

**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): **March 14, 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 March 14, 2024, Renalytix plc issued a press release entitled “KidneyIntelX™ included in Final KDIGO 2024 Clinical Guideline for Chronic Kidney Disease (CKD).” The press release is attached hereto as Exhibit 99.1.

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 March 14, 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: March 14, 2024

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

KidneyIntelX™ included in Final KDIGO 2024 Clinical Guideline for Chronic Kidney Disease (CKD)

Guidelines highlight the importance of risk prediction and personalized treatment to reduce risk

LONDON and SALT LAKE CITY, March 14, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) (Renalytix) announces that the KidneyIntelX *In-Vitro Diagnostic* test has been included in the final KDIGO (Kidney Disease Improving Global Outcomes) 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD), published on March 13, 2024. In the release of the new guideline, timed to coincide with World Kidney Day on March 14, the KDIGO committee highlighted the role of risk prediction in guiding care for patients. In this context, KidneyIntelX is recommended for use as an externally validated tool for predicting disease progression in people with CKD stages G1-G3.

The Guideline Work Group recognized that the progression of CKD can occur at all stages, and that in earlier stages of disease (G1–G3), understanding the risk of 40% decline in kidney function over a short term 5 years, as per the indicated use of KidneyIntelX, is important for guiding early intervention, particularly in people at intermediate or high risk for progression. Renalytix received FDA de-novo marketing authorization for kidneyintelx.dkd in June 2023 for use in assessment of the risk of progressive decline in kidney function in patients with CKD stages G1-G3 and Type 2 Diabetes.

Subsequent to the release of the draft content of this updated guideline in July 2023, further evidence has been published from clinical utility and outcomes studies with a current enrollment of more than 9,000 patients with Type 2 Diabetes and CKD G1-G3. In January 2024, published outcomes data from an analysis of more than 2,500 patients with one year of follow-up demonstrated that providing clinicians access to KidneyIntelX risk assessment to inform care was associated with clinical actions that resulted in sustained reduction in eGFR decline, improved diabetes management and improved cardiovascular health.

In the KDIGO announcement of the publication of the 2024 CKD guideline, Adeera Levin MD, one of the Guideline Committee Co-Chairs said, “Recent advancements in GFR evaluation, risk prediction, and the arrival of novel treatments are poised to enhance CKD prognosis and management. We also hope the guideline’s emphasis on multidisciplinary teamwork, patient engagement, and a holistic, evidence-based approach to care will help catalyze positive change, resulting in more coordinated CKD care management worldwide. By integrating the latest evidence and expert consensus, we aim to empower healthcare professionals, and patients with actionable recommendations to optimize patient outcomes and enhance quality of life.”

*Commenting on the guideline release **Michael J. Donovan, PhD, MD, Chief Medical Officer at Renalytix stated, “Patients with type 2 diabetes and CKD are benefitting from the evidence gathered from a number of recent clinical trials and access to accurate risk assessment to inform care in a significant and growing healthcare challenge in the United States and globally. Renalytix welcomes these new updates from KDIGO which provide for clear and timely treatment strategies for health care professionals and we look forward to continuing to release evidence to highlight the role that KidneyIntelX is playing achieving the goal of optimizing patients’ outcomes and enhancing quality of life.”***

For further information, please contact:

Renalytix plc
James McCullough, CEO

www.renalytix.com
Via Walbrook PR

Stifel (Nominated Adviser, Joint Broker)
Alex Price / Nicholas Moore / Nick Harland / Samira Essebiyea

Tel: 020 7710 7600

Investec Bank plc (Joint Broker)
Gary Clarence / Shalin Bhamra

Tel: 020 7597 4000

Walbrook PR Limited
Paul McManus / Alice Woodings

Tel: 020 7933 8780 or renalytix@walbrookpr.com
Mob: 07980 541 893 / 07407 804 654

CapComm Partners
Peter DeNardo

Tel: 415-389-6400 or 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.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.

About the Kidney Disease: Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD)

The Kidney Disease: Improving Global Outcomes (KDIGO) 2024 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (CKD) is an update to the KDIGO 2012 guideline on the topic. The aim is to assist clinicians caring for people with CKD, both adults and children. People receiving dialysis and kidney transplant recipients are not the focus of this guideline. The scope includes chapters dedicated to the evaluation of CKD, risk assessment in people with CKD, management to delay CKD progression and manage its complications, medical management and drug stewardship in CKD, and optimal models of CKD care. In addition, this guideline includes a

comprehensive introduction from the guideline Co-Chairs, a patient foreword, a discussion of special population considerations, a presentation of the relative and absolute risks associated with specific outcomes from the CKD Prognosis Consortium (CKDPC), and an extensive section dedicated to research recommendations based on the current gaps in evidence. The goal of the guideline is to generate a useful resource for clinicians and patients by providing actionable recommendations based on a rigorous formal evidence review, practice points that serve to direct clinical care or activities for which a systematic review was not conducted, and useful infographics. The guideline targets a broad audience of healthcare providers involved in the care of people with CKD as well as people with CKD themselves while being mindful of implications for policy and payment. Development of this guideline update followed an explicit process of evidence review and appraisal. Treatment approaches and guideline recommendations are based on systematic reviews of relevant studies, and appraisal of the certainty of the evidence and the strength of recommendations followed the “Grading of Recommendations Assessment, Development, and Evaluation” (GRADE) approach. Limitations of the evidence are discussed, with areas of future research also presented.

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 ability of KidneyIntelX to predict disease progression in people with CKD stages G1-G3 and guide early intervention; the ability of KidneyIntelX risk assessment to inform care resulting in sustained reduction in eGFR decline, improved diabetes management and improved cardiovascular health; and the ability of the KDIGO 2024 Clinical Guideline’s emphasis on multidisciplinary teamwork, patient engagement, and a holistic, evidence-based approach to care to help catalyze positive change, resulting in more coordinated CKD care management worldwide. 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.
