Issue:
May 4, 2012

CEOCFO Magazine - The Most Powerful Name In Corporate News and Information

The Opportunity for Critical Diagnostics' Presage ST2 Assay is Equal To, if not Greater Than the Current Market for the Natriuretic Peptides – Used in Identifying Patients at Increased Risk of Morbidity and Mortality due to Heart Failure

Healthcare
Cardio
(Privately Held)

Critical Diagnostics

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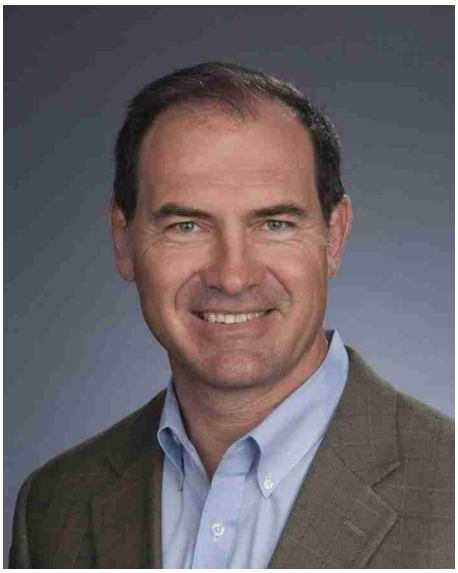

James V. Snider, Ph.D.
President

BIO:
James joined Critical Diagnostics as President in 2005, shortly after the company's formation. He has extensive experience in product development and operations in both startup and large companies. Prior to joining Critical Diagnostics, James was the Executive Vice President of Business & Operations for IntelligentMD, an early-stage medical device company that focuses on the essential elements of disease diagnostics and therapeutic intervention. Previously, he spent eight years in a series of marketing and product development positions at Applied Biosystems (ABI). James holds a B.S. in chemistry from Grand Valley State University and a Ph.D. in chemistry from the University of South Carolina.

Company Profile:
Critical Diagnostics helps physicians optimize patient care in cardiovascular diseases, such as heart failure. Our high sensitivity Presage® ST2 Assay measures the level of soluble ST2 in blood, identifying patients at increased risk of morbidity and mortality. ST2 has been evaluated in multiple clinical studies, now spanning more than 30,000 subjects.

ST2 signals the presence of adverse cardiac remodeling and fibrosis, which occurs in response to myocardial infarction (MI), ischemia, or worsening heart failure. Remodeling and fibrosis can also contribute to the development of future adverse events, such as secondary MI or sudden cardiac death (SCD), and to progression of heart failure.

The Presage ST2 Assay helps clinicians assess patient prognosis in order to better personalize their care. By selecting the most appropriate treatments and interventions for each patient, a physician can maximize the clinical benefit from increasingly limited healthcare resources.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Snider, would you give us a brief overview of Critical Diagnostics?

Dr. Snider: Critical Diagnostics is an early stage company that was formed to develop a test for the cardiac biomarker protein called ST2, which has been shown to be useful in providing prognostic and risk stratification information for patients with cardiovascular diseases particularly heart failure. Critical Diagnostics was formed to develop an in vitro diagnostic test, a laboratory based test for this product; move that through the clinical regulatory process and commercialize it. We have received regulatory approval both in Europe and the US to market this test for clinical use.

CEOCFO: Would you tell us about ST2 and why it is so important to be able to do the assessment?
Dr. Snider: ST2 is a protein that is expressed both as a cell surface receptor as well as a soluble form. On the surface of cardiac cells, cardiomyocytes, when those cells are subjected to injury or illness, that receptor responds to a signal through an interleukin called interleukin 33. If that signal is blocked when those cells are subjected to an injury or illness and do not get that positive signal from interleukin 33, then those cells move into apoptosis, necrosis and eventually fibrosis and remodeling. Cardiac remodeling results in impaired cardiac function, which is by definition heart failure. Soluble ST2, which is the protein that we measure, blocks that signal of interleukin 33 to the receptor. Soluble ST2 is a different gene product of the ST2 receptor gene and is expressed at higher concentrations in patients who are progressing toward worsening disease. The biology of their cardiac tissue is such that for some reason it goes into a deteriora-

tion mode rather than a recovery mode. Soluble ST2 initiates a series of cellular events that lead toward increasing fibrosis, cardiac remodeling and impaired cardiac function. If left unchecked ultimately leading to the patient's death. In the clinical contextmeasuring ST2 identifies patients that are beginning this process. If you can identify those patients then the physician has the opportunity to intervene earlier and more effectively with appropriate therapeutics or device treatments to reduce disease progression.

CEOCFO: Is there a test for it now that you would be replacing or is this a new area?
Dr. Snider: There are other cardiac biomarker tests but this is a new area. This is the first clinical test for this marker, ST2, that has ever been available.

