CEO CFO

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With a Special Mouse Model Demonstrating a High Degree of Efficacy for their Lead Therapeutic Program that uses RNA Interference Against the Hepatitis C Virus, SomaGenics, Inc. is ready to go into Clinical Trials

Healthcare
Biotechnology
(Private)

Dr. Brian Johnston
President and CEO

BIO:
Brian Johnston is Founder, President, and CEO of SomaGenics, a company specializing in RNA-based therapeutics and diagnostic tools. He has more than 30 years' research experience in molecular biology and the development of new biomedical technologies. After graduating with honors in chemistry from Pomona College, he earned his Ph.D. in biophysical chemistry from the University of California, Berkeley. This was followed by postdoctoral research at UC San Francisco and MIT, where he pioneered methods for analyzing unusual DNA structures. He subsequently moved to SRI International, where he was founding director of the Nucleic Acids Program before starting SomaGenics. Awards and honors include postdoctoral fellowships from the American Cancer Society, the National Institutes of Health, and The Medical Foundation and the Cecil H. Short Prize from Pomona College. He is a member of the industrial advisory board for the University of the Pacific's doctoral programs in biotechnology and has served on peer-review panels for grants for the National Science Foundation and the National Institutes of Health. He is author of some 50 research publications and reviews and has been principal investigator or co-investigator on research grants totaling over $18 million. He has held faculty appointments at MIT and the University of Paris, and is currently a Consulting Professor of Pediatrics at the Stanford University School of Medicine.

Company Profile:
SomaGenics, Inc. is a biotechnology company specializing in RNA-based technologies for therapeutic and diagnostic uses. SomaGenics' lead therapeutic program, which uses a proprietary method of RNA interference against the hepatitis C virus, has proven highly effective in preclinical animal models and is ready for clinical development.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Johnston, SomaGenics is translating RNA discoveries into innovative products. What are you actually doing?
Dr. Johnston: As you might recall from your high school biology, RNA is a cousin of DNA. Chemically, it is a very similar molecule except that it has one extra oxygen atom in each subunit. But it has very different functions than DNA. It has the capability of doing something called RNA interference, which was discovered about fifteen or twenty years ago and was the subject of a Nobel Prize for two of its discoverers about six years ago. We have focused on developing therapeutic products using RNA interference, and we developed a proprietary platform which is independent of the technology that that other RNA therapeutic companies are using. It is at least as powerful and has some advantages of cost, efficiency and potency. We have had great luck with it in our initial focus, which is on liver disease and particularly viral hepatitis. We also have part of the company doing RNA-related diagnostic development. Our expertise is in RNA and we have found applications for our discoveries in both therapeutics and diagnostics. So even though we are small, we have some activity in both areas.

CEOCFO: What have you figured out that others have not?
Dr. Johnston: There are two standard ways of doing RNA interference. One of them uses what are called siRNAs, which are just two strands of RNA hybridized together—meaning that they are complimentary and they form a double helix. The other way is to express small RNAs from cells through a DNA vector, as it is called. In that case, people have usually used hairpins, which are two strands that are connected by a little loop and which still form this double helix. Both of these are active, although through different mechanisms, in the RNA interference process. RNA interference is useful in that it allows you to design an RNA molecule that can tar-

get any gene at the messenger RNA level. It seeks out the messenger RNA corresponding to a gene, and a protein, and breaks it in two. Now both technologies, the hairpin and the siRNA, are effective. We followed a path somewhat in between these two. We used small hairpins, but they are synthetic rather than being delivered from a vector, and we discovered a design which is quite different from those that have been used by others. We found that these hairpins, which we call sshRNA, are extremely potent. Because of their structure, they are cheap to produce and they have natural stability. We have chemically modified them to make them even more stable and eliminate any undesired immune stimulation. To make these into therapeutic molecules requires some kind of delivery particle because RNAs are not naturally drug-like molecules. We have collaborated with Tekmira Pharmaceuticals, a public company in Canada, which is really the premiere company for delivering siRNA or sshRNA to cells in the liver. That is where they excel. We have focused on liver diseases, so they are a natural partner.

CEOCFO: Where are you in the development process?

