ceocfointerviews.com

Issue: June 26, 2017

CEOCFO Magazine

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

these folks typically get a CT scan, which today is unfortunately considered the gold standard of care in the emergency department. The problem today is that you have five million people getting CT scans, which do not detect the minute levels of blood that are present when you have a mild traumatic brain injury or a concussion. What they are really doing in the ER is just making sure that you do not have a hemorrhage that requires surgical intervention. However, less than ten percent of the time is the CT positive and only one percent of the time does the CT show the need for surgical intervention. Therefore, you have this incredible inefficiency in the hospitals, where patients are tied up, often for hours, waiting for a CT scan and they do not even actually need any kind of surgical intervention. And the CT scan itself is a safety issue. I do not know if you realize this, but a CT scan is equivalent to approximately two hundred to four hundred chest X-rays. Therefore, you have a safety and cost and an inefficiency issue with CT scans in hospitals today that we believe we can dramatically resolve.

CEOCFO: ***What would happen if the blood test is done and it is positive? What would be the next steps for the medical care?***
Mr. Goorno: Our first product is going to be utilizing our diagnostic test as a screen to reduce unneeded CT scans. We have had our presubmission meeting with the FDA and they have approved this pathway. Our initial preclinical data is really strong, showing one hundred percent sensitivity to CT scans. This means that every time there is a positive CT we have a positive test. Our system, called the Tbit™ System, has demonstrated one hundred percent sensitivity, no false negatives and we have shown the ability to reduce unnecessary CTs by over forty percent. That is a huge, positive thing for our healthcare customers and for the healthcare system overall. We want our Tbit system to be a first line test when people come into the ED with suspected traumatic brain injury. They can take our test and if the TBIT System is negative they can basically send the person back home within minutes, versus hours if they need a CT. In the case where the TBIT is positive they would move on to the current standard of care, which is to have that CT scan and then move through the normal treatment regimen provided today. However, you can really cut out a whole ton of folks that go through that process unnecessarily today with the use of our Tbit test.

"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."- Eric Goorno

CEOCFO: ***Do you have some concern that hospitals or doctors will be leery not to do the CT as it has been so accepted? Even if they have seen your research is there fear of malpractice or are they afraid that a parent will say, "Well, I want it anyway?" How do you help encourage that mindset change?***
Mr. Goorno: That is an important question. First, it starts with solid clinical data. The nice thing is that with our system we have the ability to detect one biomarker, twenty biomarkers or more. We are a platform company; we are not a biomarker company. We let the biomarker research be done and then we can apply it on to our system. The good news is that the biomarkers that we have selected have a long history, decades really, of clinical legitimacy and research that has shown that they are very sensitive and correlated with CT scans. That is number one. Now, there is always the challenge of trying to change medical practice. However, in almost every trauma center in the US and really around the world, there is the knowledge that CT scans are really not ideal. There are efforts in almost all of these trauma centers to reduce unnecessary CTs. The problem is that because there is no objective test today the hospitals have quite frankly had really limited success in trying to do that. That is because they are basically using those same cognitive tests and rules to reduce the unneeded CTs. Therefore, when there is an objective test with very strong clinical data we believe that over time--we are not going to turn it over tomorrow-- but over time we can become the standard of care as the first line diagnosis for TBI in the emergency department.

CEOCFO: ***What was the reception at the World Congress on Brain Injury?***
Mr. Goorno: For us personally, it was a real coming out party. Our clinical data was compelling enough that our poster and our abstract was accepted for presentation. Then we made the presentation and we actually won an award for the best overall abstract in neuro technology. For us that was a huge validation, because there were over eight hundred abstracts presented or submitted for consideration. Therefore, for us to win that at the World Congress, which is the world's largest gathering of folks focused solely on brain injury, was a big validation for us. We received lots of visibility, and gained additional legitimacy for our technology and of course as a result we had many additional conversations with folks that are really interested in our system, interested in clinical research with us, interested in potential strategic partnerships and so on.

CEOCFO: ***Would you tell us about your recent funding and where that will take you?***
Mr. Goorno: We have just closed an interim round of funding of two million dollars, which we used as a bridge to our next and we hope last round of funding; our Series C round, which is a fifteen million dollar round that we just kicked off. The interim funding will enable us to continue to fully fund our development and clinical work. Then we will bridge that to our C round, which once complete will take us through to commercialization and ideally through to break even.

