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The innovative QCDx technology may lead to truly optimized cancer treatment and have a significant impact on patient outcomes.



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“The RareScope™ maintains focus on characterizing cancer heterogeneity by enrichment-free, circulating tumor cell detection which leads to inclusive representation of the CTC population from the patient’s blood sample. From patient studies, we receive evidence that the RareScope approach can be used to truly personalize treatment, allow multiple concordant therapies and have significant impact on patient outcomes.” Dr. Triantafyllos (Fyl) Tafas

CEOCFO: *Dr. Tafas, what was the vision when you founded QCDx, LLC and what is your focus today?*

Dr. Tafas: The vision behind founding QCDx was to deliver real time and precise detection of cancer and to enable precision medicine. Accordingly, the RareScope 3-dimensional, microscopy system characterizes disease-specific biomarkers in tumor cells circulating in the patient’s blood to provide clinical oncologists with information for real-time, personalized treatment. Our focus today is to deliver the RareScope system to the clinical and biopharmaceutical markets, while we continue clinical studies to demonstrate the efficacy of our technology for optimization of cancer treatment. In an ongoing study of a novel breast cancer diagnostic test with the University of Connecticut Comprehensive Cancer Center, we see very exciting results regarding real-time optimization of therapeutic options for patients. A second study involving recurring glioblastoma patients, is beginning in collaboration with the Duke University Brain Cancer Center to characterize prospectively and adjust treatment of this devastating disease.

CEOCFO: *What is your approach? How does it differ from what other methods are available today?*

Dr. Tafas: We developed the RareScope™ technology to address the unmet need of characterizing cellular heterogeneity which is the hallmark of cancer. Cancer cells are genetically abnormal, and as they divide, they create offspring cells that are also abnormal and potentially different from their parent. This simply means that a cellular marker that could be a therapeutic target in a paternal cancer cell, may not exist in its

offspring cells which may end up creating treatment-resistant clones. Today, the disease heterogeneity is mapped with a tissue biopsy test, typically at the time of diagnosis. This guides therapeutic decisions that are often beneficial for the patient. However, in cases where clones of cancer cells do not respond to treatment, tumor growth may persist, and it is essential to continue mapping the disease heterogeneity and identify new cellular markers that may lead to real-time optimization of therapeutic protocols.

Sampling cancer cells and mapping heterogeneity through repeated tissue biopsies is rarely possible because of the tissue biopsy invasiveness. However, tumors are releasing cancer cells in the blood starting early at the disease onset. These are known as Circulating Tumor Cells (CTCs) and can be detected via a simple blood draw that can be repeated often. CTCs are live representatives of the tumor's heterogeneity and can be very rare among blood cells, down to one per milliliter of blood. With sensitive detection, CTCs can provide real-time and actionable information on new treatment targets against the developing tumor and become a valuable advisor to the clinical oncologist for delivering precision medicine.

The RareScope is designed for sensitive and unbiased CTC detection. It does that by analyzing nucleated cells from the patient's blood sample in an immobilized suspension, after staining with fluorescent probes that target cancer-specific proteins. CTCs are the cells that stand out among the surrounding blood cells because they express such proteins. Our approach differs from other systems which enrich CTCs from blood samples by selecting them for specific biochemical or morphological features. The RareScope maintains focus on characterizing cancer heterogeneity by enrichment-free, circulating tumor cell detection which leads to inclusive representation of the CTC population from the patient's blood sample. From patient studies, we receive evidence that the RareScope approach can be used to truly personalize treatment, allow multiple concordant therapies and have significant impact on patient outcomes.

CEO CFO: *What is it about your equipment that allows you to find this?*

Dr. Tafas: The RareScope is using fluorescence, 3-D optical tomography microscopy for analyzing blood samples that can contain millions of cells immobilized in special, transparent gels. All cells are morphologically intact and stained with immunofluorescent probes. The instrument collects 3-dimensional images that are analyzed with specialized image analysis software, also involving artificial intelligence to identify and characterize rare cells such as CTCs, that express the proteins targeted by the immunofluorescent probes. Furthermore, the RareScope technology offers the option to detect live CTCs by analyzing cell suspensions that have been stained with "vital" protein markers and isolate them for downstream, single-cell molecular analyses.

