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## **JOB PROFILE**

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**Position:** Program Manager, Algisyl-LVR™

**Overview:** LoneStar Heart, Inc. is an early-stage biomedical company developing new therapies to preserve and restore adequate heart function in patients with Congestive Heart Failure (CHF). The therapies are based on scientific discoveries of the physical, biologic, and molecular mechanisms involved in the development of CHF and the ability to modify these mechanisms for therapeutic gain at a cellular and molecular level. The company has a product candidate pipeline consisting of long-term implantable biopolymers, cardiac stem cell modulators (small molecules and other peptides) as well as cell-and gene therapeutic approaches. Together with its scientific founders, Dr. James T. Willerson, Chief of the Texas Heart Institute, and Dr. Eric N. Olson, Distinguished Chair of the Dept. of Molecular Biology at the University of Texas Health Sciences Center in Dallas, LoneStar Heart has acquired and developed significant intellectual property as well as an international, thought-leading network of scientists, clinicians, and corporate partners.

LoneStar Heart's lead program, Algisyl-LVR, is a medical device under clinical development intended to prevent or reverse the progression of CHF in patients who have an enlarged left ventricle as a result of mitral valve regurgitation, ischemia, dilated cardiomyopathy and/or other disorders. The product consists of an injectable proprietary biopolymer that is administered directly into strategic areas of the left ventricle muscle. As it is injected, the biopolymer thickens and forms gel-like bodies that remain in the heart muscle as permanent implants and perform the function of a prosthetic scaffold. These implants provide several beneficial functions:

- Thickening of the muscle wall
- Reduction of chamber size
- Decrease of local muscle wall stress
- Re-shaping of the dilated ventricle based on the location of the implants
- Re-alignment of the papillary muscles

Algisyl-LVR is currently being tested in a safety and feasibility clinical study in Germany in patients with a dilated left ventricle who are undergoing heart surgery for bypass or valve repair. Additionally, the company expects to start a clinical study where the biopolymer is administered alone in a minimally invasive procedure in patients with more advanced CHF (NYHA Classes III and

IV). The outcomes of these two studies will be used to obtain a European market approval (CE Mark) and to expedite efficacy trials in the US.

LoneStar Heart is now seeking to hire a Project Manager to lead the execution the Algisyl-LVR program and oversee its development process from its present state to commercialization.

Location: Laguna Hills (South Orange County), California.

Date: LoneStar Heart expects to fill this position in Quarter 3, 2010.

Supervisor: The position reports to the President & Chief Operating Officer.

Travel: Occasional domestic and foreign travel required.

Description: Plans, directs, and coordinates all activities of Algisyl-LVR program to ensure that goals or objectives of program are accomplished within prescribed time frame and funding parameters.

Formulates and/or reviews project management plans in accordance with the company's Quality Systems to determine procedures for accomplishing projects, time frame, funding needs, staffing requirements, and allotment of available resources to various project phases.

Directs and coordinates activities of project personnel to ensure project progresses on schedule and within prescribed budget.

Manages the manufacturing process including key vendor relations for the supply, assembly, and distribution of all product components (biopolymers, delivery devices, and neuro-stimulation devices).

Confers with project staff to outline workplan and to assign duties, responsibilities, and scope of authority. Collaborates closely with R&D and regulatory management to determine the best development strategies and activities while ensuring their timely and cohesive performance.

Prepares and / or reviews status reports and modifies schedules or plans as required. Prepares project reports for management, client, or others.

Confers with project personnel to provide technical advice and to resolve problems.

May coordinate project activities with activities of government regulatory or other governmental agencies.

May negotiate contracts with consulting firms to perform research studies.

**Profile:** Significant (5-years or more) experience in program management in the medical device and biotech / pharmaceutical fields; experience with drug-device combination products a plus.

Experience and knowledge in the cardiovascular therapies market; experience in the cardiac surgery and the arrhythmias markets a definite plus.

Direct experience in the preclinical and clinical development stages of implantable or critical care devices.

Significant experience in managing complex vendor relations with suppliers, manufacturers, and distributors.

Intimate familiarity with ISO standards, quality systems, standard operating procedures, and regulatory requirements for the domestic and European markets.

Ability to work effectively in a rapidly-changing, small company environment.

**Education:** Minimum undergraduate degree in engineering or life sciences. Additional business administration background (MBA or similar) a plus.

**Compensation:** Based on experience.

Participation in the company's employee stock option plan.

For enquiries or to submit your resume, please contact:

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