CEO CFO

advanced cancer therapeutics®

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# Discovery and development company, Advanced Cancer Therapeutics (ACT) will be entering Phase I Human Clinical Trials in 2013 for their Glycolysis Inhibition Program that has shown the ability to Choke Off the critical Fuel Supply that Tumors Use to Grow and Metastasize leading to Apoptosis or Cell Death

**Healthcare**
**Drug Development**

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**Randall B. Riggs**
**CEO**

**BIO:**
Randall B. Riggs joins ACT with over twenty (20) years of corporate strategy and business development experience within the pharmaceutical and biotechnology industries. From 2005 to October of 2007 he was the Senior Vice President of Corporate Development for BioCryst Pharmaceuticals and was responsible for approximately $1 billion dollars in strategic partnerships with multi-national firms including Hoffman-La Roche, Shionogi & Co., Mundipharma International LTD, and Green Cross Corp. Prior to BioCryst Pharmaceuticals, Mr. Riggs held the position of Senior Vice President of Corporate Development for Lexicon Pharmaceuticals (1998 – 2004). As a member of the executive management team, over $200 million was raised through their initial public offering in April 2000. In addition to his key role in Lexicon's successful IPO, Mr. Riggs oversaw an increase in strategic partnership revenue from less than $2 million to over $60 million each year.

**About Advanced Cancer Therapeutics:**
Advanced Cancer Therapeutics (ACT) is leading innovation within the biotechnology industry. Founded in January 2007, the company is focused on the discovery and early development of novel cancer therapeutics as well as selection for partnership, commercialization and manufacture of the most promising discoveries. Utilizing its groundbreaking business arrangement with the James Graham Brown Cancer Center and the University of Louisville Research Foundation, ACT will establish exclusive rights to specific novel therapeutics and fast-track these leading edge discoveries to the pharmaceutical industry, and ultimately the patients who need them.

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

**CEOCFO:** Mr. Riggs, what is the focus at Advanced Cancer Therapeutics?
**Mr. Riggs:** Advanced Cancer Therapeutics is developing breakthrough treatments for cancer patients. We are developing products that basically have not been explored at this time in small molecule area, so novel targets and drugs we think are important to go after cancer because ever since President Nixon back in the early seventies declared war on cancer, we have not done too good of a job at defeating cancer. Usually the only way you get that progress is by not doing the same thing but by doing more innovative things in trying to attack cancer at novel areas where they have not been attacked before.

**CEOCFO:** Would you give us some specifics about what you are looking at and why you have decided to look at that item?
**Mr. Riggs:** Something exciting coming up is about the start of Phase I clinical trial in 2013, it chokes off a critical fuel supply that tumors use to grow and metastasize. This critical fuel supply is sugar glucose and it was professed to be a critical intervention point in the area of cancer metabolism. In the late 1920's, Dr. Otto Warburg who was a German doctor professed that cancer cells heavily depend on sugar/glucose for their insatiable desire to grow and metastasize. Not much work has been done since then and now technology has advanced further and we are able to do more things, we have been able to see and develop a compound inhibitor that chokes off this critical fuel

line for tumors, but does not appear to negatively impact healthy cells. Unlike cancer cells, healthy cells do not have the same level of dependence on glucose/sugar because healthy cells are not in the mode of uncontrolled proliferation or growth. Through a PET Scan in animals, which basically images cells in vivo, we see that those tumors treated with our drug are not able to uptake the glucose while those untreated cells with our drug continue to uptake glucose as a key fuel source for growth. What is very exciting for ACT is that this will be the first drug in its class to start a human clinical trial in 2013 as a novel approach to potentially defeat certain types of cancers.

**CEOCFO:** How does it inhibit the progress of the disease; what is actually happening in the cell?

**Mr. Riggs:** What happens in cancer cells is that they have an inefficient nucleus and they have a desire to proliferate and expand uncontrollably. To make a crude analogy, cancer cells is like an old car that needs more fuel to travel to a certain long distance trip than a new car that operates efficiently. The cancer cell is very inefficient and it needs a great deal fuel to satisfy its insatiable growth patterns and inefficient nucleus. By chopping off this source of fuel, you send the tumor into a state of shock because it cannot do what it wants to do and then goes into apoptosis or cell death. The healthy cells do not appear affected by this approach because healthy cells do not have an insatiable desire to proliferate uncontrollably and they have an efficient nucleus. Therefore, healthy cells are able to function appropriately with less glucose or sugar while cancer cells are not able to do so.

**CEOCFO:** You mentioned this concept was known about but not tried; has there been much research in this area and what have you figured out that others have not?

