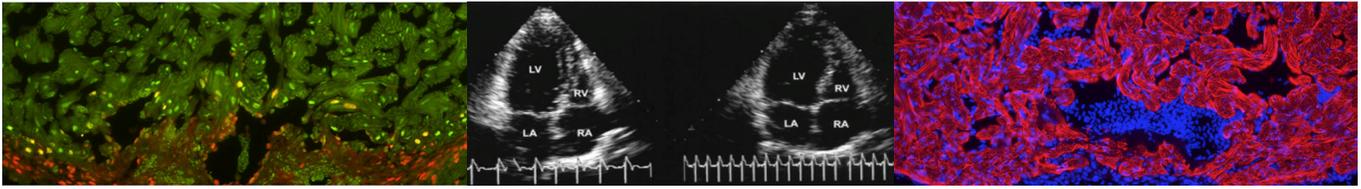


Novo Biosciences

Unlocking Our Regenerative Power™



Executive Summary

Novo Biosciences, Inc. (www.novobiosciences.com) is a regenerative medicine company developing first-in-class small molecule therapies to activate endogenous tissue regeneration processes. Our lead candidate MSI-1436 dramatically stimulates regeneration of injured heart, skeletal muscle, skin, bone, nerve, connective and vascular tissues and complex organs in lower vertebrates and mice.

MSI-1436 has previously been tested in human Phase 1 and 1b clinical trials for the treatment of obesity and type 2 diabetes and has been shown to be safe. Doses of MSI-1436 that activate tissue regeneration are **50-times lower** than the maximum safe human dose. The target and mechanism of action of MSI-1436 are well understood.

Novo Biosciences' studies of MSI-1436 have undergone extensive peer review. Our work on MSI-1436 has been published (www.nature.com/articles/s41536-017-0008-1) and a recent NIH Direct to Phase II SBIR grant application has been funded. Peer reviewers of the SBIR application recognized the "*novelty of cardiac regeneration as a pharmacological target*" and the potential of MSI-1436 to meet a "*compelling unmet clinical need*". **MSI-1436 is the only small molecule drug candidate known to activate regeneration of the adult mammalian heart following heart attack.**

Therapeutic indications and market: Novo Biosciences is developing MSI-1436 for treatment of acute heart attack, Duchenne muscular dystrophy (DMD) and traumatic skeletal muscle injuries. U.S. patent protection (U.S. #9,504,700) for the use of MSI-1436 to treat heart injury has been obtained. Additional U.S. and foreign patent applications are pending.

Heart disease is the leading cause of death throughout the world. Coronary heart disease (CHD) is the most common type of heart disease and is responsible for ~7.4 million annual deaths worldwide. The human heart has very limited ability to repair or regenerate muscle cells killed or damaged by a heart attack. Instead, dead cells are replaced by nonfunctional scar tissue that weakens the heart and can ultimately lead to complete heart failure and death. Current healthcare costs for CHD in the U.S. alone are \$126.2 billion and are expected to rise to \$177.5 billion by 2040.

Duchenne muscular dystrophy is a genetic orphan disease characterized by progressive skeletal muscle degeneration and greatly shortened life expectancy due to heart or respiratory failure. Skeletal muscle has robust regenerative capabilities. In DMD, however, these regenerative processes cannot keep pace with the rate of muscle degeneration, which leads to disease symptoms. U.S. healthcare costs for treating DMD are \$400-500 million a year. The annual costs for treating all musculoskeletal diseases in the U.S. are over \$800 billion.

Competition: Regenerative medicine R&D efforts for acute heart attack and muscle injuries focus primarily on development of stem cell- and tissue engineering-based therapies. To date, these approaches have shown no or very limited efficacy in treating heart and skeletal muscle damage. A growing body of evidence indicates that the modest effects of stem cells on heart function observed by some groups are not due to cell engraftment with subsequent tissue repair. Instead, transplanted stem cells appear to secrete paracrine factors that activate **endogenous regenerative mechanisms**.

Novo Biosciences is pioneering novel approaches to identify endogenous tissue regeneration mechanisms and to develop small molecules that activate them. Small molecules like MSI-1436 have considerable advantages over stem cell and tissue engineering therapies including much lower costs, lower regulatory hurdles, lack of ethical concerns, ease of administration and ready reversibility.

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