CEO CFO

GeneCentric

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Molecular Diagnostic Company, GeneCentric Diagnostics, Inc. and their Lung Subtype Platform (LSP™) are helping Clinicians Categorize Lung Tumors to better Personalize Treatment for Patients

Healthcare
Oncology
Diagnostics
(Private)

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Dr. Myla Lai-Goldman
CEO

BIO:
Dr. Myla Lai-Goldman is the Chief Executive Officer and President of GeneCentric Diagnostics. She is also a founder and director of the Company. Dr. Lai-Goldman spent more than 18 years at Laboratory Corporation of America, Holdings (LabCorp), the last 10 years as Executive Vice President, Chief Medical Officer and Chief Scientific Officer. She served on LabCorp's Executive and Management Committees, with strategic and operations responsibilities for 3 major genomic laboratories comprising more than 700 people. During her tenure at the Company, she led all clinical, scientific and medical activities, including the introduction of more than 400 clinical assays. Her experience includes the development of partnerships, licensing, and acquisitions. After leaving LabCorp, Dr. Lai-Goldman became a Venture Partner at Hatteras Venture Partners and is the managing partner of Personalized Science, LLC, a consulting company founded to assist customers achieve successful adoption of innovative diagnostics. Dr. Lai-Goldman received her BS from the University of Pennsylvania and MD from Columbia University College of Physicians and Surgeons. Dr. Lai-Goldman is Board-certified in anatomic and clinical pathology.

Company Profile:
GeneCentric Diagnostics, Inc., based in Durham, NC, is a molecular diagnostic company, which develops and commercializes novel assays that enable oncologists and their patients make more informed treatment decisions.

Interview conducted by:
Lynn Fosse, Senior Editor
CEOCFO Magazine

CEOCFO: Dr. Goldman, what is the basic vision and focus at GeneCentric?
Dr. Goldman: The mission of GeneCentric is the development and commercialization of novel diagnostic assays for cancer patients. We are beginning with a focus in lung cancer. GeneCentric has licensed novel technology from the University of North Carolina at Chapel Hill. We are combining the research of Drs. Chuck Perou and Neil Hayes who developed this technology with my expertise in diagnostics, to bring novel assays to patient care.

CEOCFO: Why the interest in the lung cell area?
Dr. Goldman: Lung cancer is one of the most frequent cancers both in the United States and around the world. Unfortunately, patients diagnosed with lung cancer too often have poor survival. Even with several new targeted medicines that have recently come to market, the long-term survival is still not good. GeneCentric has developed a novel lung subtype platform that will better allow for personalized treatment for each lung cancer patient.

CEOCFO: What is it about the technology that leads you to believe it will have an effect?
Dr. Goldman: Recent advances in the use of targeted therapeutics rely upon very specific knowledge of the type of tumor. When I trained in medicine and pathology, we would look under the microscope and make a primarily descriptive interpretation of the type of tumor. For lung cancer, what was important was whether it was a small cell cancer or a non-small cell cancer. After making this interpretation, we would describe additional features, but the reality was that it really did not impact therapy because the determinant of treatment in non-small cell lung cancer was primarily based on stage of the disease. More recently, new targeted therapies have become available and they require a much more specific diagnosis for the patient. These drugs not only require knowing the major category (e.g. non-small cell cancer versus small call

cancer) but also require accurate determination of the subtype. In the case of non-small cell lung cancer, the subtypes are known as adenocarcinoma and squamous cell carcinoma. Some of the new drugs only work in one subtype. Other drugs may cause side effects in patients who have the squamous subtype. What we found through a study called VOILA, is that pathologists, even the lung cancer experts, often do not agree with each other regarding the subtype. The GeneCentric technology, known as the Lung Subtype Platform or LSP™ assists pathologists with making this important interpretation. From a test adoption perspective, what makes this so important is that determining subtypes is already defined as having clinical utility in drug labels. Subtype determination is already necessary, but we know through our studies that the way it is being done today has challenges, so there is an unmet need in the market that our LSP™ test can meet.

