

2020 TIBBETTS AWARD WINNER

Actuated Medical, Inc.



U.S. Small Business Administration



SBIR · STTR
America's Seed Fund
POWERED BY SBA

AMI is improving the understanding of the brain & pursuing FDA approval for its electronically controlled oscillated needles to improve healthcare outcomes & reduce healthcare costs.

LOCATION

PA
Bellefonte

PHASE III SUCCESS

AMI's NeuralGlider-Cortical Inserter has gone into a Phase III project with DARPA and is generating commercial sales.

FUNDING AGENCIES

HHS
Department of Health and Human Services

NSF
National Science Foundation

Impact & Achievement

While it might sound like something out of a sci-fi story, neural implants are being increasingly used to treat disease, rehabilitate the body after injury, improve memory, communicate with prosthetic limbs, and more. Actuated Medical, Inc. (AMI), a woman-owned and led business in Bellefonte, PA, is working to develop the inserters for neural implant placement that will revolutionize the way we think about disease and injury treatments in the coming decade.

Over the last 13 years, under the leadership of Maureen L. Mulvihill, Ph.D., President and CEO, AMI has become a leading product developer for the clinical and preclinical markets. The company has established a robust product development startup ecosystem that creates and quickly tests ideas, and its team of highly diversified and engaged engineers and scientists create with the 'voice of the customer' in mind while working under a certified medical device quality management system standard (ISO 13485). The company's products have helped hundreds of critical care patients and enabled researchers to collect data to better understand the brain. AMI's goal is to develop technology that enables penetrating neural electrode arrays to be placed accurately at the target location with minimal tissue trauma and displacement – eventually paving the way for minimally invasive surgery (MIS) approaches for clinical placement of neural implants.

Using the Small Business Innovation Research (SBIR)-developed technology of electronically controlled oscillated needles, AMI is improving the understanding of the brain – a medical priority of both the National Institutes of Health (NIH) and the Defense Advanced Research Projects Agency (DARPA) - while still pursuing Food and Drug Administration (FDA) approval to improve healthcare outcomes and reduce healthcare costs. Medical device development has seven stages of development, and the IntelliNeedle System is at Stage 5, having passed most verification and validation tests required for an FDA pre-market application. Presently, there are eight U.S. patents that support this technology, and about 20 patent applications pending. The technology has also transitioned into a Phase III project with DARPA, and the NeuralGlider-Cortical Inserter is now commercialized and generating sales. Working with the SBIR program allowed AMI's team the flexibility to develop innovative technologies that can impact science and healthcare. Without SBIR funding, NeuralGlider would exist on paper only – the funding allowed for testing, development, and partnerships with local, regional, and national researchers to continue. In addition to the commercialization of the NeuralGlider inserter, AMI has successfully commercialized several other medical devices, including its TubeClear® system.

AMI's capital-efficient location places AMI within driving distance of several top research and clinical facilities, making it possible to forge strong relationships. Within Pennsylvania, AMI is partnering with clinicians and researchers at Children's Hospital of Philadelphia, Penn State University, and the University of Pittsburgh. SBIR funding allows AMI to stay in central Pennsylvania, serving the local community with family-sustaining jobs and providing an opportunity for science, technology, engineering, and mathematics (STEM) outreach and education to students in the area, as well as commercialization expertise for faculty at nearby Penn State University, local doctors, and small business.

www.actuatedmedical.com