CEOCFO: ***Have you found it a bit easier to get funding because it is a pretty clear cut premise? It is easy to understand what you are doing. Your approach makes perfect sense.***
Mr. Goorno: On one level I would say absolutely; that the critical need is so clear. Concussions used to be called the silent epidemic a decade ago. However, as we all know it is no longer silent. The issue of concussions, not just among athletes, but among the general population, is pretty well known now. The clinical need is big and the problem of concussion diagnosis today is a big concern. I think the other element for us is that we now have good preclinical data, which really has helped us accelerate funding, because now we know that our solution can work. Those factors have really helped ramp up funding. I would also say on the flip side, the venture capital world has changed a lot over the years. There are still a lot of headwinds in the medical device field when it comes to raising capital. The VCs have become a little more conservative. They like to invest in later and later stage investments. Therefore, we still have those headwinds, but to your point, compared to other opportunities, especially in therapeutics, we do have an easier scenario, just because, as you said, the problem and our solution are pretty straightforward.

CEOCFO: ***You have a long history in the industry. What have you learned; both what to do and what not to do, in moving a product or a concept forward?***
Mr. Goorno: For me, I have been involved in many different medical specialties and many different functions over my career. What I do find is that every scenario is a bit unique and so getting into the world of in vitro diagnostics with biomarkers is still something new to me and it was still an emerging opportunity as I stepped in. Yet, like everything else, over time you gain more and more knowledge and experience. There are fundamental rules here when it comes to commercializing an emerging new medical technology. The first thing of course starts with the fact that they system has to work and you have to prove it clinically. Therefore, that is really where we have focused most of our attention up until now. It is to get and make sure that we have pristine clinical data and that it demonstrates the value proposition that we are trying to provide to the clinical community and to the general public. It always starts there. Everything else, quite frankly to me, flows from that. Once you get a system that works; works clinical and is in an area that is in need of a clinical solution, it gives you confidence that you can ultimately commercialize this technology. Beyond that of course, there is the need to promote the product and work closely with top notch clinical investigators. That is pretty universal when it comes to launching something in the healthcare field. Our belief at BioDirection is that by the time we get close to commercialization we will have developed a huge network of people that support our technology that are very well known in the clinical community. We will be able to promote our product because of the important solution that we are providing. Therefore, we expect to hit the ground running when we get FDA clearance.

CEOCFO: ***What is the timetable going forward?***
Mr. Goorno: The time table requires us to go through a three-phase clinical path. The first one we have already completed. Phase I is to have successful preclinical data. Now that we have that we know that we have a baseline system that works. Phase II is to complete a pilot study, which is a much more statistically significant level of samples that we have actually already obtained in order to perform enough tests that we can optimize the threshold levels of these two proteins and the associated algorithm that our machine will provide--basically, that is the combination of the proteins and other factors, that will provide the most optimum diagnostic performance when people are using our system. Once that is in place then we will conduct our pivotal trial. What is nice about our system is that once the pilot study is completed and our algorithm is optimized the pivotal study really becomes a conformational study. This is different than a therapy. We will have already proven out the system on real blood samples in our pilot, so the pivotal study is really just to confirm that the results we saw in pilot are as we expect them to be for the commercial system. It is a much less rigorous pivotal study than you will see with other technologies. Going back to the actual timeline, we still have to tweak the system a bit and if that all works well we can start our pilot in the next few months. That is a very quick pilot, because all of the samples are already set aside for us. Once that is done the pivotal can start soon after that.

CEOCFO: ***What should our readers remember most about BioDirection, Inc?***
Mr. Goorno: Actually two points. One is that we are a platform technology. Therefore, our first product, which is acute TBI diagnosis, is really going to be just the first in a series of planned products that we expect to roll out after our first one. We are going to start in the ER as a screen to CT scans, but the opportunity for our product is really endless. We can utilize the Tbit system in so many other areas. First, staying within traumatic brain injury, we can utilize the test from a broad

concussion diagnosis, to stratifying the injury, to prognosis or even return to play. We envision seeing the system being used in many settings, from doctor's offices to nursing homes, to athletic fields, to hazardous work environments, where we would not just diagnose TBI, but other potential neurological conditions such as stroke and Alzheimer's and other disease states; obviously, we really are excited about the potential! This is the first phase in a big platform opportunity that we will roll out. I guess the second thing I would say is that we believe we have the right solution to take care of an enormous unmet clinical opportunity with a system which is extremely flexible, quick, portable, and which can be provided in any environment where there is an injury. Tbit will be a real game changer.