

**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): August 21, 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 has been notified that KidneyIntelX™ is included in the draft Kidney Disease Improving Global Outcomes (KDIGO) 2023 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease (the "KDIGO 2023 Guideline"). KDIGO guideline development follows an explicit process to translate global scientific evidence review and appraisal into practical recommendations for clinicians and patients. A 30 day open public comment period on the draft KDIGO 2023 guidelines that began in July is now closed, and the final version of these kidney disease guidelines is expected to be released in the fourth quarter of 2023.

The KDIGO 2023 Guideline is a comprehensive update of the current KDIGO guideline for kidney disease evaluation and management issued in 2012. The aim of the update is to generate a useful resource that clearly and concisely addresses relevant questions with actionable recommendations based on a formal evidence review and consensus-based practice points to guide clinical practice. Guideline recommendations were based on systematic reviews of relevant clinical trials and publications. Appraisal of the quality of the evidence and the strength of recommendations for graded recommendations followed the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach.

Renalytix believes that inclusion of KidneyIntelX in the KDIGO 2023 Guideline would be significant for broader adoption, clinical acceptance, and reimbursement of KidneyIntelX testing for risk assessment of patients with type 2 diabetes and early-stage kidney disease in the United States and abroad.

KDIGO is a global non-profit organization developing and implementing evidence-based clinical practice guidelines in kidney disease that are followed by clinicians in the United States and around the world. It is an independent, foundation incorporated in Belgium and accountable to the public and the patients it serves. KDIGO has a network of dedicated volunteers from around the world who promote awareness, dissemination, adoption, and clinical integration of KDIGO Guidelines both globally and in their respective countries or regions.

The information contained in this Item 7.01 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 such information is not incorporated by reference into any registration statements or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, regardless of the general incorporation language contained in such filing, except as shall be expressly set forth by specific reference to this filing.

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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 potential for KidneyIntelX to be included in the final KDIGO 2023 Guidelines, 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 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. Inclusion of KidneyIntelX in the draft KDIGO guidelines does not guarantee inclusion in the final guidelines. 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 20-F filed with the SEC on October 31, 2022, 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: August 21, 2023

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

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