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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health



National Institutes of Health Commercialization Assistance Program  
(NIH-CAP)

## Company Overview

**Industry Sector:** Biotechnology/Pharmaceutical

**Company Overview:** SonoGene LLC (SonoGene) is an early-stage pharmaceutical discovery company developing novel platforms for therapeutic delivery of genes and pharmaceuticals using nonviral-mediated, ultrasound-directed systems. SonoGene has developed a method for successfully delivering gene therapy for treatment of individuals with low HDL (Hypoalphalipoproteinemia)

### Target Market(s):

- (1) Treatment for 50M "at risk" individuals with low HDL for prevention of premature CV disease
- (2) Dyslipidemia market: Statin market > \$50B/annually exclusive for LDL cholesterol
- (3) Increasing market for intravenous drug/gene delivery (i.e., Walgreens-Option Care \$850M)

## Management

**President:** Steve Feinstein, MD, is an NIH funded, Professor of Medicine in the Section of Cardiology at Rush University Medical Center. He has published over 320 manuscripts, chapters, book on ultrasound contrast agents and he is the inventor of the first commercial, FDA approved ultrasound contrast agents.

**CEO:** Eric Coles, PhD: Research biochemist with broad experience in diagnostic and pharmaceutical product development, finance and marketing

**Vice President:** Michael Davidson, MD, Professor of Medicine and Chair of Preventive Cardiology, University of Chicago, Current President of the National Lipid Association (NLA)

## Key Value Drivers

**Technology\*:** Non-invasive, low cost, safe technology for novel drug/gene delivery. The patented SonoGene technology consists of the following: (1) vehicle = ultrasound contrast agent, (2) external activator = commercial ultrasound system, and (3) drug/gene = plasmids. The SonoGene therapeutic method uses a peripheral, intravenous injection site followed by 1 minute of targeted external ultrasound energy to disrupt microspheres locally within the liver, resulting in direct, plasmid transfection of ApoA1 and subsequent increase in serum HDL cholesterol.

**Competitive Advantage:** (1) Currently, there exists no effective treatment for low HDL, a known CV risk factor, (2) SonoGene has developed a novel drug/gene delivery system using ultrasound-directed, non-viral methods that uniquely increase de novo HDL, (3) SonoGene uses an intravenous therapy as the standard of care

### Plan and Strategy:

Pursue Phase I clinical trials for dyslipidemia and license the technology to Pharma for Phase II-III clinical trials. The estimated market is > \$50B; SonoGene will pursue pipeline of products for generalized use.

\*Technology funded, in-part via NHLBI SBIR HL 95238-01, and commercialized by CAP

## Product Pipeline

Initial product development designed for treatment of dyslipidemia (hypoalphalipoproteinemia, Tangier's Disease)

Current development is preclinical with clinical trials planned for year 2-3

Future: Multiple gene delivery programs for dyslipidemia; products in early stage of preclinical testing