



Renalytix Reports Financial Results for Third Quarter of Fiscal Year 2024

May 15, 2024

LONDON and NEW YORK, May 15, 2024 (GLOBE NEWSWIRE) -- 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
- 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>

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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)

	For the Three Months Ended		For the Nine Months Ended	
	March 31,		March 31,	
	2024	2023	2024	2023
(in thousands, except share data)				

Revenue	\$ 535	\$ 724	\$ 1,703	\$ 2,885
Cost of revenue	<u>601</u>	<u>603</u>	<u>1,583</u>	<u>2,010</u>
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	<u>—</u>	<u>—</u>	<u>—</u>	<u>(19)</u>
Total operating expenses	<u>6,487</u>	<u>11,038</u>	<u>24,203</u>	<u>33,162</u>
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	<u>(49)</u>	<u>310</u>	<u>212</u>	<u>521</u>
Net loss before income taxes	(7,743)	(12,107)	(26,378)	(34,505)
Income tax (expense) benefit	<u>—</u>	<u>1</u>	<u>(4)</u>	<u>2</u>
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	<u>21</u>	<u>505</u>	<u>(338)</u>	<u>6</u>
Comprehensive loss	\$ (7,567)	\$ (11,008)	\$ (26,490)	\$ (34,427)

RENALYTIX PLC
CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share data)	<u>March 31, 2024</u>	<u>June 30, 2023</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 4,704	\$ 24,682
Accounts receivable	554	776
Prepaid expenses and other current assets	<u>1,082</u>	<u>1,424</u>
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	<u>1,139</u>	<u>1,101</u>
Total assets	<u>\$ 8,769</u>	<u>\$ 30,629</u>
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	<u>4,449</u>	<u>4,463</u>
Total current liabilities	14,988	16,136
Convertible notes-noncurrent	4,892	7,485
Noncurrent lease liability	—	41
Total liabilities	<u>19,880</u>	<u>23,662</u>

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

Additional paid-in capital	368	286
Accumulated other comprehensive loss	194,786	186,456
Accumulated deficit	(1,558)	(1,450)
	<u>(204,707)</u>	<u>(178,325)</u>
Total shareholders' (deficit) equity	<u>(11,111)</u>	<u>6,967</u>
Total liabilities and shareholders' (deficit) equity	<u>\$ 8,769</u>	<u>\$ 30,629</u>

RENALYTIX PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(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	<u>(22,285)</u>	<u>(25,452)</u>
Cash flows from investing activities:		
Purchase of equipment	(3)	—
Payment for long term deferred expense	—	(59)
Net cash used in investing activities	<u>(3)</u>	<u>(59)</u>
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	<u>2,461</u>	<u>16,484</u>
Effect of exchange rate changes on cash	<u>(151)</u>	<u>721</u>
Net decrease in cash and cash equivalents	<u>(19,978)</u>	<u>(8,306)</u>
Cash and cash equivalents, beginning of period	<u>24,682</u>	<u>41,333</u>
Cash and cash equivalents, end of period	<u>\$ 4,704</u>	<u>\$ 33,027</u>
Supplemental noncash investing and financing activities:		
Cash paid for interest on convertible debt	\$ 249	\$ —