

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

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**FORM 8-K**

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

Date of Report (Date of earliest event reported): June 14, 2024

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**Renalytix plc**  
(Exact name of registrant as specified in its Charter)

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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)

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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:

<b>Title of each class</b>	<b>Trading Symbol(s)</b>	<b>Name of each exchange on which registered</b>
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.

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### Item 7.01 Regulation FD Disclosure

On June 14, 2024, Renalytix plc issued a press release entitled “Medicare Issues Final Coverage Determination for 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	<a href="#">Press release dated June 14, 2024</a>
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: June 14, 2024

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



This announcement contains inside information for the purposes of Article 7 of the UK version of Regulation (EU) No 596/2014 which is part of UK law by virtue of the European Union (Withdrawal) Act 2018, as amended ("MAR"). Upon the publication of this announcement via a Regulatory Information Service, this inside information is now considered to be in the public domain.

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

**Medicare Issues Final Coverage Determination for kidneyintelX.dkd**

*Company has Achieved Prerequisites for Growing Test Adoption with FDA Authorization, Clinical Outcomes Data, Inclusion in Clinical Guidelines, and Broad Insurance Coverage*

**LONDON and NEW YORK, 14 June 2024** – Renalytix plc (NASDAQ: RNLX) (LSE: RENX) announces that on June 13, 2024 Medicare issued a final Local Coverage Determination ("LCD") for the Company's kidneyintelX.dkd testing. The final LCD can be accessed at [LCD - KidneyIntelX and KidneyIntelX.dkd Testing \(L39726\) \(cms.gov\)](#), and is effective for dates of service on or after August 1, 2024. The established Medicare price for kidneyintelX.dkd is \$950 per test. Distinct CPT Codes (Common Procedural Terminology Codes) have been established for kidneyintelX.dkd and is published in CMS' 2024 Clinical Lab Fee Schedule.

The LCD specifies coverage for use of 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 issued by National Government Services ("NGS"). NGS is a subsidiary of Elevance Health, Inc. (previously Anthem, Inc.), a Medicare Administrative Contractor responsible for claims processing for testing performed in the Company's New York City laboratory.

"With final Medicare Coverage, an FDA authorization, and an April recommendation in the international clinical guidelines, kidneyintelX.dkd is poised to be a preventative medicine standard for 14 million people in the United States living with diabetes and kidney disease. We expect this Medicare coverage will prompt additional major coverage decisions and help accelerate testing adoption," said James McCullough CEO of Renalytix. "We remain focused on incremental sales growth in targeted US regions with a now significantly lower cost of operations."

**For further information, please contact:**

**Renalytix plc**  
 James McCullough, CEO

[www.renalytix.com](http://www.renalytix.com)  
**Via Walbrook PR**

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

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**CapComm Partners**

### **About Renalytix**

Renalytix (NASDAQ: RNLX) (LSE: REX) is an artificial intelligence enabled *in-vitro* diagnostics and laboratory services company that is the global founder and leader in the field of bioprognosis™ for kidney health. In late 2023, our kidneyintelX.dkd test was recognized as the first and only FDA-authorized prognostic test to enable early-stage CKD (stages 1-3b) risk assessment for progressive decline in kidney function in T2D patients. By understanding how disease will progress, patients and clinicians can take action earlier to improve outcomes and reduce overall health system costs. For more information, visit [www.renalytix.com](http://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, and the commercial prospects of KidneyIntelX. 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; and that the Company has only recently commercially launched KidneyIntelX. 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, and any risks that may be contained in any subsequent filings that the Company makes with the SEC. 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.

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