CEO CFO

BIO THERANOSTICS
A BIOMÉRIEUX COMPANY
SOLUTIONS FOR METASTATIC CANCER

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With a Family of Diagnostic Tests Including Its CancerTYPE ID® Molecular Classifier That Can Predict the Tumor Type in Metastatic Cancer Patients, bioTheranostics Is at the Forefront of Diagnostic Innovation in Personalized Medicine

Healthcare
Personalized Medicine

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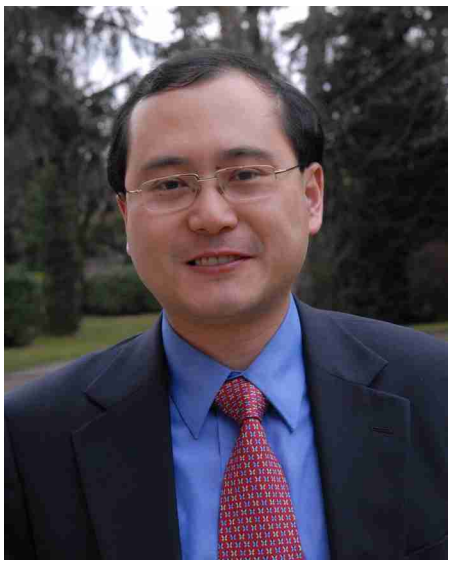

Richard Ding
CEO

BIO:
Richard Ding has 20 years of management experience in the biotech, pharmaceutical and diagnostics industries. As a member of the team at Myriad Genetics that cloned the BRCA1 gene, Richard made a significant contribution to the development of one of the first molecular genetic tests. Prior to becoming CEO of bioTheranostics, he held various cross-functional positions at Eli Lilly and Company. Most recently, Richard served on the Executive Committee at bioMérieux as head of Strategy and Business Development. He holds an MBA from the University of Utah and received his undergraduate education and scientific training at Fudan University, China.

About bioTheranostics:
bioTheranostics discovers, develops, and commercializes molecular-based diagnostic, prognostic, and predictive tests that support physicians in the treatment of patients with cancer. The company operates a CLIA-certified, CAP-accredited diagnostic service laboratory in San Diego, CA.

Interview conducted by:
Lynn Fosse, Senior Editor

CEOCFO: Mr. Ding, your website indicates that bioTheranostics is changing the way you see cancer. What is it that you are doing and the vision?
Mr. Ding: Personalized medicine is really the key message. Our goal is to provide the best clinical diagnostic solutions to help cancer disease management at the personal level. That is what drove the establishment of bioTheranostics, and we continue to execute on that vision. Personalized medicine on the drug side is making waves of innovation, which requires its diagnostic partners to step up as well. The critical issue is how you translate scientific discovery into a clinical solution that changes patient care. Recognizing the significant need in this area, in 2008 we formed a company focused on developing novel oncology diagnostic solutions that could positively impact patient care.

CEOCFO: What have you figured out that others have not?
Mr. Ding: Most biotech and diagnostic companies come from a discovery mentality. However, oftentimes their innovations never find a clinical application. With our expertise, what we have done in the last four years is demonstrate and translate innovative science into diagnostic solutions that can really change and improve patient care. That is the integration of push and pull—cutting edge diagnostic solutions integrated into clinical practice. That is what we strive for.

CEOCFO: What are some of the highlights of the last few months and what have you specifically developed at this point?
Mr. Ding: We offer a family of diagnostic tests that use molecular biology to diagnose cancers. Our first product, introduced in 2008, is our CancerTYPE ID® molecular classifier, designed to predict the tumor type in patients with metastatic cancers of unknown or uncertain origin. For this product, we have made significant progress, demonstrating a survival benefit when physicians use CancerTYPE ID to diagnose cancer, which allows treatment using site-specific therapy. This was a rare event—the first prospective study in which molecular profiling was used to direct site-specific therapy in cancer of unknown primary patients. The study was published in the *Journal of Clinical Oncology.* A second key study, published in the *Journal of Molecular Diagnostics,* showed that CancerTYPE ID is more accurate than the standard of care in diagnosing metastatic tumors.

CEOCFO: What made you feel that a molecular based test would be better?
Mr. Ding: It is really about accuracy, objectivity and sensitivity. CancerTYPE ID is more accurate than the standard of care, immunohistochemistry, for example. Our molecular tests also are based on a very objective algorithm. Molecular biology also is a more sensitive technology compared with the standard of care—it can get down to tens to hundreds of cancer cells and give you a very precise diagnosis. We have demonstrated this in the two recent studies with CancerTYPE ID, which is strong clinical evidence supporting use of the test.

Our second product is our PRÉCIS® Precision Medicine biomarkers, which we launched in early 2012. The concept is that precision medicine has two components: accurate diagnosis and personalized treatment driven by the molecular pathway in the tumor. CancerTYPE ID gives you the precise diagnosis. PRÉCIS pinpoints where the mutations are, which allows physicians to use targeted therapy. In other words, cancers may look the same under the microscope, but their biological and molecular mechanisms may be quite different. You want to use the right drug for the right patient. That is the concept with PRÉCIS, which is being well received in the clinical community.

