

A Non-Invasive Test for Detecting and Monitoring Early-Stage Lung Cancer



Maria Zannes
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- Maria Zannes**

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CEOCFO: Ms. Zannes, would you tell us the overall vision at bioAffinity Technologies?

Ms. Zannes: bioAffinity Technologies is committed to continual scientific exploration, transparency and collaboration, and the development and commercialization of patient-friendly tests that accurately diagnose early stage cancer. The company has a strong international patent portfolio surrounding breakthrough technology for the early detection, monitoring and treatment of cancer. Our initial product will be an early-stage non-invasive test for lung cancer. We call our product CyPath®. We intend to develop a platform of products built around a very exciting technology.

CEOCFO: Is there a common thread among the technologies other than early detection?

Ms. Zannes: Our technology was initially developed at Los Alamos National Laboratory in New Mexico, and based on a porphyrin compound that preferentially binds to cancer cells. In doing so, the cancer cells fluoresce a brilliant red as compared to non-cancer cells. The detection technology is quite beautiful in that a sample with cancer cells is so distinct from a sample free from cancer. In other words, cancer cells take up significantly more of our proprietary assay. Not only can you see this phenomenon under a microscope, but the uptake can be quantitatively measured. The assay has a unique spectral signature. The signature peaks at a specific wavelength of light. We can quantitatively measure the emission of light at a specific wavelength and from that, detect whether or not a cell has taken up more or less of our CyPath® assay. In doing so, we detect cancer.

CEOFO: *What is the process in the body when you are testing?*

Ms. Zannes: The assay is in vitro, meaning that it is conducted outside of the body. Perhaps it is helpful to walk through the process of collection and testing of a sample. Let's look at how our first test would work, how a patient and his or her physician would use the CyPath® diagnostic assay to detect early stage lung cancer. We use sputum, more commonly known as phlegm, as the sample for testing. People at high risk for lung cancer would provide a sputum sample. A high risk individual is someone who has smoked for more than 30 pack years, which is the equivalent of smoking a pack a day for 30 years. These individuals who are at high risk would collect sputum over a three-day period. Sputum is coughed up using an assist device called an Acapella® that is made by Smiths Medical. This device is used as effective therapy by many people who have COPD or other lung ailments. The Acapella® device helps to break up mucus. After the sputum is collected, the sample is given to a lab and the lab labels the sputum with our proprietary and patented test. If there are cancer cells present, we can see those cancer cells, measure them and diagnose cancer. The process allows for a wide variety of uses and applications for our platform technology.

CEOFO: *Where has this concept been until now?*

Ms. Zannes: We've built on the research at Los Alamos National Laboratory, and incorporated discoveries of researchers in our own laboratories and by others in the field of imaging to develop an assay that binds specifically to cancer. In addition to the exciting work we've accomplished in our laboratories, the improvements in imaging and measurement are taking our research from the bench to the physician's practice. We have a strong scientific foundation on which to build and have completed a clinical trial, the results of which were published in the September issue of the *Journal of Thoracic Oncology*. That study analyzed sputum from 128 participants including cancer patients and people at high-risk for lung cancer. The test resulted in distinguishing cancer patients from high-risk patients with 81% overall accuracy. Since the end of the trial several years ago, we have entered into a collaborative relationship with the University of Texas Health Science Center in San Antonio. That collaborative effort has led to significant findings and broader application of the technology. We are working with a team of researchers led by Vivienne Rebel, who is both a M.D. who brings clinical experience and has a Ph.D. focusing on cancer stem cell biology. Dr. Rebel and her team of researchers along with our internal group of researchers have optimized the assay to achieve greater accuracy.

