

Targeting Colon Cancer

An Interview with Kevin T. Conroy,
President and Chief Executive Officer, Exact Sciences Corp.



Research scientist Tanya Quint works to process Cologuard samples in Exact Sciences' Madison, Wisconsin laboratory.

EDITORS' NOTE Kevin Conroy was named to his current post in 2009 and also serves as a director of the company. In 2005, he was appointed President and Chief Executive of Third Wave, and served in that position until the company's acquisition by Hologic in 2008. He joined Third Wave in 2004 and functioned as the company's General Counsel. Prior to Third Wave, Conroy was the Intellectual Property counsel at GE Healthcare and, earlier, he was Chief Operating Officer of two early stage, venture-backed technology companies in Northern California. Before this, he was an intellectual property litigator in private practice in Chicago. Conroy earned a Bachelor of Science degree in electrical engineering from Michigan State University, as well as a law degree from the University of Michigan Law School.



Kevin T. Conroy

COMPANY BRIEF Exact Sciences Corp. (exactsciences.com) is a molecular diagnostics company focused on the early detection of colorectal cancer. The company has exclusive intellectual property protecting its convenient, noninvasive stool-based DNA technology for the detection of colorectal cancer.

How has Exact Sciences evolved from its inception?

Exact was founded in the mid-90s by Stan Lapidus, a brilliant entrepreneurial scientist, who saw three of his companies go public.

His notion was that by screening for colon cancer noninvasively, you could move colon cancer to where cervical cancer is, which has been largely eradicated among women who are regularly screened with the Pap smear. He took the early learnings from DNA mutations in colon cancer cells and determined that you could look for those mutations in a patient's stool sample.

The early work was focused on screening the stool sample, looking for DNA mutations that would indicate whether the patient had cancer or precancerous polyps, but the early DNA detection technology didn't perform well enough to be an effective screening tool.

In 2009, the company was not in good shape. It had laid off almost all of its employees and had a small amount of capital, but had strong patents and a board committed to the long-term success of eradicating colorectal cancer.

The board recruited me to join the company at that time, and I saw a real opportunity to rebuild Exact Sciences. I was inspired by a visit to the Mayo Clinic, where I saw work showing that with different biomarkers and detection technologies, you could detect up to 90 percent or more of cancers and half of small precancerous polyps.

Maneesh Arora (Exact's COO) and I set about rebuilding the company, implementing a new vision for a path forward, and developing a new scientific team, as well as a test that detected 92 percent of

colon cancers noninvasively, and a majority of the large precancerous polyps most likely to develop into cancer.

Since 2009, we have built the company, laid out the vision, created a test, and run a huge, successful clinical trial. At the end of March, we had a panel meeting with the FDA where the advisory committee reviewed all of the data from the clinical trial and we are hopeful that the FDA will approve Cologuard.

When you joined the company, how tough was it to bring everyone onboard for the required transition?

We had to build a brand new team, and we had to convince Wall Street, which had soured on Exact Sciences, that a new approach was achievable, and that the fundamental problem was solvable.

Over time, investors came to realize that this is a really important cancer screening test.

When we started, our market cap in 2009 was about \$30 million and the company had \$30 million in cash.

Today, the market cap is around a billion dollars and we have more than \$100 million in cash. This was a slow five-year process with the stock price going from 80 cents before we joined the company to more than \$12 on February 3, 2014 and we have raised north of \$250 million.

It hasn't been easy. But we have done something many people thought could not be achieved.

How close are you to finally achieving success?

Our product is called Cologuard. In one of the largest colon cancer screening trials ever conducted – 10,000 patients – Cologuard has been shown to detect 92 percent of patients with cancer, all stages, and 66 percent of two centimeter precancerous polyps, as well as 42 percent of all precancerous polyps. Precancerous polyps

typically take 10 to 15 years to develop into cancer, so the idea is that with repeat testing – like with the Pap smear, which detects about 50 percent of advanced pre-cancers – you can, over time, cull out and remove those precancerous polyps in a population, which leads to disease prevention.

There are very few cancers where you can screen for pre-cancers. Here, you have the luxury of looking for a precancerous polyp that you can then remove.

The data is very clear. Colonoscopy has a huge effect on preventing cancer. The problem with colonoscopy is that many people refuse to be screened with one. The current noninvasive screening test only looks for blood and is not as accurate as Cologuard. We hope to displace other noninvasive tests so that people over the age of 50 will either undergo colonoscopy or use Cologuard.

We believe that Cologuard, if FDA approved, will make a significant difference in screening patients for pre-cancers and early cancers where you can make a difference.

Has the industry come onboard to support this work?

It's a disease where everyone wants to see better screening tools because it's the most preventable yet least prevented of all cancers.

It typically takes 10 to 15 years to go from a small precancerous polyp to Stage 1 cancer; it takes another couple of years to go from Stage 1 cancer to late-stage metastasized cancer. If we detect Stage 1 cancer, most of those patients won't undergo chemotherapy – they will have surgery, go home, and lead a full life.

Nine out of 10 early-stage cancers are cured; 9 out of 10 late-stage cancers result in death.

Where do we stand today in terms of health care reform?

I strongly believe in the notion that all of our citizens should have access to decent health care.

I also believe that market forces could drastically bring down the cost of health care delivery, and that we don't have enough market forces at play today. These mainly involve consumerism: giving people access to prices, and options for choosing a lower cost product or service will bring down the cost.

By giving the patient an incentive to look for the lower cost procedure, you will see procedure cost come down. Today, though, most people who have health insurance don't significantly care about the cost of any one service they get. ●