CEOCFO Interviews & News!

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# DiagnoCure Is Focused On High-Value Molecular Markers For Cancer Diagnostics, Allowing Physicians To Answer Key Questions In Managing Patients With Cancer

**Healthcare**
**Cancer Diagnostic Tests**
**(CUR-TSX)**

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**John C. Schafer**
**President and CEO**

## BIO:

John C. Schafer cumulates over 30 years experience in the field of diagnostics, along with an excellent track record in management and growth of high technology diagnostics companies. He holds a BA in Biology and Chemistry from Carthage College (1972) and has advanced coursework in medical technology from St. Luke's School of Medicine, health care administration from Central Michigan University, and finance from Boston University. Before joining DiagnoCure, Mr. Schafer led a Montreal based biosensor company with target applications in biodefense, medical diagnostics and immunodiagnostics. Prior to that, as President and CEO of Boston Medical Technologies, he led the introduction of an important new diagnostic instrument for physician treating patients with diabetic autonomic neuropathy. During his 14 years at Baxter International, Mr. Schafer held key sales, marketing and operational positions prior to being named president and general manager of several Baxter diagnostic divisions.

Mr. Schafer spent three years as a Vice President of business development in the life Science division of $6 billion consulting firm CAP-Gemini. Mr. Schafer is the past Director of numerous life science companies. Mr. Schafer has received numerous awards as a leading biotech entrepreneur. He has been President and CEO of DiagnoCure since August 23, 2006.

**Company Profile:**
DiagnoCure (TSX: CUR) is a life sciences company commercializing high-value cancer diagnostic tests and delivering laboratory services that increase clinician and patient confidence in making critical treatment decisions. DiagnoCure is currently preparing to launch the Previstage(TM) GCC Colorectal Cancer Staging Test, the first GCC-based molecular test for the management of colorectal cancer. In 2003, the Company entered into a strategic alliance with Gen-Probe (NASDAQ: GPRO) for the development and commercialization of a second generation test for PCA3, DiagnoCure's proprietary molecular marker highly specific to prostate cancer. The test is now available through laboratories in the U.S. using PCA3 analyte specific reagents (ASR) from Gen-Probe, in Europe as the CE-marked PROGENSA(TM) PCA3 in vitro assay, and in Canada. In addition to its own research, the Company intends to acquire or in-license additional promising cancer biomarkers from both academic and commercial institutions.

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

**CEOCFO:** Mr. Schafer, what is the vision and focus of Diagnocure?
**Mr. Schafer:** "We have put together a very tight focus on high-value molecular diagnostics for cancer. We want to use the technology of molecular diagnostics to answer the key questions that physicians have in managing patients with cancer."

**CEOCFO:** Are the tools available today?
**Mr. Schafer:** "We have a full pipeline of products today. One of them is PCA3, a marker for prostate cancer. The test based on the PCA3 marker is available in the marketplace now through our license to Gen-Probe (NASDAQ: GPRO). The test is presently CE-marked in Europe and being sold actively there, and it is an ASR (analyte specific reagents) product in the United States and Canada. PCA3 is a highly specific for prostate cancer, in the range of 75%. It is a very good indicator as to whether or not a patient is going to be positive on the prostate biopsy, and if the cancer is growing vs. whether the gland is simply growing. So it distinguishes between an enlarged prostate and a prostate that actually has cancer."

