

NANOSCOPE TECHNOLOGIES - CHANGING LIVES

ABOUT NANOSCOPE. Nanoscope Technologies, a Bedford, Texas company, was founded in 2009 with an objective to develop new methods and devices for scientific, industrial and biomedical applications. Nanoscope has developed a range of biomedical technologies which include diagnostics, therapeutic devices and molecules. These technologies have already generated interest from clinicians, industries and health care leaders. Nanoscope strives to translate the technology to market and bedside.

THE CHALLENGE. TMAC, a NIST MEP affiliate, began working with Nanoscope through the TECH Fort Worth / TMAC partnership. TECH Fort Worth's programs are intended to mentor and coach the inventors, founders and managers of these early stage companies. Their goal is to keep them focused on the important work of long-term strategy while they also do the tough day-to-day work of getting the company started, and to connect them with the resources they need to get new technologies to the market that will broaden and strengthen the area's economy and that will better the world in the years ahead.

Nanoscope Technologies, a TECH Fort Worth customer, was in the process of developing a life changing drug. The drug Multi-Characteristic Opsin (MCO) is delivered by either virus (AAV) or laser (Near Infrared) techniques which works by inserting the MCO-gene into healthy cells that bypass damaged retina cells in the eye. The gene then produces a protein (MCO) that is ambient light sensitive which works in the ganglion or bipolar cells to regain sight.

MEP CENTER'S ROLE. Nanoscope Technologies asked TMAC to advise and assist them on navigating the regulatory pathway to market for the MCO gene therapy product. Assistance delivered included the preparation and submission of the Orphan Drug Designation (ODD) application for this invention. This designation is defined as a drug that provides effective treatment or prevention of diseases that affect less than 200,000 people in the United States. To enable Nanoscope to initiate clinical trials associated with the MCO, an Investigational New Drug (IND) application must be submitted to the FDA. TMAC continues to assist and support in the preparation and review of the IND along with pre-clinical studies. TMAC also continues to support and develop processes for Nanoscope to gradually establish their own manufacturing site that is cGMP (Good Manufacturing Practices) compliant. As development of the facility and manufacturing processes continues, TMAC conducted an evaluation of a Contract Manufacturing Organization (CMO) to ensure compliance with cGMP and ability to manufacture products for Phase I clinical trials.

"Nanoscope Technologies is the only industry to be awarded Audacious Goal Initiative grant and major Bioengineering Research Grant by National Eye Institute to advance delivery as well as optogenetic modulation and activity monitoring platforms."

-Sulagna Bhattacharya, CEO

RESULTS



Fast-tracked FDA accelerated path to market accelerated **2** to 3 years



Orphan Drug Designation which provides access to financial benefits up to **\$10M**



10 new jobs

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