



KidneyIntelX clinical testing launch

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Renalytix AI PLC

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This announcement contains inside information

Renalytix AI plc

("RenalytixAI", the "Company")

RenalytixAI Reaches Milestone of KidneyIntelX Commercial Testing with Mount Sinai Health System

NEW YORK, September 18, 2020 - [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX), an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, announces the commercial launch of the KidneyIntelX clinical test reporting platform within the Mount Sinai Health System (Mount Sinai) in New York City. KidneyIntelX risk assessment of progressive decline in kidney function or kidney failure, including education support for treating clinicians, is now commercially available for patients with early stage diabetic kidney disease (DKD).

In addition to patient testing and risk assessment, a central component of this launch milestone is the physician education and support program developed in close collaboration with leadership of the Mount Sinai Departments of Medicine and Population Health Science and Policy, with input from patient advocacy groups and the broader clinical community. This expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website - www.kidneyintelx.com. We believe this education and support program will be an important resource to help improve care for early stage DKD patients at Mount Sinai and support future deployments of KidneyIntelX.

Agreements with Laboratory Corporation of America and a national medical logistics provider were entered into in calendar Q3 to support sample collection at five patient service centers servicing Mount Sinai patients. The Company intends to scale this process with laboratory service providers and logistics providers across multiple territories in the United States to ensure patient blood samples can be efficiently and securely delivered to RenalytixAI laboratories in New York, New York and Salt Lake City, Utah.

In June 2020, the Company announced that it received a clinical laboratory permit from the New York State Department of Health to provide commercial testing of KidneyIntelX. The Company is currently licensed to provide testing services for patients in 48 states. With the commercial launch at Mount Sinai, RenalytixAI expects revenue generation to increase in the near-term.

Renalytix plans to continue to add to the quality and capability of the KidneyIntelX platform through ongoing integration with healthcare system information technology platforms to facilitate ordering, educational programs, laboratory and logistical operations, and other core program elements.

KidneyIntelX is designed to provide potentially critical new information about the rate of disease progression and risk of kidney failure in early stage kidney disease to health care providers, insurance payors and population health managers in an effort to support optimization of care delivery, improve patient outcomes and reduce the \$120 billion annual cost of chronic and end-stage kidney disease to the United States healthcare system alone.

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 recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD 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 in the United States die 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. RenalytixAI'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 www.renalytixai.com.

KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to RenalytixAI. Mount Sinai and Mount Sinai faculty, including a small number of inventors, have a financial interest in RenalytixAI.

About the Mount Sinai Health System

The Mount Sinai Health System is New York City's largest academic medical system, encompassing eight hospitals, a leading medical school, and a vast network of ambulatory practices throughout the greater New York region. Mount Sinai is a national and international source of unrivaled education, translational research and discovery, and collaborative clinical leadership ensuring that we deliver the highest quality care-from prevention to treatment of the most serious and complex human diseases. The Health System includes more than 7,200 physicians and features a robust and continually expanding network of multispecialty services, including more than 400 ambulatory practice locations throughout the five boroughs of New York City, Westchester, and Long Island. The Mount Sinai Hospital is ranked No. 14 on *U.S. News & World Report's* "Honor Roll" of the Top 20 Best Hospitals in the country and the Icahn School of Medicine as one of the Top 20 Best Medical Schools in country. Mount Sinai Health System hospitals are consistently ranked regionally by specialty and our physicians in the top 1% of all physicians nationally by *U.S. News & World Report*.

For more information, visit <https://www.mountsinai.org> or find Mount Sinai on [Facebook](#), [Twitter](#) and [YouTube](#).

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the commercial prospects of KidneyIntelX, our ability to generate increased revenue in the near term, our ability to enter into and maintain agreements with laboratory service providers and logistics providers across multiple territories in the United States to ensure secure and efficient delivery of patient samples to our laboratories, and the ability of KidneyIntelX to curtail costs of CKD and end-stage kidney disease and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our final prospectus filed with the SEC on July 17, 2020, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

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