



## Data Presentations at ADA 82nd Scientific Sessions

June 6, 2022

RNS Number : 6870N  
Renalytix PLC  
06 June 2022

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

#### Renalytix held Two Data Presentations on KidneyIntelX at American Diabetes Association 82<sup>nd</sup> Scientific Sessions®

*Real-world clinical utility in 1,112 patients tested with KidneyIntelX  
KidneyIntelX stratification for cardiovascular risk in 1,278 diabetic kidney disease patients*

**NEW YORK, NY and SALT LAKE CITY, UT June 6, 2022** - Renalytix (**NASDAQ: RNLX**) (**LSE: RENX**) participated at the American Diabetes Association (ADA) 82<sup>nd</sup> Scientific Sessions® meeting in New Orleans from June 3-7, 2022. There were two data presentations focused on the value of KidneyIntelX in care for adult patients with type 2 diabetes (T2D) and early-stage chronic kidney disease (CKD), including a late-breaking ePoster and an oral presentation.

The ePoster, "*Clinical Utility of KidneyIntelX on Patients with Early-Stage Diabetic Kidney Disease-A Real-World Evidence Study*" was the first time Mount Sinai Health System presented data from its real-world evidence clinical utility study with Renalytix in 1,112 patients tested with KidneyIntelX. The poster was presented to in-person and virtual conference attendees on June 5, at 12:00 p.m. CT, with commentary on behalf of the study investigators by Joji Tokita, M.D., Clinical Director, Division of Nephrology and Associate Professor of Medicine at the Icahn School of Medicine at Mount Sinai. Michael J. Donovan, Ph.D., M.D., Chief Medical Officer of Renalytix, was also on-site for commentary.

A second oral presentation, "*KidneyIntelX Association with Clinical Outcomes in Diabetic Kidney Disease*" was held on June 3, at 4:45 p.m. CT by Steven G. Coca, D.O., M.S., Icahn School of Medicine at Mount Sinai, and Co-Founder of Renalytix.

*"We've seen the ADA's dedication to improving kidney health in people with T2D firsthand as part of our ongoing collaboration to develop a care pathway to advance screening, diagnosis and early-stage treatment for the 40% of these patients who will develop CKD," said Tom McLain, President, Renalytix. "Chronic kidney disease can lead to significant complications for diabetes patients including cardiovascular disease and heart failure, and when left untreated can lead to dialysis and kidney transplant. Our mission is to give healthcare professionals new tools to understand an individual's risk for rapid progression of CKD, allowing them to appropriately prescribe therapeutics and to utilize specialist consultation when necessary. We look forward to joining other industry leaders at this year's Scientific Sessions in showcasing our research efforts."*

The ePoster and oral presentation abstracts are available at the 2022 [ADA Scientific Sessions Online Planner](#).

KidneyIntelX is based on technology developed by Mount Sinai faculty and licensed to Renalytix. Mount Sinai and Mount Sinai faculty, including Dr. Coca, have a financial interest in Renalytix. Mount Sinai also has representation on the Renalytix Board of Directors.

#### About Kidney Disease

Kidney disease is a public health epidemic affecting over 850 million people globally.<sup>1</sup> The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people<sup>2</sup>, have chronic kidney disease (CKD). Nearly 95% of

people with CKD are in early stages 1-3<sup>3</sup>. Despite its magnitude, early-stage (1-3) CKD is underdiagnosed and undertreated, largely because it's asymptomatic at this time in the disease. As many as 9 in 10 adults with CKD, and 2 in 5 adults with severe CKD do not know they have the condition.<sup>2</sup>

#### **About Renalytix**

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis™ for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed KidneyIntelX to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D with early CKD stages 1-3 through its KidneyIntelX™ laboratory-developed test. We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit [www.renalytix.com](http://www.renalytix.com).

#### **About KidneyIntelX™**

KidneyIntelX™ is a laboratory-developed test demonstrated to be a highly reliable, bioprognostic™ methodology, that yields a simple-to-understand, custom risk score, predicting which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate or high risk for rapid progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has a demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). KidneyIntelX has also received Breakthrough Device Designation from the U.S. Food and Drug Administration and has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the evidence, visit [www.kidneyintelx.com](http://www.kidneyintelx.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. 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 the 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*.

#### **Sources**

<sup>1</sup><https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/>

<sup>2</sup><https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html>

<sup>3</sup><https://www.cdc.gov/kidneydisease/basics.html>

#### **For further information, please contact:**

##### **Renalytix plc**

James McCullough, CEO

[www.renalytix.com](http://www.renalytix.com)

Via Walbrook PR

##### **Stifel (Nominated Adviser, Joint Broker)**

Alex Price / Nicholas Moore

Tel: 020 7710 7600

##### **Investec Bank plc (Joint Broker)**

Gary Clarence / Daniel Adams

Tel: 020 7597 4000

##### **Walbrook PR Limited**

Paul McManus / Lianne Applegarth / Alice Woodings

Tel: 020 7933 8780 or [renalytix@walbrookpr.com](mailto:renalytix@walbrookpr.com)

Mob: 07980 541 893 / 07584 391 303 / 07407 804 654

##### **CapComm Partners**

Peter DeNardo

Tel: 415-389-6400 or [investors@renalytix.com](mailto:investors@renalytix.com)

#### **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 potential benefits, including economic savings, of KidneyIntelX, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, 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 21, 2021, 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 Reach, the non-regulatory press release distribution service of RNS, part of the London Stock Exchange. 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).

Reach is a non-regulatory news service. By using this service an issuer is confirming that the information contained within this announcement is of a non-regulatory nature. Reach announcements are identified with an orange label and the word "Reach" in the source column of the News Explorer pages of London Stock Exchange's website so that they are distinguished from the RNS UK regulatory service. Other vendors subscribing for Reach press releases may use a different method to distinguish Reach announcements from UK regulatory news.

RNS may use your IP address to confirm compliance with the terms and conditions, to analyse how you engage with the information contained in this communication, and to share such analysis on an anonymised basis with others as part of our commercial services. For further information about how RNS and the London Stock Exchange use the personal data you provide us, please see our [Privacy Policy](#).

END

NRASSSFAIEESES