

## Safe, Effective Drugs for Regenerative Peptide Stimulation

**Pharmaceutical Development  
BioTherapeutics**

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**Dr. Darrell Carney  
CEO**

**BIO:** Darrell H. Carney, PhD, is President and CEO of Chrysalis BioTherapeutics, Inc., a privately held biopharmaceutical development company. Dr. Carney is an academic entrepreneur with an Adjunct Professorship in the Department of Biochemistry & Molecular Biology at The University of Texas Medical Branch. Early in his career, Dr. Carney received a National Cancer Institute Career Development Award and discovered cell surface receptors for thrombin that are involved in tissue repair and regeneration. As an academic scientist, he raised over 13 million dollars in NIH funding and has over 90 publications and 28 patents. Dr. Carney established his first tissue

repair company, Chrysalis BioThechnology, Inc., in 1995 to develop thrombin peptide technologies discovered in his laboratory. Under his leadership, this company: 1) established preclinical safety, efficacy, and manufacturing to support INDs for treatment of diabetic foot ulcers and bone fracture repair; 2) completed an early stage clinical trial showing potential efficacy for treatment of diabetic foot ulcers; 3) formed strategic partnerships with two publicly-traded pharmaceutical companies; and 4) executed a successful exit strategy with acquisition of the company by OrthoLogic Corp in 2004. During that time, Chrysalis was the winner of the 2001 Frost & Sullivan National Technology Innovation Award and was recognized as a 2002 Deloitte & Touche FAST 50 Texas Technology Company and National FAST 500 Technology Company for being among the fastest growing technology companies in America.

Dr. Carney recently founded Chrysalis BioTherapeutics, Inc. to develop drug products to mitigate effects of radiation exposure. This relatively new company has raised over \$5 million in non-dilutive funding, and demonstrated that its lead product, Chrysalin®, increases survival when injected 24 hours after lethal radiation exposure and protects normal tissues from damaging effects of radiation therapy. Based on new discoveries showing that Chrysalin® stimulates stem cells within tissues, Chrysalis BioTherapeutics is exploring opportunities for development of Chrysalin® products for tissue regeneration, cardiovascular disease, and neurodegenerative diseases.

**About  
Chrysalis BioTherapeutics, Inc.:**  
Chrysalis BioTherapeutics, Inc. is a

privately held mid-stage biopharmaceutical company developing a novel platform of regenerative thrombin peptide drugs. The goal of Chrysalis BioTherapeutics is to develop safe and effective drugs that stimulate the body's natural regenerative processes to save lives and improve quality-of-life for millions of people. Chrysalis BioTherapeutics lead drug product is Chrysalin® (TP508, rousalotide acetate), which was originally developed by Dr. Darrell Carney at the University of Texas Medical Branch to stimulate tissue repair and regeneration. Chrysalis BioTherapeutics, Inc. is developing Chrysalin to mitigate effects of nuclear radiation and unwanted side effects of radiation therapy and low-dose radiation exposure.

**Interview conducted by:  
Lynn Fosse, Senior Editor  
CEOCFO Magazine**

**CEOCFO:** Dr. Carney, what is the concept behind Chrysalis BioTherapeutics?

**Dr. Carney:** The company was established to develop a specific group of regenerative peptides that stimulate tissue repair and revascularization, and determine whether these peptides can protect normal tissues from damaging effects of radiation. Initially, we looked at the effect of our lead drug candidate, Chrysalin® to determine if it could mitigate effects of nuclear radiation exposure similar to what a person could experience from a nuclear leak, a nuclear reactor explosion, or a nuclear detonation.

**CEOCFO:** Why was this the first target you looked at when these peptides have promise in other areas as well?

**Dr. Carney:** There is increasing concern that there might be a major nuclear

leak or nuclear explosion somewhere in the world, yet we do not have effective medicinal countermeasures to protect citizens and emergency personnel from this type of exposure. We were asked by individuals at NIH whether Chrysalin could increase survival after nuclear exposure or nuclear exposure combined with injury. Based on the regenerative properties of our drug, we anticipated that Chrysalin could repair tissues after radiation exposure, but at that time we really had no way of knowing if Chrysalin treatment would also increase survival.

**CEOFO:** What have you found so far?

**Dr. Carney:** We have found that if you inject this peptide drug into an animal twenty-four hours after it is exposed to a lethal dose of radiation, the peptide mitigates the effects of radiation and significantly increases survival. The amazing thing was that we were increasing survival with just a single treatment of peptide twenty-four hours after the lethal exposure.

**CEOFO:** Twenty-four hours seems like a lot of time to get help to people!

**Dr. Carney:** That is the point. If there were a nuclear detonation disaster, it is quite likely that it would take perhaps twenty-four hours to be able to deliver a drug to people. So, that is the bar that has been set by funding agencies for those who wish to look for a nuclear radiation medicinal countermeasure.

