CEO CFO

ARCA biopharma

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Dedicated to Developing Genetically-Targeted Therapies for Cardiovascular Diseases, ARCA biopharma, Inc.'s Lead Product Candidate Gencaro™ has the Potential to be the First Genetically-Targeted Atrial Fibrillation Prevention Treatment

Healthcare
Cardiovascular

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Patrick Wheeler
CFO

BIO: Mr. Wheeler has held the position of Senior Vice President, Finance of the Company since February 2008. He joined ARCA in July 2006 as Vice President, Finance. Prior to joining ARCA, Mr. Wheeler served as Director of Finance for Dharmacon, Inc., A Fisher Scientific, Inc. life science company from June 2003 to July 2006. Mr. Wheeler has B.A. in economics from the University of Colorado and an M.B.A. from Regis University.

About ARCA biopharma, Inc. (Nasdaq: ABIO):
ARCA biopharma is dedicated to developing genetically-targeted therapies for cardiovascular diseases. The Company's lead product candidate, Gencaro™ (bucindolol hydrochloride), is an investigational, pharmacologically unique beta-blocker and mild vasodilator being developed for atrial fibrillation. ARCA has identified common genetic variations that it believes predict individual patient response to Gencaro, giving it the potential to be the first genetically-targeted atrial fibrillation prevention treatment. ARCA has a collaboration with Medtronic, Inc. for support of the Phase 2B portion of the GENETIC-AF trial.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Mr. Wheeler, what is the concept at ARCA biopharma, Inc.?
Mr. Wheeler: The company was founded on the belief that a personalized medicine approach to drug development, catering medical treatment to the individual genetic characteristics of each patient, can really enable more effective therapy, improve patient outcomes and hopefully reduce healthcare costs. ARCA's development program is intended to address those specific ideas.

CEOCFO: Personalized medicine is certainly what everyone is talking about today. What do you understand about the process that maybe others do not? What is your take on how it should be utilized?
Mr. Wheeler: Personalized medicine, for all its promise, turns out to be difficult to do in practice. While ultimately the approach should lead to more effective diagnoses, therapies and outcomes it really isn't a more efficient approach to drug development. In our particular case with Gencaro™ it has taken significant time and resources, though we believe ultimately to the eventual benefit to future patients and our shareholders.

CEOCFO: Where are you in the process of development?
Mr. Wheeler: As of June we have completed an equity offering that raised proceeds of approximately eighteen million dollars. Those proceeds enable us to begin our Phase II-B / III trial. We hope to enroll our first patient in the first quarter of 2014 and complete the phase II portion of our trial within 2.5 years.

CEOCFO: How do you expect Gencaro to work?
Mr. Wheeler: Gencaro is intended to address the atrial fibrillation market. Atrial fibrillation is considered an epidemic cardiovascular disease, estimated to impact at least two point seven million Americans in 2010. With our particular compound, Gencaro, we will test potential patients and they will be placed into one of three genotype categories. Our development target is the "very favorable genotype", which is the beta-1 389 arginine/arginine genotype, which is prevalent in about fifty percent of the general population.

CEOCFO: What happens when people take this drug? What is the science?
Mr. Wheeler: Gencaro, a fourth generation beta blocker, targets the beta-1 adrenergic receptor on the cardio myocyte. It inhibits the beta-1 receptor. It also contains unique

norepinephrine lowering properties as well as acts as an inverse agnonist. Therefore, we believe the combination of those three pharmacologically unique properties potentially enable it to reduce symptomatic atrial fibrillation.

CEOCFO: How is the condition being treated now, or is it? Will this be replacing something or an entirely new method of addressing the problem?

Mr. Wheeler: We hope to be the first cardiovascular genetically targeted atrial fibrillation drug on the market. We are specifically going to run our trial in a patient population for which there are currently no therapies that are approved for the specific treatment of this patient population. We are very excited about the potential to provide treatment options to a patient population that currently has an unmet medical need.

CEOCFO: Is the medical community aware of what you are doing yet of is it a bit early?

Mr. Wheeler: I believe the medical community is somewhat aware of what we are doing. Dr Bristow, ARCA's founder and CEO, is a well known cardiologist and we have published many papers on the topic. However, I think we still are generally in the earlier stages of awareness.

CEOCFO: Do you need to foster awareness now or is it not important until you are further along the line?

Mr. Wheeler: We believe that the clinical trial itself will really increase the awareness of Gencaro. I think the trial itself will do that. We believe that this potentially high profile trial will be the only atrial fibrillation trial underway in the country. GENETIC-AF is going to be a North American trial centered on roughly fifty sites. Therefore, it will be fairly widespread throughout the country. Again, we believe that the trial itself will generate a significant degree of awareness and enthusiasm for the program.

CEOCFO: Why the decision to do the trial in North America when many companies do find Europe and other places appropriate? Was there a particular thought process here?

