CEOCFO
Interviews & News!

 Issue: January 11, 2008

ARIUS' Lead Antibody Programs, CD44, Trop-2 And CD59, Generated Through Their FunctionFIRST™ Technology, Which Focuses On Antibodies That Kill Cancer And Leave Normal Cells Alone, Is Positioned To Move Into Clinical Trials

Healthcare
Biotechnology
(ARI-TSX)

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David S. Young
Chairman, President and CEO

BIO:
David Young is the Founder of ARIUS, President and Chief Executive Officer since 1999. In this capacity, he oversees general corporate strategy and directs the ARIUS' scientific program. Dr. Young trained at the University of Toronto and received his Doctor of Medicine degree in 1990 and Master of Science degree in 1996. He was also a research fellow through the Surgical Scientist Program at the Hospital for Sick Children. He did his surgical training between 1991 and 1997, including a surgical internship at the Toronto General Hospital, residency in General Surgery at Mount Sinai Hospital and within the division of Cardiovascular Surgery at St. Michael's Hospital in Toronto. While at the University of Toronto he won over 15 academic awards or scholarships. He is an inventor, author, or co-author of over 200 patents, publications, and scientific abstracts.

ARIUS was started in part because Dr. Young was intensively involved in solving the organ donor shortage problem through research on the mechanism of human rejection of pig hearts. Serendipitously, through this research, he made scientific observations that the mechanism of pig cell rejection resembled human immune rejection of cancer cells. 1999, at the age of 34, he wound down his clinical career to pursue the idea of developing anti-cancer antibody drugs that could mimic the effectiveness of transplant rejection.

David Young solely funded the startup of ARIUS and rented space from a local Toronto biotech company. ARIUS is a unique biotechnology company in a number of ways. Dr. Young conducted the fundamental discovery and proof-of-principle experiments to obtain the patents at the core of the company's technology with the help of only one other scientist. The startup phase was radically different from most biotech companies in that the technology was developed from scratch outside of a University so that it did not enjoy the advantages of having many years of prior development before having to seek outside capital. Instead, a compelling idea and important mission attracted the support of committed investors.

Company Profile:
ARIUS is a biotechnology company discovering and developing the next wave of antibody therapeutics. Established in 1999, ARIUS has built a proprietary technology platform, FunctionFIRST™, that rapidly identifies and selects antibodies based on their functional ability to affect disease. This antibody generation engine has enabled ARIUS to assemble a portfolio of more than 400 antibody candidates. In addition to the antibodies it is developing in-house, ARIUS has ongoing partnerships with key biotechnology and drug development companies.

ARIUS' mission is to create innovative, targeted drug therapies that will revolutionize cancer care. In North America there are over 1 million people diagnosed with cancer each year with an unmet medical need for drugs that will improve their survival. ARIUS' was built and capitalized on its proprietary Function-FIRST™ technology platform. This unique approach to drug discovery creates functional anti-cancer monoclonal antibodies using a target independent approach. ARIUS' functional antibodies are toxic to cancer cells but are non-toxic to their normal cell counterparts. The approach has been validated through a number of commercial partnerships with leading pharmaceutical and antibody companies including Genentech, Takeda

Pharmaceuticals, and PDL Biopharma. ARIUS is now a leading anti-cancer drug discovery company.

ARIUS was named for a character in the movie "Ben Hur" that embodied the idea that doing good deeds comes back to the person in spades and our people philosophy and culture reflect that.

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

CEOCFO: Dr. Young, what was your vision when you founded Arius, and where are you today?

Dr. Young: "The vision when I founded the company really centered on the idea that we wanted to make an impact on the treatment of cancer. We believed that we could bring a different view to generating antibody therapeutics. The field has taken a reductionist approach to generating antibody drugs and we wanted to get back to a high-level approach of results-oriented drug discovery. That underpinned the philosophical foundations of the company and drove the company culture. It reduced down to some very important patents and processes that we have been prosecuting over the last eight years. It is this whole concept of FunctionFIRST™, which is when you are looking for cancer drugs, you really want to find drugs that kill cancer cells and leave normal cells alone. We are not focused on finding targets first and doing target validation and making antibodies. We are focused on making anticancer antibodies that are physiologically specific for cancer and would have diminished side-effects because they don't kill normal cells. That really was what we settled to do when we set the company up."

CEOCFO: Where are you today?

Dr. Young: "Today we are pleasantly surprised and excited at how much success we are having. The problem when you are starting a new paradigm of drug discovery is that you just do not get immediate feedback. For many years as we were working on generating this new kind of cancer antibody, we were getting good data, but only in the last year-and-a-half or so, has some of that data really matured. We are very happy and excited because our lead antibody programs, like the CD44 program, the Trop-2 program, the CD59 program, meet the endpoints that we were looking for. Based on these positive endpoints we are about to move these programs into the clinic now."

CEOCFO: Do you have over 400 antibodies today?

Dr. Young: "Yes absolutely. The technology, which generates these antibodies, has yielded over 400 antibodies and we are closer to 500 now; these are functional antibodies that specifically kill cancer cells and leave normal cells alone. From the technology, we have generated a number of partnerships that has had a significant amount of impact on the company because they can pay out more than $400 million in milestones. They are with very well known partners such as Genentech and Takeda Pharmaceuticals. I talked a about our lead antibodies, but behind them are significant antibodies at are just at earlier stages such MCSP and CD9 antibodies that are moving forward into the pre-clinical IND-enabling development path. Behind those are dozens of other antibodies for which we have good animal data and known targets. Then behind those are of groups of antibodies at an earlier stage for which we have demonstrated proof of principle in animal models of human cancer. We have high quality antibodies at all stages of research and development."