**CEOFO:** What is the science involved with how it actually works?

**Dr. Carney:** This is an amazing bit of science. Thrombin is the enzyme that causes blood to clot every time you cut yourself. The peptide drug that we are working with, Chrysalin, is a part of that thrombin molecule. Every time a person is injured, this molecule is released and initiates the tissue regeneration and tissue repair process. In wounds and in almost any tissue, this will start the repair process and increase the blood vessel growth back into the tissue. It revascularizes the tissue, and what we have found is

that it also activates the progenitor stem cells that are within that tissue to regenerate normal, functional, tissue. This is a very natural wound tissue regeneration process that occurs basically every time a person is injured. What we have done is taken a piece of that molecule that can activate the natural repair process and stimulate those progenitor stem cells to repair the tissue or protect the tissue from the damaging effects of radiation. A number of companies are excited about stem cell therapies. You can think of Chrysalin as a next generation drug that can stimulate the body's own natural stem cells to regenerate tissue, rather than isolating stem cells and injecting them back into damaged tissue for this purpose.

**CEOFO:** Where are you today? I know you recently received \$1.5

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**- Darrell H. Carney, PhD**

million from the National Cancer Institute. What are the next steps that the funding will help facilitate?

**Dr. Carney:** This is a project that we began with funding from the National Cancer Institute almost two years ago. In these studies, we discovered that the peptide could protect regions of the brain and stimulate neurogenesis following radiation therapy. For the next phase of this project, we will determine whether the Chrysalin-induced neural protection and regeneration relates to increasing the learning capacity and cognitive function of the brain and better understand how the drug protects these neural progenitor stem cells.

**CEOFO:** Do you anticipate that the funding will get you where you need to be?

**Dr. Carney:** We have been able in the last two and a half years to raise about five and a half million dollars in non-dilutive grants and contracts. This is taking us well into product

development for mitigating effects of nuclear radiation and preventing radiation-induced normal tissue damage. I think we are now at a point where we need Series A financing to move into human clinical trials.

**CEOFO:** Do you have any programs going on in addition to the radiation?

**Dr. Carney:** The radiation is our focus at this point. We have two other areas where we are exploring opportunities. One is in tissue regeneration. We have completed clinical studies in diabetic foot ulcers and fracture repair. With what we now know, it is possible to move rapidly toward pivotal clinical trials. However, due to the cost of these trials, we need to raise a significant amount of money or partner with another company. The second area is in cardiovascular. We have very strong data from preclinical studies suggesting that Chrysalin could be developed to prevent people from dying from myocardial infarction. Again, we need to put significant dollars into this area and think that the cardiovascular area is probably best dealt with by partnering with a bigger pharma company. We are just beginning to pursue this possibility.

**CEOFO:** I know that you developed this originally. What has surprised you the most as you continue to do testing and work on the development?

**Dr. Carney:** I think the biggest surprise is that with a single topical application or a single injection at the time of the radiation therapy, we are affecting the development of the brain three months later. This molecule can set in motion a regenerative program that brings about major changes in tissue repair or in restoration of function several months later. From a biological standpoint, that was pretty surprising to us. It also speaks to the power of this particular drug.

**CEOFO:** What is next on your timetable?

**Dr. Carney:** One of our challenges is delivery of the drug for particular indications. If we are talking about the potential stockpiling of this drug by the government to be used in the case of

a nuclear disaster. We need to be able to distribute it to hundreds of thousands of people who might be affected by a nuclear disaster in a formulation that could be self-administered. The hope is that we would never have that kind of a nuclear disaster. Therefore, we also believe that we can use this drug to protect the normal tissues and improve the quality of life for the millions of cancer patients that have radiation therapy, whether it is in the brain or other tissues in the body. That is a little more practical.

**CEO CFO:** These are very exciting times!

**Dr. Carney:** I think this is a challenge, but we are pretty amazed at the data that continues to be very positive.

**CEO CFO:** Why should people in the business and investment community pay attention to Chrysalis Bio Therapeutics?

**Dr. Carney:** I think Chrysalis provides a unique opportunity for investment or partnering with tremendous upside potential because we have a drug that has already been in human clinical trials and has been shown to be safe. Approximately 600 humans have been treated with Chrysalin without any drug-related adverse events.

Moreover, GMP manufacturing is established. Therefore, we are now much farther along than most early stage companies. We also have the potential to have drugs on the market within three to five years for mitigating effects of nuclear radiation and unwanted effects of radiation therapy.

**CEO CFO:** Final thoughts?

**Dr. Carney:** We hope to initiate a Series A round of private or institutional investment later this year or early next year. We would be glad to discuss investment or partnering with interested parties.



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