

**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): May 15, 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.)

2 Leman Street
London E1W 9US
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 2.02 RESULTS OF OPERATIONS AND FINANCIAL CONDITION

On May 15, 2024, Renalytix plc (the “Company”) issued a press release announcing its financial results for the quarter ended March 31, 2024, as well as information regarding a conference call to discuss these financial results and the Company’s recent corporate highlights. The Company’s press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information included in this Item 2.02 and Exhibit 99.1 attached hereto shall not be deemed “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, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

<u>Exhibit</u>	<u>Exhibit Description</u>
99.1	Press release dated May 15, 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: May 15, 2024

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



Renalytix Reports Financial Results for Third Quarter of Fiscal Year 2024

LONDON and NEW YORK, May 15, 2024 – Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported financial results for the fiscal third quarter ended March 31, 2024.

The Company made continued progress towards commercial adoption with inclusion of KidneyIntelX in clinical guidelines, issuance of a Medicare coverage draft, performance of new direct to physician sales force, April launch of U.S. Food and Drug Administration ("FDA") De Novo authorized kidneyintelX.dkd, and release of new real-world outcomes evidence. Optimization of shareholder value continues with year over year significant expense reductions, completion of equity financing, and the initiation of a strategic sale process.

Highlights include:

- KidneyIntelX included as only biomarker test for prognostic risk assessment in landmark update of international clinical practice guidelines (<https://kdigo.org/guidelines/>)
 - Medicare Local Coverage Determination draft issued for FDA-authorized kidneyintelX.dkd by Medicare contractor National Government Services (NGS) with final issuance expected in the near term
 - Formal launch of the FDA-authorized kidneyintelX.dkd in April 2024
 - Customer experience improvements implemented including simplified physician order requisition, increased patient access to national blood draw network, revamped marketing and education materials
 - New primary care sales force completed its first quarter of operations with a 33% quarter over quarter increase in independent primary care physician test order volume during the three months ended March 31, 2024
 - Appointed Howard Doran to president concurrent with organizational changes to focus to accelerating sales and marketing of FDA-authorized kidneyintelX.dkd test
 - Formal strategic sale process initiated with multiple potential acquirers now in discussions
 - Completed common stock equity financings raising aggregate gross proceeds of \$13.5 million (including post-period activity)
 - Continued operating expense reduction with 50% year-over-year reduction in head count and approximately 40% total lower operating costs
 - With FDA and clinical guidelines achieved, process initiated for potential ex-U.S. partners to improve non-dilutive company cash position and expand incremental sales opportunities
 - U.S. government added the FDA-authorized kidneyintelX.dkd to 10-year Government-wide Acquisition Contract (GWAC) at a price of \$950 per reportable result. The contract covers tests provided by any government healthcare facility
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- Total volume of 806 tests during the quarter, of which 82% were billable

Third Quarter 2024 Financial Results

During the three months ended March 31, 2024, the Company recognized \$0.5 million of revenue, compared to \$0.7 million for the three months ended March 31, 2023. Cost of revenue for the three months ended March 31, 2024 and 2023, was \$0.6 million.

Operating expenses for the three months ended March 31, 2024 were \$6.5 million, compared to \$11.0 million during the prior year period. Operating cash burn in the fiscal third quarter was \$4.9 million, nearly 40% lower than the fiscal second quarter and a 50% reduction from the year ago period.

Within operating expenses, research and development expenses were \$2.2 million for the three months ended March 31, 2024, decreasing by \$1.7 million from \$3.9 million for the three months ended March 31, 2023. The decrease was attributable to a \$1.3 million decrease related to external R&D projects and studies with Mount Sinai, Wake Forest and Joslin, a decrease of \$0.3 million in compensation and related benefits, and a \$0.1 million decrease in other operating expenses.

General and administrative expenses were \$3.9 million for the three months ended March 31, 2024, decreasing by \$3.2 million from \$7.1 million for the three months ended March 31, 2023. The decrease was driven by even further cost cutting measures, which resulted in a \$2.6 million decrease in compensation and related benefits, a \$0.3 million decrease in other operating expenses, and a \$0.3 million decrease in insurance costs.

Net loss was \$7.7 million for the three months ended March 31, 2024, compared with \$12.1 million for the prior year period.

Cash and cash equivalents totaled \$4.7 million as of March 31, 2024.

The Company will host a corresponding conference call and live webcast today to discuss the financial results and key topics including business strategy, partnerships and regulatory and reimbursement processes, at 8:30 a.m. EDT / 1:30 p.m. BST.

Conference Call Details:

To participate in the live conference call via telephone, please register here. Upon registering, a dial-in number and unique PIN will be provided in order for interested parties to join the conference call.

Webcast Registration link: <https://edge.media-server.com/mmc/p/k57ufszy>

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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Peter DeNardo

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About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) 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.

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 commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, the Company’s expectations regarding the timing and outcome of regulatory and reimbursement decisions, the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes, the Company’s expectations and guidance related to partnerships, testing volumes and revenue for future periods, the Company’s expectations regarding the Company’s ability to obtain and maintain intellectual property protection for its diagnostic products and the Company’s ability to operate its business without infringing on the intellectual property rights of others, and the forecast of the Company’s cash runway and the implementation and potential for additional financing activities and cost-saving initiatives. 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, the Company’s Quarterly Report on Form 10-Q for the quarter ended December 31, 2024 filed with the SEC on February 14, 2024 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.