Our third product, and perhaps the most exciting, is our Breast Cancer Index℠. This product quantifies the risk of recurrence of estrogen-receptor positive, lymph-node negative breast cancer. In the United States, we have done a good job on surveillance, and 70–80 percent of breast cancer patients are diagnosed in the early stages, stages I and II. But for many patients and physicians, questions remain about treatment and the benefits of chemotherapy and extended endocrine therapy. Breast Cancer Index is a second-generation biomarker addressing unmet medical needs beyond first generation biomarkers such as Genomic Health's Oncotype DX, which assesses the risk of recurrence during the first five years. Clinical experts know that breast cancer is not a five-year disease, and there are probably more patients who have recurrence after five years than within the first five years. First-generation biomarkers have good prognostic powers for the first five years and predict chemotherapy benefit, but only Breast Cancer Index predicts with statistical accuracy both early and late recurrence. A study demonstrating this superior performance was just presented at the San Antonio Breast Cancer Symposium. We did a head-to-head comparison with Genomic Health and demonstrated that although both biomarkers predict the risk of recurrence in the first five years, only Breast Cancer Index predicts recurrence at 5-10 years, which is a key unmet medical need for breast cancer management. Breast Cancer Index also predicts which patients will benefit from endocrine therapy beyond five years.

CEOCFO: Has the medical community been paying attention in general? Do they know you from the earlier products or is it really one by one?
Mr. Ding: We are definitely a corporate brand. That actually adds value. People look at the data, but they also want to trust the name. With CancerTYPE ID, we have been in the field for several years, and about one-third of oncologists and pathologists in this country have used the test. We also are in the early stages in international expansion. We still have a lot of customer education to do. With Breast Cancer Index, we have just shared pivotal data at a major conference and are in the process of launching the product. There are significant commercial channel synergies and physician synergies that will contribute to our clinical and commercial success.

CEOCFO: What is the key to commercialization? What do you and your team understand about how to get it accomplished?
Mr. Ding: In the diagnostic space, it has to do with clinical utility and reimbursement hurdles. Companies oftentimes focus on developing robust tests, but based on our experience in the pharmaceutical and biotech fields, medical adoption really centers on clinical utility and health economics. In other words, your products need to help change the standard of care or be integrated into the standard of care, and demonstrate diagnostic and therapeutic utility. It requires a very clear strategy and execution to deliver those things. To answer your question on how to make sure that you have success with your product, you have to have a very good product in terms of analytical performance, you have to have the clinical package demonstrating that it has clinical validity and, more importantly, the clinical utility that can help improve patient care. We have made good progress on all of these fronts—many of our studies are targeted toward clinical utility, and that is a somewhat novel concept in the diagnostic community. I really think we have helped to reshape the landscape in this regard.

"Targeted therapies continue to be developed, so getting the diagnosis right and choosing the right therapies will continue to be a major imperative for cancer management. bioTheranostics is very much at the forefront of diagnostic innovation in these areas."- Richard Ding

CEOCFO: What do you see a year or two down the line for bioTheranostics?
Mr. Ding: We are very excited about the opportunities ahead of us! For each of our products, the current unmet medical needs are tremendous. Each of them targets probably a few hundred thousand patients within the United States alone. Therefore, each product in our family has great clinical and market potential, and we are educating physicians about the benefits for their patients. Targeted therapies continue to be developed, so getting the diagnosis right and choosing the right therapies will continue to be a major imperative for cancer management. bioTheranostics is very much at the forefront of diagnostic innovation in these areas. What is exciting for us is that we know today

that every cancer is different. Diagnostic tests are needed in order to pinpoint where the disease originates and how to treat cancer patients. I believe that we are at the forefront of diagnostic innovation—we have the formula for successful adoption of new innovations in cancer diagnostics.

CEOCFO: Is bioTheranostics funded to get through the next steps?

Mr. Ding: We currently have a corporate investor, a multibillion-dollar company that has a strong commitment in public health. That has helped us to complete those clinical studies, which are resource consuming. If you have a short-term investment focus, that is a challenge for many diagnostics companies. We have de-risked the technical, clinical part of our products. We have had some early to mid-stage commercial success and are focused on increasing our success on the commercial side. The key thing is that we have been very cognizant of our commercial strategy. We have used our resources very judiciously. For the first few years, we were focused on R&D and getting a product profile and clinical evidence in place. Now we are increasing our commercialization efforts in a step-by-step and efficient manner. That commercial model, in our minds, will be more investor friendly and capital efficient. That is what we are executing now.

CEOCFO: Why does bioTheranostics stand out for investors and people in the business community?

Mr. Ding: Successful medical companies have great science. bioTheranostics stands out because we do good science. That is the most important thing. Our clinical evidence is robust and abundant. In the end, physicians are data driven, and you need clinical evidence to drive guideline change and clinical adoption. In addition, our clinical adoption model segments the market into national key opinion leaders, top-tier regional practices, and middle-tier and community oncologists. We have a three-pronged approach to target these different segments of customers and have a clear strategy to execute that. Finally, our stable investor base allows us to focus long term, and get the medical community to adopt our products based on the clinical data and customer outreach. That is why we will be successful on a continued basis.

Personalized medicine is multifaceted. We are focused on integrating diagnostics with therapeutics, and really trying to be a partner to physicians. In the end, whoever can integrate science with unmet medical needs will be successful. We believe our products meet that criteria, and we have a high level of confidence in our ability to execute our plan. We are very excited about the industry in general and about strategy execution at bioTheranostics.

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