CEOFO: *Why was lung cancer chosen as your first target?*

Ms. Zannes: We chose lung cancer first because it has a dismal survival rate. My own father died of lung cancer when he was only 39 years old. He was a heavy smoker and veteran of WWII, a glider pilot. WWII glider pilots had a very low rate of survival, but for my father, his survival was even less as a smoker. Even now, lung cancer has a survival rate of about 17% over a five-year period. Breast cancer and prostate cancer have five-year survival rates of 90% and 100%. The difference between lung cancer survival rates and prostate and breast cancer rates is largely a function of the ability to catch the disease early. Lung cancer, unfortunately, is most often caught in very late stages; it does not show symptoms in early stages, so we catch it most often in later stages when treatment is less effective. Our test is designed to catch cancer early when there is a much greater likelihood of treatment and survival. There

is one additional reason why lung cancer was the first indication. Very early work with Los Alamos National Laboratory was done with uranium miners in Colorado and lung cancer patients. This early research looked at sputum from lung cancer patients and uranium miners to see if the researchers could detect lung cancer. In fact, they could. In these early studies, they detected cancer at very high accuracy.

CEOCFO: *Do you envision a time when these tests would be standard for annual physicals?*

Ms. Zannes: We do envision a time when this simple test is administered throughout the world to individuals at an annual exam. We have a very strong patent portfolio of 40 patents in twenty-one countries. Our initial market entry will be as a test in combination with low-dose computed tomography, or low-dose CT, which is the standard for imaging and screening and detection of lung cancer. In addition to commercializing the technology in the U.S., we will be commercializing in the European Union and in Japan and following with global commercialization. CyPath® is a technology that may be used in different parts of the globe in different applications. One of the benefits of the global marketplace for this technology is that it is simple; it is not expensive in comparison to other tests and it is easily available. You can imagine that in a less sophisticated market than the U.S., our test may become very important to a physician.

CEOCFO: *Your site indicates that bioAffinity Technology supplies experience, intelligence and creativity to the global fight against cancer. Would you tell us about the creativity side?*

Ms. Zannes: Science is a field of revelation. We are revealing the chemistry and science associated with cancer. If we've learned one thing in research, it is that Mother Nature keeps her secrets well hidden. In order to uncover the secrets, you have to be creative and you have to expand your horizon. Clearly, if you just simply stay within the box, if you stay within what is known, you are not going to reveal or discover. It's equally important to build upon what is known and proven. Our scientists use their own creativity and understanding of science to push the envelope, so to speak, and to learn why and how this specific assay works and then push it to do even more. That is where the creativity comes in. The other thing that we very much stress and as a group believe in is transparency. That means that good science requires you put your work out and your data out in order to have it criticized and reviewed and questioned. It is only through that constant questioning of the research data and studies that you move forward. It is important to be transparent in all walks of life, but in science transparency is definitional.

CEOCFO: *Do you have the funding for the steps you would like to take or are you seeking partnerships or investment?*

Ms. Zannes: We are seeking investment now for our Series A funding. We are a small privately held company with investors who continue to support our work. We have an exciting technology ready for commercialization and require \$12 million to get it into global markets. The funding allows us to commercialize in the U.S. as a laboratory developed test, complete larger clinical trials for FDA approval as a device with pre-market approval and commercialize in Europe and Japan. This Series A funding also will provide proof of concept on a number of other cancers such as bladder, prostate and cervix. Research

also will include use of our technology for treatment of cancer. There is a lot that can be done.

CEOCFO: *Do you feel that because it is a simple concept to understand it is easier to get funding?*

Ms. Zannes: Funding is difficult for all biomedical devices right now. Despite the overall landscape, we see a significant amount of interest in bioAffinity by the investment community. We're confident that after completing due diligence, we'll have high quality investment. Ours is a compelling story and we have the science behind us to tell that story.

CEOCFO: *What should people take away when they read about bioAffinity Technologies?*

Ms. Zannes: The bioAffinity Technologies platform is innovative, accurate and compelling in the global fight against cancer. It provides a technology that can, in a non-invasive manner, detect cancer at its early stage. We are extremely encouraged with our research findings and we are very optimistic about the value of our technology in other cancers as well. bioAffinity Technologies' strengths are in its people, its collaborative research with the UT Health Science Center and its own scientists, management, Board of Directors and advisors. The commitment is exceptional with regard to moving forward with this platform technology. We have investors who are focused on putting their money where it will help humanity, where their money provides not just an excellent return on investment but also an excellent return for people who are facing a terrible disease and where early detection makes a big difference.

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

