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**Rancho Santa Fe Bio, Inc. (“RSF Bio”)** is a San Diego, CA, clinical-stage, biotechnology company developing and seeking to commercialize drugs for the treatment of a range of cardiovascular diseases. Our lead drug, Ataciguat™, utilizes technologies exclusively licensed on a worldwide basis from Mayo Clinic and has been shown in a Phase IIb clinical trial to slow the progression of aortic valve stenosis (“**AVS**”) in patients. RSF Bio is also involved in licensing and the development of additional synergistic technologies (e.g., biomarkers and next generation technologies which have additional applications in the cardiovascular field).

**A Large Unmet Cardiac Treatment Need: Aortic Valve Stenosis.**

AVS is the most common valvular lesion in the elderly. It affects nearly 3% of the population over the age of 55 with a prevalence of approximately 2 million people in the United States and over 3 million worldwide. While patients are often asymptomatic in early stages of AVS, its presence can be readily detected by auscultation of a heart murmur and confirmation of disease presence and severity with echocardiography. Once confirmed, disease progression is assessed annually and the current standard of care involves “watchful waiting” as patients progress from mild to moderate to severe stenosis. Previously, a number of drugs have been investigated to slow the progression of AVS, but all have failed to achieve their primary endpoints. Once AVS progresses to the severe stages of disease it requires either a transcatheter aortic valve replacement (“**TAVR**”) operation or surgical aortic valve replacement (“**SAVR**”), which are both fairly invasive, costly and include the risk of significant complications.

**Ataciguat™ Development through the NIH’s NCAT’s Program.**

Ataciguat™, originally developed by Sanofi, was selected for the New Therapeutic Uses Program within the NIH’s National Center for Advancing Translational Sciences (“**NCATS**”). While Sanofi had previously tested the drug in Phase I and II clinical trials on nearly 1,000 patients in non-AVS multiple disease indications, they were unable to identify signals suggesting clinical efficacy. This work, however, did establish a robust dataset demonstrating a strong safety profile and excellent tolerance. Based on its reported mechanism of action, Dr. Jordan Miller of Mayo received a multi-million dollar grant from NCATS to execute a series of preclinical experiments to demonstrate that Ataciguat™ could slow progression of calcification in a mouse model of AVS. Subsequently, Dr. Miller, with support from Sanofi to supply product, executed Phase Ib and IIb trials to confirm safety and efficacy of slowing disease progression in AVS at Mayo Clinic.



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### **Phase II Clinical Trials Show Great Promise for Ataciguat™ in Treatment of AVS.**

The randomized, double-blind, placebo-controlled, Phase IIb clinical trial conducted at Mayo Clinic yielded exciting results, demonstrating that Ataciguat™ elicited (1) a significant 70% reduction in progression of aortic valve calcification, (2) a 50% reduction in progression of aortic valve dysfunction, (3) the tendency to prevent declines in left ventricular function, and (4) no negative impact on bone formulation. Similar results and trends were seen at six and twelve months of daily oral treatment.

### **Broad Patent Coverage.**

Following negotiations with Mayo Clinic, RSF Bio exclusively licensed on a worldwide basis all rights to three patents and a number of patent applications that provide it with broad patent coverage on Ataciguat™ and similar compounds for the treatment of AVS until 2037. In addition, RSF Bio is completing an exclusive worldwide license to all of the rights to supporting regulatory data/documentation, trial results, and related intellectual property owned by a third party. RSF Bio also plans to expand its patent coverage with the exclusive licensing of additional intellectual property in this field from third parties.

### **A Phase III Ready Asset.**

RSF Bio will engage the FDA in a Type C meeting in Q1 2021 in which it plans to present a proposal to (1) seek “breakthrough” status and (2) seek endorsement for advancing directly to a multi-site Phase III trial with its primary endpoint being slowed progression of aortic valve dysfunction. Concurrently, RSF Bio is also considering plans for clinical trials of Ataciguat™ in potentially in the European Union, the United Kingdom and Canada.

### **Our Financing and Use of Proceeds**

To accelerate advancing this important technology towards clinical impact, RSF Bio is seeking to raise a Series A round. These funds will be utilized to complete the following milestones based on the amount raised: (1) preparation and completion of our FDA Type C meeting, (2) completion of initial activities needed for ramp-up of manufacturing of Ataciguat™, (3) licensing of additional potential pipeline technologies for certain biomarkers and next generation platform technologies, (4) preparation for additional follow-up FDA meetings related to obtaining “breakthrough” status for our technology and an end of Phase II/Pre-Phase III meeting, and (5) potentially begin our Phase III trial.

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