**CEOCFO:** Is this being used routinely, replacing something or adding to something?

**Mr. Schafer:** "PCA3 is one of our markers, but it is being launched by Gen-Probe, so all of the marketing and sales activity is presently being handled by our partner Gen-Probe. I am not going to be able to speak to you on a specific basis as to what they are doing. I can tell you, because I have been in the diagnostic world a long time, what PCA3 is being positioned for now. The test itself has been out there since 2006. Since then, numerous papers have been published by key opinion leaders in the urology market place for the use of PCA3. Right now, it is being positioned pretty much as a test that is going to be able to determine whether or not a patient is a candidate for a second biopsy. Today there is a test in the market called PSA (Prostate Specific Antigen). There are about 45 million of those tests done worldwide. PSA is elevated quite frequently when a man is over fifty; men at that age normally have an enlarged prostate gland, 60 or 70%, at which point PSA also is elevated. We then have a dilemma: is it prostate cancer or something quite normal in men over fifty? In order to find out, today, patients have to have a biopsy of the prostate gland, where a very large needle is inserted into the prostate gland to extract tissue out of it. A pathologist then looks under a microscope to see whether or not he can find any cancer cell in the tissue extracted from the prostate gland. It might not be so bad if they did just one needle shot but they usually do twelve to sixteen needles into the prostate gland. Then when he looks under the microscope, and the pathologist doesn't find anything, it does not mean it is negative for cancer. It might have just been missed and they have to do another biopsy, again, and again. Some men go through this many times. Instead, physicians could ask for a PCA3 test. It is more specific, and it is going to tell you whether or not this patient should in fact have even the first biopsy. That is the issue out there in the street right now. Once you have an elevated PSA and a negative biopsy, what do you do? Twenty million men are walking around with an elevated PSA these days. PCA3 is positioned to be able to tell most people whether or not they have prostate cancer."

**CEOCFO:** And that is a non-invasive urine test!

**Mr. Schafer:** "What we have is a non-invasive urine test for prostate cancer. Everyday you hear of some study talking about some marker for this or that and most of those are just research studies. What we have is a real test that is on the market and there is not a man or a doctor in US, North America or Europe that cannot get this test done today, so we are excited about that."

**CEOCFO:** It sounds like a no-brainer!

**Mr. Schafer:** "It is going to catch on and it is going to be a very useful test for physicians and patients, no question."

**"With Previstage GCC, we measure 50% of each lymph nodes resected during the surgery, and amplify the GCC signal with molecular technology. With this method, we can find one cancer cell in ten million normal cells. The pathologist can find one cancer cell in about two hundred normal cells. Therefore, this test is about 100,000 times more sensitive than looking under a microscope, and we think we can find the 30% of patients that were missed by the traditional method" - John C. Schafer**

**CEOCFO:** What other types of tests are you working on?

**Mr. Schafer:** "When we formed our strategy about entering high-value diagnostics, instead of trying to discover biomarkers on our own, we decided to go out and find assays that already had patient data on them and we raised $25 million to do some M&A activity. Using that money, we made two acquisitions in the US. We acquired a company in Boston called Catalyst Oncology, and we acquired the GCC marker from a company in Philadelphia called TDT (Targeted Diagnostic and Therapeutics). We took that GCC marker and developed a test for the staging of colorectal cancer, called Previstage GCC. In North America about 174,000 people are diagnosed every year with colorectal cancer. If you are a fortunate one and the cancer has not spread to other organs, which can be found by cat scans or x-rays, then the treatment of choice is surgery. What they do then is cut out a piece of the colon about five inches on both sides of the tumor. The first thing that the patient asks when he or she wakes-up from the anesthesia is, 'Did you get it all, am I cured?' Presently, that question is answered by a pathologist that takes a look at the lymph nodes that were surrounding that piece of resected colon. The pathologist takes a thin slice of each lymph node, and looks at them under a microscope to see if he can identify any cancer cell. If he finds no cancer cell in the lymph nodes, then he says 'you are cured.' In Canada and in Europe where there is socialized medicine, most people are sent home and get no adjuvant chemotherapy. In the US, physicians ask if your father or mother had cancer and consider other aspects of the tumor, trying to find the 30% of the patients who relapse after being told they were cured following the surgery. It is very difficult for a physician to stand across the table from a patient and say "you are cured, go home and be happy", when he knows three out of ten relapse. Our test measures the messenger RNA from the GCC gene, and if it is present in the lymph node, it is a colon cancer cell that came from the inside of the intestinal tract, because there has never been any GCC found in tissue outside of the colon. We measure 50% of each lymph nodes resected during the surgery, and amplify the GCC signal with molecular technology. With this method, we can find one cancer cell in ten million normal cells. The pathologist can find one cancer cell in about two hundred normal cells. Therefore, this test is about 100,000 times more sensitive than looking under a microscope, and we think we can find the 30% of patients that were missed by the traditional method"

**CEOCFO:** Are you launching this yourself or are you doing it with a partner?

**Mr. Schafer:** "We purchased a CLIA-certified laboratory in the United States in the Philadelphia area, in West Chester Pennsylvania and we have that lab now up and running. We are putting the test

into that laboratory and this summer we will be launching that test directly to physicians. We are launching it ourselves."

