

## www.revidiatherapeutics.com

**Company overview:** Revidia Therapeutics, Inc. is an IND-ready cardiac regenerative medicine company pioneering the discovery and development of first-in-class drug therapies that activate intrinsic regenerative and repair mechanisms in damaged heart muscle.

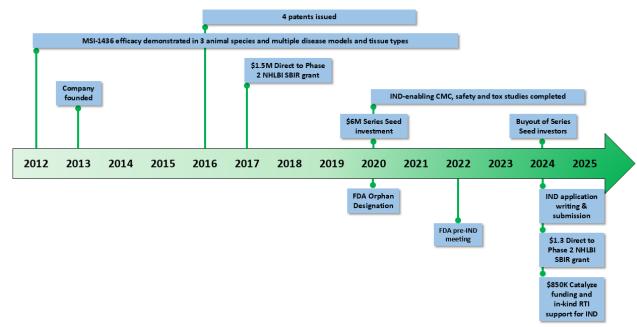
Revidia's paradigm shifting solution: Revidia Therapeutics was founded to address the serious limitations and challenges of stem cell- and gene-centric cardiac regenerative medicine R&D. Our paradigm shifting approach focuses on activating intrinsic regenerative capacity in damaged tissues using small molecules. Revidia's lead drug candidate, MSI-1436, reverses acute ischemic heart injury in mice and pigs, reverses dilated cardiomyopathy and heart failure in mice, and slows and reverses heart muscle degenerative changes in a mouse Duchenne muscular dystrophy (DMD) model. MSI-1436 is the only small molecule in development that activates regeneration in the adult mammalian heart.

Target and mechanism of action: The tyrosine phosphatase PTP1B disrupts signaling pathways that control intrinsic regeneration and repair mechanisms following injury in diverse tissue types. MSI-1436 is a first-in-class allosteric PTP1B modulator. Reduction of PTP1B activity by MSI-1436 allows normal activation of damage repair and regeneration mechanisms including progenitor cell proliferation, resolution of inflammation and anti-inflammatory pathways, neovascularization and scar resolution mechanisms.

## Major R&D milestones:

- Cardiac efficacy demonstrated in 3 species and 6 cardiac injury models; target and cellular MOAs well-defined
- Efficacy demonstrated in multiple other tissue types including skeletal muscle and nerve tissue
- Previously established human safety
- FDA-required safety and toxicity testing complete; manufacturing methods established
- FDA pre-IND meeting complete
- Planned IND submission and request for FDA Fast Track Designation in Q4 2025

Timeline of company development and major value inflection points:



**Intellectual Property:** U.S., E.U., Canadian and Japanese patents and FDA Orphan Drug Designation for treating dystrophinopathies. New composition of matter, formulations and druggable tissue repair and regeneration targets identified.

**Previous and current funding:** Revidia was founded in 2013. Early discovery and efficacy studies were funded by peer-reviewed NIH research grants, startup company funding from the Maine Technology Institute and a \$100,000 angel

investment. In 2017, Revidia was awarded a peer-reviewed \$1.5M Direct to Phase 2 SBIR grant from NIH-NHLBI. Cambrian Biopharma made a \$6M Series Seed investment in Revidia in May 2020. Together with his partners in Prometheus Cardiology and Rare Diseases, Revidia's founder and CEO Dr. Kevin Strange bought out Cambrian's equity and acquired all Revidia's intellectual assets in August 2024. In September 2024, Revidia was awarded its second peer-reviewed NIH-NHLBI Direct to Phase 2 SBIR grant of \$1.3M. Also in September 2024, Revidia was one of two companies awarded peer-reviewed support from the cardiovascular sciences section of the highly competitive NHLBI Catalyze Program. Catalyze support includes \$850K in funding and extensive in-kind support from the Research Triangle Institute (RTI) for clinical trial design, regulatory affairs, FDA meetings and interactions and IND application preparation and submission. Grant review panels have noted that successful commercialization of MSI-1436 will meet "clear" and "compelling unmet clinical need(s)", will "result in first-in-class drug to regenerate cardiac tissue", "have a high overall impact on DMD treatment and on the market", and that the knowledge resulting from Revidia's development program can be "applied to other cardiovascular diseases".

## **Leadership Team:**

- Kevin Strange, Ph.D.: Founder, President and CEO
- Michael Christensen, Ph.D.: Executive VP for Business Development
- Michael Stein, M.D.: VP for Clinical Development
- Ed Turnley, J.D.: VP for Legal and Regulatory Affairs

## **Medical and Scientific Advisory Boards:**

- Linda Cripe, M.D.: Professor of Pediatrics and pediatric cardiologist, OSU College of Medicine and The Heart Center
  at Nationwide Children's Hospital; Scientific Advisory Board member for Parent Project Muscular Dystrophy (PPMD).
- Richard Lee, M.D.: Professor of Stem Cell and Regenerative Biology Harvard University; Professor of Medicine, cardiologist, Harvard Medical School.
- **Jennifer Monti, M.D.:** Board-certified cardiologist subspecialized in cardiogenetic disorders of young adults; health team member @Meta; entrepreneur in residence at Northeastern University's Roux Institute.
- Tom Rando, M.D., Ph.D.: Director, UCLA Broad Stem Cell Research Center; Professor of Neurology and Molecular, Cell and Developmental Biology, UCLA.

**Seeking Series A Investment:** Revidia is seeking \$20M in Series A investment to advance a novel subcutaneous MSI-1436 formulation through Phase 1/2a trials in DMD cardiomyopathy patients and to further develop and protect our IP pipeline.

Subcutaneous MSI-1436 formulations to treat fatal cardiomyopathy in Duchenne muscular dystrophy patients. DMD is an FDA-designated orphan disease characterized by progressive muscle degeneration and greatly shortened life expectancy. Less than 13% of DMD patients have access to treatment options other than steroids. Annual U.S. healthcare costs for treating DMD are >\$500 million. The global DMD drug market size is expected to reach \$18.1 billion by 2030 with a CAGR of 42.5%.

Most DMD patients die from heart failure in their mid-20s. The majority of DMD companies are developing skeletal muscle therapies. DMD genetic therapies in development aim to partially restore dystrophin function in skeletal muscle and have not yet shown clear and consistent clinical efficacy. Improving skeletal muscle function will likely lead to further cardiac injury making it imperative to treat heart and skeletal muscle damage concurrently.

There are no approved medications for DMD cardiomyopathy. Revidia is addressing this major unmet medical need and has developed novel MSI-1436 formulation and dosing strategies for DMD patients. KOLs have referred to MSI-1436 as a potential DMD "game changer".

Extended-release (ER) depot MSI-1436 formulations to treat heart attack and heart failure. MSI-1436 stimulates heart regeneration, reduces scarring and improves cardiac function in heart attack and heart failure animal models and has been shown to induce weight loss and reduce atherosclerotic plaque formation. Revidia has established proof-of-principle for MSI-1436 ER depot formulations. ER formulations provide unique market opportunities for heart attack and heart failure indications and development of new cardiac reparative devices and therapies. The treatment of cardiovascular disease worldwide has a 2024 projected market revenue of \$440 billion and a 5-year CAGR of 4.5%. The American Heart Association has estimated that cardiovascular disease costs will exceed \$1.1 trillion in the U.S. by 2035.

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