StageZero Life Sciences Initiates Testing for COVID-19 In the USA

written by Raj Shah | April 20, 2020

April 20, 2020 (Source) – StageZero Life Sciences, Ltd (TSX:SZLS) ("StageZero" or the "Company") announced today that it is initiating testing for the SARS-CoV-2 virus from its CLIA-certified high complexity lab in Richmond, Virginia. The Company will offer both the PCR-based nucleic acid tests as well qualitative antibody testing. Quantitative antibody testing will be added once fully validated and approved.

The Company is first directing its testing to healthcare groups and frontline workers, which will include employers of frontline workers. As capacity grows, testing will be offered to physician groups with established patient relationships.

The PCR test:

PCR tests help determine if a patient has an active infection. StageZero is using Thermo Fisher Scientific's TaqPath RT-PCR Covid-19 kit to test for the SARS-CoV-2 virus. The kit has an EUA clearance and StageZero will operate under this authorization. The Company routinely uses Thermo Fisher Scientific equipment and procedures to conduct its RT-PCR mRNA analyses for its cancer screening tests, and is completing validation of the Covid-19 assay. This will be filed with the FDA this week which will allow testing to begin.

Qualitative antibody test:

Antibody tests can aid in the diagnosis of patients with suspected SARS-CoV-2 virus infection in conjunction with clinical presentation and the results of other laboratory tests. Antibody tests help determine if a patient has already been infected with the virus and is producing antibodies. StageZero is partnered with BTNX Inc. and will offer qualitative antibody testing using BTNX's Rapid Response COVID-19 IgG/IgM Test. The assays test for the presence of IgM and IgG and have a validated specificity of 99%, the key benchmark for these tests. On March 16, 2020 BTNX submitted under Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 and is listed on the FDA site. Subsequently, they submitted the kits to the New York State Department of Health for evaluation and confirmation of their results and are presently submitting an EUA to the FDA for approval.

StageZero will initially offer the BTNX Rapid Response test under Section IV.D of the FDA's Policy for Diagnostic Tests for Coronavirus Disease-2019 while awaiting EUA approval. FDA, CLIA and CAP guidelines lay out how the testing is to be conducted at this time:

- The tests must be conducted within a CLIA-certified high complexity lab.
- The test must be performed on a venous blood sample collected by a certified healthcare professional.
- The tests need an authorized test requisition.
- The results must be reported daily to the relevant State and Federal authorities under the signature of the lab.

"This is a highly coordinated effort to deliver COVID-19 testing as correctly and accurately as possible," said James Howard-Tripp, Chairman and CEO of StageZero Life Sciences. "In recent weeks there have been growing backlogs of patient samples being

held up for testing due to high demand and limited capacity. These partnerships will ease some of that backlog".

COVID-19 Testing for Frontline Workers

StageZero Life Sciences will initially be offering SARS-CoV-2 virus testing to employers and healthcare workers serving on the frontlines. This will be expanded to physician groups with established patient relationships as testing capacity increases. Capacity is anticipated to ramp-up fairly quickly.

Telehealth a Critical Component of Testing to Reach Employees and Patients

StageZero Life Sciences has been offering testing via its own telehealth platform for well over a year. StageZero's Telehealth Platform allows physicians to initiate an order for blood tests for prostate, colorectal or breast cancer. Once authorized, the test requisitions are sent to a lab partner or our proprietary network of mobile phlebotomists who can perform blood draws in a patient's home.

"The telehealth model which has been thrust upon the country in recent weeks is something StageZero has been preparing for for well over a year," said Howard-Tripp. "Now, because of advanced planning, we are uniquely positioned to be able to get to "socially distanced" employees and patients to offer COVID-19 testing. We are, however, first and foremost a Cancer diagnostic company and will remain focused there. For now though, we are very pleased to be able to help."

About StageZero Life Sciences, Ltd.

StageZero Life Sciences is dedicated to the early detection of cancer and multiple disease states through whole blood. Aristotle®, our next generation test, is a panel for

simultaneously screening for 10 discrete cancers from a single sample of blood with high sensitivity and specificity for each cancer. Aristotle is built on our proven and proprietary Sentinel Principle Technology Platform which has been validated on 10,000 patients and used to develop the first liquid biopsy for Colorectal Cancer, with further validation currently underway. In addition to building a pipeline of products for early cancer detection, the Company operates a CAP accredited and CLIA certified reference laboratory based in Richmond, Virginia that offers the ColonSentry® test as well as licensed biomarker tests for breast and prostate cancers. To learn more visit www.stagezerolifesciences.com.

Forward-Looking Statements

This press release contains forward-looking statements identified by words such as “expects”, “will” and similar expressions, which reflect the Company’s current expectations regarding future events. The forward-looking statements involve risks and uncertainties that could cause the Company’s actual events to differ materially from those projected herein. Investors should consult the Company’s ongoing quarterly filings and annual reports for additional information on risks and uncertainties relating to these forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. The Company disclaims any obligation to update these forward-looking statements, except as required by law.