CEO CFO

Biomoda, Inc.

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In-Vitro Diagnostic Company Biomoda Has Developed A Test For Cancer Based On A Proprietary Molecule That Binds With Cancer Cells And Fluoresces Red Under Ultraviolet Light – Focusing First On Lung Cancer

Healthcare
Diagnostic Substances
(BMOD-OTC: BB)

Biomoda, Inc.

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John J. Cousins
President and CEO

BIO:
John J. Cousins, President, Chief Executive Officer and Director, has 25 years of management experience. He also serves as Biomoda's Chief Financial Officer and has 10 years experience as a public company CFO. Mr. Cousins began his career as an electronics engineer, and he has worked for the ABC Television Network and Ampex. He has also been an entrepreneur and owned and operated his own businesses. Mr. Cousins holds undergraduate degrees from the Massachusetts Institute of Technology and Boston University. He earned an MBA from the Wharton School of Business at the University of Pennsylvania.

Company Profile:
Biomoda is a cancer diagnostics company focused on the development of inexpensive, simple and highly accurate in-vitro tests for the early detection of cancer. The diagnostics are based upon Biomoda's patent estate centered on molecular marker technology, originally developed at Los Alamos National Laboratory. Current research and development operations, laboratory functions and administrative offices are located at 609 Broadway NE, in Albuquerque, New Mexico.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFOinterviews.com

CEOCFO: Mr. Cousins, what is the vision of Biomoda?
Mr. Cousins: "Biomoda is an in-vitro diagnostics company. We are developing diagnostic tests for cancer based on a proprietary molecule that binds with cancer cells and fluoresces red under ultraviolet light. We have a patent portfolio around that molecule and diagnostic assays that we develop from it. Our first test is a lung cancer diagnostic. We are taking sputum, which is the deep lung fluid that people cough up, and we process it under microscope slides, incubate it in a formulation with this molecular compound and then review the slides under a microscope with an ultraviolet light source, looking for fluorescent red cells."

CEOCFO: How is lung cancer currently diagnosed now and how is your test better?
Mr. Cousins: "Lung cancer is diagnosed now using radiology tools, the CT (computed tomography) scans. Lung cancer has fallen way behind the other cancers [in terms of research and funding], but lung cancer is the largest killer of the cancers. It also has the most dismal survival rates. Only 15% of people that are diagnosed with lung cancer now survive five years. About 60% of people diagnosed with lung cancer die within one year of being diagnosed. Fifty years ago, other cancers such as breast, cervical and prostate, had similar survival rates, but because of significant funding and research into the cancers, they've come up with screening protocols that have actually boosted the five-year survival rates to about 90% in all of those cases. That is due to mammograms, PAP cervical tests and the PSA tests for prostate cancer. The problem with lung cancer is two-fold really as far as getting funding for the research. One reason is that it has had a stigma because 85 to 90% of lung cancer is caused by long-term effects of smoking tobacco. People have thought that lung cancer is self-inflicted, so it has had that stigma. The other part is that the other cancers have had significant survivor constituents that lobbied for funding for their cancers and advocated for it as a survivors movement. Lung cancer has not had that type of survivor community unfortunately.

About three years ago, Senators Hillary Clinton and Chuck Hagel from Nebraska introduced a Senate resolution to identify and spend federal funds to come up with diagnostic tools for diagnosing lung cancer early and trying to increase the survival rate. The Senate resolution was unanimously passed in May of 2006. After that, there seemed to be a turn toward looking at lung cancer and raising the survival rate. One of my board members, who is an old-time Washingtonian, and I

went to Washington and lobbied the Hill, talking to everybody. We got a very good response to our diagnostic at a federal program on lung cancer where we advocated to screen veterans for lung cancer. When we came back to New Mexico, we actually started testifying and advocating before the New Mexico State Legislature. They really caught the ball and to their credit funded a program where Biomoda has been screening veterans for lung cancer in New Mexico for the past two years. The program started basically from scratch and in the last 18 months or so, we went from zero to developing a protocol, getting it approved by an IRB (Institutional Review Board), and recruiting about 500 veterans. We have screened about 100 of them and the program is moving forward under the funding. It's a real credit to New Mexico that the state government had the foresight to support the veterans screening. It's a unique program that is being watched nationally and by other states who are interested in similar programs to help their veterans."

CEOCFO: Could this test apply to other cancers?

Mr. Cousins: "Our technology was developed at Los Alamos National Laboratory. The molecular marker binds with cancer cells and has a signaling quality that fluoresces red under ultraviolet light. It will work with any cell sample and identify any cancer. We chose lung cancer as our first assay because it is the largest cancer killer, it has the most dismal survival rates, and it really needs an early diagnostic tool. A study that came out about a year and a half ago in the New England Journal of Medicine advocated for diagnostics for lung cancer. That study, which was done by the International Early Lung Cancer Action Program (I-ELCAP) along with the Lung Cancer Alliance, an advocacy and lobbying organization in Washington, was done with CT scans. CT scans were read under the I-ELCAP protocol for cancer nodules in the lungs. As part of the study, done in conjunction with Weill-Cornell Medical College and New York Presbyterian Hospital, they did the statistical analysis of 30,000 CT scans and concluded that if lung cancer is identified and diagnosed in Stage I, the survival rates go from 15% in five years to 92% in five years. That is a huge difference. The research supports our premise that if lung cancer is diagnosed early, there's a huge increase in survivability. So those are the reasons we've identified lung cancer as our first test. Our test is non-invasive, it doesn't expose you to radiation, it's based on sputum, which is the deep lung fluid that people cough up. It's inexpensive. We think it will probably cost about $100. We're looking at it as an annual screening test, especially in high-risk patients, people who have smoked for 20 years, have lung cancer in the family, or are reaching the age where lung cancer starts to become prevalent. There are 100 million current and former smokers in the US. Every one of those people should have this screening test done on an annual basis because you have to identify lung cancer in the early stage. Once it starts, it moves at a rapid pace. It's like a brushfire, so it's really important to catch it quickly. If you are identified in a high-risk group, it makes sense to be screened. If you start looking at just the market for lung cancer in the US for a $100 test with a market potential of 100 million a year, it starts to really get into some significant numbers."

