

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): January 10, 2024

Renalytix plc

(Exact name of registrant as specified in its Charter)

England and Wales
(State or other jurisdiction
of incorporation)

001-39387
(Commission
File Number)

Not Applicable
(IRS Employer
Identification No.)

Finsgate
5-7 Cranwood Street
London EC1V 9EE
United Kingdom
(Address of principal executive offices) (Zip Code)

+44 20 3139 2910
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Ordinary shares, nominal value £0.0025 per ordinary share	n/a	The Nasdaq Stock Market LLC*
American Depositary Shares, each representing two ordinary shares, nominal value £0.0025 per ordinary share	RNLX	The Nasdaq Stock Market LLC

* Not for trading, but only in connection with the listing of the American Depositary Shares on The Nasdaq Stock Market LLC.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Item 7.01 Regulation FD Disclosure

On January 10, 2024, the Company issued a press release entitled “New published data demonstrates KidneyIntelX™ has broad implications for winning war on chronic kidney disease.” The press release making this announcement is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

The information in this Item 7.01, including Exhibit 99.1, shall not be deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit</u>	<u>Exhibit Description</u>
99.1	Press release dated January 10, 2024
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

RENALYTIX PLC

Dated: January 10, 2024

By: /s/ James McCullough
James McCullough
Chief Executive Officer



New published data demonstrates KidneyIntelX™ has broad implications for winning war on chronic kidney disease

Electronic health record deployment of KidneyIntelX was associated with clinical actions that slowed progression of chronic kidney disease and improved Type 2 diabetes control in just 12 months

Results demonstrated a 61% increase in preventative drug prescriptions among patients in the high-risk group and improved specialist referrals which can significantly reduce overall cost of care and improve patient outcomes

LONDON and SALT LAKE CITY, January 10, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces publication of Real World Evidence (“RWE”) after 12 months of follow-up in 2,569 patients with Type 2 diabetes and diabetic kidney disease (“DKD”) at a major U.S. health system in *Primary Care and Community Health*. Results in the diverse cohort, including 27% black patients, demonstrate that electronic health record deployment of KidneyIntelX *in vitro* prognostic testing was associated with clinical actions that led to a significant slowing of chronic kidney disease progression and improved Type 2 diabetes control most notably in the highest risk patients.

Improved kidney health was evidenced by reduction in the rate of kidney function decline (eGFR slope) and diabetes control was evidenced by improved A1C levels. KidneyIntelX testing achieved scale through electronic health record integration, deploying directly to large treating groups of primary care physicians. These improvements, coupled with increase in percentage of KidneyIntelX high-risk patients achieving blood pressure control, have been shown to be associated with improvements in cardiovascular health and outcomes in CKD.

KidneyIntelX has received broad insurance payment coverage including through Medicare, Medicaid, and Blue Cross Blue Shield programs. The Food and Drug Administration (FDA) issued a de Novo Marketing Authorization of the kidneyIntelX.dkd version of the test in June 2023 with an indicated use addressable market of approximately 14 million patients with adult diabetes and kidney disease.

“The demonstrated benefits of KidneyIntelX early risk assessment at one year are significant and go to the core of chronic disease preventative medicine. This real-world data highlights the critical importance of early preventative care and the ability to better control cost and outcomes through efficient electronic deployment of KidneyIntelX bioprognosis,” said Michael J. Donovan, PhD, MD, Chief Medical Officer at Renalytix. “We look forward to continuing published data releases in coming months in order to support our belief that KidneyIntelX provides actionable information leading to preventative care and improving healthcare outcomes.”

“This published real world evidence puts KidneyIntelX at the intersection of multiple established diabetes, kidney and cardiovascular care guidelines. This data is compelling and shows the importance of adopting KidneyIntelX across primary care networks to help control these unsustainable chronic diseases that unnecessarily effect millions of patients,” said James McCullough CEO of Renalytix.

The study population includes representation of a number of high-risk factors for disease progression including (a) patient median baseline age of 68 years (b) 27% Black, (c) median BMI of 30 (d) evidence of hypertension in 89% of subjects and (e) 9% with stage A-D, American Heart Association functional classified heart failure. Analysis of treating physicians shows that the majority of patients were being treated by their primary care physician.

The RWE study results demonstrated that patients with Type 2 Diabetes and Stage 1-3 CKD and a high-risk KidneyIntelX score received higher frequency of clinical management visits, improved utilization of guideline-recommended medications, and appropriate specialist referral or consultation for disease management compared to those who were identified as low or intermediate risk patients.

For further information, please contact:

Renalytix plc
James McCullough, CEO

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Via Walbrook PR

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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.¹ 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 disease². Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with type 2 diabetes are undiagnosed³. 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 patients⁴.

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.

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 announcement 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 and kidneyintelX.dkd, including whether KidneyIntelX and kidneyintelX.dkd will be successfully adopted by physicians, inform clinical guidelines, lead to clinical actions that improve patient outcomes, 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 the impact and benefits of the CMS action on the value or pricing of KidneyIntelX, our expectations with respect to reimbursement decisions, our intellectual property position, our competitive position 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. 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 our most recent Quarterly Report on Form 10-Q and the “Risk Factors” section of our Annual Report on Form 10-K filed with the SEC on September 28, 2023, 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.
