

Company Summary

SECTOR

Metabolic diseases associated with mitochondrial dysfunction, especially insulin resistance and type 2 diabetes.

DEVELOPMENT STATUS

- Developing novel insulin sensitizers that are selective for a molecular target connecting mitochondrial metabolism to cell function. The compounds' PPAR-independent pharmacology results in improved insulin action without weight gain and other PPAR-related side effects.
- MSDC-0160 (Phase 2b—T2DM); MSDC-0602 (Phase 2a—T2DM); and MSDC-0160 (Phase 2a—ALZ).

INTELLECTUAL PROPERTY

Composition of matter, use, and process patents issued and pending.

FUNDING STATUS

Raised \$55 million from inception. Seeking \$40 million in Q1 2012 to advance Phase 3-enabling development.

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Metabolic Solutions Development Company, LLC is a drug discovery and development company exploiting novel molecular targets to develop new therapies to treat diseases associated with mitochondrial dysfunction, especially insulin resistance and type 2 diabetes. The company has raised approximately \$55 million in support of the development of its pioneer and lead products, MSDC-0160 and MSDC-0602 — novel insulin sensitizers that are selective for a molecular target that invokes a “switch” to connect mitochondrial metabolism to cell function.

Founded in 2006 by Jerry Colca, Ph.D. and Rolf Kletzien, Ph.D., former researchers at The Upjohn Company, MSDC is headquartered in Kalamazoo, MI.

Product Development Pipeline

	2011	2012	2013	2014	2015	2016
MSDC-0160* (T2DM)	Phase 2b	Phase 3		NDA	Launch	
MSDC-0602 (T2DM)	Phase 2a	Phase 2b	Phase 3		NDA	Launch
MSDC-0160 (ALZ)	Phase 2a Imaging Study		Phase 2 Cognition Study	Phase 3		NDA

* MSDC-0160 development focus expected to be shifted to neurodegenerative diseases.

MSDC-0160 is currently being studied in a Phase 2b 90-day, randomized, double-blind, comparator- and placebo-controlled clinical trial involving approximately 330 patients with type 2 diabetes at 26 sites throughout the U.S. Data from this study are expected in December 2011. In a recently completed Phase 2a study, MSDC-0160 successfully achieved effective glucose control and improvement in a number of other metabolic parameters, without the fluid retention or weight gain associated with current insulin sensitizers.

MSDC-0602 was studied in a recently-completed Phase 2a 28-day, randomized, double-blind, comparator- and placebo-controlled, multi-dose study in 129 patients with Type 2 diabetes at 15 sites throughout the U.S. This study followed the completion of two Phase 1 trials in which no safety concerns were observed. Additional safety and expanded efficacy data will be obtained from a Phase 2b study of MSDC-0602 that is targeted to begin in the first quarter of 2012.

MSDC-0160 is currently being studied in a Phase 2a trial at Rush University Medical Center, Chicago involving patients diagnosed with mild Alzheimer's disease funded by the Alzheimer's Drug Discovery Foundation. Data from this study are expected in the second quarter of 2012.

FOUNDERS

- Jerry R. Colca, PhD
- Rolf F. Kletzien, PhD

BOARD OF DIRECTORS

- Mark Olesnavage, Board Chair (Managing Director, Hopen Life Science Ventures)
- Stephen Benoit (CEO)
- Jerry Callahan, PhD, MBA (Managing Director, Hopen Life Science Ventures)
- Jerry Colca, PhD (CSO)
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- Rolf Kletzien, PhD (Sr. VP Research)
- John Landis, PhD (Adjunct Professor, Purdue Univ. Department of Chemistry)
- William Parfet (Chairman and CEO, MPI Research)

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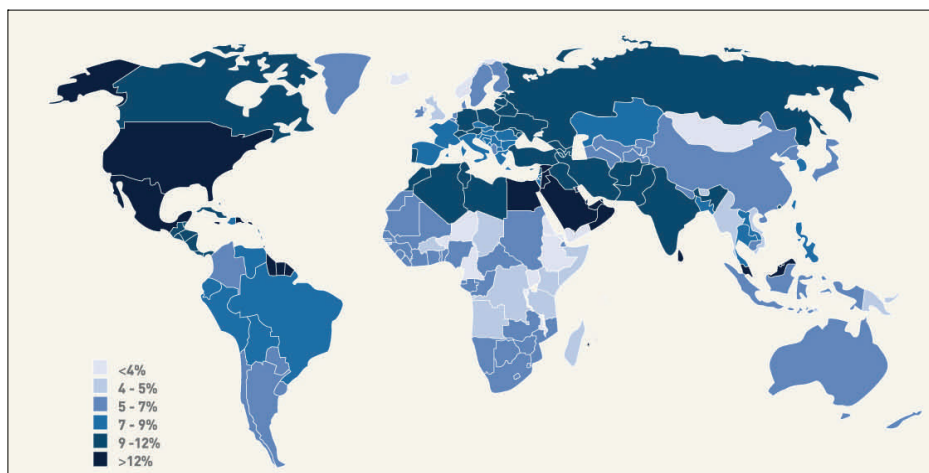
- John Amatruda, MD (former Sr. VP Diabetes & Endocrinology, Merck & Co)
- Douglas Morton Jr., PhD (former Group VP, Technology Acquisitions Operations, Pfizer)
- Charles Burant, MD, PhD (Dr. Robert C. and Veronica Atkins Professor of Metabolism, University of Michigan Medical School)
- William Baer, MD, PharmD (Exec. Director and CMO, ClinXus)

September 2011

Market

Diabetes is a metabolic disease that is caused by changes in metabolism that alter both the ability of insulin to work on its target tissues and the cells in the pancreas that make and secrete insulin. According to the World Health Organization (WHO), more than 220 million people worldwide have diabetes, and 90 percent of those afflicted have type 2 diabetes. In 2005, WHO estimated that 1.1 million people died from diabetes and the organization expects that number to double by 2030.

As of 2007, the Center for Disease Control estimated that 23.6 million Americans, 7.8 percent of the population, had diabetes. The CDC stated that 1.6 million new cases of diabetes were diagnosed in people aged 20 and older in 2007.

Prevalence (%) Estimates of Diabetes (29-79 years), 2030

IDF Diabetes Atlas, 4th ed. © International Diabetes Federation, 2009

Insulin Sensitizers

- Insulin sensitizers have positive effects in the treatment of diabetes and can preserve β -cell function.
- The promise of the class has not been realized because of separate and distinct problems with troglitazone, rosiglitazone, and pioglitazone, the only three insulin sensitizers to be approved for clinical use.
- Therapeutic improvements have been limited by a misunderstanding of the molecular mechanism of action.
- MSDC is developing a new way forward through its novel compounds that are selective for a molecular target that invokes a "switch" connecting mitochondrial metabolism to cell function. This PPAR-independent pharmacology results in improved insulin sensitivity, generation of brown fat, and regeneration of β -cells without weight gain and other PPAR-related side effects.