Mr. Wheeler: Our primary reason for that was twofold. First, we believe that we have the best cardiovascular centers right here in the United States, and, second, with our partnership with Medtronic, we feel that we can find sites that will enroll this patient population in an appropriate time frame, which will be helpful for us.

CEOCFO: You recently added to your team. Is everyone in place now? Do you still need to make additions as you go forward?

Mr. Wheeler: We have largely completed our team. There will be some strategic additions here and there. We recently added a few key people to our team; namely Dr Chris Dufton, as our VP of clinical development. He has had significant prior experience in drug development and managing clinical trials. He was formerly from Myogen and Gilead. He helped lead the successful FDA approval for Letairis (ambrisentan). We also added Monique Plamandon who is also from Myogen, as the VP of Regulatory. We also added Gordon Davis, a Vice President of clinical information systems. We are very pleased to have these folks on board with us to help us implement a successful trial.

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CEOCFO: How far will the funding that you recently acquired take you?

Mr. Wheeler: The funding raised in June will help us or enable us to start on the GENETIC-AF clinical trial in which we hope to enroll our first patient in June of 2014. We believe that it will fund a substantial portion of the Phase IIb component of the GENETIC-AF trial.

CEOCFO: Would you tell us a little bit more about your agreement with Medtronic?

Mr. Wheeler: We are very excited about our collaboration with Medtronic, which is one of the world's largest medical technology companies. They are a leader in medical technologies helping to improve the treatment of chronic diseases, including cardiac rhythm disorders, which we are focused on here today. It is a very large company of forty five thousand or so employees, with sixteen billion dollars in revenue. Our collaboration with them is primarily centered around measuring atrial fibrillation burden within the GENETIC-AF trial by means of an implanted Medtronic continuous monitoring device. As a result, all of the patients in our Phase II-B trial, of two hundred patients, will be implanted with a continuous monitoring device to monitor atrial fibrillation burden, which is defined as a patient's percentage of time in atrial fibrillation over the course of a twenty-four hour period. The collaboration will expand slightly should the DSMB move the trial forward after the phase IIb portion of the trial is complete. The collaboration will expand into the Phase III trial and measure another one hundred patients. Medtronic will provide a centralized determination of data endpoints. They will collect and analyze the AF burden data that will help the DSMB make their decision on whether to move the trial forward.

CEOCFO: Is it difficult to get people to enroll in a trial where they do have to have a device implanted?

Mr. Wheeler: No question; there are several important entry criteria for our trial. However, we do feel that people will be very interested in enrolling in this trial for several reasons. One will be the increased medical attention they will receive, using state of the art genetically targeted therapy to help them. We believe these components

along with others will motivate patients to enroll and be excited about participating in our trial. Lastly, in our preliminary work with those potentially involved in the trial lead us to believe everyone is very excited about the trial and enthusiastic about enrolling patients.

CEOCFO: How do you, both personally and as a company, deal with the frustration of how long it takes for trials for trials to progress when you have something that could potentially help people so greatly?

Mr. Wheeler: It is frustrating and very time consuming and in particularly very costly. There is no question about that. However, I think that one of the things that is very exciting for us at ARCA is the fact that this trial GENETIC-AF is, as far as cardio vascular trials go, a relatively small trial and is actually a relatively short trial as well. Our hope is that the Phase IIb portion of this trial will take approximately two to two and a half years to complete and then hopefully another two to two and a half years after that, should the DSMB decide to move the trial forward. Therefore, in terms of length and the number of patients enrolled, for a cardiovascular trial anyway, six hundred and twenty patients and on order of four to five years is a relatively short time frame, which we are excited about. We believe there is a very large market. As I mentioned earlier, there are roughly two point seven million people that are afflicted with atrial fibrillation. Therefore, we feel that it is important to take the time to do this trial right and to hopefully ultimately gain approval in an area of need. Therefore, while it is frustrating at times, we try to keep our eye on the endgame, which is to try to help this large patient population.

CEOCFO: Why does ARCA Biopharma stand out for investors and people in the business community?

Mr. Wheeler: One of the reasons the company stands out is the approach the company takes in terms of our personalized medicine approach to drug development. We feel that, with the funding we recently secured in June, enables us to start the clinical evaluations of Gencaro in atrial fibrillation in connection with our collaboration with Medtronic. We believe, it is an exciting investment thesis in terms of looking at the company from an investment standpoint or just from a science and drug development viewpoint. This is a fairly unique trial that we are about to undertake. I would also like to point out that we have some interesting milestones that are upcoming. The Gencaro AF IND application is anticipated to be submitted in the third quarter of this year, our GENETIC-AF clinical trial patient enrollment initiation will occur in the first quarter of 2014. Then of course we will have enrollment updates, hopefully shortly thereafter.

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