



THE CEO-CFO GROUP

WHAT'S HAPPENING IN BUSINESS IN LAS VEGAS

Bio-Tech in Henderson: Nevada's Rising Biotech Star

Henderson-based CardioVascular BioTherapeutics, Inc. (CVBT) has big plans. The company's first goal is to deliver a treatment for no-option heart patients of growing new blood vessels for their hearts. Next, the company plans to develop therapeutics for growing blood vessels for treatment of strokes, lower back pain and peripheral arterial disease (PVD). And still, there are other medical problems that they believe they can help such as intestinal ischemia, diabetic neuropathy and bed sores. If Cardio pulls off one of these treatments, it will put Henderson and Nevada on the Biotech map and give a boost to Nevada's growing but small Biotech industry.

Cardio has developed a drug that causes growth in new blood vessels, primarily arteries (which is referred to medically as angiogenesis) in the heart. Cardio has a jump-start on most biotech companies; they know that their product already works in humans. The company's co-founder Dr. Thomas Stegmann had previously developed and tested this angiogenesis treatment in Germany. Dr. Stegmann is a cardiovascular surgeon and director of the cardiovascular Surgery of Fluda Medical Center in Germany. After reading a study about how tumors survive and grow because they are able to make new blood vessel growth, Dr. Stegmann thought that there must be a way to use these "growth factors" that cause new blood vessel growth for treatment of heart patients, where they need new blood vessels. Many of his patients needed to grow new arteries in their heart to provide blood around blocked arteries that they suffered from. Growth Factors are a fairly new area of medical research. They are proteins that signal the body to repair itself after an injury. After nearly three years of experiments, Dr. Stegmann in 1995 began limited experiments on humans injecting a special Growth Factor into the heart of no-option heart patients. Starting with 40 patients of which 20 were a control group, he worked with group for three years. His experiments showed that the growth factor had created a significant growth in arteries and therefore new blood flows to the ischemic (decreased blood supply caused by obstruction of the blood vessels) areas in the heart; without any side effects.

In 1998 Dr. Stegmann results from his first human trial were published in the American Heart Associations journal, *Circulation* (Feb 1998). The study was seen by a reporter from the Wall Street Journal who wrote an article about the breakthrough. On the same day that it was published, a businessman from California named Dan Montano called Dr. Stegmann. The next day Montano flew to Germany and the two agreed to commercialize the process; thus, CardioVascular Genetic Engineering, later named CardioVascular BioTherapeutics, was born.

Montano brought more than capital and business experience; he had remembered that scientists that he had met in the Ukraine had developed a cheaper method of making the pharmaceutical proteins that are the basis for most growth factors. Working with the Ukrainian scientists, the company was able to duplicate the process for their growth factor, Fibroblast Growth Factor (FGF-1). Now they had an inexpensive supply of material. In 1999 Dr. Stegmann used the new FGF-1 for his second human trial, again in Germany, which duplicated the previous results.

The next step was to get permission to sell in the United States, the world largest pharmaceutical market, by obtaining approval of the USA FDA. Initially they had set up a Delaware Company operating in California and began preparing for their application for the FDA. They also set up a sister company called Phage BioTechnology

Corporation. Phage was formed to commercialize the Ukrainian process to make proteins. Now they were ready.

In 2003 the FDA approved Cardio's Vascu-Grow for clinical trials in the US. This was the same year that Montano decided to move the company to Nevada. By the end of the year the first US clinical trial had begun at the University of Cincinnati and five other USA Medical Hospitals, the first American no-option heart patients had received Stegmann's growth factor proteins injected into their heart muscles. Three months after the tests had started, the University of Cincinnati held a press conference to announce the results of their first three patients. The 2nd part of this article will review the patients and the results of the current clinical trials.

John Laub is the chairman of the CEO-CFO Group. (The author purchased shares in CVBT after writing these articles.)

1. "New Vessels for the Heart." Thomas J. Stegmann, MD. Self Published by Cardio Vascular Bio Therapeutics. 2004.
2. 2005 1st Quarter 10-Q for Cardio Vascular Bio Therapeutics. 2005.
3. <http://www.cvbt.com/>

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