

Fast ForwardSM

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.

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| <i>Primary Investigator</i> Eric Eastman, PhD Chief Scientific Officer DioGenix, Inc. Gaithersburg, MD | <i>Project Title</i> Diagnosing Relapsing- Remitting MS Based on Patterns of Antibody Gene Mutations | <i>Amount to be Committed</i> \$479,000 Term – 15 months |
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About the Company

DioGenix, Inc. is a molecular diagnostics company intent on commercializing novel molecular tests for neurological diseases where the current standard of care lacks diagnostic certainty. The company was founded to apply management's significant experience in utilizing cutting-edge technologies to identify and clinically validate new molecular biomarkers that can be reliably measured to improve neurological healthcare decision-making. DioGenix' approach chooses the best technology to measure specific aspects of human biology involved in specific neurological diseases. The company's lead program is focused on improving the ability of neurologists to diagnose and treat patients that have, or are suspected of having, Multiple Sclerosis (MS).



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Project Background & Goals

Right now, there are no symptoms, physical findings or laboratory tests that can, by themselves, determine if a person has MS. Physicians must use several strategies in combination to determine if a person meets the criteria for a diagnosis of MS, while ruling out other possible causes of the observed symptoms.

DioGenix is using a unique approach that may provide an earlier and more confident diagnosis of MS based on the pioneering work of Dr. Nancy Monson and colleagues at The University of Texas Southwestern Medical Center. Dr. Monson's team demonstrated that patterns of variations in certain B cell genes that encode important immune system proteins differ in people with MS as compared to people with other neurological diseases. Using this insight, Dr. Monson and her team developed a DNA mutation "signature" for MS. Early data suggest that a numerical score based on this signature might be used to identify people with relapsing-remitting MS early in the disease course. Interestingly, people who were at high risk for MS and who eventually converted to definite MS had scores similar to people with relapsing-remitting MS, suggesting that the emergence of this particular molecular signature may be an early event in the development of MS. DioGenix has recently worked with Dr. Monson to expand her research and develop a molecular test, **MSPrecise**TM, that utilizes cutting-edge next-generation DNA sequencing to more accurately measure this signature, by providing a very rich database of DNA mutations on each patient. Early results from multiple clinical studies suggest that this approach may be useful in generating similar "signatures" that are specific for other related neurological diseases in addition to MS.

To date, this research has involved, primarily, analysis of cerebrospinal fluid (CSF). Although a good starting point for a first generation commercial test given its role in the central nervous system, it is not the most convenient biofluid to collect. For these reasons, Fast Forward has partnered with DioGenix to use its novel approach in developing a blood-based MS diagnostic test. The funding from Fast Forward will allow DioGenix to analyze blood and CSF in a multi-site, prospective clinical study of 50 people with MS and 50 people with other neurological diseases. This study should provide results that can be validated in a much larger study leading to a simple blood test that can aid physicians in the clinical diagnosis and monitoring of MS.