EMERGING MEDICAL VENTURES

START-UP BI

PROFILES | Start-Ups Across Health Care

CANCER DIAGNOSTICS

Preora Diagnostics Inc.

Minimally invasive lung cancer detection

1801 Maple Avenue
Evanston, IL 602013
Phone: +1 (847) 609-0500
Web Site: www.PreoraDx.com

Contact: John Hart, President & CEO
Business: Partial wave spectroscopy identifies cellular changes early
Founded: March 2015
Founders: John Hart; Hariharan Subramanian, PhD, CTO; Vadim Backman, PhD (Northwestern University, Evanston, IL); Hemant Roy, MD (Boston University Medical Center)
Employees: 9
Financing To Date: $4.8 million
Investors: Angel Investors; National Institutes of Health grant funding
Board Of Directors: John Hart; Vadim Backman; Hemant Roy; Stuart Cornew (Answermine Inc.)

Just as the PAP smear has drastically reduced the incidence and number of deaths from cervical cancer over the decades, **Preora Diagnostics Inc.** expects its low-cost test to be an effective prescreening tool for lung cancer, in the convenience of a primary-care setting. A patient's cheek cells are simply swabbed and the sample mailed to the company's centralized laboratory for analysis and results.

"Currently, lung cancer does not present itself until stage 3 or stage 4, where there is only a 3.9% survival rate for these two stages," says Preora's president and CEO John Hart. "We believe our test will be able to identify asymptomatic stage 1 and stage 2 cancers. The only other test able to do this is low-dose computed tomography (LDCT)."

Preora's test relies on partial wave spectroscopy (PWS) nanocytology, which can detect cellular changes on a nanoscale level, as opposed to the gold standard of evaluating biopsied cells/tissues at the microscopic level (nanoscale images are 1,000 times smaller than microscopic images). "Think of our test as a metal detector that can quickly assess structures as small as 20 nanometers," Hart says.

In reality, a standard microscope, along with a proprietary light and lens, is used to bounce one colored lightwave (ranging from blue to red: 450 nm to 700 nm) at a time across a cell, then the light scattering off of that cell is collected. Next, a data cube is created and analyzed. "We are using the light scattering in order to understand the nanostructure of the cell," Hart explains. "Changes within the cells (mutations) can be detected much earlier than at the micro-level."

Because PWS offers a cellular approach, it signals the early cellular changes that produce cancer, as well as being able to detect any type of lung cancer.

According to the 2010 US Census and American Cancer Society statistics, there are 11.7 million people between the ages of 55 and 80 with a history of heavy smoking, all of whom are potential candidates for the Preora test, representing an annual market opportunity of roughly $2 billion. The in vitro diagnostic test is scheduled to be launched as a laboratory developed test (LDT) in late 2016, while the company simultaneously pursues CE mark and PMA, which are anticipated in 2017 and 2019, respectively.

PWS nanocytology was developed at **Northwestern University** in Evanston, IL, with support of approximately $20 million of grants from the National Institutes of Health and the National Science Foundation between 2008 and 2014, spearheaded by Vadim Backman, a professor of biomedical engineering at the university, who, to this day, continues to be extremely frustrated with America's health care system. "It is 2015, and we still do not have a successful PAP smear-like screening program for lung cancer," observes Hariharan Subramanian, chief technology officer at Preora, who received his PhD in biomedical engineering from Northwestern in 2009 and, along with Backman, was one of the principal co-founders of the technology.

"Dr. Backman believes our technology can help turn the tide to win the war on cancer," Subramanian states. Because PWS offers a cellular approach, it signals the early cellular changes that produce cancer, as well as being able to detect any type of lung cancer.

In 2012, the product-development company NanoCytomics LLC, also based in Evanston, was formed by Backman, Subramanian and others to dramatically improve cancer survival rates. Preora was spun off in March of this year to commercialize the lung-cancer lab test and similar lab tests for other cancers as well. The start-up has licensed the technology from Northwestern,

for which there are five issued and three pending patents.

Hart's career spans nearly 40 years in health care, including 20 years at Baxter Healthcare Corporation, from 1977–1997, the last three years as vice president of business development for the IV Systems division. Afterward, Hart served as vice president of strategy and business development for Cardinal Health Inc., from 2000–2003. He also spent 10 years as a health care consultant for Everest Strategic Advisors LLC, in Wilmette, IL, from 2003–2012.

To administer the Preora test, a physician, technician or nurse uses a standard cytobrush (as for a PAP smear) to collect cheek cells from within the patient's mouth and deposits the swab sample in a small vial of Preora's ethanol solution. The preparation and actual sampling takes less than three minutes. The sample vial is then overnighted to Preora's lab in Evanston, where a slide is created and an analysis performed, taking between 30 and 45 minutes total. Risk index results are transmitted electronically via email to the physician either later that same day or early the next day.

The risk index indicates the patient's risk for lung cancer, divided into three ranges (similar to cholesterol level): low risk, medium risk or elevated risk. "There will be a point on the scale to indicate the patients level of cellular disorder (Ld value)," Hart says. "We also believe our simple, minimally invasive technique will result in a lot more patients willing to be screened for lung cancer, including those that are asymptomatic."

The PWS lab test has been used to screen about 550 clinical and volunteer patients for lung cancer, in five studies over the past five years, resulting in nearly 85% sensitivity and 88% specificity.

Competitor technology LDCT by companies such as **GE Healthcare** and **Siemens AG** requires screening in the radiology department rather than an office-based setting. The cost of LDCT is also approximately $450 versus only about $125 for the Preora test. However, the sensitivity of LDCT is slightly better, around 92%, according to Subramanian, while specificity is slightly lower than the Preora lab test. A second screening modality is sputum cytology from **Quest Diagnostics Inc.**, which has close to 100% specificity. "Sputum sampling can never predict a normal patient to have cancer, but its sensitivity is extremely low for early-stage cancers, in the range of 50% to 60%, resulting in a high number of false negatives," Subramanian conveys. But the sputum test is comparably priced to the Preora test.

The Preora lab test is expected to become commercially available in the US in late 2016, through a direct sales force and on a regional, selected market basis. Reimbursement will be via either a current cytology code or a pending specific CPT code for the test. During the time period that the test is LDT sanctioned, all cell samples will be shipped to the single Illinois location for evaluation. However, after FDA approval, multiple lab sites will be established. And, long term, the goal is to license and sell the technology to a company like Quest Diagnostics or Laboratory Corporation of American Holdings, both of which have locations throughout the US. Upon CE mark, multiple labs will be created in Europe.

Most of the $4.8 million raised to date by Preora and its parent company NanoCytomics constitutes three government grants totaling $3.8 million, starting with $150,000 from NSF in 2012. That same year, NanoCytomics received two separate grants, both from NIH. Two angel investors have also contributed $1 million. Preora expects to close an additional angel round of $2 million to $4 million by the end of the year.

The company is actively seeking strategic alliances with existing laboratories and diagnostic firms. The most probable exit strategy is a sale to one of these commercial partners within the next two to three years.

Colon cancer will be the second cancer pursued by Preora, with a commercial lab test likely available in late 2017/early 2018. The colon cancer market is much larger than lung, encompassing all people between the ages of 50 and 75. The test will entail a swab of rectal cells in a primary-care office, "for which we would expect a similar performance to lung cancer detection," Hart says. The colon test will identify patients with polyps and who should immediately have a follow-up colonoscopy to remove them. **SU**

[A#2015900134]

– Bob Kronemyer