CEOCFO: What would be the indication? Why would a physician decide to test with your array?
Dr. Snider: This is not a diagnostic test. This is a test for assessing the prognosis or the risk stratification of patients that have disease, such as in the context of managing patients with heart failure. Our current indication for use, as defined by the FDA, is for use as an aid in risk stratification of patients with chronic heart failure. This is a population of patients that doctors are already treating and the Census of heart failure patients in the US is approximately 6 million. It is approximately twice that in Europe. The challenge is that when patients are being treated, they are being treated primarily for their symptoms, not necessarily for the biology of their disease. If their symptoms change, it is usually a reflection of a biological change that was happening some time previously. What ST2 provides is that indication that the biology of the patient is changing prior to their symptoms changing. For instance, before a patient with heart failure becomes decompensated. That patient may show up in the emergency room or clinic for treatment, because he or she is in distress or a patient that is in early stages of disease, but does not have a compromised ejection fraction so the ejection fraction not decreased. Therefore, remodeling is not yet visible by echocardiography. ST2 can identify which patients are progressing down that pathway. So, it can be used as an early indicator of patients that should be monitored more closely for a potential change in their status or to introduce treatment to delay the progression of the disease.

CEOCFO: Would this eventually become something standard to use for cardio patients?
Dr. Snider: Yes, risk stratification of patients with heart failure is an accepted clinical practice. And research projects that are currently in place, both in the US and Europe, are being evaluated to better ascertain the appropriate medical response to this assessment of risk. The objectives of these projects include establishing what the optimum frequency is of testing is and what treatment implementation or therapeutic changes should be made to these patients and their care. This clinical adjustment is expected to result in a delay in the patients' progression of disease, keep them out of the hospital and improve their quality of life.

We believe that the opportunity for the Presage ST2 Assay is equal to, if not greater than the current market for the natriuretic peptides. - James V. Snider, Ph.D.

CEOCFO: What is the product that Critical Diagnostics will be bringing to the market; is it a device with a razor/razor blade component?
Dr. Snider: It is a laboratory test, a kit that can be performed in any standard medical laboratory.

CEOCFO: Will expense be a factor?
Dr. Snider: Certainly, it is not free, but we priced it very fairly and reflective other tests in the category. In vitro diagnostic tests run anywhere from commodity tests that are just a few dollars per test. For example, there is troponin, which is right now reimbursed at around $10, and then there are natriuretic peptides, such as BNP and NT-proBNP, which are reimbursed at $49. We do not yet have an analyte specific reimbursement code for ST2 so we priced it at $26.00.

CEOCFO: Critical Diagnostics has named some distributors at Asia Pacific; would you tell us about that?
Dr. Snider: Since receiving clearance from the FDA, we have been working globally. In the US, we work directly. We also have relationships with some of the reference testing laboratory companies, such as ARUP Laboratories in Salt Lake City. The test has been available through them first as a research use test and now as the FDA cleared test. We are establishing agreements with additional reference testing laboratories companies in the US. We are also selling directly with our own sales and marketing force in the US. Internationally, we are leveraging with experts in individual countries; some in Europe as well as in Asia. In Asia, we have engaged exclusive distribution and marketing agreements with companies right now in China, Korea, and in Indonesia. We are working on final stages of agreements with the companies in several other Asian countries. By the end of this year, we expect that we will have six or seven countries, with the major Asian countries represented and moving forward.

CEOCFO: Development is a costly process; is Critical Diagnostics funded to get to commercialization?
Dr. Snider: Yes. The investment group that I worked with, that actually founded the company, Carrot Capital Healthcare Ventures, has been extremely committed to the development and success of the company. We have managed the company very conservatively through this development cycle; minimizing our investment, maximizing our return. We have kept the company very small with a modest internal deployment force, leveraging significantly on resources that we could obtain through subcontracting and through OEM. Our manufacturing has been through OEM. Going forward, because we were so conservative in the development cycle, they are very comfortable with the additional investment necessary to move into commercialization and through the marketing efforts that we are in process of executing. The revenue stream will offset a signifi-

cant amount of our expenses going forward.

CEOCFO: What is the potential market?

Dr. Snider: The best thing that we can do is benchmark to the most comparable existing test, the natriuretic peptides. Right now worldwide, the natriuretic peptide tests market, the combination of BNP and NT-proBNP, is approximately $800 million. The clinical evidence that we have developed with ST2 is in the context of patients with heart failure, which is the dominant use of the natriuretic peptides. A significant amount of that business is in patient management, which is exactly where ST2 should be used. We believe that the opportunity for the Presage ST2 Assay is equal to, if not greater than the current market for the natriuretic peptides.

CEOCFO: Why should investors pay attention to Critical Diagnostics today?

Dr. Snider: What differentiates the Critical Diagnostics product is that ST2 is completely unique in the product. We already touched on the point that there is not a product that it is replacing. It is a new clinical opportunity, a new clinical value to the market for managing patients and making treatment decisions for patients with cardiovascular diseases, heart failure as well as other cardiovascular diseases. Therefore, it is a completely new opportunity in the market space with very high clinical value. Critical Diagnostics has exclusivity of intellectual property around the clinical uses of this biomarker. We also have the proprietary reagents and components of the test, so the test that is approved for clinical use can only be produced with materials that we own and under our intellectual property. Right now as a company, we are completely unencumbered by relationships with any other partners. We have not entered into any licensing agreements for instance with a major company in the IVD industry. We are certainly open to discussions for partnership arrangements with large IVD companies, but we have not yet entered into any of those agreements. Therefore, we have complete latitude to consider any opportunity or structure that somebody might be willing to present. Our investment group is extremely committed to the success of the company and to this product. This test is comparable to any of the other high success products such as the natriuretic peptides. The experts in the field, the key opinion leaders that we work with, fully believe that this test is potentially more valuable than the natriuretic peptides, which are established and have proven value in managing patients with cardiovascular diseases.

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