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CEOCFO: Where are you in development, trials and what is the path towards commercialization?

Mr. Cousins: "We are in clinical trials right now for our lung cancer diagnostic assay, which is trademarked as CyPath®, short for cytology-pathology. With CyPath®, we've completed the Phase I clinical trial, which is the validation part. We are now screening veterans in New Mexico in our Phase II clinical trial, the pilot study required for an in-vitro diagnostic. We are looking to go for FDA approval with a PMA IVD Class III, which is a premarket approval of an in-vitro diagnostic in Class III which is the highest basic approval. We are anticipating that we will complete our pilot study of about 200 to 250 participants within the next couple of months. We are working with Quintiles, which is the largest runner of clinical trials in the world. They are our regulatory consultants and our study designers. Our second partner is a group called Alquest which is out of the Mayo Clinic, in Minneapolis, Minnesota. Alquest is a contract research organization which helped us design the study, develop a protocol, get the IRB approval and manage the study. Once we finish our Phase II study, our pilot trial, where we work out all of the kinks, we scale it up to Phase III, which is the final study, the pivotal study. We will probably start that late fall (2009) as we finish up our trial study. Our study designers estimate that we are going to need 3,500 participants for that, because we want to identify between 40 and 50 cases of asymptomatic lung cancer, which is Stage I. Once you have symptoms like shortness of breath or pains in the chest, it's Stage III or IV when you have only a 40% chance of living another year. So, we want to identify early in an asymptomatic stage."

CEOICFO: What is the financial picture like for Biomoda today?

Mr. Cousins: "We were able to raise capital in the markets a couple of years ago and we have received government funding, but we're in the process of doing another capital raise."

CEOCFO: What about the patent that was announced in July?
Mr. Cousins: "We were just awarded patents in Japan and Australia for our technology covered by earlier patents in the US. We just submitted another US patent application for a quantitative system and method of analyzing samples, which goes into detail about how our test works and the mechanism behind it with the signaling properties of the cell. We also just responded to another divisional patent that was off of one of our earlier patents. We keep increasing our patent portfolio. We expect to file a couple more patents in the next several months."

CEOCFO: How do you gain acceptance in the marketplace?
Mr. Cousins: "In the studies that we have been doing, we've been developing a medical advisory board and a number of key opinion leaders who will basically go out and spread the gospel. Right now, they are experts in radiology and various fields related to lung cancer. As we write up the results from the pilot study, we expect to publish in peer-review journals and present at various medical conventions. One of our partners, New Mexico Tech, recently presented results at the World Conference on Lung Cancer in San Francisco. That is how we are promoting the technology, through peer-review journals, scientific writings, and our experts speaking at conferences."

CEOCFO: Addressing potential investors, why does Biomoda stand out?
Mr. Cousins: "We have an inexpensive test designed to screen very large populations. Our business model does not call for developing kits, keeping a lot of inventory and tying up our working capital. Preliminary results show that our test works. We are going to get our lung cancer diagnostic through the FDA in the next year here or so and at that point, we will be able to address markets worldwide. The US market alone, looking at 100 million current or former smokers, is a very big number. The CyPath® test isn't just for screening and diagnosing. It can also be used to monitor the efficacy of treatment therapies. Once we have established it as the gold standard for lung cancer diagnosis, we can adapt it for different cell samples so that we can do a breast cancer diagnostic based on ductal lavage, which is a washing of the breast ducts. We can adapt the protocol for stool samples and colorectal cancer, for urine and bladder cancer. There are a lot of cancers that lend themselves to easily obtainable, not invasive cell samples. We hope to develop about a half dozen different cancer diagnostics and, once we get FDA approval, look to regulatory approval in the European Union and Japan, moving into those markets as well.

Lung cancer is a worldwide phenomenon, and we're looking initially at first- world markets which already have the medical infrastructure, the reimbursement codes. We've done a reimbursement code study and there are reimbursement codes in place in the US and the EU to pay for this test. If we can get approved, these are large markets. We filed financial projections in the UK about a year ago, very conservative ones, but they're public information and filed with the SEC. We are also looking to ramp up to be a $200 million revenue company in the next three to five years. That means a lot of good things for this stock. It is a $100 million company that's valued at two times revenue. There is a lot of room just on book value too and then we start looking into these other cancers and start to give the stock an enterprise value. We could easily see the stock at $5 to $6 in several years."

CEOCFO: And help a ton of people in the process!
Mr. Cousins: "Right, to do good and well at the same time. That is really the key. Even with our results and what we are doing with the veterans here in New Mexico, we've identified some cases of early lung cancer, and they're getting their follow-up care. So we are saving lives, and that is really the bottom line. There's a lot of research with diagnostics and things relative to genomics and proteomics where they are looking at protein paths and gene expressions. Those tests will tell you if you have a predisposition for a particular cancer and can indicate your risk levels, but they're not actual diagnostic tests. We are unique in that space, and that is what the medical community is looking for. We are not a disruptive technology where we are going in to knock out some other technology. We're not going to replace radiology, CT scans, or anything like that. We are complementary to the tools that are already out there. We see ourselves as a front-end screening tool so that people who test positive on our test are routed to the more expensive and scarcer resources like CT scan. So we are helping the medical community use those assets more efficiently."

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