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BIOMED

B U S I N E S S J O U R N A L

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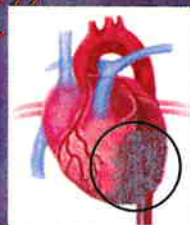
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Turning Injection-Only Drugs into Oral Blockbusters

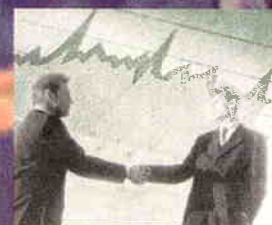


All Eyes Upon the "Perfect" Cardiology Drug



Robust M&A Environment Drives Creative Deal Structures

Strategy and Tactics for Winning Investor Confidence



Targeted Therapies Make Decisive Inroads against Cancer, Infections, and Endocrine Disorders

All eyes upon the “perfect” cardiology drug

VasoGenix Pharmaceuticals is pursuing a promising way to treat heart attacks and other cardiovascular conditions. CEO G. Lee Southard tells us why his company may have found the “perfect cardiology drug.”



G. Lee Southard, Ph.D.
President and
Chief Executive Officer



www.vasogenix.net Phone: 913-888-4773

G. Lee Southard, Ph.D., President and Chief Executive Officer, spoke with *Wall Street Reporter Magazine* on April 22, 2005.

WSR: *In the five years since it was founded, VasoGenix Pharmaceuticals has made enormous strides. Could you provide us with an overview of this progress to date?*

SOUTHARD: VasoGenix Pharmaceuticals, Inc. was founded in 2001 by my son Jeff. At that time, it was focusing on cardiac vasospasms. I got involved in mid-2003, being brought on to be Board Chairman. It became necessary to make some management changes and to change the company's focus from vasospasms myocardial infarction, i.e., to reverse the damage that is caused by heart attacks. Myocardial infarction became our first product goal because of the need and the market potential. We are currently focused on this indication. Our second product goal is congestive heart failure. The science on CGRP suggests that it could be the perfect drug for these indications.

WSR: *What would you outline in terms of focus and the core competencies of the company?*

SOUTHARD: The chief competency in the company is in the drug that we have selected to develop into a treatment. The drug is calcitonin gene-related peptide (CGRP). CGRP is an important cardiovascular agent. When a person has a heart attack, the drug is naturally secreted by the nerves around the heart. We believe that this is an attempt by the heart to try to protect itself. Unfortunately, the heart does not produce enough of the drug to provide sufficient protection. So, our goal is to supplement and amplify the solution that the heart knows to follow.

For an MI diagnosed patient the product would be administered by IV in the emergency room and continue to be administered through interventional procedures, and probably into

recovery. Clinical study protocols are being designed to cover a 20 hour period of administration but I expect a 4 to 8 hour administration will be sufficient.

WSR: *And in terms of these potential applications in addressing the opportunities for marketing, what are the numbers for this potential market?*

SOUTHARD: Obviously, heart attack being America's number one killer, the market is huge. We think the potential market for our product, given the fact that there are about 1.1 million acute cardiac MIs a year, would be \$4 billion. The follow-on product in the pipeline, congestive heart failure, would be \$3 billion to \$5 billion based on 2 million patients. The third pipeline product would be renal insufficiency, which is about 600,000 patients, for a total of about \$1 billion. So, the potential U.S. market for our product line would be \$8 billion to \$10 billion just based on its cardiac applications alone. Now, we have other plans for other indications, but because of some IP concerns I can't really talk about them at this time.

WSR: *What would you highlight to our audience in terms of the technology and*

SUMMARY

Privately held VasoGenix Pharmaceuticals is developing a natural cardiovascular agent to treat heart attack damage. The company's drug candidate alleviates infarction both before and after heart attacks, salvaging healthy tissue in animal trials. Substantial toxicology, dosage and other clinical data already exist. Series B and C capital rounds are open, with funds earmarked for moving the drug to proof of concept in post-heart attack contexts while pursuing applications for congestive heart failure and renal insufficiency. Development model is fully virtual, reducing costs and accelerating the path to profitability. IP position is strong. Aggregate market opportunity is above \$8 billion in cardiac applications alone. Management has a track record of building successful start-up pharma companies.

“When a person has a heart attack, the drug is naturally secreted by the nerves around the heart. We believe that this is an attempt by the heart to try to protect itself. Unfortunately, the heart does not produce enough of the drug to provide sufficient protection. So, our goal is to supplement and amplify the solution that the heart knows to follow.”



science behind this company?

SOUTHARD: First of all, in animal studies, the drug has been demonstrated to reduce infarct size by 90% when given prior to a heart attack. That is an interesting academic result. However, it's not very practical because no one can predict when they are going to have a heart attack. When the drug is given an hour after a heart attack a 40% reduction in infarct size is achieved. That is still huge and something to be excited about because if you can minimize the damage to the heart by 40%, then you have just made an enormous contribution to the salvation of tissue with regard to a heart attack. Reduced damage is expected to have significant effects on the quality of life and chronic

progression of the disease. Concurrent with that is the fact that the drug immediately lowers the CPK inflammatory enzyme release that is used as a marker for heart attack. Therefore, we know the drug is working through a post-infarct inflammatory lowering mechanism. The second important set of data is the tremendous safety experience reported in the literature with this drug. Back in the late 1980s and early 1990's, the drug was clinically and pharmacologically evaluated for a variety of human conditions. None of these were myocardial infarction but one was congestive heart failure. The other conditions were Raynaud Syndrome, arthritis, migraine. There were 27 different human studies done on the drug totaling 338 patients. This data is a gold mine for us. Through demonstrated human experience with CGRP, both the minimum risk dosage and the duration of administration of this drug intravenously can be closely approximated. The savings in time and money has huge implications for our development plan with regard to establishing safety of the drug preclinically and clinically. We will still need

to complete our preclinical work and clinical work to demonstrate conclusively the dose to be used in MI but we can do so without searching, but rather focusing on documenting what is already known. As a matter of fact, if we had to go to the clinic today, I think we could successfully and safely predict the dosage and the duration of administration. The very reason we are raising funds right now is to complete the preclinical work and to complete a Phase I/II clinical trial. This amounts to a proof of concept trial.

WSR: *In terms of competitive advantage, how does the company stand in relation to competitors?*

SOUTHARD: Competitor-wise, we know of no one else that is going after tissue salvage or cardio protection for the heart attack itself. There is one drug in development that is aimed at reperfusion injury, which is a smaller incremental ischemic injury resulting from interventional procedures. Our approach is designed to cover the tissue damage resulting from ischemic injury due to the heart attack and the damage from reperfusion injury due to interventional procedures. I know of no one else taking that approach. There are other current standard of therapy drugs like beta-blockers, heparin, the thrombolytics that are very important to treatment, but none of these work by the same mechanism as CGRP. We want to demonstrate that our product will improve significantly beyond the standard of therapy. With the exception of the thrombolytics our drug has some of the same activities and has the additional potential benefit of reducing cardiac workload. In addition it has been observed to reduce platelet aggregation, increases blood flow to the heart and the kidneys, and we have just recently shown in some work at Tulane University that it decreases cell death in cardiac

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