



Banyan Biomarkers, Inc.

Novel Method to Monitor Traumatic Brain Injury

Banyan Biomarkers, Inc. is a development stage company focused on commercializing novel biomarker *in vitro* diagnostic and therapeutic products to address unmet clinical needs associated with organ injury. Our initial diagnostic products will be used for the detection and monitoring of traumatic brain injury (TBI). Until now, no simple, point-of-care blood test existed for use by physicians in the emergency room or in the hospital to detect the presence and severity of brain trauma.

Technology

Diagnostics: Banyan research has identified unique and proprietary biomarkers present in the patient's blood following injury to the brain. Detecting these biomarkers will provide early indications of brain trauma essential for rapid intervention and improved management. Banyan's other diagnostic development program includes biomarker tests for other injured organs such as liver and kidney.

Therapeutics: Banyan's therapy development program is based on Banyan's proprietary biomarkers and focuses on a compound that will block two enzymes which cause additional brain cell death following the initial damage to the brain tissue. By blocking the action of these enzymes, subsequent tissue damage can be reduced or even eliminated, thus improving patient outcomes.

Research: Banyan's ongoing research is performed at the company's Center of Innovative Research (CoIR) which is a unique self-supporting research infrastructure focused on developing a pipeline of novel products for both diagnostic and therapeutic applications.

Service: Using our proprietary biomarker panel, Banyan also provides analytical laboratory services to pharmaceutical companies in their efforts to evaluate candidate drug compounds with regard to their potential neurotoxicity or neuroprotective action.

Market Potential

Traumatic brain injury (TBI) is a significant public health problem representing a potentially catastrophic debilitating medical emergency with poor prognosis for long-term recovery. Each year in the United States at least 1.4 million people seek medical help for a TBI. TBI is one of the most common neurological disorders and a leading cause of death and disability. Of the 1.9 million TBI's that occur annually, the vast majority, between 75 and 90% are mild or moderate (MTBI). Because MTBI produces a number of imprecise perceptual symptoms without diagnosable objective structural brain alterations, MTBI's are challenging to diagnose. Furthermore, many people sustaining a MTBI fail to recognize the potential severity and seriousness of their injury and do not seek medical attention. MTBI is thus under-diagnosed and under-represented in medical statistics. It is anticipated that 3-5 specific biomarkers will be used in the detection and monitoring of patients that sustain traumatic brain injury. This translates into a potential market in excess of \$250 million in the U.S. alone.



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Strategy

Banyan has secured grants to clinically validate their biomarkers. Upon completion of Banyan's clinical validation, the company will seek FDA approval to market the biomarkers as *in vitro* diagnostic products for detection and monitoring of TBI. Banyan's patent portfolio consists of three issued U.S. patents and three U.S. patent applications that broadly cover the use of our biomarkers. In addition, international patent applications have been filed. With Banyan's intellectual property position and clinically validated biomarkers for TBI, Banyan expects to supply most of the major clinical laboratory instrumentation companies with the essential components (capture antibody, conjugate antibody, calibrators and positive controls) necessary for preparing test kits to be use on their individual instrument platforms.

To date, Banyan has secured more than \$20 million in grants from the U.S. Department of Defense and the National Institutes of Health for biomarker discovery, diagnostic product development, biomarker clinical validation and therapy development. In addition to TBI, Banyan has successfully secured grants for development of biomarkers for stroke and liver injury.

Management Team

Gary A. Ascani – Director, President & Chief Executive Officer

Mr. Ascani has more than 30 years of managerial and executive experience in the *in vitro* diagnostic products and biotherapeutics industries. He has held management and executive positions with Hyland Labs, Diamedix, Inc., and two biotechnology start-up companies, Monoclonal Antibodies, Inc. and Molecular Analysis, Inc.

Ronald L. Hayes, PhD – Director, Founder & Chief Clinical Programs Officer

Dr. Hayes has more than 25 years of experience studying brain injury. He joined Banyan on a full time basis in October 2007 and was formerly the director of the University of Florida Center for Traumatic Brain Injury Studies and a professor at the McKnight Brain Institute of the University of Florida.

Kevin K.W. Wang, PhD – Director, Founder & Chief Scientific Officer

Dr. Wang is the director of Banyan's Center of Innovative Research. Prior to joining Banyan in October 2007, he was the director for the Center for Neuroproteomics and Biomarkers Research, Scientific Director of the Center for Traumatic Brain Injury Studies, and an associate professor at the McKnight Brain Institute of the University of Florida. He obtained his Ph.D. in pharmaceutical sciences from the University of British Columbia.

Uwe Muller, PhD- VP, Product Development

Dr. Muller has nine years experience in academia and more than 20 years experience in industry, where he had lead IVD research and development efforts for small companies (Vysis, Nanosphere, Neoclone) as well as large companies (Amoco Oil, Corning), in capacities ranging from director to CSO. His expertise is in single and multiplex assay development for nucleic acid and protein biomarkers for tissue trauma, infectious and genetic diseases.

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