BrainBox Solutions innovates concussion testing

BY JOHN REID BLACKWELL
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A startup company based in the Virginia Bio+Tech Research Park is making progress in its mission to provide better tools for diagnosing mild traumatic brain injuries suffered in accidents or sports-related injuries.

BrainBox Solutions Inc. announced this month that the U.S. Food and Drug Administration has granted "breakthrough device designation" for a test the company has developed to aid in the diagnosis and prognosis of mild traumatic brain injuries, commonly referred to as concussions.

The company also is starting a new clinical trial for its BrainBox test, which uses a combination of cognitive tests and a blood test to detect biomarkers that are present during a brain injury.

The test is designed to identify brain injuries that may not be detectable by a CT scan or MRI, and it uses a computer algorithm to provide a single measurement of the injury's severity to help doctors determine the best treatment.

"Our goal is to set the standard of care for mild traumatic brain injury," said Donna Edmonds, the company's president and chief executive officer.

More than 5 million patients a year in the United States are evaluated for concussions, which can cause long-lasting symptoms, so the market for better diagnostic methods is significant, Edmonds said.

The company wants to make its test available at hospitals, urgent care centers and physician offices, and it plans to tailor the test for pediatric, adult, geriatric and military patients.

"Ideally, wherever you go to get care, and whenever you go to get care, the product will be there to deliver it," Edmonds said. "Wherever means if you go to a hospital or an urgent care center or a doctor's office. Whenever means the time when you have just had an injury or three weeks later if you have just had symptoms."

The FDA's "breakthrough device designation" is intended to help speed the development of medical devices.

"It puts us on a track to be aligned with the FDA and interacting with them at every step," Edmonds said. "Everything we do, they know about it. At the end, the usual outcome is a faster release."

"This process is the FDA at its best, in my opinion, because of their close involvement with us," said Edmonds, a longtime life sciences industry professional who has worked on bringing numerous other products to market through FDA approval.

The company's new clinical trial, called HeadSMART II, follows a previous clinical trial that involved more than 700 patients. The new trial, expected to take 18 to 20 months, will enroll more patients at 20 sites worldwide and is designed to produce research to support U.S. and international regulatory filings to bring the product to market.

The University of Virginia, Virginia Tech and Virginia Commonwealth University all will have a role in the clinical trial, with Virginia Tech and UVA enrolling patients and VCU serving as the core site for the review of CT scan and MRI imaging reports in the study.

BrainBox is in the process of closing a $20 million investment round.

The company was spun-off in 2018 as a separate business from ImmunArray, another biotech firm in Richmond that developed a proprietary test to rule out the presence of the autoimmune disease lupus in blood samples.

Edmonds, who had served as Immunarray's CEO, became CEO of BrainBox with the spinoff. The company employs eight people full-time along with some consultants and part-time professionals.

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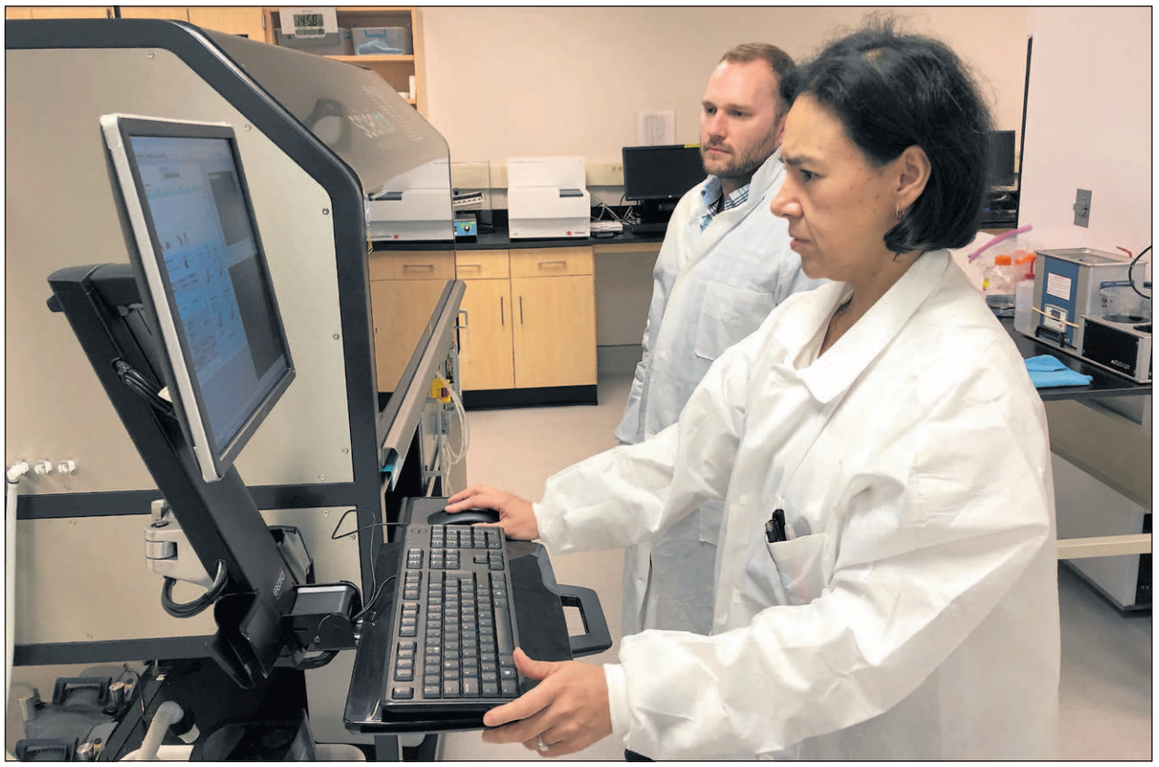

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Vanessa Cabra-Hodge (front), senior scientist at BrainBox Solutions Inc., and senior laboratory technician Joseph Green work on a micro-array printer in the company's laboratory at the Virginia Bio+Tech Park in Richmond.

BrainBox Solutions Inc. is led by President and Chief Executive Officer Donna Edmonds and Chief Operating Officer Steve Wallace.