RENALYTIX PLC
Consolidated Statements of Operations and Comprehensive Loss (Unaudited)

(in thousands, except share data)	For the Three Months Ended March 31,		For the Nine Months Ended March 31,	
	2024	2023	2024	2023
Revenue	\$ 535	\$ 724	\$ 1,703	\$ 2,885
Cost of revenue	601	603	1,583	2,010
Gross profit (loss)	(66)	121	120	875
Operating expenses:				
Research and development	2,216	3,943	8,228	11,026
General and administrative	3,854	7,095	15,252	22,155
Impairment loss on property, equipment and other long-lived assets	417	—	723	—
Performance of contract liability to affiliate	—	—	—	(19)
Total operating expenses	6,487	11,038	24,203	33,162
Loss from operations	(6,553)	(10,917)	(24,083)	(32,287)
Equity in net losses of affiliate	—	—	—	(9)
Foreign currency gain (loss), net	15	(461)	215	238
Fair value adjustment to VericiDx investment	40	129	(205)	(1,070)
Fair value adjustment to convertible notes	(1,196)	(1,168)	(2,517)	(1,898)
Other (expense) income, net	(49)	310	212	521
Net loss before income taxes	(7,743)	(12,107)	(26,378)	(34,505)
Income tax (expense) benefit	—	1	(4)	2
Net loss	\$ (7,743)	\$ (12,106)	\$ (26,382)	\$ (34,503)
Net loss per ordinary share—basic	\$ (0.08)	\$ (0.14)	\$ (0.27)	\$ (0.44)
Net loss per ordinary share—diluted	\$ (0.08)	\$ (0.14)	\$ (0.27)	\$ (0.44)
Weighted average ordinary shares—basic	97,654,961	85,560,783	98,184,650	78,366,984
Weighted average ordinary shares—diluted	97,654,961	85,560,783	98,184,650	78,366,984
Other comprehensive income (loss):				
Changes in the fair value of the convertible notes	\$ 155	\$ 593	\$ 230	\$ 70
Foreign exchange translation adjustment	21	505	(338)	6
Comprehensive loss	\$ (7,567)	\$ (11,008)	\$ (26,490)	\$ (34,427)

RENALYTIX PLC
CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share data)

	March 31, 2024	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,704	\$ 24,682
Accounts receivable	554	776
Prepaid expenses and other current assets	1,082	1,424
Total current assets	6,340	26,882
Property and equipment, net	230	1,027
Right of Use Asset	—	159
Investment in VericiDx	1,060	1,460
Other Assets	1,139	1,101
Total assets	\$ 8,769	\$ 30,629

Liabilities and Shareholders' Equity

Current liabilities:		
Accounts payable	\$ 2,101	\$ 1,485
Accounts payable – related party	3,027	1,451
Accrued expenses and other current liabilities	4,273	6,644
Accrued expenses – related party	1,060	1,963
Current lease liability	78	130
Convertible notes-current	4,449	4,463
Total current liabilities	14,988	16,136
Convertible notes-noncurrent	4,892	7,485
Noncurrent lease liability	—	41
Total liabilities	19,880	23,662

Commitments and contingencies (Note 10)

Shareholders' equity:

Ordinary shares, £0.0025 par value per share: 128,042,743 shares authorized; 119,916,187 and 93,781,478 shares issued and outstanding at March 31, 2024 and June 30, 2023, respectively	368	286
Additional paid-in capital	194,786	186,456
Accumulated other comprehensive loss	(1,558)	(1,450)
Accumulated deficit	(204,707)	(178,325)
Total shareholders' (deficit) equity	(11,111)	6,967
Total liabilities and shareholders' (deficit) equity	\$ 8,769	\$ 30,629

(in thousands)	For the Nine Months Ended March 31,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (26,382)	\$ (34,503)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	304	388
Impairment loss on property, equipment and other long-lived assets	723	—
Stock-based compensation	1,291	2,358
Equity in losses of affiliate	—	9
Reduction of Kantaro liability	—	(55)
Fair value adjustment to VericiDx investment	205	1,070
Unrealized foreign exchange loss	—	327
Realized loss on sale of ordinary shares in VericiDx	94	—
Realized foreign exchange gain	(144)	—
Fair value adjustment to convertible debt, net interest paid	2,255	1,898
Non cash lease expense	67	78
Changes in operating assets and liabilities:		
Accounts receivable	222	154
Prepaid expenses and other current assets	310	(77)
Accounts payable	617	358
Accounts payable – related party	1,576	370
Accrued expenses and other current liabilities	(2,519)	2,704
Accrued expenses – related party	(904)	(485)
Deferred revenue	—	(46)
Net cash used in operating activities	(22,285)	(25,452)
Cash flows from investing activities:		
Purchase of equipment	(3)	—
Payment for long term deferred expense	—	(59)
Net cash used in investing activities	(3)	(59)
Cash flows from financing activities:		
Payment of convertible notes principal	(1,660)	(3,262)
Proceeds from issuance of ordinary shares in Private Placement	5,072	20,296
Payment of offering costs	(1,044)	(666)
Proceeds from purchase of ordinary shares under employee share purchase plan	93	116
Net cash provided by financing activities	2,461	16,484
Effect of exchange rate changes on cash	(151)	721
Net decrease in cash and cash equivalents	(19,978)	(8,306)
Cash and cash equivalents, beginning of period	24,682	41,333
Cash and cash equivalents, end of period	\$ 4,704	\$ 33,027
Supplemental noncash investing and financing activities:		
Cash paid for interest on convertible debt	\$ 249	\$ —

