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Exclusive: Delco firm preparing to launch oral cancer screening test kit

Oct 30, 2014, 2:35pm EDT Updated: Oct 30, 2014, 2:48pm EDT



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A Broomall, Pa., personalized medicine company is getting ready to launch its first product: a test kit for use in a dental office that can detect early-stage oral cancer from a small amount of saliva.

"We have no doubt this will save lives," said [Stephen M. Swanick](#), the chairman, CEO and founder of PeriRx. The company's other initial investors are Dr. [Neil Gottehrer](#), a practicing dentist; and Dr. [Jack Martin](#), a cardiologist who is the company's chief medical officer.

PeriRx plans to introduce SaliMark, its molecular DNA biomarker test to local dentists and hygienists at a free continuing-education course being held Nov. 6 in Havertown, Pa. The test kit will get a larger unveiling in December when it's presented at the Greater New York Dental Meeting in New York City, a conference expected to draw 50,000 people including 25,000 dentists and 10,000 hygienists.

PeriRx obtained its patented and patent-pending technologies from the University of California at Los Angeles and RNAmErix, the company founded by the technology's inventor, Dr. [David Wong](#).

After spending more than a year negotiating the licensing deal, Swanick said the company spent the past four years developing and conducting clinical testing of its product. Those tests showed SalimArk performed with a 95 percent sensitivity, or accuracy, rate.

PeriRx had help. It collaborated on the creation and development of the test with scientists at the Diatherix Laboratories Inc. in the HudsonAlpha Institute for Biotechnology in Huntsville, Ala.

The initial investors of PeriRx put in about \$3 million of their own money to launch the company.

[When I first talked to him in 2011](#), Swanick hoped raise to another \$1 million and have a product ready to launch in two years.

"I could not have been more wrong," he said during an interview last week. "It took twice the amount of money and twice the amount of time."

The company ended up raising \$2.3 million from a group of angel investors.

Martin said the result is a product that is simple to use. A patient spits into a tube and seals the tube, which is placed in a plastic pouch and a mailing label is attached. The package is then sent to PeriRx for analysis at its affiliated lab. The test is used to detect biomarkers — which are measurable indicators of the severity or presence of a disease — for oral cancer.

Martin said dentists are supposed to screen patients for oral cancer, but it can be difficult for them to follow through on the process.

Said Martin, "They say, 'I see all these lesions in patients' mouths all the time. What am I supposed to do, send everybody for a biopsy?' We are hopeful our test will change that" by giving dentists a simple diagnostic test they can use in their office."

Swanick said the company's biomarkers have been clinically validated in multiple large trials including studies done in collaboration with the **National Cancer Institute**.

The test shows what lesions are pre-cancerous or cancerous, and which patients need to be monitored and which should be sent to specialists for treatment.

"The test is extremely accurate and can detect cancer and catch pre-cancerous displaysia," Swanick said. "That's huge."

The Oral Cancer Foundation and the National Cancer Institute estimate about 43,000 people in the United States will be diagnosed with oral cancer this year.

Swanick said catching oral cancer early is critical for beating the disease. The survival rate for patients treated with stage-1 oral cancer is 95 percent, and recurrence rate is 10 percent. For those at stage-4 when treatment begins, the survival rate is about 50 percent and the cancer returns on average 30 percent of the time.

SaliMark will be initially introduced as a CLIA-approved test, meaning it can be marketed under the **Food and Drug Administration's** Clinical Laboratory Improvement Amendment regulations that govern laboratory-based tests. PeriRx is continuing clinical testing of SaliMark so it can get FDA clearance to market it more broadly.

The kits will sell for \$20 and the test will cost \$145. Swanick said PeriRx is working with two of the country's largest dental insurers, Delta Dental and UnitedHealthcare, to obtain reimbursement codes that will allow dentists to bill the insurers directly for the diagnostic test. Until the separate codes are secured, dentists will be able to add the screening to existing procedure codes.

PeriRx has formed a partnership with two dental-device suppliers, **Henry Schein** Inc. and Patterson Dental — both of which have local offices in Boothwyn, Pa. — to market the test kits

directly to dentists.

"They each have 1,000 sales people," Swanick said. "They'll be knocking on every dentist's door around the country."

Martin said the company is working on screening-test kits to detect biomarkers for non-small-cell lung cancer and Sjögren's syndrome, a systemic and chronic inflammatory disorder that causes dry mouth and dry eyes.

John George covers health care, biotech/pharmaceuticals and sports business.