



## KidneyIntelX in Multi-Center Study

August 3, 2020

Renalytix AI plc

("RenalytixAI", the "Company")

KidneyIntelX in Multi-Center Study to Monitor and Predict Kidney Risk in COVID-19 Patients

Surge in Chronic Kidney Disease and Kidney Failure Expected Post-COVID-19

*Mount Sinai-Led Study to Assess 4,000 Surviving COVID-19 Patients*

**NEW YORK, August 3, 2020** - Mount Sinai Health System and [Renalytix AI plc](#) (LSE: RENX) (NASDAQ: RNLX), announce the initiation of a multi-center study to conduct in-depth investigations into kidney-related complications and long-term outcomes linked to COVID-19. KidneyIntelX, the artificial intelligence-enabled *in vitro* diagnostic platform, will be used to assess the risk of kidney disease progression and kidney failure, among other kidney complications, in patients surviving COVID-19 from multiple centers in the United States. As of July 30, 2020, [over 300,000 Americans had been hospitalized for COVID-19](#).<sup>1</sup>

The study, titled "Multi-center Assessment of Survivors for Kidney Disease after COVID-19 (MASKeD-COVID)," expands on the Pred-MAKER study previously announced April 20, 2020 which focuses on the impact of COVID-19 in the acute hospitalized setting (<https://renalytixai.com/kidneyintelx-covid-19/>). Investigative teams expected to participate in the study include the Mount Sinai Health System Icahn School of Medicine at Mount Sinai in New York, Yale New Haven Health/Yale School of Medicine, Michigan Medicine/University of Michigan Medical School, Johns Hopkins Medicine/The Johns Hopkins University Medical School, and Rutgers, The State University of New Jersey/Rutgers New Jersey Medical School.

KidneyIntelX will be used to assess risk for new chronic kidney disease (CKD) in the short-term or kidney disease progression over the longer-term in patients who have recovered from COVID-19. Diverse data inputs, including validated blood and urine-based biomarkers, inherited genetics and extensive patient data from electronic health record systems, will be incorporated into the KidneyIntelX machine learning-enabled algorithm to generate a unique patient risk score. In addition, Mount Sinai Health System's high-performance serologic SARS-CoV-2 testing will be used to assess a patient's antibody levels to COVID-19 over time, providing valuable insights into the interaction between immune response and kidney-related complications in this patient population.

*"With the pandemic spread of COVID-19 and the increased morbidity and mortality from COVID-19 in patients with diabetes, CKD and acute kidney injury, it is imperative to define the underlying mechanisms of COVID-associated kidney disease and develop solutions to guide patient care," said F. Perry Wilson, M.D., MSCE, MASKeD-COVID Principal Investigator, Yale School of Medicine. "This can be best achieved through collaboration in all aspects including data sharing, biomarker analysis, data analytics and clinical translation. RenalytixAI and Mount Sinai have assembled an outstanding team to address critical issues regarding COVID-19 and kidney disease."*

*"This collaborative approach is vital for us to further develop some important findings by the respective groups to date," said Matthias Kretzler, M.D., MASKeD-COVID Principal Investigator at University of Michigan. "We have demonstrated that ACE2 (the SARS-CoV-2 receptor) is co-expressed with a set of genes in the proximal tubules also having functions in viral entry, establishment of viral replication, and innate immunity.<sup>2</sup> We look forward to working with this outstanding team to further expand on this research and further define the underlying mechanisms of COVID-associated kidney disease."*

SARS-CoV-2 is believed to result in acute kidney injury through multiple mechanisms, including severe inflammation, endothelial damage, microthrombi, and possibly direct invasion of the virus into kidney epithelial cells.<sup>3</sup> *The burden and incidence of post-COVID-19 CKD and end-stage kidney disease (ESKD) is currently unknown, given the recency of the pandemic. However, emerging evidence suggests patients surviving COVID-19 will experience a significant increased risk of kidney disease, including the following:*

- *Approximately 20% to 45% of patients hospitalized with COVID-19 in the United States and over 60% of patients admitted to the ICU for COVID-19*

*in the United States experience acute kidney injury (AKI), approximately 25% to 45% of whom require acute dialysis;<sup>4</sup>*

- Data from an analysis of over 3,000 patients admitted to Mount Sinai indicates that 50% of surviving patients who experienced AKI during hospitalization for COVID-19 had persistently abnormal kidney function at the time of discharge;<sup>5</sup>*
- It has been established in the literature that AKI is strongly associated with development of CKD, CKD progression, and ESKD;<sup>6</sup>*
- Given the observed severity of kidney injury in many COVID-19 patients, both clinically and histopathologically, the risk for subsequent transition to CKD and ESKD is likely to be high in survivors.<sup>7</sup>*

*"There are so many questions yet to be answered regarding COVID-19 and kidney disease. For example, we don't yet know the risk factor and mediators of AKI to CKD transition after COVID-19. We also don't know the predictors of long-term outcomes after COVID-19," said Evren Azeloglu, Ph.D., Assistant Professor of Nephrology and Pharmacological Sciences at the Icahn School of Medicine at Mount Sinai. "Moreover, we need to understand how this "second hit" from COVID-19 interacts with other risk factors such as underlying APOL1 genotypes to heighten the potential for proteinuric nephropathy. Additional work with biomarker research, kidney tissue histopathology, and gene expression signatures is needed to understand the disease and the long-term implications."*

*The MASKeD-COVID study will be coordinated by Mount Sinai, which has already implemented a COVID-19 Center of Excellence Registry and begun longitudinal follow-up with detailed assessments along with biospecimens collection.<sup>8</sup> Initial research findings are expected to be reported in late 2020, with the goal of launching KidneyIntelX commercialization activities in this COVID-19 population targeted for H1 2021.*

#### 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 are 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](#).

