

VasoGenix Pharmaceuticals, Inc.

Newsletter

Business

VasoGenix Pharmaceuticals, Inc. ("VasoGenix" or the "Company"), founded in 2001, is developing intravenous (IV) and controlled release drug (CRD) treatments for addressing Heart Failure ("HF") and other cardiac diseases in order to reduce the recurrence of these diseases and their resulting hospital and medical costs. VasoGenix's initial goal is to develop both an in-hospital IV drug and a post-hospital CRD treatment to address Acute Decompensated Heart Failure ("ADHF") and to reduce the need for subsequent hospitalization.

The Company's technology combines a potent drug and established IV and biodegradable CRD delivery systems. The drug is based on human alpha Calcitonin Gene Related Peptide ("CGRP") and the Company's synthetic analogs.

VasoGenix is in the final stages of completing its preclinical testing of a selected analog for the treatment of ADHF. When completed, the Company will seek Investigational New Drug ("IND") approval from the FDA for clinical evaluation in Phase I and II trials at the Cleveland Clinic. The Company's Clinical Research Steering Committee ("Committee"), established in conjunction with the Cleveland Clinic ("Clinic"), has guided the Company's clinical process and the Clinic has developed clinical protocols.

Because of CGRP's existing clinical and safety data, the Committee recognized that CGRP matched up well as a treatment for HF and in particular, ADHF. The profile of the Company's product has potential to have an enhanced patient benefit, reduction in medical and hospital expenses, and a significant market potential. The Committee has identified discernable clinical end points and milestones which it believes should provide a path to commercial success.

Heart Failure ("HF"), which is the most common reason for hospitalization among the aged, affects five million people with 550,000 new patients annually and is the largest medical expense. It is responsible for 250,000 deaths annually, more than any other disease, and is responsible for the majority of deaths among people over 65. Each year, HF is the reason for over 12 million doctor office visits and around 1 million hospital admissions. ADHF is the single most expensive medical expense and about 50% of ADHF patients are readmitted within 90 days. VasoGenix believes that its product will lower the ADHF readmittance rate while providing enhanced health and financial benefits over existing therapies.

Product

CGRP is a 37-amino-acid peptide. There is a significant body of human clinical data, developed over almost 20 years, that confirms the potential safety and efficacy of CGRP in treating heart failure and the often resulting kidney failure. This prior research, combined with the knowledge that CGRP occurs naturally in the heart, has eliminated the need for many costly tests and accelerated the Company's development process.

The Company is selecting an analog of CGRP that will possess a biological profile and potency (*agonist properties*) equivalent or better than CGRP. The new analog will be delivered by IV for in-hospital treatment of ADHF, as well as combined with a CRD system tailored to the post-hospital treatment of ADHF. The analog and CRD system would also provide the basis for a pipeline of products with potential benefits in chronic heart failure and additional medical applications in the heart, the kidneys and the lungs.

Competitive Advantages

CGRP is different from other drug treatments as it provides multiple mechanisms to treat heart failure and other cardiac diseases. No other existing or potential drug provides the combined potential advantages of improving blood circulation, reducing inflammation of the heart muscles, and is so readily accepted by the body because it is natural to it. The IV product will be administered to a patient while they are hospitalized to provide these benefits.

Administering CGRP through a biodegradable CRD product to a stabilized patient at the hospital prior to discharge is aimed at maximizing the post-hospital stabilization period and minimizing the need for the patient to return to the hospital by reducing subsequent acute heart problems. Repeated CGRP treatments could be administered on an outpatient basis. These collective benefits, particularly the elimination of hospital expense, will result in significant cost reduction in the treatment of HF.

None of VasoGenix's potential competitors have this combination of advantages. This is verified by an exhaustive review of current products in development and supported by the Company's patent position.

Technology

The Company's present Intellectual Property (IP) covers the application of CGRP for heart and heart related issues. The Company currently has 15 U.S. and foreign patent filings. These patents do not cover the basic chemical composition of CGRP, but provide methods and use coverage for CGRP. The Company's new analogs however, are being patented as new compositions of matter.

VasoGenix outsources its R&D to specialists in FDA drug development and it believes that the progress made to date, with expenditures to date of about \$4 million, verify the cost effectiveness of this approach. The Company is currently in the process of conducting confirmatory tests for safety and efficacy.

Regulatory

In 2007, VasoGenix, in connection with a pre-IND filing meeting with the Cardio-Renal Division of the FDA, received important regulatory guidance concerning its treatment of HF with CGRP. As a result, in order to file its IND, the Company will validate its Chemistry, Manufacturing and Control ("CMC") package, and conduct toxicology, pharmacodynamic, pharmacokinetic evaluations on its selected analog and CRD product. The expected direct costs, prior to filing the IND, are expected to approximate \$4.5 million. This will be followed by Phase I and Phase II Clinical Trials at the Cleveland Clinic to confirm proof of concept with the resulting aggregate costs projected to be about \$12 million.

Management

G. Lee Southard, Ph.D, President and CEO, has successfully started two previous life science startup companies, Atrix Laboratories, Inc. and Vipont Pharmaceuticals, which sold collectively for almost \$1 billion. While in these positions, as well as positions at Eli Lilly and Johnson and Johnson, he has been associated with the success of ten innovative marketed drugs and medical devices during his 40 years of experience.

Jeff Southard, Vice President Drug Development, is an experienced product discovery and drug development researcher who has 20 years experience working with major pharmaceutical companies and start-ups, as a researcher, manager and consultant.

Financial Summary

The Company believes that it could complete Phase I and Phase II clinical trials within 5 years for a total investment of about \$15 million, and after that time license its technology to a major pharmaceutical firm for a royalty, estimated as follows:

	Year 1	Year 2	Year 3	Year 4	Year 5	Year 6	Total
Treatment Revenue (\$000)							
In-Hospital Drug Revenue	\$57,750	\$127,050	\$209,633	\$307,461	\$422,759	\$558,042	
CRD - Initial Visit Patients Revenue	42,900	94,380	155,727	228,400	314,049	414,545	
CRD - Repeat Visit Patients Revenue	85,425	185,504	301,517	435,424	589,433	765,969	
CRD - VasoGenix Recurring Patients Revenue	-	64,162	155,983	267,618	398,816	551,445	
Total Treatment Revenue	186,075	471,097	822,859	1,238,903	1,725,058	2,290,001	
License	10%	10%	10%	10%	10%	10%	
Total Royalty (\$000)	\$18,607	\$47,110	\$82,286	\$123,890	\$172,506	\$229,000	\$673,399



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