Dr. Johnston: We have nearly completed the preclinical development of our lead agent, which consists of a mixture of two shRNAs that target two targets on the hepatitis C virus. HCV, as probably everybody knows, is a huge problem in the world. There is no vaccine for it. Only about half of the patients that get the strain of the disease that is predominant in the West and are curable by standard treatments. There are emerging treatments that are more effective than the standard treatments have been, but effective treatment remains a problem. We chose to go after HCV partly to develop a more potent treatment and partly to develop an alternative for one component of the standard, which is interferon alpha. Although it is a natural protein, it is toxic and has really bad side effects—it makes you feel like you have the flu for the six to twelve months that it usually takes to go through a course of treatment. It is tough to complete, there are many people that just fall off the wagon or are not healthy enough to go through with it. As far as we can tell, our molecules are non-toxic. We have demonstrated a high degree of efficacy in a special mouse model that can support hepatitis C infection, and we have presented this at international meetings in Europe, the US, and China in recent months. The next step is to go into clinical trials.

CEOCFO: Do you have enough funding?

Dr. Johnston: We pretty much have adequate funding for our preclinical work. We still need to raise money for Phase 1. Much of our funding for development has come from NIH grants. We have been quite successful with grants, having raised about $18 million that way. We have been seeking pharmaceutical partners who are best able, in terms of their finances and their expertise, to help us in the clinical trials, although that is not an absolute requirement. We have had two major pharmaceutical partners in succession, both of which were excited about the scientific progress but then made top-level strategic decisions to move away from the field that we were working in. So we are again seeking a partner for the HCV work.

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- Dr. Brian Johnston

CEOCFO: Would you tell us more about the diagnostics?

Dr. Johnston: We have a platform we call miR-ID. miR refers to microRNAs, which are natural hairpin-like molecules that are produced in every cell in virtually all living things. All of their functions are not fully known, but they are involved in regulating the expression of the majority of genes, and in some organisms they also seem to help protect against foreign genetic material. There is a need for better ways to detect and quantify them due to their potential use as diagnostic indicators. This potential is based on a number of papers showing that microRNAs levels can provide signatures relating to specific diseases and even subtypes of those diseases. Most of these studies are on cancer. For example, lung cancer may be caused by mutations in certain genes, and each pattern of mutation could be considered as a subtype of lung cancer. Each subtype seems to have a particular signature—a particular pattern of expression—of microRNAs. We are developing the capability of having an FDA-approved assay or package of assays based on a group of microRNAs that constitute the signature for a specific cancer. Like the therapeutics, the beauty of this RNA is it can be applied to any disease. We are initially going after a couple of cancers types to show feasibility and seeking partners in the diagnostics area.

CEOCFO: How do you decide which cancers to go after initially?

Dr. Johnston: We rely partly on the medical need. That always guides us, because we want to serve unmet medical and diagnostic needs. But it is based primarily on the medical literature—which cancers have been the subject of studies that identified at least provisional microRNAs signatures. Many of these are not validated to be sure that they are really reliable diagnostic signatures. But there are many papers saying that in cancer "X", you see microRNAs A, B, and C elevated and D, E, and F down-regulated, and that could be a signature.

CEOCFO: There are many companies to look at in your industry, why should investors and people in the business community pick SomaGenics out of the crowd? What is special about SomaGenics?

Dr. Johnston: From my point of view, one of the special things about us is that we have not simply put together a company that in-licenses technology from an outside source and then tries to commercialize it. We have, over a number of years, developed the scientific horsepower and expertise to develop our own technol-

ogy. We have a package of patents that together allow us to get real benefit from our expertise. Part of the consequence of that is, when we sell a product, we will not have to obtain licenses from various other IP holders that take away from the potential profit. In other words we avoid stacking royalties, which can sometimes make a promising technology unprofitable. Also, we are a stable company that has been around for a while, although we are relatively small. We have a track record in terms of publications and patents that quite impressive, I would say. We have garnered considerable respect in the community, so I think partners take us seriously and investors will also.

CEOCFO: What should people remember most about SomaGenics?

Dr. Johnston: For those who have not heard of SomaGenics, it may be because we have consciously been a bit "under the radar." However, that is changing, and I would like people to know that we have a novel and powerful therapeutic platform that has shown a high degree of efficacy against hepatitis C. We expect it to be equally effective against other liver diseases, and with appropriate delivery methods, to a variety of other unmet medical needs.

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