



# California Commercial Lab Certification Received

September 22, 2020

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Renalytix AI PLC

22 September 2020

**This announcement contains inside information**

**Renalytix AI plc**

("RenalytixAI", the "Company")

## **RenalytixAI Receives California Commercial Laboratory Certification**

*RenalytixAI is now currently licensed to provide KidneyIntelX testing services for patients in 49 states*

**NEW YORK, September 22, 2020** - [Renalytix AI, Inc.](#) (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, announced today that it has received a California Clinical Laboratory License from the California Department of Health for its clinical laboratory in Salt Lake City, Utah. [KidneyIntelX™](#) may now be used to report risk assessment of progressive decline in kidney function for patients in California with early stage diabetic kidney disease (DKD). With this certification, the Company is now licensed to provide KidneyIntelX testing services for patients in 49 states.

According to the [American Society of Nephrology](#), California has more than five million patients with kidney diseases, 94,000 patients diagnosed with kidney failure and 68,000 patients on dialysis,<sup>1</sup> one of the highest rates of CKD in the nation.

In August 2020, RenalytixAI announced that it filed a submission seeking clearance of KidneyIntelX with the U.S. Food and Drug Administration (FDA). This FDA filing builds on the Company's regulatory and commercialization program, which includes the September 18<sup>th</sup> announcement of the commercial launch of the KidneyIntelX clinical test reporting platform within the Mount Sinai Health System. This launch follows the announcement that the New York State Department of Health issued a clinical laboratory permit for commercial clinical testing of KidneyIntelX in June 2020.

KidneyIntelX is designed to provide potentially critical new information about the rate of disease progression and risk of progressive kidney decline 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.

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

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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](http://www.renalytixai.com).

Notes:

1: <https://www.asn-online.org/policy/webdocs/CA-FactSheet.pdf>

**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 and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery 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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