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Issue: September 28, 2015
The Most Powerful Name in Corporate News

Advanced Cell and Particle-Based Precision Diagnostics

Dr. Todd Johnson
President
CytoVas, LLC

CEOCFO: *Dr. Johnson, what is the vision and concept behind CytoVas?*
Dr. Johnson: CytoVas is a precision diagnostics company. We are using computational biology combined with what we call deep phenotyping to find new diagnostic tests to help us better understand and more precisely predict patients' risk of disease.

CEOCFO: *How is your approach different from what is currently utilized today?*
Dr. Johnson: Most diagnostic tests are discovered testing single hypotheses at a time. Scientists find a chemical or biological marker that appears to coincide with disease, and then measure that marker in many patients to see how often it is present in patients who have or don't have that disease. For example, medical professionals have been looking at LDL lipoproteins because they were observed to be elevated in many patients with heart disease. However, most diseases aren't about a single marker. A single marker may tell you something about the patient – their diet, or their metabolism, for example - but it does not give you a very accurate picture of what is happening in the human body. A patient with high LDL may have recently eaten a steak dinner, but may be at very low risk of heart disease. Many other markers used today are very far upstream from disease – they often coincide, but don't reflect a disease-causing process. We now know that LDLs are actually very weak markers for cardiovascular disease – a significant percentage of patients with heart attacks have normal LDL levels. And many patients with high LDL levels never have a heart attack. Even for cardiovascular disease – the #1 killer in the developed world – medicine hasn't yet developed a way to accurately identify and measure the processes causing it.

At CytoVas, we are taking a different approach to developing tests that more precisely evaluate disease biology. We are finding patients who have a given disease, and then we are evaluating many different markers in their blood at the same time. We call this Deep Phenotyping. Then we are tracking which patients get worse – which ones experience complications from their disease. We call this Cytometric Fingerprinting. Taking this outcomes-based approach generates hypotheses in retrospect. It allows us to ask which if any of those markers in combination could have warned us that an event was coming. This approach is yielding far more accurate and predictive hypotheses for us to use to develop diagnostics than the industry has seen before.

CEOCFO: *Does the medical community believe that you can find an answer with this approach or are people skeptical?*
Dr. Johnson: The medical community has totally embraced this. In the last 10 years medicine has come to recognize the power of personalized medicine. We can and need to define more and better markers in order to personalize treatment. Genomics has really paved the way for us, because genomics uses a similar retrospective approach, studying patients who have developed disease and then figuring out which genes they have and evaluating whether those genes could have predicted higher risk. We're applying the genomic approach to cytomics, looking at markers from the actual cells and the protein

markers expressed on cells involved in the disease. The runway is set. As with every new scientific event, you need to bring the data next and that is what we are in the process of developing.

CEOCFO: *What is the business model?*
Dr. Johnson: We are in the process of developing our first tests using this approach. For cardiovascular disease, our goal is to deliver tests with far better predictive power than tests like cholesterol testing, HSCRP, LP-PLA2, or intravascular ultrasound. We believe we have found several markers that are close to the cholesterol plaque and demonstrate when that cholesterol plaque is becoming inflamed and stressed, making it more likely to develop into a heart attack. If our current clinical trials return the same data as our early studies, we plan to begin making this available to patients in the next 2-3 years.

CEOCFO: *How did you decide what to look at first?*
Dr. Johnson: We looked at areas of greatest unmet medical need. Cardiovascular disease is still the number one killer in the developed world. It kills more people in the United States than any other disease. Fifty percent of patients who experience a heart attack have normal cholesterol levels, and have no markers that would have predicted that event was coming. We saw cardiovascular disease as an area there was an incredible need for new tests and a new way to segment patients who need closer medical attention, as well as targeted medical or surgical interventions to prevent a heart attack.

CEOCFO: *Where was the biggest challenge in putting the technology together?*
Dr. Johnson: The ability to combine cellular markers computationally is extremely difficult, requiring deep knowledge of vascular biology, bioinformatics, and supercomputing power. The instrumentation required to measure the particles we are testing is very advanced – we are at the forefront of the industry on this. Both of those present difficult challenges and make it hard for anyone to come behind us.

"CytoVas is on the verge of proving that the combination of computational biology and deep phenotyping can dramatically improve the ability to predict a patient's risk of heart attack or stroke. That will really turn the diagnostics and pharmaceutical and biotech research communities upside down." - Dr. Todd Johnson

CEOCFO: *What is the timetable?*
Dr. Johnson: We are in a very important clinical trial right now that will end in 2016, so next year we will start our pivotal trials that will be sent to the FDA for approval.

CEOCFO: *Who will be doing the tests or clinical trials?*
Dr. Johnson: Our clinical trials are being performed by a network of academic hospitals. Eventually, the tests will be offered to patients at any hospital or doctor's office, taking a blood sample and sending it to a central lab such as Quest or LabCorp.

CEOCFO: *What have you learned so far that was unexpected?*
Dr. Johnson: As we started talking to research partners, we realized there was a very significant opportunity to also assist pharmaceutical and biotech companies in their innovation process in developing their new therapeutics in clinical trials. 21% of all late stage clinical trials for new medications fail because of heart attacks in the clinical study population. We are now working with pharmaceutical companies and contract research organizations to help them innovate their new medications faster.

CEOCFO: *Put it all together for our readers. Why is CytoVas a noteworthy company?*
Dr. Johnson: CytoVas is on the verge of proving that the combination of computational biology and deep phenotyping can dramatically improve the ability to predict a patient's risk of heart attack. That will really turn the diagnostics and pharmaceutical and biotech research communities upside down.

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