

**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): February 9, 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 February 9, 2024, Renalytix plc issued a press release entitled “Centers for Medicare & Medicaid Services Publishes Draft Local Coverage Determination for KidneyIntelX and kidneyintelX.dkd” 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 February 9, 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: February 9, 2024

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



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

**Centers for Medicare & Medicaid Services Publishes Draft Local Coverage Determination
for KidneyIntelX and kidneyintelX.dkd**

LONDON and SALT LAKE CITY, February 9, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces that on February 8, 2024 the Centers for Medicare and Medicaid Services ("CMS") published a draft Local Coverage Determination ("LCD") for the Company's KidneyIntelX and kidneyintelX.dkd testing. The draft LCD can be accessed at <https://www.cms.gov/medicare-coverage-database/>. The established Medicare price for KidneyIntelX and kidneyintelX.dkd is \$950 per test. Distinct CPT Codes (Common Procedural Terminology Codes) have been established for KidneyIntelX and kidneyintelX.dkd and are published in CMS' 2024 Clinical Lab Fee Schedule.

The draft LCD specifies coverage for use of KidneyIntelX or kidneyintelX.dkd for patients with diagnosed Type 2 diabetes and Stage 1-3b Chronic Kidney Disease is reasonable and necessary. Any specified limitations for use conform to the U.S. Food and Drug Administration ("FDA") label for kidneyintelX.dkd.

The LCD was submitted by National Government Services ("NGS"). NGS is a subsidiary of Elevance Health, Inc. (previously Anthem, Inc.), a Medicare Administrative Contractor with CMS and responsible for claim review and payment for testing performed in the Company's New York City laboratory. A 45-day public comment period began on February 8, 2024, and ends on March 23, 2024.

The Company 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 Committee meeting on August 29, 2023, where a panel of external experts reviewed and discussed the clinical evidence. We believe that based on the evidence, and the FDA's De Novo Marketing Authorization for the kidneyintelX.dkd™ test, that there was 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.

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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Walbrook PR Limited

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CapComm Partners

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: timing and outcome of LCD determination. Words such as “anticipates,” “believes,” “estimates,” “expects,” “intends,” “plans,” “seeks,” and similar expressions are intended to identify forward-looking statements. The Company may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on the Company’s 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; the Company has only recently commercially launched KidneyIntelX; and risks relating to the impact on the Company’s business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in the Company’s filings with the Securities and Exchange Commission (SEC), including the “Risk Factors” section of its annual report on Form 10-K filed with the SEC on September 28, 2023, the Company’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 14, 2023 and other filings the Company makes with the SEC from time to time. All information in this press release is as of the date of the release, and the Company undertakes 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.