For further information, please contact:

Renalytix AI plc [www.renalytixai.com](http://www.renalytixai.com)

James McCullough, CEO Via Walbrook PR

**Stifel (Nominated Adviser, Joint Broker)** Tel: 020 7710 7600

Alex Price / Nicholas Moore

N+1 Singer (Joint Broker) Tel: 020 7496 3000

Aubrey Powell / George Tzimas (Corporate Finance)

Tom Salvesen (Corporate Broking)

## About RenalytixAI

[RenalytixAI](#) is a commercial-stage artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management in CKD to help drive improved patient outcomes and significantly lower healthcare costs. KidneyIntelX, our first-in-class diagnostic platform, employs a proprietary artificial intelligence-enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and extensive personalized patient data from electronic health record, or EHR, systems to generate a unique patient risk score. KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to RenalytixAI. Mount Sinai and Mount Sinai faculty have a financial interest in RenalytixAI.

## Notes:

- <sup>1</sup> <https://covidtracking.com/data/download>
- <sup>2</sup> <https://www.medrxiv.org/content/10.1101/2020.05.09.20096511v1>
- <sup>3, 4</sup> <http://www.nephjc.com/news/covidaki>
- <sup>5</sup> <https://www.medrxiv.org/content/10.1101/2020.05.04.20090944v1>
- <sup>6</sup> <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3788581/>
- <sup>7</sup> <https://jasn.asnjournals.org/content/31/7/1380>
- <sup>8</sup> <https://www.fiercehealthcare.com/hospitals-health-systems/mount-sinai-launches-post-covid-care-center-for-ongoing-treatments>

## Forward-Looking Statements

Certain statements made in this press release are forward-looking statements including with respect to the admission of the new ordinary shares to trading on AIM. These forward-looking statements are not historical facts but rather are based on the Company's current expectations, estimates, and projections about its industry; its beliefs; and assumptions. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates" and similar expressions are intended to identify forward-looking statements. These statements are not guarantees of future performance and are subject to known and unknown risks, uncertainties, and other factors, some of which are beyond the Company's control, are difficult to predict, and could cause actual results to differ materially from those expressed or forecasted in the forward-looking statements, including if the new ordinary shares are not admitted to trading on AIM or admission is delayed. The Company cautions security holders and prospective security holders not to place undue reliance on these forward-looking statements, which reflect the view of the Company only as of the date of this press release. The forward-looking statements made in this press release relate only to events as of the date on which the statements are made. The Company will not undertake any obligation to release publicly any revisions or updates to these forward-looking statements to reflect events, circumstances, or unanticipated events occurring after the date of this announcement except as required by law or by any appropriate regulatory authority.

For readers in the European Economic Area ("EEA") and the United Kingdom

In any EEA member state and the United Kingdom, this communication is only addressed to and directed at qualified investors in that member state and the United Kingdom within the meaning of the Prospectus Regulation. The term "Prospectus Regulation" means Regulation (EU) 2017/1129.

For readers in the United Kingdom

This communication, in so far as it constitutes an invitation or inducement to enter into investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000 as amended ("FSMA")) in connection with the securities which are the subject of the offering described in this press release or otherwise, is being directed only at (i) persons who are outside the United Kingdom or (ii) persons who have professional experience in matters relating to investments who fall within Article 19(5) ("Investment professionals") of the Financial Services and Markets Act 2000 (Financial

Promotion) Order 2005 (the "Order") or (iii) certain high value persons and entities who fall within Article 49(2)(a) to (d) ("High net worth companies, unincorporated associations etc.") of the Order; or (iv) any other person to whom it may lawfully be communicated (all such persons in (i) to (iv) together being referred to as "relevant persons"). The ADSs or ordinary shares offered in the Global Offering are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such ADSs or ordinary shares will be engaged in only with relevant persons. Any person who is not a relevant person should not act or rely on this document or any of its contents. This communication does not contain an offer or constitute any part of an offer to the public within the meaning of sections 85 and 102B of FSMA or otherwise.

Not for release, publication or distribution, in whole or in part, in or into or from any jurisdiction where to do so would constitute a violation of the relevant laws of such jurisdiction

This press release contains forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are statements that are not historical facts, and in some cases can be identified by terms such as "may," "will," "could," "expects," "plans," "anticipates," and "believes." These statements include, but are not limited to, statements regarding the conduct, design and timing of the MASKeD-COVID clinical trial, including the timing of initial research findings and the timing and viability of commercialization of KidneyIntelX in the COVID-19 population, as well as the participation of other institutions in the MASKeD-COVID clinical trial and the potential benefits of KidneyIntelX in assessing kidney disease in the context of COVID-19. 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. 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. Various important factors could cause actual results or events to differ materially from those that may be expressed or implied by our forward-looking statements, including those described in the "Risk Factors" section of our final prospectus filed with the Securities and Exchange Commission (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.

This information is provided by RNS, the news service of the London Stock Exchange. RNS is approved by the Financial Conduct Authority to act as a Primary Information Provider in the United Kingdom. Terms and conditions relating to the use and distribution of this information may apply. For further information, please contact [rns@lseg.com](mailto:rns@lseg.com) or visit [www.rns.com](http://www.rns.com).

END

MSCUURWRRUUWRAR