CEO CFO: *Is the medical community onboard? Do the people who should know about QCDx know about you? Do they understand the difference or is there still a lot of education yet to be done?*

Dr. Tafas: The company has been operating for the past three years and we are developing close contacts with leading medical oncology

groups from major Cancer Centers. We are excited that Senior Clinical Oncologists appreciate the benefits that RareScope-based CTC detection can offer for their patients. In a collaboration with the University of Connecticut, Comprehensive Cancer Center, we are conducting a clinical study for real-time diagnosis of breast cancer heterogeneity. The study started in July of 2020, and we are already seeing positive results which, according to the Clinical Oncologists have the potential to "... truly personalize and allow multiple concordant therapies to be engaged and have significant impact on patient outcomes".

In a second clinical study with the Duke University, Brain Cancer Center we shall work for disease characterization and treatment optimization in glioblastoma. Patient enrollment is projected to begin in October 2021, and the Neuro-Oncologists at Duke stated that they "...are looking forward to be able to follow prospectively the status of the [glioblastoma] tumors and adjust treatment more rapidly with the help of the RareScope system".

Working with our Oncology Advisors we are extending outreach to other Clinical Oncology Groups around the country, to show how clinical results obtained by RareScope support personalized and real-time, treatment optimization for their patients.

CEOCFO: Are there certain cancers that are more appropriate for this approach? What have you found so far?

Dr. Tafas: We believe that our technology can contribute significantly in precision medicine of different disease types. Our initial focus was set to breast cancer because it is the most common among American women and we aim to be a major lever for clinical oncologists to fighting back early stage and advancing or metastatic breast cancer. Glioblastoma is a more rare but fast-growing tumor with restricted treatment options and devastating outcomes. We anticipate that our real-time disease characterization, will reveal critical information for the Neuro-Oncologists to optimize treatment and potentially revert the disease course.

Drawing experience from these two studies in very different disease types, we believe that after appropriate selection of molecular targets, our technology will be applicable to lung and other types of tissue cancer as well as to blood cancers.

CEOCFO: Would you tell us about the different products you have available and how they are used?

Dr. Tafas: The main component in our product offering is the RareScope, for cancer research, biopharmaceutical product development, and for clinical cancer diagnosis. The first instrument is scheduled to be delivered to the University of Connecticut Cancer Center in July 2021 where it will be used for cancer research.

We are introducing the RareScope to other Cancer Research Centers for basic and applied cancer research as well as to biopharmaceutical companies where it can contribute in all clinical trial phases of cancer therapeutic development. A major goal for us is to offer the RareScope as a medical device to benefit patients from the diagnostic phase through their treatment trajectories and post-treatment monitoring or survivorship phase. We aim to place the RareScope system in the US Clinical Laboratory market in accordance with safety and performance regulatory requirements mandated by the Centers for Medicare and Medicaid Services (CMS) and the Food and Drug Administration. We shall

also seek certifications that will allow RareScope placement to the European and other world markets.

QCDx is also developing the MultiFluor™ technology and products for multiplex, immunofluorescent staining of intact and live cell preparations visualized with the RareScope as well as for cell preparations made on glass slides. This will enable characterization of detected cancer cells with more than two dozen biomarkers and expand on the number of detected treatment targets. Since the RareScope visualizes all nucleated cells from the patient's blood sample, MultiFluor probes can offer simultaneous characterization of lymphocytes and enhance real-time information for optimizing targeted treatments.

CEO/COO: *What surprised you from the founding of the company, from the original idea, to where you are today?*

Dr. Tafas: Presence of circulating tumor cells in the blood has been known for more than 100 years, but despite the existence of CTC detection systems since the beginning of the 2000s, CTCs have not become the important tool they can be for cancer diagnosis when a biopsy is not possible. We believe that the QCDx enrichment-free approach for detecting intact CTCs combined with multiplex marker identification in each CTC and selected lymphocytes, will advance decisions for treatment-optimization and help in reducing cost of treatment.

CEO/COO: *Are you seeking funding, investment or partnerships?*

Dr. Tafas: We are. The company is working on an institutional financing round and our goal is to raise four to six million dollars over the coming few months. At the same time, we are looking into partnering with pharmaceutical companies, for collaborations in the development of cancer therapeutics.

CEO/COO: *There are so many ideas in the medical field that should be looked at. Why does QCDx stand out? Why pay attention?*

Dr. Tafas: Cancer changes continually as it grows and the QCDx technology can characterize the changes in real time at the cellular level to fight back the disease. When tissue biopsy is not an option, circulating tumor cells are the best source of information for optimizing treatment and counter the disease growth. At the same time, immune cell characterization can help in optimizing immunotherapeutic treatments. The QCDx technology can offer both, starting from a minimally invasive blood sample. We believe this will fulfill our mission to create a solution for precise oncology that benefits the patients' treatment outcomes and improves their quality of life.

