

**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 17, 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 17, 2024, the Company issued a press release entitled “Update on kidneyIntelX.dkd Local Coverage Determination Consideration.” The press release making this announcement 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 January 17, 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 17, 2024

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



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

Update on kidneyIntelX.dkd Local Coverage Determination Consideration

*Local Coverage Determination would result in contracted coverage
for an estimated additional five million Medicare patients with Type 2 diabetes and early-stage chronic kidney disease*

LONDON and SALT LAKE CITY, January 17, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces that on January 11, 2024, the Medicare Administrative Contractor (MAC), National Government Services (NGS), Inc., released the agenda for a Local Coverage Determination (LCD) Open Meeting taking place on February 29, 2024. The Renalytix KidneyIntelX™ and kidneyintelX.dkd prognostic test for adults with Type 2 diabetes and early-stage chronic kidney disease are one of five proposed LCDs for consideration on the agenda. There are currently an estimated 14 million patients with Type 2 diabetes and early-stage kidney disease in the United States.

The proposed LCDs will be published on February 8, 2024. A 45-day public comment period begins on February 8, and ends on March 23, 2024.

NGS is a subsidiary of Elevance Health, Inc. (previously Anthem, Inc.), contracting with the Centers for Medicare & Medicaid Services (CMS) for Jurisdiction 6, encompassing Illinois, Minnesota and Wisconsin, and Jurisdiction K, encompassing Maine, New Hampshire, Vermont, Massachusetts, Rhode Island, Connecticut, and New York. Any Medicare Fee For Service claims for patients tested anywhere in the United States and processed in the Renalytix New York City laboratory are submitted to NGS for payment at the rate established by CMS.

Renalytix formally requested an LCD from NGS and submitted substantial peer reviewed published evidence in support of coverage of KidneyIntelX and kidneyintelX.dkd. NGS held a Contractor Advisory Board meeting on August 29, 2023, where a panel of external experts reviewed and discussed the clinical evidence. Based on this evidence, along with the FDA's de novo marketing authorization for the kidneyintelX.dkd™ test, Renalytix believes that there is a strong basis for NGS determining that these tests are reasonable and necessary for Medicare beneficiaries. Following the Open Public Meeting, NGS will review public comments and issue a final LCD which is expected in calendar year 2024.

Renalytix also continues to expand private payer coverage agreements across the United States. This coverage includes a January 2024 contract with Velocity National Provider Network, covering 2.7 million member lives nationwide.

The full agenda of the February 29, 2024 LCD Open Meeting can be found on the NGS Medicare website at www.ngsmedicare.com.

For further information, please contact:

Renalytix plc
James McCullough, CEO

www.renalytix.com
Via Walbrook PR

Stifel (Nominated Adviser, Joint Broker)
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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.

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 Local Coverage Determination process, timeline and outcome for kidneyIntelX.dkd, 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, 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. 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.