**Mr. Riggs:** There has been other research in this area, but I think many people get too enamored with requiring what we call biomarkers before they go into humans. A biomarker is basically when you give your drug you are able to look at a surrogate marker to see if your drug is actually working the way you think it should be mechanistically. However, If you look at drugs through recent history that have been very successful what we see is that many of them do not have a biomarker – those drugs (e.g., Avastin and Taxol) simply work. That is, those successful drugs work through disrupting basic and fundamental growth needs of cancer cells. For example, Avastin works by choking off the supply of blood nutrients tumors require grow their blood vessel network. Taxol works as a cytotoxic drug that attacks cancer cells but, unfortunately, also healthy cells. Although Avastin or Taxol remain top anti-cancer drugs used today by oncologists, neither drug has an established biomarker. In today's drug discovery world, everyone seems to require a biomarker so they can pre-select specific patients for their clinical trials that would provide them the best likelihood of such cancer patients responding favorably to their drug. Perhaps not having a validated biomarker against this novel cancer target may explain why several companies have not ventured into the area of glycolysis inhibition to treat cancer. However, I think most scientists will agree that Avastin and Taxol remain as some of the biggest discoveries we have had in cancer up to this time. Sometimes I think we try to become too smart and we just do not go after the fundamental approaches that can deter or stop the cancer growth.

**"We have had many interested parties especially for the glycolysis inhibition program. I think many people in the pharmaceutical industry want to see you go further than what they normally would have in the past. Presently, we have completed all the necessary studies to enter human clinical trials. The drug is well tolerated in all animals and has a favorable anti-cancer profile. We will be going into Phase 1 studies in 2013. During or after the completion of the Phase I human clinical study, we intend to seek a corporate partner for further development". - Randall B. Riggs**

**CEOCFO:** Would you tell us about the recent NIH grant?

**Mr. Riggs:** The NIH grant was recently awarded to us through this program, which is a highly competitive program and we were awarded the SBIR Phase I grant to evaluate our drug's potential efficacy in gliomblastoma multiforme, which is the most common type of brain cancer. Certain tumors have higher rates of glucose consumption than other tumors. Solid tumors such as lung cancer, prostate and brain cancer tend to have an enormous appetite for glucose to in order to grow aggressively. This SBIR grant recognizes this scientific discovery that will now allow us to further explore our drug's anti-cancer impact in an area that we normally would not have sufficient funds to explore. I believe this SBIR grant underscores the importance of our anti-drug's potential in the area of brain cancer.

**CEOCFO:** Would you tell us about the HPV vaccine?

**Mr. Riggs:** That is being worked on with the James Graham Brown Cancer Center and we basically transfect in tobacco plants the HPV L1 & L2 capsid protein virus. The idea is that employing plant made pharmaceutical (PMP) approaches in tobacco plants; the end product would have a broader and more cost-effective vaccine than currently marketed products. Even though the United States is considered a rich country, we are starting to come under pricing pressures from various payers to provide more value for less. This an innovative way to use the natural machinery of the tobacco plant to develop a cost-effective, broad spectrum HPV vaccine cervical cancer in many females and has recently been linked to head and neck cancer.

**CEOCFO:** Has the medical community paid attention to ACT or is it too early?

**Mr. Riggs:** I think they are. We have had many interested parties especially for the glycolysis inhibition program. I think many people in the pharmaceutical industry want to see you go further than what they normally would have in the past. Presently, we have completed all the necessary studies to enter human clinical trials. The drug is well tolerated in all animals and has a favorable anticancer profile. We will be going into Phase 1 studies in 2013. During or after the completion of the Phase I human clinical study, we intend to seek a corporate partner for further development.

**CEOCFO:** How do you as a company and personally deal with the frustration of how long it takes to get drugs moving and things to market when you have something that seems to have so much potential?

**Mr. Riggs:** If you go into this industry thinking everything is going to be fast and easy, you are probably in the wrong industry. The biotechnology industry is very risky but also affords excellent return rates if a drug is successful. However, even today, there remains a lot questions an unknowns regarding certain human diseases such as in cancer. You have to take it in stride and you have to realize that you are going to encounter many challenges and potential failures, but it is what you do after such failure or challenge that leads to ultimate success or failure.

**CEOCFO:** Why should the business and investment community pay attention to Advanced Cancer Therapeutics?

**Mr. Riggs:** ACT stands out because we have set up the first symbiotic partnership with the James Graham Brown Cancer Center that is part of the University of Louisville Medical School where they spend $30 million each year in cancer drug discovery. Our business arrangement with the James Graham Brown Cancer Center allows ACT to exclusively license certain products under preset business terms, and in exchange, the James Graham Brown Cancer Center owns 30% of ACT and will be eligible for milestone and royalty payments on products commercialized. Therefore, we are both aligned and incentivized to succeed and help each other in a harmonious manner. On top of that, we are leveraging existing resources they have established over time. The James Graham Brown Cancer Center has over fifty scientists performing research and drug discovery with significant capital investments. As a partner with the James Graham Brown Cancer Center, ACT is able to leverage this infrastructure and focus on transitioning early discoveries into better products through our medicinal chemistry and our focused biological studies to advance them into Phase 1 human clinical trials. During or promptly after Phase I, then we look to partner or sale the asset to leading pharmaceutical companies. I believe ACT has established an effective niche in the drug discovery value chain, and we look forward to working with leading pharmaceutical companies in the near future to introduce breakthrough treatments for cancer patients.

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