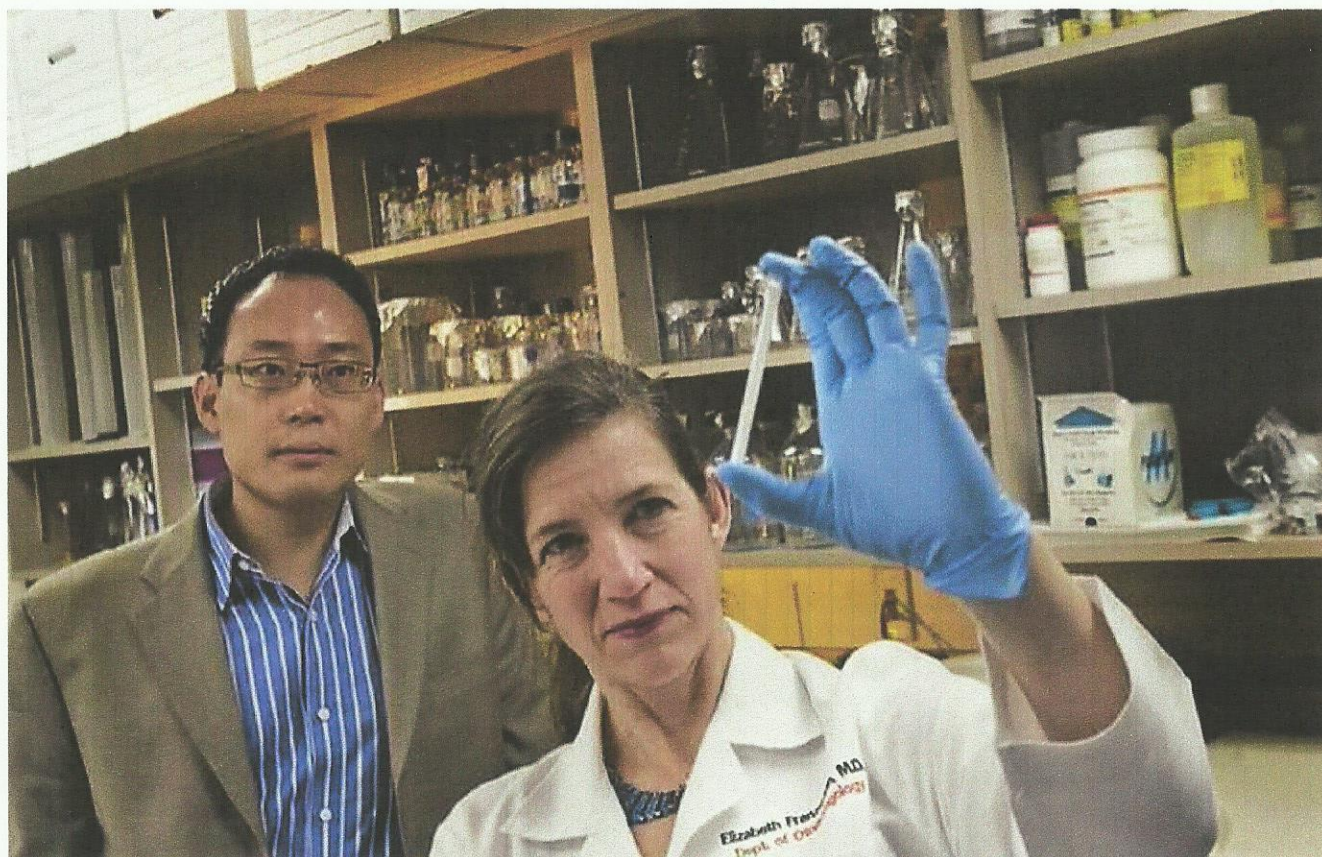


BUSINESS MAY 4, 2016 9:45 AM

Vigilant Biosciences cleared to launch its oral cancer test across Europe

HIGHLIGHTS

CEO Matthew H.J. Kim called the CE Marking a major milestone for the Fort Lauderdale-based life sciences company



Vigilant Biosciences cleared to launch its oral cancer test across Europe | Miami Herald

Vigilant Biosciences CEO Matthew H.J. Kim is shown with scientific founder Dr. Elizabeth Franzmann, who is looking at a OncAlert point-of-care test prototype for an early detection system for risk of oral cancer. **PATRICK FARRELL** - Miami Herald File Photo

BY NANCY DAHLBERG

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Vigilant Biosciences, an early-stage Fort Lauderdale-based company that develops solutions that aid in the early detection and intervention of cancer, announced that it has CE Marked its OncAlert Oral Cancer RAPID Test, meaning it can market the product in the 28 countries of the European Union as well as Norway, Iceland, Liechtenstein and Switzerland.

