New Diagnostic Development for the Oncology and Metabolic Diseases Fields

About Nuclea Biotechnologies
Nuclea is a translational medicine company dedicated to the discovery of proprietary biomarkers and in vitro companion diagnostic assays based on corresponding gene and protein expression profiles associated with an individual’s tumor or specific disease state. Nuclea’s differentiated DecisionDx™ platform technology greatly improves the efficiency of genomic discovery by utilizing proprietary software in the genetic and molecular analysis of a biorepository of highly characterized clinical patient samples. The Company has applied these discovery efforts to the development of in vitro companion diagnostics for use in therapeutic and medical imaging applications across the five major cancer types: colon, stomach, leukemia, lung and prostate. Nuclea is also utilizing its DecisionDx™ platform technology to develop companion diagnostics for other disease indications such as cardiovascular, neurological, inflammation and metabolic disorders.

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

CEOCFO: Mr. Muraca, what is the concept for Nuclea Biotechnologies?
Mr. Muraca: The vision of the company is to identify biomarkers to further the field of personalized medicine. We develop and manufacture new diagnostics for unmet needs in the field of oncology and for metabolic diseases. Within the area of metabolic syndromes, we focus on Type-II diabetes. With respect to oncology, we look at new diagnostics to help physicians determine specific treatments for patients with breast cancer and prostate cancer.

CEOCFO: Why the decision to work in those specific area?
Mr. Muraca: These areas have unmet diagnostic needs. There are quite a few treatments for both breast cancer and prostate cancer. Diagnostics allow physicians to determine which patient will respond best to different treatment options. One of the things that we do is help look at their genetic profile and proteomic profile to determine who will respond better to a specific drug. There are new therapeutics and approaches to managing Type-II diabetes. However, there are not enough diagnostics that have been developed over the past 20 years. We also focus on the management of obesity and cardiovascular disease for Type-II diabetes patients utilizing our new diagnostic biomarkers.

CEOCFO: Would you give us an example in the various areas of what you are providing that is not there and how it is useful?
Mr. Muraca: There are two key biomarkers in our portfolio of diagnostics that we believe will address unmet needs for both cancer patients and diabetics. One of these tests is an FDA approved product called HER-2/neu. This assay monitors patients with metastatic breast cancer that have been diagnosed as HER-2 positive using the IHC or FISH test. We can monitor these patients for recurrence and physicians can treat as well as alter courses of treatment depending on a patient’s HER-2 levels. Late detection of recurrence is a major problem in breast cancer. This test will help monitor HER-2 levels and detect recurrence early enough for physicians to alter treatment. HER-2/neu is an FDA-approved product, and that is manufactured at our Cambridge, Massachusetts site. Fatty Acid Synthase (FAS), which is currently under development, holds the potential to be a diagnostic for both cancer and metabolic syndrome patients.

CEOCFO: What is the science? What are you measuring that is not measured in other ways?
Mr. Muraca: What the assay is measuring is the HER-2 protein level in metastatic breast cancer patients. The level of this protein circulating in a patient’s blood provides information about the progression or regression of the patient’s disease. The HER-2/neu test is a simple, non-invasive blood test that can be performed at a routine visit.

CEOCFO: When would a physician use that test and how often should they be using it?
Mr. Muraca: About 20 to 30 percent of all metastatic breast cancer patients are HER-2 positive, and those patients can be monitored any time and at any frequency utilizing this diagnostic.
CEOCFO: Tell us about the metabolic area.
Mr. Muraca: We are developing a new diagnostic test called Fatty Acid Synthase (FAS). We believe that there could be applications of the diagnostic for both cancer and metabolic syndromes. In patients with metabolic syndrome, we measure FAS levels; a higher level of FAS circulating within the bloodstream indicates increased glucose levels. There is a correlation between increased glucose levels and potential complications in cardiovascular disease, renal disease and hepatic disease. As glucose level recedes so will FAS levels. This provides insight into whether insulin, or other treatments, are working. If FAS does not decrease in the bloodstream, then there are additional problems that need to be examined. It indicates the body is not responding to insulin, and likely there are other drugs that these people need to go on to ensure that they do respond.

CEOCFO: Are the tests currently in use or are they still in development? Where are you in the process?
Mr. Muraca: The HER-2/neu assay for metastatic breast cancer is currently in use. We offer this test to physicians and labs and it is being manufactured in our Cambridge facility. We have major clinical laboratories that are utilizing that test now and awareness continues to grow. The FAS assay is currently in development in partnership with the Dana Farber Cancer Institute and Joslin Diabetes Center in Boston.

