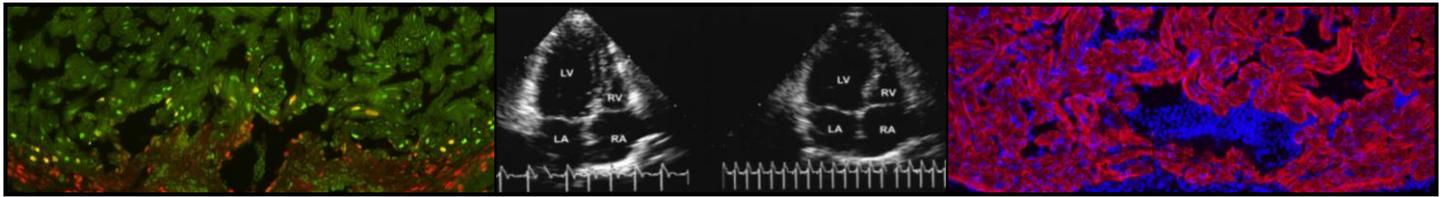


# Novo Biosciences

## Unlocking Our Regenerative Power™



## Executive Summary

**Novo Biosciences, Inc.** ([www.novobiosciences.com](http://www.novobiosciences.com)) is a regenerative medicine company developing first-in-class small molecule therapies to activate endogenous tissue regeneration processes. Our lead drug candidate trodusquemine (aka MSI-1436) significantly slows degenerative changes in skeletal and heart muscle in a mouse Duchenne muscular dystrophy (DMD) model and stimulates regeneration of injured heart, skeletal muscle, skin, bone, nerve, connective and vascular tissues and complex organs in lower vertebrates and mammals.

**Trodusquemine has undergone extensive safety testing in animals and humans.** Doses of trodusquemine that activate tissue regeneration are **50-times lower** than the maximum safe human dose. The target and mechanism of action of trodusquemine are well understood.

Novo Biosciences' studies of trodusquemine have undergone extensive peer review and pre-IND review by the FDA. Our work on trodusquemine has been published ([www.nature.com/articles/s41536-017-0008-1](http://www.nature.com/articles/s41536-017-0008-1); **Scientific American, April 2019**) and funded through NIH, DoD and private investment mechanisms.

Peer reviewers of a recently funded Direct to Phase II NHLBI SBIR grant recognized the *"novelty of cardiac regeneration as a pharmacological target"* and the potential of trodusquemine to meet a *"compelling unmet clinical need"*. **Trodusquemine is the only small molecule drug candidate known to activate regeneration of the adult mammalian heart following heart attack.**

**Intellectual property, therapeutic indications and market:** Novo Biosciences is developing trodusquemine for slowing and reversing heart and skeletal muscle degeneration in DMD patients and activating heart regeneration following acute heart attack. U.S., European and Japanese patent protection for the use of trodusquemine as a regenerative medicine therapeutic to treat heart damage and other tissue injuries has been obtained. Additional patent applications are pending.

DMD is a genetic orphan disease characterized by progressive muscle degeneration and greatly shortened life expectancy due to heart or respiratory failure. U.S. healthcare costs for treating DMD are ~\$500 million a year. Annual U.S. costs for treating all forms of musculoskeletal diseases exceed \$800 billion.

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 billion and are expected to rise to \$178 billion by 2040.

**Competition:** Regenerative medicine R&D efforts for acute heart attack and skeletal muscle injuries focus primarily on the development of stem cell-based therapies. This type of treatment approach has been defined as "halfway medical technology". It has generated no approved therapies despite over 20 years of R&D.

The Novo Biosciences' approach is pioneering. We are focused on developing "decisive medical technology" for the treatment of severe tissue injuries. Our scientists identify the endogenous mechanisms of regeneration that exist in all of our tissues and then develop small molecules that activate these processes. The discovery of trodusquemine underscores the power of this R&D strategy. **Small molecules have considerable advantages over stem cell-based therapies** including much lower costs and complexity, lower regulatory hurdles, lack of ethical concerns, ease of administration and ready reversibility.

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