The OncAlert RAPID Test is an easy-to-use oral rinse test to aid healthcare clinicians assessing potentially at-risk patients for oral cancer, a disease that brings more than 600,000 new cases each year worldwide. The company said it is the first and only rapid test to detect a tumor-initiating and stem cell associated biomarker for head and neck cancer. The test results can be read by the clinical professional within 20 minutes.

The venture-backed company said it has multiple distribution agreements secured throughout Europe and the Asia/Pacific region and it expects to begin shipping the product during the second half of this year. It is not available in the U.S., but is undergoing FDA regulatory approval processes. Vigilant has received nearly \$8 million in funding, including from the Florida Institute for the Commercialization of Public Research.

Matthew H.J. Kim, founder, chairman and CEO of Vigilant Biosciences, called the CE Marking a major milestone because it enables the company to begin manufacturing and sales efforts. "We have built, and will continue to build upon, a strong distribution network across the EU and other regions of the world, and we are looking forward to making an impact on the high rate of late-stage oral cancers diagnosed globally," Kim said.

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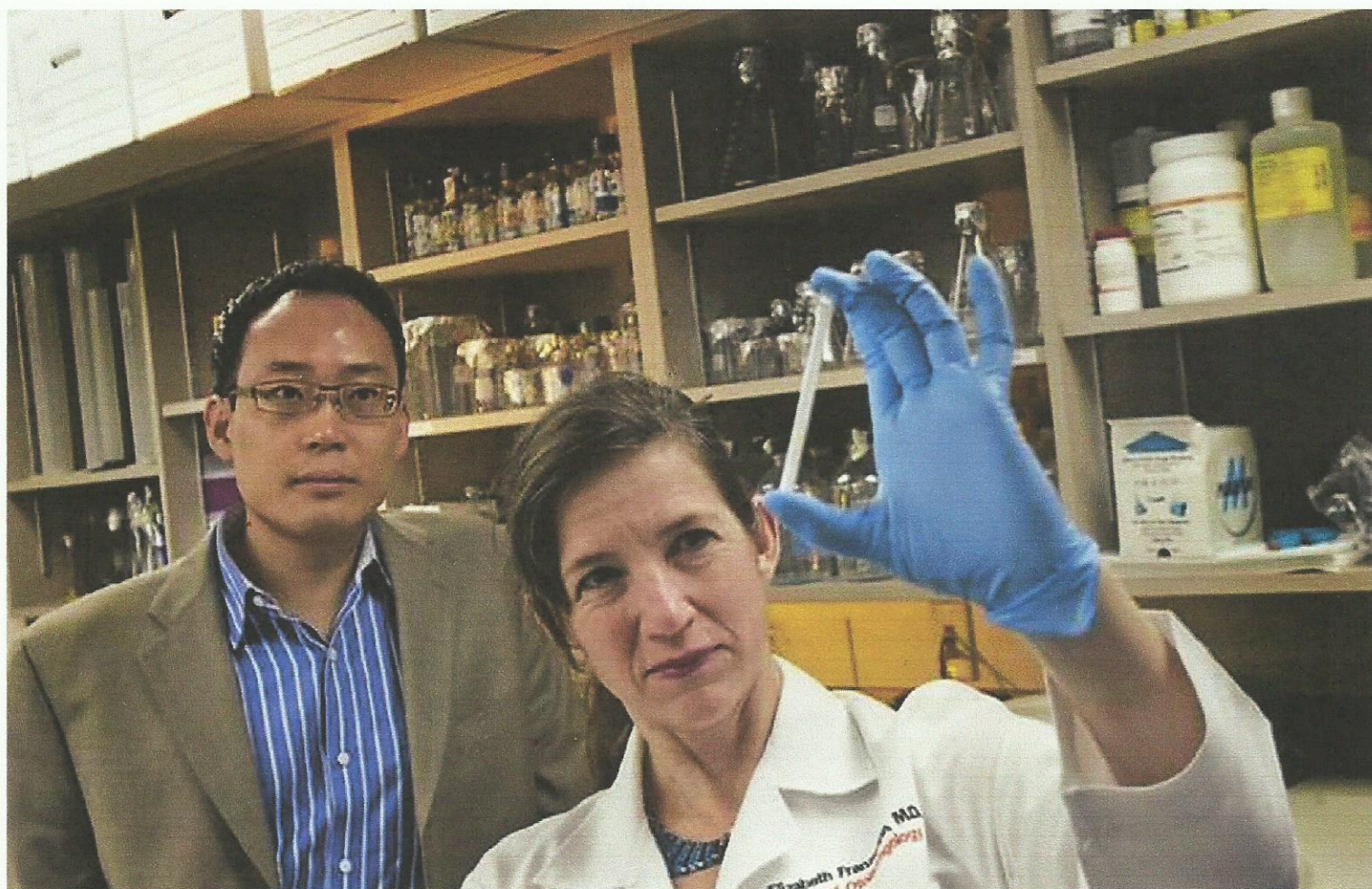
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BUSINESS FEBRUARY 24, 2015 5:47 PM

Miami life science startup stems from personal mission to fight oral cancer

HIGHLIGHTS

Vigilant BioSciences announced it has raised \$5.5 million in Series B funding, which will be used for development and commercialization of its product line that can aid in the early detection of oral cancer risk.