CEOCFO: Are people aware that the test is being developed or is it too early?
Mr. Muraca: Yes, we have worked to educate research institutions and clinical laboratories about its development. We have spent significant time developing strategic partnerships with world-renowned research institutions and hospitals to provide a better understanding of its potential and to promote its use. We offer it now as a laboratory developed test.

CEOCFO: Why isn’t everyone using HER-2/neu?
Mr. Muraca: In 2013, we acquired Wilex, Inc. Oncogene Science, which held the intellectual property rights to HER-2/neu. Wilex did not promote the use of the test as aggressively as the company has done in the past 9 months. We are working to educate doctors, patients and advocates about the test and its potential.

CEOCFO: You mentioned that as one of the things that you did last year. What other changes have happened to the company?
Mr. Muraca: The acquisition of Wilex, Inc. was a major milestone for Nuclea Biotechnologies. We were named Healthcare Deal of the Year / Americas by Acquisition International Magazine for 2013. We secured a Good Manufacturing Practice (GMP) facility as part of the acquisition that allowed us to begin manufacturing other tests in our portfolio. We are currently manufacturing CA-IX test for renal cell carcinoma as a Class I IVD. We also have become ISO certified through our LRQA program and received our secondary inspection this year. Due to its scope, this acquisition was our primary focus in 2013.

CEOCFO: I know you recently raised some money. How will that be utilized?
Mr. Muraca: The funds raised will be utilized for marketing and manufacturing. We are processing current orders and building inventory. In addition, the funds will be used to develop a sales force that will broaden our reach.

CEOCFO: What is the key to getting attention for your sales force?
Mr. Muraca: The key to getting attention for our sales force is leveraging our strategic relationships with world-renowned research institutions and hospitals that are currently utilizing the tests. We are building awareness about the tests and their efficacy with industry thought leaders. In addition to our sales force, trade publications and conferences are valuable tools for promotion amongst physicians, advocates and patients. Our goal is when a sales rep walks into a doctor’s office, patients and physicians are already aware of the tests.

CEOCFO: What else have you taken from previous ventures as to how to run the company and be successful?
Mr. Muraca: I am extremely proud of my time at Oncor. In 1998, I was the team leader for the first HER-2/neu test to be approved by the FDA. It is not a serum-based test, it is what was called a fluorescent and type-II hybridization test, or a fish test, and that was the first gene based assay ever approved by the FDA. I gained valuable insight from that experience and others that have been the cornerstone of my success with building Nuclea. These experiences provided me the knowledge to validate new assays, perform clinical trials and work with federal agencies as well as the regulatory agencies.

“We have an expertise in biomarker development and a good sense of emerging opportunities in the market. Personalized medicine is a burgeoning filed in healthcare and we are poised to capitalize on it.” - Patrick J. Muraca
CEOCFO: What might be different a year or two down the line for the company?
Mr. Muraca: A year or two down the line, we hope that we will be working with one of the very large suppliers of diagnostic clinical assays. We will also be focusing more on developing the diagnostics for metabolic syndromes.

CEOCFO: Do you see moving outside the United States or not yet?
Mr. Muraca: Several of our diagnostic tests are CE Marked in Europe and we work with distributors outside of the United States. It is unknown if at this time we will ever have a physical presence outside of the US.

CEOCFO: There are many companies in your industry for people to pay attention to. Why does Nuclea Biotechnologies standout?
Mr. Muraca: I think we stand out because we have an expertise in biomarker development and a good sense of emerging opportunities in the market. Personalized medicine is a burgeoning field in healthcare and we are poised to capitalize on it.

BIO: Mr. Muraca was formerly the President and Chief Operating Officer of Clinomics Biosciences, Inc. and Vice President of Cytogenetic Diagnostics for Oncor, Inc. While at Oncor, Mr. Muraca was instrumental in obtaining Food and Drug Administration (FDA) approval for the HER-2neu test kit, the first gene-based breast cancer test approved by the FDA. Mr. Muraca has over 22 years of experience in the development of life science technology, including the development of microscopic-based digital imaging technology. Mr. Muraca graduated from Clark University in Worcester, Massachusetts. He has approximately twenty scientific abstracts and publications concentrating in the area of new biomarkers in cancer. He is also a named inventor on approximately twenty US and international utility and design patents. Mr. Muraca is currently an affiliate member of the American College of Medical Genetics and a member of the American Association of Tissue Banks. He is also currently a board member of the Jimmy Fund Council of the Berkshires and a member of the Jimmy Fund Visiting Committee for Dana Farber Cancer Institute. Mr. Muraca is also a board member of Jenesis Biosciences, LLC, a Joslin Diabetes Center for profit entity.