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Bioarray Genetics Focuses on Eliminating the Trial and Error Approach to Cancer Therapies by combining Gene Profiling with Machine Learning; an Interview with Founder Marcia Fournier

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CEOCFO: ***Ms. Fournier, would you tell us about Bioarray Genetics?***

Ms. Fournier: Bioarray's mission is to eliminate the trial and error approach to cancer treatment. Notwithstanding all of the advances achieved in medicine, 60% – 70% of patients do not experience a complete response to standard of care chemotherapy. Not knowing which patients will achieve a complete response to the treatment has created a trial and error process as clinicians move their patients from one treatment to another searching for something that will kill their cancer. Trial and error is not the ideal way to treat a patient as it creates a tremendous burden on them, their families and the healthcare system as a whole. At Bioarray, we want to eliminate the error and fear inherent in cancer treatment by combining gene profiling with machine learning algorithms to identify the best treatment option for a patient to achieve remission of their cancer.

CEOCFO: ***What have you developed so far?***

Ms. Fournier: Bioarray's first test addresses the trial and error in the most aggressive type of breast cancer, Triple Negative Breast Cancer (TNBC) which comprises about 20% of all breast cancers. Our studies show that 67% of women with TNBC will not achieve a complete response to the standard of care chemotherapy. Knowing if your tumor has had a complete response to chemotherapy is a critical waypoint in a woman's treatment, because, although all breast cancer patients will have a mastectomy, TNBC patients who have residual tumor before surgery have a very higher likelihood of relapsing soon after treatment. Said another way, a woman whose mastectomy was successful in removing the tumor still has a very high chance of her cancer recurring if the chemotherapy she had prior to surgery was not completely effective. Bioarray's BA100 Triple Negative Breast Cancer Stratification Test tells the Oncologists and Patient – prior to treatment – whether or not the standard of care chemotherapy will be effective on her cancer. Using our BA100 Stratification Test, we can help protect the approximately 67% of TNBC patients that we now know will not achieve a complete response from the standard of care treatment, enabling patients to move to more aggressive modalities.

CEOCFO: ***What is the medical view of looking at the potential results?***

Ms. Fournier: Most Oncologists are very eager for a stratification test for Triple Negative Breast Cancer because they see the harmful effects of the trial and error approach to treatment. There are genomics tests for other types of breast cancer, but they are not addressing specific questions within Triple Negative Breast Cancer. When we share with

Oncologists that we are developing the BA100 Stratification Test, they are excited about the potential benefits for their Triple Negative Breast cancer patients.

CEOCFO: ***What happens when you are testing a sample?***

Ms. Fournier: The BA100 Stratification Test is positioned at the beginning of the treatment journey. Before treatment begins, doctors order the BA100 test and find out if their patient will achieve a complete response to the standard of care chemotherapy. All we need to run the BA100 test is a few extra slides of tissue from the original biopsy. The slides are sent to our laboratory where we take the RNA from the tissue and measure it using the BA100 biomarker set. The BA100 Stratification Test generates a final score that predicts whether a patient will or will not achieve complete response which we provide back to the Oncologist.

CEOCFO: ***Where are you in the process?***

Ms. Fournier: The BA100 Stratification Test is in the research and development stage. We recently completed a retrospective clinical validation study and have submitted the findings for publication. We are opening a prospective study at the end of 2018 because rather than looking backward at patient data (like you do in a retrospective study), we allow Oncologists to use the BA100 Stratification Test on new Triple Negative Breast Cancer Patients. With this prospective study, we collect validation data that the test is doing what we say it does. This type of study also allows us to understand how the BA100 Stratification Test impacts clinical decisions. We plan to launch the BA100 Stratification Test in the second quarter of 2019 with the select group of oncologists that are participating in our clinical trials.

"At Bioarray, we want to eliminate the error and fear inherent in cancer treatment by combining gene profiling with machine learning algorithms to identify the best treatment option for a patient to achieve remission of their cancer."- Marcia Fournier

CEOCFO: ***What have you learned so far and what might have changed in your approach since you started to look at the problem?***

Ms. Fournier: When we started, we were very ambitious. We wanted to solve the trial and error approach to treatment in multiple cancers immediately. We thought we could develop a test for everything, but we learned that it is essential to focus on specific areas, so we concentrated our efforts on Triple Negative Breast Cancer, which is a very aggressive form of cancer that could benefit from the BA100 Stratification Test to guide its treatment. We have already started development of our second test by leveraging the same laboratory structure and technologies. Now that our development process and technologies are validated, it is synergistic for us to develop a pipeline of tests that will help patients across multiple types of cancer.

CEOCFO: ***Are you funded for your projects and are you seeking partnerships?***

Ms. Fournier: Very early on we were awarded a grant from the Avon Foundation for Women, which was critical early-stage funding for Bioarray when we were in the early research and development process. Currently, Bioarray is funded through a group of angel investors as well as Connecticut Innovations which is a quasi-public venture capital. We have most recently added a global biotech investor called Quark Venture.

CEOCFO: ***What is the competitive landscape?***

Ms. Fournier: Several companies are developing molecular tests to help cancer patients and doctors. Although the precision medicine concept has been around for a long time, it is still a young industry. The precision medicine concept is based on the ability to make treatment decisions based on a patients' unique biology. That is what diagnostics are doing, leveraging that information so that doctors and patients can make better decisions. The competitive landscape is growing, but specifically for the Bioarray, there are no direct competitors. Triple Negative Breast Cancer treatment prediction is a large unmet need and we are excited to be the first to market with a unique test like the BA100 Stratification Test.

CEOCFO: ***How do you know when the machine learning has reached critical mass?***

Ms. Fournier: The more data you have, the better machine learning works. We have much more data available than companies did just five years ago. That has allowed us to leverage historical data to provide enough samples for

statistical power in the predictions we make. We are excited about what the future holds as we build better and better machine learning algorithms and more and more clinical data become available.

CEOCFO: ***What surprised you throughout the process?***

Ms. Fournier: Many things surprised me. For example, there are three significant roadblocks for the industry. The first is intellectual property. The US Patent Office is still drafting a path for molecular diagnostics because we cannot patent genes or algorithms. This lack of a clear path for intellectual property rights puts the industry in a place where we would like to have IP protection, but we have to go around corners to create barriers. Second, the regulatory path is still developing. It is not clear whether the FDA wants to regulate molecular diagnostic tests or not. The FDA does not regulate us, but we have that shadow over our heads that we must be mindful of on a daily basis. Lastly, there is resistance from payers to provide reimbursement. There is no specific playbook for getting reimbursement and the process is both expensive and cumbersome.

It is not easy, especially for a young company like ours to continually navigate changing rapids in reimbursement, regulation, and intellectual property. I have been surprised by these roadblocks because the concept of precision medicine has been around for some time, yet the industry is still very young when it comes to knowing what to do with molecular diagnostics.

CEOCFO: ***Why pay attention to Bioarray Genetics and how does the company stand out in a very crowded field?***

Ms. Fournier: We have a strategic plan that applies our cutting-edge technology to one area of unmet medical need after another to eliminate the trial and error process in cancer treatment. We have built tools that have not been available to answer some of the toughest medical questions in the past, and we are excited to apply those tools to some incredibly frustrating areas of unmet medical need. We plan to make these technologies available across the globe and work closely with the medical and patient community to provide the best information possible. We have a tremendous team, and I am confident it will be hard to ignore the successes we have in providing greater confidence to clinicians, patients, and their families.