

**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): October 3, 2023**

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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 share	n/a	The Nasdaq Stock Market LLC*
American Depositary Shares, each representing two ordinary shares, nominal value £0.0025 per 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.**

Renalytix plc (the “Company”) reports that the Centers for Medicare & Medicaid Services (“CMS”) has published the price for the Company’s Food and Drug Administration (“FDA”) authorized kidneyintelX.dkd test on the nationwide Clinical Laboratory Fee Schedule at \$950.

The Company notes that earlier this year an American Medical Association (“AMA”) panel of experts recommended that the FDA-authorized kidneyintelX.dkd test be assigned a new code to differentiate it from the original Laboratory Developed Test (KidneyIntelX). The recommendation by the AMA also required a national CMS (Medicare) pricing review that has now been affirmed at a published price on the national Clinical Laboratory Fee Schedule at \$950.

When finalized in the fourth quarter of 2023, this pricing will be effective as of January 1, 2024 and maintained for a minimum of three years. The Company believes this CMS action, which has included both expert and public review and comment, affirms the value of the KidneyIntelX testing platform and importantly streamlines the pathway for maintaining and expanding health insurance coverage in the United States. The Company also believes it provides a strong pricing basis for international distribution agreements.

The information contained in Item 7.01 of this Current Report on Form 8-K is being furnished and shall not be deemed to be “filed” for the 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 in any filing 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. Exhibits.**

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

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## Forward Looking Statements

Statements contained in this Current Report on Form 8-K 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, 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, 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 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 Current Report on Form 8-K 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.

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**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: October 3, 2023

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

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