CEO CFO

BLINDED DIAGNOSTICS

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Using the Latest FDA Cleared and CE Marked Portable Diagnostic Testing Tools, Blinded Diagnostics is providing Same Day, Point-of-Care Lab Test Results to Pharmaceutical and Biopharmaceutical Companies Worldwide for their Clinical Trials

Healthcare
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Steve Karuppan
CEO

BIO:
Mr. Karuppan, a graduate of Rutgers University, performed clinical research at Robert Wood Johnson Hospital, UMDNJ Medical School, Merck Pharmaceuticals, and GlaxoSmith-Kline before becoming the Sr. Business Development Manager for International Technidyne Corporation, one of the leading point-of-care manufacturing companies. During his tenure at ITC, Steve was involved with the sourcing, training and completing of twenty major clinical trials using both blinded and un-blinded point of care (POC) medical devices.

About Blinded Diagnostics:
Blinded Diagnostics is a privately held contract service organization providing same day lab test results for pharmaceutical clinical trials. The management team specializes in the application of point-of-care diagnostic platforms for testing trial participants at investigator sites or remote locations. The company's solutions are designed to optimize results and efficiencies by reducing time to therapy and cost of specimen shipments. Blinded Diagnostics offers encrypted software versions of point of care diagnostic devices so that test results can be blinded to the investigator and participant to avoid bias in a trial.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Karuppan, what is the vision at Blinded Diagnostics?
Mr. Karuppan: We are committed to becoming a worldwide leader in point-of-care diagnostic solutions specifically for pharmaceutical clinical trials. Using the latest FDA cleared and CE marked portable diagnostic testing tools, pharmaceutical and biopharmaceutical companies can achieve cost and time efficiencies. Blinded Diagnostics provides same day lab test results to a segment that is used to waiting 2-3 days for results and shipping patient specimens half way around the globe to reach a centralized lab.

CEOCFO: Are point of care and immediate results something that is unusual for the industry?
Mr. Karuppan: Yes. The clinical trial testing market is about 10 years behind in the adoption of this technology. There is a significant difference in what is being done in standard care versus pharmaceutical clinical trials. Approximately 35% of diagnostic testing performed in hospitals and doctor's offices is conducted using point of care devices. However, in the clinical trial segment, only 1% of all testing is done using point of care test platforms. We see the change coming.

CEOCFO: Why has that traditionally been done the way it has? How easily are people adapting to the fact that it can and should be done differently?
Mr. Karuppan: The pharmaceutical industry requires standardized lab test results. Traditionally, standardized tests were only available through the use of contracted central labs, which ran tests on identical instruments. Today, because of advancements in microfluidics and biosensor technology, there are over 100 standardized POC tests on the market. The increased use of point of care in the development of new drug therapies is largely due to the fact that drug companies needed a reliable diagnostic tool to safely manage patients in dose adjustment studies. For example, POC has been used with developments in warfarin replacement, heparin replacement and chronic kidney disease. As drug development professionals are becoming aware of the POC test menu, adoption is increasing.

CEOCFO: How do you target your potential customers? What is the "aha" moment when they understand "this is a real great way to do things?"

Mr. Karuppan: Blinded Diagnostics recognized the need for innovation in the pharmaceutical industry. The innovation means achieving time and cost efficiencies while maintaining operational excellence. We work together with our pharmaceutical clients to identify specific opportunities to use POC tests in trials when it can be a value. POC may not completely replace the central lab, however, we believe in the hybrid laboratory solution - using point-of-care in combination with the central lab when and where it makes sense like:

Patient enrollment and screening; having the ability to screen and randomize a patient into a trial on the same visit.

Blinded studies using encrypted Point-of-care devices, useful in dose adjustment settings and in preserving blinded diagnostic data.

Remote patient testing in countries where it is difficult to transport blood samples in and out of the region. Or, just for testing patients at their home or healthcare facility.

Adaptive trials when a pharmaceutical company wants to see data, as close to real time as possible to make critical decisions.

Our prospective clients realize the value of this option when they see the proof that point of care devices are well accepted diagnostics tools that can potentially reduce their drug development cost.

CEOCFO: How do you reach your potential customers?
Mr. Karuppan: We network with industry professionals to present our value proposition. The initial push of Blinded Diagnostics has been all about education. We share the clinical trial experience with case studies highlighting how and why point-of-care has been used in clinical trials. And we have sponsored speakers who have had direct involvement with the use of this technology at pharmaceutical industry meetings. We call on the procurement groups of pharmaceutical companies and present the cost reduction potential of point-of-care testing. They understand that 30% of a typical clinical trial budget for diagnostic testing is spent on shipping patient samples alone. With point-of-care, this cost is significantly reduced considering samples would not have to be shipped to central labs. So, this potential savings gets their attention. Then we present the clinical applications with R&D scientists and the clinical affairs team who are involved in protocol development about the advantages of point-of-care in meeting study goals and inclusion/exclusion criteria.

"Blinded Diagnostics provides same day lab test results to a segment that is used to waiting 2-3 days for results and shipping patient specimens half way around the globe to reach a centralized lab. Today, because of advancements in microfluidics and biosensor technology, there are over 100 standardized POC tests on the market. Our prospective clients realize the value of this option when they see the proof that point of care devices are well accepted diagnostics tools that can potentially reduce their drug development cost. The clinical trial testing market is $3.5B and growing at 11% per year. The choice is clear: ship a patient sample and wait three days for results or run the test on site to get the results today without shipping."

- Steve Karuppan

CEOCFO: You have mentioned international. Is that an area you are working on or is that, perhaps, something for the future?
Mr. Karuppan: We have the capability to work on international trials through our scalable project management resources. The management team of Blinded Diagnostics has been in involved in 20 trials and the largest of those trials was 1,500 sites globally, with 22,000 patients.

CEOCFO: How is business these days? Is Blinded Diagnostics funded to continue to tell your story to the appropriate people?
Mr. Karuppan: We are a private organization and are self-funded. Blinded Diagnostics has created a strong brand name and reputation in the marketplace. With the projects we have in our pipeline now we are well positioned to meet our financial objectives in 2013 and beyond.

CEOCFO: What about the competitive landscape?
Mr. Karuppan: The services Blinded Diagnostics provide are unique. There are two companies overseas that supply some point-of-care solutions; however, their primary business is the rental of freezers and centrifuges. Our model is built around delivering clinical trial support services along with cost and time saving diagnostic tests.

CEOCFO: You personally have a background in clinical trials and business development. What have you learned in your past experience that is most helpful for you with Blinded Diagnostics?
Mr. Karuppan: Taking care of the customer is of upmost importance. In the clinical trial space, you must have a sense of urgency. You need to respond and act immediately to resolve issues. We focus on proactively addressing our client's needs. We look to provide a best fit point of care solution and support the client throughout the duration of the clinical trial. Ultimately, this will lead to Blinded Diagnostics' sustainability.

CEOCFO: Why should investors and people in the business community pay attention to Blinded Diagnostics?
Mr. Karuppan: The clinical trial testing market is $3.5B and growing at 11% per year. The choice is clear: ship a patient sample and wait three days for results or run the test on site to get the results today without shipping.