therapeutics, via this platform we have a program with the National Cancer Institute (NCI) to develop the next generation of human papillomavirus (HPV) vaccines using a new protein owned by the NCI. The current HPV vaccine for cervical cancer requires cold storage or has to be frozen. There will be limited distribution of these vaccines in India, China, and Africa where the need is the greatest. This is a great opportunity. Another key need is for a typhoid antigen worldwide. People forget that, worldwide, typhoid is still a very big killer. Once again, using our platform polymer, we have a program with the National Institutes of Health to develop an antigen for typhoid. If you look at the world's need for deliverable vaccines over a range of temperatures and diseases, you have problems with tuberculosis, malaria, typhoid, and HPV. We believe our platform will be useful in all these areas. I stated once before that I believe the DelSite platform technology will do to vaccine and drug delivery what chips did for computers and transistors did for radio, and I still believe this statement to be true. It is an exciting time with an extraordinary technology."

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