

RENALYTIX AI

Joint venture for scaled production of COVID-19 antibody test kits

May 20, 2020

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Renalytix AI plc (LSE: RENX), a commercial-stage artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs, announces that its wholly-owned subsidiary, Renalytix AI, Inc. has entered into a joint venture with the Icahn School of Medicine at Mount Sinai ("Mount Sinai"), Kantaro Biosciences, LLC ("Kantaro"), to develop and scale production of COVID-19 antibody test kits.

Highlights

- Mount Sinai and Renalytix AI, Inc. form joint venture, Kantaro, to develop and scale production of covid antibody test kits
- Kantaro has partnered with Bio-Techne Corporation (NASDAQ: TECH) for manufacturing and global kit distribution
- Scaled kit production planned to enable clinical laboratories to conduct 10M tests per month beginning July

Background to the antibody test

RenalytixAI, Inc. and Mount Sinai today announce the formation of Kantaro, a Mount Sinai venture, to develop and scale production and distribution of a test kit based on the Mount Sinai-developed high-performance serologic assay for SARS-CoV-2 antibodies. Kantaro has partnered with Minneapolis-based Bio-Techne Corporation to develop and launch the new kit, with the goal of producing more than ten million patient tests per month by July. The two companies have formed a joint commercialization and distribution team to support the rapid distribution of kits to clinical laboratories in the US and around the world.

Kantaro's SARS-CoV-2 test kits are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. The technology underlying the kits was created by a team of internationally recognized scientists and clinicians, including members from the Departments of Microbiology and Pathology, Molecular and Cell-Based Medicine within the Icahn School of Medicine at Mount Sinai. The original Mount Sinai test was validated in The Mount Sinai Hospital's Clinical Laboratories, and has been performed on over 30,000 patient samples. The Kantaro test kit, an enzyme-linked immunosorbent assay (ELISA), builds on this test technology and is designed to measure the presence or absence of anti-COVID-19 antibodies in addition to measuring the titer (level) of antibodies a person has produced. The kit will utilize not one, but two virus antigens, the full-length spike protein, and its receptor binding domain, necessary for viral entry into cells.

Mount Sinai developed the underlying assay in response to the critical needs of thousands of patients within the hospital system, including those who were severely ill and could potentially benefit from convalescent plasma for emergency therapy. Mount Sinai was issued an Emergency Use Authorization (EUA) by the U.S. Food and Drug Administration (FDA) for clinical testing in its CLIA certified laboratory on April 15th. Kantaro plans to seek EUA for the test kit following final validation.

"Antibody testing will be critical to providing patients and governments the essential information they need to help the world economies reopen and begin to recover from COVID-19," said Florian Krammer, PhD, Professor of Microbiology at the Icahn School of Medicine. "With the launch of Kantaro, we look forward to bringing a kit based on our highly specific and sensitive test to every corner of the globe." The serological assay developed by Dr. Krammer and colleagues for the screening and identification of human SARS-CoV-2 seroconverters was described in a paper published in Nature Medicine on May 12, 2020.

"We believe that this technology has the potential for providing insight into immunity, and we're working intensely to develop a quantitative version," said Carlos Cordon-Cardo, MD, PhD, Irene Heinz Given and John LaPorte Given Professor and Chair of Pathology, Molecular and Cell-Based Medicine at Mount Sinai. "We expect that future findings will be critical to vaccine development and the development of advanced therapeutics." Due to the large number of COVID-19 patients who have been treated at Mount Sinai, with over 5,000 patients returning home to date, the Mount Sinai technology has been utilized across a large and highly diverse population.

"This technology reflects our commitment to everyone affected by SARS-CoV-2 and to developing tools for effectively combatting this disease," said Erik Lium, PhD, Executive Vice President and Chief Commercial Innovation Officer at Mount Sinai. "We believe that the rapid development, scaleup and distribution of these kits, based on the highly accurate Mount Sinai assay, can be a cornerstone in the global battle against COVID-19."

"Diagnostics are a national strategic priority and we are now witnessing unprecedented cooperation between academic medicine and private industry to innovate," said James McCullough, Chief Executive Officer of Renalytix AI. "Working together there is no doubt we can rapidly and safely advance the science to begin winning the war on COVID."

Related party transaction

Kantaro has been formed as a joint venture between Mount Sinai and RenalytixAI's wholly-owned subsidiary, Renalytix AI, Inc., in order to develop and scale production and distribution of COVID-19 antibody test kits.

Kantaro's founding board members include Erik Lium, PhD, Executive Vice President and Chief Commercial Innovation Officer at Mount Sinai, Niyum Gandhi, Executive Vice President and Chief Population Health Officer at Mount Sinai, and James McCullough, CEO of Renalytix AI. Dr. Lium will serve as Chairman.

Mount Sinai has granted a non-exclusive licence to Kantaro to use certain of its intellectual property in connection with the test kits in return for equity interests in Kantaro and a customary sales royalty. Renalytix AI, Inc. will provide key strategic, regulatory, reimbursement and commercial advice to Kantaro in return for equity interests in Kantaro. Mount Sinai will initially hold 75% of the equity interests in Kantaro with Renalytix AI, Inc. initially

holding the remaining 25% of the equity interests. Mount Sinai has the ability to appoint up to three board managers to Kantaro with Renalytix appointing one. The joint venture agreements contain customary provisions, including standard indemnities in the event of third party claims against the parties arising out of negligence or actions unrelated to the joint venture to the extent the losses are not covered by insurance. Both Renalytix, AI Inc. and Mount Sinai will advance initial start-up funding to Kantaro in the form of interest bearing loans. The total quantum of the loans is not of a significant nature.

The entry by Renalytix AI, Inc. into the joint venture together with the associated agreements and obligations contained within them is deemed to be a related party transaction pursuant to AIM Rule 13 as Mount Sinai is a substantial shareholder in the Company. The directors of the Company, excluding Erik Lium and Barbara Murphy, who are not considered to be independent for this purpose on account of their connection with Mount Sinai, having consulted with the Company's nominated adviser, Stifel, consider the terms of the joint venture to be fair and reasonable insofar as the Company's shareholders are concerned.

The person responsible for arranging the release of this announcement on behalf of the Company is James McCullough, CEO.

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About Kidney Disease

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control estimates there that 15% of United States adults or 37 million people currently have kidney disease. It is reported that 9 out of 10 adults with chronic kidney disease do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day 13 patients die in the United States while waiting for a kidney transplant.

*<https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

About RenalytixAI

RenalytixAI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. The Company's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit renalytixai.com