Matthew H.J. Kim, who founded Vigilant Biosciences, and serves as the company's chairman and CEO, is shown with Dr. Elizabeth Franzmann, who is looking at a OncAlert point-of-care test prototype. Vigilant is working on an early detection system for risk of oral cancer. **PATRICK FARRELL - MIAMI HERALD STAFF**

BY NANCY DAHLBERG

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Matthew H.J. Kim, a patent attorney by training, was heart-broken seeing the the suffering and aggressive treatment his mother went through with oral cancer. He also saw first-hand the results of what he calls an inadequate standard of care resulting in most cancers of the mouth not being detected until stage three or four. A mortality rate as high as 50 percent could be cut way back with early detection, he believed.

"I felt helpless and wanted to do more. ... You are fighting great odds by the time you get to that stage," Kim said, explaining his mother had to lose a portion of her jawbone as part of her treatment.

More than four years ago, Kim began researching early-detection technologies in development and found one at the University of Miami. After more research and talking to the scientists there, he began negotiating the license. "In homage to my mother, I executed the license on Mother's Day of 2011," he said, and Miami-based Vigilant Biosciences was born.

Since then Vigilant's initial products — a point-of-care oral rinse test and a more quantitative lab test that can aid in early detection of risk for oral cancer — have been in development and have passed one of the key regulatory hurdles toward commercialization in Europe. On Tuesday, the company announced it has completed its Series B round of funding, which will pay for commercialization in Europe and the start of the regulatory process in the U.S. this year.

ADVERTISING



The company's \$5.5 million investment round brings the total amount raised to date to \$7.8 million. The financing includes investments by White Owl Capital Partners, venVelo, the Florida Institute for the Commercialization of Public Research and several existing investors, as well as a group of private and angel investors committed to the life sciences.

Specifically, Vigilant will use the funds to drive toward CE Mark approval in Europe and U.S. regulatory approval for its OncAlert Oral

Cancer Risk Assessment System. The funds raised will support the international product launch and commercialization of the OncAlert System as well as other products in Vigilant's pipeline.

"As hundreds of thousands continue to be diagnosed with oral cancer every year, we are committed to providing an accurate, effective and affordable way to aid in the early detection of risk for the disease. This funding will enable us to address this critical market need that has gone unmet for far too long," said Kim, who founded two other companies and developed a number of medical screening and monitoring systems.

Vigilant's OncAlert Oral Cancer Risk Assessment System is based on patented technology that detects specific protein markers known to indicate an elevated risk for oral cancer, even prior to the observation of visual or physical symptoms. The simple, oral rinse procedure is easy to administer during a dental checkup and non-invasive for the patient, the company said. Both the rapid point-of-care test and the more extensive lab assay that comprise the OncAlert Oral Cancer Risk Assessment System could be on the market in Europe by mid-year.

"Together, it will be a very effective early detection system for the risk of oral cancer. Our test is a very simple and elegant solution that can be easily integrated into the standard of care," said Kim. While his mother is now five years cancer free, others aren't so lucky.

“We are now focused on oral cancer but we believe the technology has promise for other cancers,” said Kim.

According to the World Health Organization, there are more than 600,000 new cases of head and neck cancer and 300,000 deaths each year worldwide. Currently, the vast majority of patients are detected through a visual exam and/or are symptomatic, at which point they are likely late stage. As a result, oral cancer often goes undetected to the point of metastasizing. Early diagnosis of oral cancer results in a cure rate of up to 90 percent, the company said.

Dr. Elizabeth Franzmann, an associate professor of otolaryngology at the University of Miami’s Sylvester Comprehensive Cancer Center, is scientific founder and chief scientific officer of Vigilant. Her clinical research on selective salivary biomarkers for head and neck squamous cell carcinoma serves as the foundation for the company’s initial product. The company last week added a vice president of global sales and marketing to the team.

Vigilant, now a team of 10, received support and mentorship from the U Innovation team, led by Norma Kenyon, chief innovation officer at the UM Miller School of Medicine. U Innovation also connected Vigilant with the Florida Institute for the Commercialization of Public Research, which provided the company’s initial seed funding of \$300,000 that served as a catalyst to attract more seed capital.

The Institute invested another \$200,000 in the Series B round, and like U Innovation, it helped with introductions and access to resources, Kim said.

“Matthew started the company to address the lack of good diagnostics for oral cancer, a disease that both of his parents suffered from,” said Jane Teague, chief operating officer of the Institute. “Vigilant exemplifies what programs like ours are all about, providing seed funding to early-stage companies to bridge the gap until they qualify for and can attract later-stage financing.”

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