

Point of Care Blood Test for Diagnosing Concussions and Traumatic Brain Injury



Eric Goorno
President & Chief Executive Officer

BioDirection, Inc.
www.biodirection.com

Contact:
Eric Goorno
508-308-8592
egoorno@biodirection.com

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: *Mr. Goorno, according to the BioDirection site you are reshaping point of care diagnosis of brain injury. How so?*

Mr. Goorno: We are uniquely positioned to be the first objective point of care blood test to diagnose concussions and other traumatic brain injury (TBI). Delivering on this objective fills an enormous unmet clinical need and one that requires a technology like ours to completely change the way care is delivered today.

CEOCFO: *You said objective. How so?*

Mr. Goorno: The fact that it is a blood test is what makes it objective. The problem today is--and you are seeing more and more about this in the press-- that the way traumatic brain injury and concussions broadly are diagnosed is with a series of inaccurate cognitive tests. There is really nothing truly objective being administered. Instead, current practice utilizes a series of questions or symptoms that are being looked at when someone has a suspected traumatic brain injury. The problem with that is that it is not consistent. It is subjective. As a result it leads to an enormous amount of misdiagnosis and even more importantly, under diagnosis. It is estimated that in the field when injuries occur, anywhere from fifty to ninety percent of head trauma, especially mild head trauma like concussions, go undiagnosed. That is an enormous and unacceptable problem!

CEOCFO: *What are you measuring with the blood test?*

Mr. Goorno: There is an exploding field out there studying biomarkers, particularly blood-based protein biomarkers. What we are seeing is that more and more research is done that shows when there is a traumatic brain injury there are certain proteins that are released from the brain that jump the blood brain barrier and are in the peripheral blood stream. In the case of our system we have selected two very well researched biomarkers for our first product-- the TBI biomarkers that we think are really most ready for prime time. Our test detects the levels of those protein biomarkers in the blood stream after a suspected traumatic brain injury and those blood biomarkers are already proven in independent studies to be correlated with levels of traumatic brain injury.

CEOCFO: *Who would be administering the blood test? Do you need to do it intravenously or just a finger stick?*

Mr. Goorno: There are a couple of different points here. Ultimately our vision is that the way the system will be used is just like a glucose monitor, which is that it is a blood stick that anyone can administer. You take a drop of blood and you can put it onto our system and literally within two minutes you will get a reading of these biomarkers that are in the blood. Also, more importantly for a layman, you will get an indication that either the person may have a significant injury or does not have an injury where you do not have to take any kind of intervention. That is the vision. Initially, in order to get this approved by the FDA and to legitimize the technology, our first product will be delivered in the emergency departments of trauma centers and other hospitals. Today, there are over five million people that come into emergency departments with suspected traumatic brain injury. The standard of care in the ER today is to review the patient's symptomology and then