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- David S. Young

CEOCFO: How do you decide what you partner with and what you want to develop internally?

Dr. Young: "That is driven by corporate development strategy. As the company evolved, we started partnering according to the stage of the company. Therefore, in the early days, we didn't have the ability to do target discovery, so we partnered through target discovery with another company as we were generating antibodies. As we did not have the capacity to move things into the clinic, for example, we have licensed CD63 and its antibodies to Genentech. Now our partnering strategy is to find co-development partners for some of our lead antibodies and that is going to be driven economically in some parts by what kind of terms we get for any one of the lead antibodies. As you connect the dots, the next stage of our development will be partnering after we have taken some of these antibodies through Phase I and/or Phase II. It is really a partnership strategy driven by the stage of the company as well as the assets."

CEOCFO: Speaking of assets, please tell us about the financial picture of the company.

Dr. Young: "The company is a publicly listed company listed on TSX. We did our last fundraising in April of 2006, and raised about $26 million dollars, of that we still have about $14.9 million and we are running at a burn rate of little under $1 million a month, so we have a more than five quarters of cash. Our objectives are, via business development, to raise cash through partnerships, and that will allow us to not have to raise a round of financing through the capital markets any time soon."

CEOCFO: There are so many biotech companies in the cancer area; how do you stand out and get investors to pay attention?

Dr. Young: "We are somewhat lucky in the sense that right now large pharma, and large biotech companies are very interested and have been ramping up the efforts in biologics and especially in the area of cancer antibodies. That is primarily driven by key strategic considerations; one is that anticancer antibody drugs are doing very well commercially. Examples include those antibodies such as Rituxan, Avastin, and Herceptin marketed by Genentech and Roche. Those are ringing up blockbuster numbers and the added attraction is that there is still no genericization strategy for antibodies. In the antibody sector, very few stand-alone biotechnology companies have the technology or differentiated pipeline that Arius has. The reason it is differentiated and garnering a lot of partnership attention is that the FunctionFIRST™ technology is able to generate potent functional antibodies targeting important cancer biology that have a high likelihood of clinical translation. If you look at the difficulty of drug discovery starting from a target and then eventually ending up trying to get a functional antibody that works in animal models, we turn that on its head, by generating a functional antibody that works in animal models, and then go back to doing target discovery. If you think about where having that functional antibody early gets you, it's why a lot of our partners see the advantage to working with ARIUS. We are hedging a development risk by generating the drug candidate molecules very early on. That is one differentiation: the technology works by turning the drug discovery process on its head. The second point of differentiation which excites investors just as much as partners is that our pipeline is about to hit the clinic and the targets that our lead antibodies directed against are novel targets. In the antibody space, the targets certainly generate as much excitement as the antibodies do.

The target of our lead antibody, CD44, is a cancer stem cell antigen. There is a big paradigm shift in cancer drug discovery and development because people are starting to understand the role of cancer stem cells as being the lethal cell in a tumor mass. Historically cancer drug developers have been generating drugs or developing therapies that reduce tumor mass, but in a tumor there are many different cell populations and it is the cancer stem cells, which are not cycling, which are quiescent, that resist these therapies that ultimately end up repopulating the tumor, metastasing and killing the patient. One of the transforming concepts that is gaining a lot of traction in oncology is the idea that the cancer stem cell is the thing that kills a patient. The question becomes: what are the markers that identify these lethal cells and therefore, what are the drugs that can be developed toward towards? CD44, which is the target of our lead antibody, has been shown to be a pan solid tumor stem cell marker. For example, there is data to support this in breast cancer, prostate cancer, head and neck cancer, as well as an AML. This antibody garners a lot of attention because this antibody will be the first cancer stem cell specific drug going into clinical trials. Beyond the rest of our pipeline of later stage antibodies, which include antibodies to the novel-signaling molecule, Trop-2, and the complement inhibitor, CD59, are two additional antibody programs targeting cancer stem cells. Serendipitously, and maybe not so serendipitously because we look for the most potent antibodies against cancer, we find exciting cancer targets that are biologically important to the pathophysiology of the disease. So having drugs to three targets of six or seven known cancer stem cell markers is a something that people stand up and pay attention to."

CEOCFO: What should people remember about Arius and why should they be looking to invest now?

Dr. Young: "I believe the investment thesis is multifold. We have a differentiated technology and pipeline. There is a lot of pull from pharma and biotech. If you look at the space over the last eighteen months or so, there have been many take-outs of private companies in either the antibody space or the antibody-like fragment business or the antibody tool business. That tells you that there is a tremendous demand for both technology and pipeline. Because of this, we are getting a lot of attention from potential partners. These market forces, I think, are going to pull this company's valuation up because we are busily partnering, and partnering becomes potential acquisition interest. We will evaluate those things as they come along but those are dynamic drivers of what the value of this company will be over the short-term. Perhaps more importantly, the company's pipeline is about to reach an inflection point because they are going to hit the clinic. That sets up for long-term value creation because of the success of those molecules and the validation of the technology platform. The Function FIRST™ technology continues to generate additional molecules as exciting as the lead antibodies in our pipeline."

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