

# **Business update**

August 17, 2022

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This contains inside information

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

**Business update** 

**NEW YORK, NY and SALT LAKE CITY, UT August 17, 2022 (GLOBE NEWSWIRE)** - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) provides the following business update.

Based on recently secured private payer and Medicaid insurance coverage contracts for KidneyIntelX, Renalytix plc is disclosing that the upper Midwest region of the United States, and specifically Illinois and Iowa, are now primary commercial expansion markets. Private insurance coverage contracts secured and effective during the quarter ending September 30, 2022 include Blue Cross Blue Shield Illinois (estimated over 8 million covered lives) and Molina Healthcare Illinois (estimated 0.5 million covered lives). This complements coverage already secured with Wellmark Blue Cross Blue Shield in Iowa and South Dakota (estimated 2.1 million covered lives). Additionally, Renalytix has contracted with Illinois Medicaid as a provider for their program. Illinois Medicaid is estimated to provide medical insurance to over 20% of (or 3.3 million) Illinois residents and the contracts with BCBS and Molina provide insurance coverage for a significant proportion of that population. Illinois will now play a critical part in the KidneyIntelX health equity strategy to help drive down disparities in community care for individuals with diabetes and kidney disease.

With clarity on comprehensive insurance coverage now emerging on a region-by-region basis, the Company has taken steps in the current quarter ending September 30, 2022 to focus operating resources on near-term revenue opportunities, such as those disclosed above, and also reduce cash expenditure.

The Company has already executed changes designed to yield over \$12 million in annual savings in fiscal 2023, with more in process. Full effects of cash burn-rate reduction are expected to be realized in the fiscal second and third quarters ending December 30, 2022 and March 31, 2023, respectively. A regional commercial focus dictated by growing insurance payer coverage also complements efforts to introduce KidneyIntelX testing through the seven Veterans Health Administration Centers serving Illinois and Iowa. Renalytix previously contracted with the US Government under a General Service Administration contract for up to 10 years. The contract allows Renalytix to provide KidneyIntelX testing to any of the 140 U.S. government departments, agencies and affiliates offering healthcare services. Under the contract KidneyIntelX pricing was set at \$950 per reportable result.

For further information, please contact:

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

#### About Kidney Disease

Kidney disease is a public health epidemic affecting over 850 million people globally.<sup>2</sup> The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or over 37 million people<sup>3</sup>, have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3<sup>4</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>3</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<sup>TM</sup> 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 with 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 <u>www.renalytix.com</u>.

# About KidneyIntelX<sup>TM</sup>

KidneyIntelXTM is a laboratory-developed test demonstrated to be a reliable, bioprognosticTM methodology that yields a simple-to-understand, custom risk score, enabling prediction of 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 <u>www.kidneyintelx.com</u>.

# **Forward Looking Statements**

Statements contained in this Report on Form 6-K (this "Report") regarding matters that are not historical facts are "forwardlooking 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 effects of our cost-saving initiatives; our commercial expansion opportunities; the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether and to what extent 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 Report is as of the date of this Report, 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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