**CEOCFO:** How do you decide whether you partner or launch on your own? With so many possibilities for acquisition how do you decide what you want to take in the fold to look at further?

**Mr. Schafer:** "In launching the test ourselves, we will look at what the call point is, how many physicians we have to talk to get an order for the test. When you look at the number of oncologists that treat colorectal cancer in the US, the number is pretty small; it is more like a couple thousand. That requires a very specialized sales force, one that a company like ours can easily afford. In fact, we are only talking about fifteen or twenty sales people to cover the whole US.

Making a decision on whom to partner with depends on what needs to be done to sell the test. With a test like our PCA3 prostate cancer test, where you have to call on all of the urologists in the US and Europe, that is tens of thousands of people, you would need a partner, because a small company has a difficult time raising enough money in order to launch from that large of a sales organization. Secondly, the PCA3 urine test sits on an instrumentation platform which means we would have to develop an instrument platform to put the test on and that is not in our strategic plan."

**CEOCFO:** How do you decide what market to look at?

**Mr. Schafer:** "It is amazing because research scientists have been writing about these molecular tests and molecular markers since they started playing with the human genome. This means it has been about seventeen years of good science that has already been done. Among these scientists with several papers written on all of these markers, some of them go to the next step and they skim the patent out of the university to form a little company. When we started our M&A efforts last year, we identified over 400 of these little companies. When you make acquisitions, the key is looking at companies that have lots of published data on real patients. The assay that we acquired from TDT, had received an NIH grant for $10.7 million for two five-year 2,500 patient prospective studies. The one on the staging of colorectal cancer has now been completed and results were presented at the ASCO meeting at the end of May. Our GCC staging testis very well documented and we are excited."

**CEOCFO:** What else is in your pipeline?

**Mr. Schafer:** "We also have products using that same GCC marker to answer the next question patients have; is my cancer coming back? Previstage GCC answers the question, 'Am I cured?' In other words, 'Did you get it all?' With the next test using the same marker, we will use a blood sample to tell whether or not the patient's cancer has come back; in other words, this second test will be for monitoring colorectal cancer patients. The GCC blood test is in fact the object of the second NIH-sponsored 5-year study conducted by Dr. Waldman, and it is now into its fourth year. We also have Shc proteins in the pipeline for breast cancer and gastric cancer. In summary, our pipeline is very rich."

**CEOCFO:** You have carved out a nice niche for yourselves!

**Mr. Schafer:** "We think so. It is important to focus. We know molecular diagnostic is a wonderful tool for lots of different diseases, and some very good work is being done. At DiagnoCure, we are focusing on cancer."

**CEOCFO:** What is your financial position?

**Mr. Schafer:** "We are a public company listed on the TSX, and we have had a new financing of $25 million in April 2007. In our last quarterly statements, we had $30 million in cash. Therefore, we are in good shape financially for our launch and for our commercialization."

**CEOCFO:** Why should potential investors be interested? There are many companies in your industry; why does DiagnoCure stand out?

**Mr. Schafer:** "In the last year and a half, we made milestone statements about what we were going to accomplish. We said we were going to focus in cancer, molecular diagnostic particularly, and we said these were going to be high-value cancer tests. We built the pipeline to the strength that is now. We acquired the clinical lab in West Chester and set it up. Over this year, we have presented our soon-to-be launched Previstage GCC test in several meetings, including the ASCO GI meeting, Colorectal Surgery Meeting, ASCO, Pathology Meeting. We have done what we said we were going to do and we are quickly moving into commercialization. It is an opportune time to get in at the beginning of growth of a company."

**CEOCFO:** Final thoughts, what should people remember most about DiagnoCure?

**Mr. Schafer:** "They should know that the Company is focusing on extremely high-value diagnostic tests that are going to change the way treatment of major cancers are handled today and we are going to continue to answer key questions for patients."


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