



## Mount Sinai Initiates Scale-Up of KidneyIntelX

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**This announcement contains inside information**

**Renalytix plc**  
("Renalytix" or the "Company")

### **Mount Sinai Initiates System-wide Scale-Up of Renalytix KidneyIntelX™ Enabled Health Care Model**

*Targeted testing run rate of 300 diabetic kidney disease patients per week in calendar Q4 2021*

**NEW YORK and SALT LAKE CITY, September 14, 2021** - [Renalytix plc](#) (NASDAQ: RNLX) (LSE: RENX) and the **Mount Sinai Health System** today announced scaled-up implementation of the KidneyIntelX early-stage risk assessment testing and care management program across primary care and specialty clinician networks under a real-world evidence development program for patients with diabetic kidney disease (DKD). KidneyIntelX enables a shift in focus from care coordination efforts focused on Mount Sinai's late-stage kidney disease patients to a focus on patients with early stages of the disease where prognosis and treatment with population health care navigation assistance can improve patient care and outcomes and generate cost savings. Before the end of 2021, Mount Sinai expects to provide KidneyIntelX testing and downstream care management at a rate of 300 patients per week with approximately 6,000 eligible patients tested by calendar Q2 2022 under this development program.

In an initial rollout across seven primary care practices in Manhattan, New York City, the KidneyIntelX program has demonstrated value for clinical care delivery by identifying patients with DKD at low, intermediate, and high risk of declining kidney function or kidney failure early in the disease lifecycle when treatment has the potential for maximum effect. KidneyIntelX access is now expected to grow to over 300 treating physicians in calendar Q4 2021. The number of eligible patients who have scheduled physician interaction with active electronic health record access to KidneyIntelX is expected to grow up to sixfold in the same period.

*"Our KidneyIntelX™ enabled diabetic kidney disease program allows us to provide a high standard of care in early-stage kidney disease patients where we have the best chance to help patients avoid significant kidney damage", said Robert Fields, MD, MHA, Executive Vice President and Chief Population Health Officer at Mount Sinai Health System. "Ongoing analysis and sharing of doctor and patient user experience combined with population level data insights is helping to drive systemwide access to early-stage risk-assessment and treatment."*

*"Systematically identifying high-risk patients with DKD under primary care at the earliest stages of their disease is essential for improving outcomes, quality of life, and reducing health care cost in the population with kidney disease", said David C. Thomas, MD, Professor of Medicine, Medical Education and*

**Rehabilitation and Human Performance and Interim System Chair, Department of Medicine, Icahn School of Medicine at Mount Sinai.** *"We now have the tools, including care navigation, and pharmacy and dietician support, in place to do more than manage the transition to dialysis or transplant. We believe this program will enable advanced support for our primary care teams to help improve the long-term outlook and quality of life for our patients with diabetic kidney disease."*

In 2021, Mount Sinai's KidneyIntelX enabled care program has achieved significant milestones, including successful integration into the clinical workflow across the Health System's network of primary care and specialty physician practices. Early results of the real-world evidence program are aligned with published utility study data. These results indicate that appropriate pharmacy management and specialist referrals are more likely when KidneyIntelX testing is integrated into the care plan. These actions are important for slowing the progression of DKD. Under Mount Sinai's population health guided care model, primary care physicians can receive direct test ordering, education and advanced pharmacy, dietary and specialist support information for their DKD patients.

KidneyIntelX includes technology that was initially developed by Mount Sinai faculty. This technology has been licensed by Mount Sinai to Renalytix. Mount Sinai and a small number of Mount Sinai faculty inventors have a financial interest in Renalytix. Mount Sinai also has representation on the Renalytix Board of Directors.

*The person responsible for this announcement is James McCullough, CEO*

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### **About KidneyIntelX**

KidneyIntelX, is a first-of-kind, solution that enables early-stage diabetic kidney disease progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

### **About Renalytix**

Renalytix (LSE: RENX) (NASDAQ: RNLX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully enables early-stage chronic kidney disease, progression risk assessment. The Company's lead product is KidneyIntelX, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit [www.kidneyintelx.com](http://www.kidneyintelx.com)). For more information, visit [www.renalytix.com](http://www.renalytix.com).

### **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. We advance medicine and health through unrivaled education and translational research and discovery to deliver care that is the safest, highest-quality, most accessible and equitable, and the best value of any health system in the nation. The Health System includes approximately 7,300 primary and specialty care physicians; 13 free-standing joint-venture centers; more than 410 ambulatory practices throughout the five boroughs of New York City, Westchester, and Long Island; and more than 30 affiliated community health centers. The Mount Sinai Hospital is ranked in *U.S. News & World Report's* "Honor Roll" of the top 20 U.S. hospitals and among the top in the nation by specialty: No. 1 in Geriatrics and top 20 in Cardiology/Heart Surgery, Diabetes/Endocrinology, Gastroenterology/GI Surgery, Neurology/Neurosurgery, Orthopedics, Pulmonology/Lung Surgery, Urology, and Rehabilitation. Mount Sinai Kravis Children's Hospital is ranked in *U.S. News & World Report's* "Best Children's Hospitals" among the country's best in four out of 10 pediatric specialties. New York Eye and Ear Infirmary of Mount Sinai is ranked among the Top 20 nationally for ophthalmology. The Icahn School of Medicine at Mount Sinai is one of three medical schools that have earned distinction by multiple indicators: ranked in the top 20 by *U.S. News & World Report's* "Best Medical Schools," aligned with a *U.S. News & World Report* "Honor Roll" Hospital, and No. 14 in the nation for National Institutes of Health funding. *Newsweek's* "The World's Best Smart Hospitals" ranks The Mount Sinai Hospital as No. 1 in New York and top five globally, and Mount Sinai Morningside as top 20 globally, and "The World's Best Specialized Hospitals" ranks Mount Sinai Heart as No. 1 in New York and No. 5 globally and the Division of Gastroenterology as No. 5 globally. 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, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, our expectations regarding reimbursement decisions 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 annual report on Form 20-F filed with the SEC on October 28, 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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