



## Business Update

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Renalytix PLC

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THIS ANNOUNCEMENT CONTAINS INSIDE INFORMATION AS DEFINED IN ARTICLE 7 OF MAR. THE PERSON RESPONSIBLE FOR ARRANGING FOR THE RELEASE OF THIS ANNOUNCEMENT ON BEHALF OF RENALYTIX IS JAMES MCCULLOUGH, CEO.

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

### Business Update

LONDON and SALT LAKE CITY, August 21, 2023 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces it has been notified that KidneyIntelX™ is included in the draft Kidney Disease Improving Global Outcomes (KDIGO) 2023 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (the "KDIGO 2023 Guideline"). KDIGO guideline development follows an explicit process to translate global scientific evidence review and appraisal into practical recommendations for clinicians and patients. A 30 day open public comment period on the KDIGO draft 2023 guidelines that began in July is now closed, and the final version of these kidney disease guidelines is expected to be released in the fourth quarter of 2023.

The KDIGO 2023 Guideline is a comprehensive update of the current KDIGO guideline for kidney disease evaluation and management issued in 2012. The aim of the update is to generate a useful resource that clearly and concisely addresses relevant questions with actionable recommendations based on a formal evidence review and consensus-based practice points to guide clinical practice. Guideline recommendations were based on systematic reviews of relevant clinical trials and publications. Appraisal of the quality of the evidence and the strength of recommendations for graded recommendations followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Renalytix believes that inclusion of KidneyIntelX in the KDIGO 2023 Guideline would be significant for broader adoption, clinical acceptance, and reimbursement of KidneyIntelX testing for risk assessment of patients with type 2 diabetes and early-stage kidney disease in the United States and abroad.

KDIGO is a global non-profit organization developing and implementing evidence-based clinical practice guidelines in kidney disease that are followed by clinicians in the United States and around the world. It is an independent, foundation incorporated in Belgium and accountable to the public and the patients it serves. KDIGO has a network of dedicated volunteers from around the world who promote awareness, dissemination, adoption, and clinical integration of KDIGO Guidelines both globally and in their respective countries or regions.

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Tel: 415-389-6400 or [investors@renalytix.com](mailto:investors@renalytix.com)**About Chronic 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, more than 38 million people, currently have chronic kidney disease (CKD). Diabetes is the leading cause of kidney failure, accounting for 44% of new cases. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.<sup>1</sup> 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.

**About Type 2 Diabetes**

More than 37 million Americans have diabetes (about 1 in 10), and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over age 45, but more and more children, teens, and young adults are also developing the disease<sup>2</sup>. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with type 2 diabetes are undiagnosed<sup>3</sup>. Type 2 diabetes affects many major organs, including the heart, blood vessels, nerves, eyes and kidneys. Diabetic kidney disease develops in 30-50% of type 2 diabetes patients<sup>4</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 its KidneyIntelX laboratory developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D and early CKD (stages 1-3). 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).

**Sources**

- 1 <https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/>
- 2 <https://www.cdc.gov/diabetes/basics/type2.html>
- 3 <https://www.cdc.gov/diabetes/data/statistics-report/index.html>
- 4 <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5297507/>

### Forward Looking Statements

Statements contained in this Current Report on Form 8-K 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 for KidneyIntelX to be included in the final KDIGO 2023 Guidelines, the commercial prospects of KidneyIntelX and kidneyintelX.dkd, including whether KidneyIntelX and kidneyintelX.dkd will be successfully adopted by physicians, inform clinical guidelines, achieve expanded insurance coverage and be successfully distributed and marketed, the potential for KidneyIntelX and kidneyintelX.dkd to be expanded and approved for additional indications and in additional jurisdictions, our expectations regarding reimbursement decisions and the ability of KidneyIntelX and kidneyintelX.dkd 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. Inclusion of KidneyIntelX in the draft KDIGO guidelines does not guarantee inclusion in the final guidelines. 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 and kidneyintelX.dkd are 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 31, 2022, and other filings we make with the SEC from time to time. All information in this Current Report on Form 8-K 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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