

**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): September 1, 2023

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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

Appointment of Howard Doran Jr. as Chief Business Officer

On September 1, 2023, the Company's Board of Directors appointed Howard Doran Jr. as the Company's Chief Business Officer.

Mr. Doran Jr., age 62, served as a director of OncoGenesis, Inc. from June 2018 until October 2021 and previously served as a director of CereVasc, LLC from July 2015 until October 2018. Prior to this, Mr. Doran Jr. served as President and Chief Executive Officer of LipoScience, Inc. from February 2014 until successful completion of Labcorp's acquisition of LipoScience, Inc. in November 2014. Prior to this, Mr. Doran Jr. was President and Chief Operating Officer of Constitution Medical, Inc., an early-stage in vitro diagnostics company, developer of the Bloodhound Fully Integrated Hematology System, from June 2010 to January 2014. Previously, Mr. Doran Jr. was a member of the senior executive team of Hologic, Inc. and served as President of Hologic's Global Diagnostics business. Mr. Doran Jr. joined the senior management team of Hologic in October 2007 at the time of Hologic's acquisition of Cytoc Corporation, where he had been serving as Senior Vice President and Business Unit Director of Cytoc's \$500 million in vitro diagnostics business. From 1997 through 2007, he was a key member of the management team of Cytoc Corporation, serving in a number of senior commercial roles of increasing responsibility including physician sales and marketing, managed care initiatives and laboratory sales and marketing. Mr. Doran Jr. received a Bachelor of Science degree in Management from West Chester University of Pennsylvania.

In connection with his appointment as Chief Business Officer, Mr. Doran Jr. and the Company agreed to the terms of an offer letter (the "Offer Letter"). Pursuant to the terms of the Offer Letter, Mr. Doran Jr. will receive the following compensation: (a) an annual base salary of \$300,000; (b) an annual bonus with a target of up to 60% of Mr. Doran Jr.'s base salary, subject to individual and Company performance; and (c) options to purchase 300,000 of the Company's ordinary shares with an exercise price per share equal to the closing price of the Company's ordinary shares on AIM, a market operated by the London Stock Exchange, on the trading day before the date of grant, which will vest quarterly over a three-year period with a one-year cliff. The options will be granted at a future date upon approval by the Company's board of directors.

There are no arrangements or understandings between Mr. Doran Jr. and any other persons pursuant to which he was appointed as Chief Business Officer. There are no family relationships between Mr. Doran Jr. and any director or executive officer of the Company, and Mr. Doran Jr. has no direct or indirect material interest in any transaction required to be disclosed pursuant to Item 404(a) of Regulation S-K.

The foregoing description of the Offer Letter does not purport to be complete and is qualified in its entirety by reference to the Offer Letter, a copy of which will be filed with the Company's Annual Report on Form 10-K for the fiscal year ending June 30, 2023.

Item 7.01. Regulation FD Disclosure.

On September 7, 2023, the Company announced the appointment of Howard Doran Jr. as Chief Business Officer. A copy of the press release issued by the Company is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information contained in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1 hereto, 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>
99.1	Press Release, dated September 7, 2023
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: September 8, 2023

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

Renalytix Appoints Senior Executive Howard Doran as Chief Business Officer

Doran Brings Significant Diagnostics Sector Experience to Lead the KidneyIntelX Global Sales Effort

LONDON and SALT LAKE CITY – September 07, 2023 - [Renalytix plc](https://www.renalytix.com) (NASDAQ: RNLX) (LSE: RENX), the first company to commercialize an FDA approved artificial intelligence (AI) enabled prognostic blood test for individuals with type 2 diabetes and chronic kidney disease, announces the appointment of Howard Doran as Chief Business Officer, effective September 1, 2023. Mr. Doran's primary responsibility will be leading the KidneyIntelX global sales effort. He is a senior executive with over 30 years of diversified general management, strategic planning, and marketing/sales experience in the diagnostics and pharmaceutical industries in domestic and international markets.

