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NICHOLAS GRINER / CONTRIBUTOR

Correlologic CEO Peter Levine thinks his and his staff's long days and all-nighters are about to pay off.

Small Company, big partners

Bethesda-based Correlologic Systems enlists allies in quest to bring its cancer detection test to market

BY CHRIS SILVA, STAFF REPORTER

Peter Levine and Ben Hitt have formed important partnerships since they founded Correlologic Systems a little more than two years ago.

Correlologic, a small bioscience company based in Bethesda, lists just four employees,

including Levine and Hitt. But the company's partners and allies have included the Food and Drug Administration, the National Cancer Institute, the Ovarian Cancer National Alliance and members of Congress.

Buzz surrounding the startup emanates from a research-phase diagnostic test that has the potential to detect early forms of cancer, including ovarian cancer. Correlologic's good news about its ovarian cancer study received positive press in

Correlogic test receives promising attention

■ CLOSE UP

CORRELOGIC SYSTEMS

■ Mission:

Bioinformatics company developing diagnostic disease tests

■ Headquarters: Bethesda

■ Founded: May 2000

■ Founders: Peter Levine, CEO; Ben Hitt, chief technology officer

■ Investment: \$1 million, through angel investors

■ Technology:

ProteomeQuest, a diagnostic test for cancer

British medical journal The Lancet earlier this year.

The screening test is based on an innovative methodology that attempts to detect diseases by looking at patterns of proteins in the blood as opposed to single biomarkers, the conventional method used by researchers. "This had such potential, both as a business and life-saving

technique, that it was very clear what we had to do," says Levine, Correlogic's CEO. "Dr. Hitt and I both dropped what we were doing and tried to get the company up and running."

Correlogic's test, called ProteomeQuest, takes a single drop of blood from a patient and scans for patterns of protein fragments through a mass spectrometer.

The company got the attention of the FDA and NCI in the summer of 1999, when Levine introduced the technology to his friend, the FDA's Emanuel Petricoin, over lunch. The data that eventually produced The Lancet article was a joint effort of Correlogic, the FDA and NCI through the FDA/NCI Clinical Proteomics Program. Results produced by ProteomeQuest were remarkable:

The test was able to detect ovarian cancer in 100 percent of patients, or 50 of 50, who participated in the study, including cancers that were in their earliest stages, or Stage 1 cancers. Health statistics show that the survival rate is near 95 percent when ovarian cancer is detected in the Stage 1 form.

"This test is exciting because it has a very high accuracy rate and it's simple and easy to administer," says Ann Kolker, executive director of the Ovarian Cancer National Alliance (www.ovariancancer.org).

"There's not a tool like the Pap Smear" to detect ovarian cancer, says Kolker.

Ovarian cancer is the deadliest of the gynecologic cancers, and is the fifth-leading cause of cancer deaths among U.S. women, OCNA says. While most ovarian cancer cases are treatable if detected early, the majority of cases are not diagnosed until the cancer has spread beyond the ovaries.

Thus OCNA's interest in seeing Correlogic's detection test expedited to market.

GETTING NOTICED

The Lancet article caught the attention of Congress and OCNA.

The Ovarian Cancer Screening Bill, introduced by House reps. Steve Israel (D-N.Y.) and Rosa DeLauro (D-Conn.), was approved by the House July 22.

The resolution directs the secretary of Health and Human Services to support further research of ProteomeQuest, and to submit to Congress a report on the research. If the report shows more positive results, then federal health care programs — including Medicare and Medicaid, and group and individual health plans — should cover the procedure, just as the Pap Smear is now covered, the resolution says.

"My staff brought The Lancet article to my attention," Israel says, recalling how he first became aware of Correlogic. "Fundamentally, you had 14,000 women die of ovarian cancer last year because of a late diagnosis. I thought that Congress needed to elevate the issue and make it a priority."

The resolution still awaits introduction by the Senate. It is believed that Sen. Harry Reid (D-Nev.) will introduce it when Congress returns from recess after Labor Day.

Even if the resolution passes the Senate, Levine says, Correlogic will still need to get FDA approval before it can market the test.

Still, he's happy with how quickly things have moved along.

"We're really pleased that both of these are moving on essentially parallel tracks," Levine says of the clinical studies and the action taken by Congress. "It means the moment the test can be used by clinical diagnostic labs around the country, it can also be reimbursed."

GETTING STARTED

But it wasn't easy for Correlogic to convince the scientific community that its test — and the science it's based upon — was worth taking a look at.

Seeking out patterns of proteins in blood samples, as opposed to looking for one single indicator, or biomarker, presented a new line of thinking to scientists.

"We had every conceivable problem that any startup has, but magnified dramatically by this simple issue: We were challenging typical orthodoxy ... a way of thinking group and individual health plans — should cover the procedure, just as the Pap Smear is now covered, the resolution says.

Levine, who has a background in law and computer software, says Correlogic was given the runaround by a well-known medical journal for nine months. The journal wanted to know particular proteins Correlogic was tracking within the protein patterns. Levine found the question redundant.

"You don't need to know the individual protein. All you need to know is that when you see the pattern, it's unequivocal that the person has the disease," he says. "There is jealousy within the peer-reviewed process, which to me is obscene."

Levine and Correlogic's work paid off with the publishing of The Lancet article. Since then, the small company has jumped to the forefront of ovarian cancer research.

Beyond that particular disease, Correlogic (www.correlogic.com) also has begun exploring development of a detection test for breast cancer, and already has completed tests for prostate cancer. The company also hopes to sign an agreement soon with a large institution to research a test on Alzheimer's.

But for Levine and his staff, the short term goal of getting the first proteomic-based diagnostic test on the market is most tantalizing.

"We've worked our butts off, and a lot of people who work hard and have good ideas don't get the breaks we've received," Levine says. "The ability to detect cancer at an early stage, that's a critical step. To be involved in that, I have no complaints about working day and night at this."

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