CEOCFO: What is it that your technology interprets that is different?

Dr. Goldman: Our technology is a genomic test; it is a 54-gene gene expression signature. It separates lung tumors into five categories; normal, small cell, carcinoid, non-small cell, and within the non-small cell category, into adenocarcinoma and squamous cell carcinoma. As I mentioned, these categories can be of use to pathologists and clinicians to better categorize lung tumors and determine whether or not the patient is likely to benefit or be harmed by a specific therapy.

CEOCFO: Where are you in the process of licensing and developing?

Dr. Goldman: We have licensed both the Lung Subtype Platform technology, which I've described, as well as a second technology known as the Hypoxia Signature. GeneCentric holds exclusive licenses from the University of North Carolina at Chapel Hill for both of these technologies. We are in the process of revalidating the technologies in partner laboratories. Those validations have been proceeding well. We anticipate proceeding from validation to commercialization within the next year.

CEOCFO: Is the revalidation just a formality or are there things that you are looking for that they might not have looked at while they were doing the development?

Dr. Goldman: It is important whenever you are bringing onboard a new technology, to be able to show that in a different setting, utilizing new and separate tumors, you can reproduce the original research results. This adds to the strength of your discovery and demonstrates that the test is robust. It is another confirmation that your discovery works.

CEOCFO: Are you aware of competing technologies?

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Dr. Goldman: Traditional pathology review with special stains known as immunostains is what is in routine practice today and is the primary competing technology. Our technology is an improvement over the existing methods. We are aware that others are exploring this type of genomic technology, but from what we have seen, we have the best platform.

CEOCFO: What have you learned from your experience at Lab Corp that is most helpful at GeneCentric?

Dr. Goldman: There are two things that I would like to discuss. First, diagnostics are very important for patient care and for the future of personalized medicine. At LabCorp, I was involved in the introduction of all of the molecular tests that are used for HIV patients, and over the last twenty years, we made tremendous progress in transforming the survival of the disease. This improvement occurred because of the successful introduction of new drugs and the genomic tests that helped guide the use of the drugs. Diagnostics that assist with the use of a drug are called Companion Diagnostics. This is an important area of diagnostics that is beginning to get a lot of attention. GeneCentric is working hard to develop Companion Diagnostic assays that can have the same impact for cancer patients that we saw for patients with HIV. Cancer is more complicated, but the role and importance of personalized diagnostics are still the same. Second, my LabCorp experience taught me that the factors that lead to a successful diagnostic are measurable and reproducible. I have extensively studied and written about these factors and GeneCentric has incorporated them into its operating plan. The majority of our dollars are spent developing evidence that our technology works, something known as clinical utility. We focus on demonstrating that utilizing our tests changes clinical practice for the better, leading to improvements in patient outcome.

CEOCFO: Development is always expensive; what is the financial picture like for GeneCentric Diagnostics today?

Dr. Goldman: In September 2011, GeneCentric received $250,000 of Series 1 financing from, Hatteras Venture Partners, a healthcare-focused venture group based in Durham North Carolina. I am also a Venture Partner at Hatteras. This funding allowed us to start the company, to license our two platform technologies, and to revalidate the technology in a partner laboratory. These first steps have allowed us to build value for the Company. We will be talking more about our decisions regarding future funding as we enter 2013.

CEOCFO: Why does GeneCentric stand out to the investment community?

Dr. Goldman: GeneCentric stands out because of our founding scien-

tists, both of whom are exceptional, and our platforms, which will allow for the development of multiple assays, critical for patients care. GeneCentric combines this science with experienced management who can focus the company's science and dollars towards building adoptable diagnostics. With my prior work in the corporate world, and current work in the venture and start-up worlds, I have learned that both of these components are very important. It is critical to have both great science and experienced management.

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