Mr. Doran served as LipoScience, Inc's President and Chief Executive Officer until successful completion of LabCorp's acquisition of the company in November 2014. Preceding LipoScience, Mr. Doran was President and Chief Operating Officer of Constitution Medical, Inc., an early-stage in vitro diagnostics company and developer of the Bloodhound Fully Integrated Hematology System, which was acquired by Roche Diagnostics, Inc. in July 2013. Prior to Constitution Medical, Mr. Doran was a member of the senior executive team of Hologic, Inc. and served as President of Hologic's Global Diagnostics business. Mr. Doran joined the senior management team of Hologic in 2007 at the time of Hologic's acquisition of Cytoc Corporation, where he had been serving as Senior Vice President and Business Unit Director of Cytoc's \$500 million in vitro diagnostics business. From 1997 through 2007, he was a key member of the management team of Cytoc Corporation during Cytoc's dramatic growth, serving in a number of senior commercial roles of increasing responsibility including physician sales and marketing, managed care initiatives and laboratory sales and marketing. Mr. Doran holds a Bachelor of Science degree in Management from West Chester University of Pennsylvania.

James McCullough, Chief Executive Officer of Renalytix, commented: *"Howard brings significant experience to benefit Renalytix's sales and strategy at a time when KidneyIntelX has achieved necessary regulatory, outcomes data and reimbursement milestones to bring lifesaving prognosis to care delivery for the approximately 14 million Americans with type 2 diabetes and kidney disease. I am very excited to begin working with Howard closely this fall to achieve our business and patient service objectives."*

"KidneyIntelX identifies patients at the highest risk of rapid progression of chronic kidney disease which opens the opportunity for earlier intervention to slow the advancement of this insidious disease. Earlier intervention and treatment can dramatically alter the trajectory of unsustainable costs associated with this disease," said Howard Doran. "Having lost a family member to end stage kidney disease and another who was a kidney transplant recipient, this mission is personal to me. I look forward to helping guide this team's journey to maximize this opportunity."

For further information, please contact:

Renalytix plc
James McCullough, CEO

www.renalytix.com
Via Walbrook PR

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

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About Chronic Kidney Disease

Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, more than 37 million people⁴, currently have chronic kidney disease (CKD). Diabetes is the leading cause of kidney failure, accounting for 44% of new cases. Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and one out of two people with very low kidney function who are not on dialysis do not know they have CKD.⁵ Kidney disease is referred to as a “silent killer” because it often has no symptoms and can go undetected until a very advanced stage. Each year, kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

About Type 2 Diabetes

More than 37 million Americans have diabetes (about 1 in 10)¹, and approximately 90-95% of them have type 2 diabetes. Type 2 diabetes most often develops in people over age 45, but more and more children, teens, and young adults are also developing the disease⁶. Type 2 diabetes symptoms often develop over several years and approximately 23% of adults with Type 2 Diabetes are undiagnosed⁷. Type 2 diabetes affects many major organs, including the heart, blood vessels, nerves, eyes and kidneys. Diabetic kidney disease develops in 30-50% of Type 2 diabetes patients⁴.

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.

About KidneyIntelX™

KidneyIntelX™ is a laboratory developed test demonstrated to be a reliable, bioprognostic™ methodology that yields a simple-to-understand, custom risk score, enabling prediction of which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate, or high risk for rapidly progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). To learn more about KidneyIntelX and review the evidence, visit www.kidneyintelx.com.

Sources

1. Centers for Disease Control and Prevention. <https://www.cdc.gov/diabetes/basics/index.html>
 2. Gheith O, Farouk N, Nampoory N, et al. Diabetic kidney disease: worldwide difference of prevalence and risk factors. *J Nephropharmacol.* 2015 Oct 9;5(1):49-56. PMID: 28197499; PMCID: PMC5297507
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3. Wu B, Bell K, Stanford A, et al. Understanding CKD among patients with T2DM: prevalence, temporal trends, and treatment patterns—NHANES 2007–2012. *BMJ*

4.

<https://www.cdc.gov/kidneydisease/basics.html>

5. <https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/>

6. <https://www.cdc.gov/diabetes/basics/type2.html>

7. <https://www.cdc.gov/diabetes/data/statistics-report/index.html>

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 potential benefits, including economic savings, of KidneyIntelX, the impact KidneyIntelX can have on patients’ enhanced understanding of kidney disease and motivation to make lifestyle changes, the commercial prospects of KidneyIntelX, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery, address systemic inequalities 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 is 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 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.
