



# **FastForward**<sup>SM</sup>

## **General Fund**

This project is funded by Fast Forward, LLC, a nonprofit organization established by the National Multiple Sclerosis Society in order to accelerate the development of treatments for MS. Fast Forward will accomplish its mission by connecting university-based MS research with private-sector drug development and by funding small biotechnology/pharmaceutical companies to develop innovative new MS therapies and repurpose FDA-approved drugs as new treatments for MS.

<i>Primary Investigators</i>	<i>Project Title</i>	<i>Amount to be Committed</i>
Melissa R. Ortega, MD Heather Katzen, PhD University of Miami in collaboration with Accera, Inc.	A Double-Blind, Randomized, Placebo-Controlled Study of Axona for Cognitive Impairment in Patients with MS	\$544,750 Term – 36 months

## **About the Company**

Accera, a privately held biotechnology company, discovers and develops breakthroughs in treating central nervous systems disorders. Accera's new and novel therapeutic approaches positively impact patients with neurodegenerative disorders, who are in need of effective, well-tolerated treatments, and their families. Through its proprietary scientific platform, Accera is developing therapies that address metabolic deficiencies and provide an alternative energy source for brain cells.



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### **Project Background & Goals**

Cognitive problems are a common symptom in individuals with MS. Symptoms vary in severity and may have a negative impact on relationships, work, and quality of life. Treatment options are limited and there is a pressing need for new interventions for cognitive impairment in MS. The University of Miami and Accera, Inc. are currently testing a unique strategy for improving cognitive function in individuals with MS.

Accera, Inc. manufactures Axona, a “medical food.” A medical food is a product intended for the clinical dietary management of a disease or condition for which distinctive nutritional requirements are established scientifically. Medical foods are intended to be used under physician supervision, must be composed of approved food ingredients or generally recognized as safe, and must comply with FDA regulations and guidelines that pertain to labeling, product claims, and manufacturing.

Axona is a prescription medical food that has been approved for the clinical dietary management of metabolic processes associated with mild to moderate Alzheimer’s disease. The human brain relies on glucose as a source of energy. Research shows that individuals with Alzheimer’s disease fail to metabolize glucose properly. The decrease in glucose use correlates with cognitive impairment associated with the disease. Axona is made from special fats (caprylic triglyceride), which the body breaks down into substances called “ketone bodies,” and these ketone bodies can provide an alternative energy source for brain cells. In clinical trials, Axona was associated with cognitive improvement in people with mild to moderate Alzheimer’s. Axona is available by prescription only and its use must be supervised by a licensed healthcare professional.

Investigators at the University of Miami in conjunction with Accera are currently undertaking a study to examine the safety, tolerability, and efficacy of Axona for the treatment of cognitive dysfunction in MS. Previous research suggests that there may be flaws in how glucose is metabolized in the brains of individuals with MS. If these metabolic abnormalities are contributing to cognitive dysfunction in MS, Axona may provide a therapeutic strategy to treat MS-related cognitive problems. This double-blind randomized placebo-controlled study will be conducted by researchers at the University of Miami MS Center and will enroll 158 MS patients over the next 3 years. The goals of this clinical trial are to determine if Axona can help restore cognitive function to people with MS.