



Renalytix Reports Financial Results for Second Quarter of Fiscal Year 2024

February 15, 2024

LONDON and SALT LAKE CITY, Feb. 15, 2024 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX) (the "Company"), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease, today reported financial results for the fiscal second quarter ended December 31, 2023. The Company plans to issue another announcement following today's report of financial results regarding the date and time of its conference call and webcast to discuss second quarter financial results and other key events.

The Company made significant progress during the quarter in revenue generation, reimbursement coverage, the publication of real-world evidence and operating cost management, setting the stage for potential future growth. Highlights include:

- During the three months ended December 31, 2023, we recognized \$0.7 million of revenue related to sales of KidneyIntelX, compared to the previous quarter reported revenue of \$0.5 million.
- KidneyintelX.dkd, the first U.S. Food and Drug Administration ("FDA"), authorized in vitro prognostic test that uses an artificial intelligence-enabled algorithm to aid in assessment of the risk of progressive decline in kidney function, officially included in the lab fee schedule by Centers for Medicare & Medicaid Services (CMS) at \$950 per test.
- KidneyIntelX™ and kidneyintelX.dkd included in the proposed Local Coverage Determination (LCD) published by National Government Services (NGS) on February 8, 2024, and on the agenda for the LCD open public meeting on February 29, 2024.
- NGS has resumed consistent payment for tests under individual claims review (ICR), allowing revenue recognition of 318 tests billed to Medicare (including prior period tests). Total billable volume of 734 tests during the second quarter (representing 69% of all tests in the period, including non-billable study tests).
- Real-world evidence continues to demonstrate the benefits of KidneyIntelX early risk assessment as published in the *Journal of Primary Care and Community Health*, in which 12 months of care following KidneyIntelX prognostic testing was associated with clinical actions that led to significant improvement in care and outcomes including a 61% increase in kidney protective drug prescriptions among patients in the high-risk group.
- Operating cost reductions commenced during the fiscal second quarter continued with a fiscal third quarter cash burn target approximately 33% less than in the prior quarter and approximately 50% less than in the first quarter of fiscal 2024.

Second Quarter 2024 Financial Results

During the three months ended December 31, 2023, we recognized \$0.7 million of revenue related to sales of KidneyIntelX. During the three months ended December 31, 2022, we recognized \$1.0 million revenue related to sales of KidneyIntelX and \$0.2 million of revenue of pharmaceutical services revenue related to services performed for AstraZeneca. The \$0.5 million decrease in revenue was primarily driven by a \$0.3 million decrease in KidneyIntelX billable testing volumes due to the transition to a commercial billing structure under our arrangement with Mount Sinai and a decrease of \$0.2 million of pharmaceutical services revenue.

Operating expenses for the three months ended December 31, 2023 were \$8.9 million, compared to \$10.1 million for the three months ended December 31, 2022. We have taken significant actions to lower annual expenditures with a targeted annualized cash burn rate of under \$23 million within our fiscal third quarter of 2024 (down from \$37 million in the 2023 fiscal year), while preserving revenue generating activity.

Within operating expenses, research and development expenses were \$3.2 million for the three months ended December 31, 2023, which decreased by \$0.1 million from \$3.3 million for the three months ended December 31, 2022. The decrease was attributable to a \$1.2 million decrease in compensation and related benefits, offset by a \$1.1 million increase related to external R&D projects and studies with Mount Sinai, Wake Forest and Joslin.

General and administrative expenses were \$5.3 million for the three months ended December 31, 2023, decreasing by \$1.5 million from \$6.8 million for the three months ended December 31, 2022. The decrease was driven by even further cost cutting measures, which resulted in a \$1.7 million decrease in compensation and related benefits, including share-based payments, due to decreased headcount, and a \$0.5 million decrease in other operating expenses, offset by a \$0.5 million increase in legal fees and a \$0.2 million increase in consulting and professional fees. We have implemented a plan to further reduce payroll expense and total general and administrative expenses while preserving our sales capacity.

Net loss was \$8.5 million for the three months ended December 31, 2023, compared to a net loss of \$10.4 million for the three months ended December 31, 2022.

Cash and cash equivalents totaled \$5.6 million as of December 31, 2023.

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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.

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 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 December 31,		For the Six Months Ended December 31,	
	2023	2022	2023	2022
Revenue	\$ 709	\$ 1,192	\$ 1,168	\$ 2,161
Cost of revenue	480	711	982	1,407
Gross profit	229	481	186	754
Operating expenses:				
Research and development	3,225	3,326	6,012	7,083
General and administrative	5,339	6,810	11,398	15,060
Impairment loss on property and equipment	306	—	306	—
Performance of contract liability to affiliate	—	(7)	—	(19)
Total operating expenses	8,870	10,129	17,716	22,124
Loss from operations	(8,641)	(9,648)	(17,530)	(21,370)
Equity in net losses of affiliate	—	—	—	(9)

Foreign currency (loss) gain, net	(89)	(108)	200	699
Fair value adjustment to VericiDx investment	202	(345)	(245)	(1,199)
Fair value adjustment to convertible notes	(114)	(440)	(1,321)	(730)
Other income, net	161	97	261	211
Net loss before income taxes	(8,481)	(10,444)	(18,635)	(22,398)
Income tax (expense) benefit	(4)	—	(4)	1
Net loss	(8,485)	(10,444)	(18,639)	(22,397)
Net loss per ordinary share—basic	\$ (0.09)	\$ (0.14)	\$ (0.19)	\$ (0.30)
Net loss per ordinary share—diluted	\$ (0.09)	\$ (0.14)	\$ (0.19)	\$ (0.30)
Weighted average ordinary shares—basic	97,268,051	74,891,844	96,017,946	74,848,278
Weighted average ordinary shares—diluted	97,268,051	74,891,844	96,017,946	74,848,278
Other comprehensive income (loss):				
Changes in the fair value of the convertible notes	—	(920)	75	(523)
Foreign exchange translation adjustment	(401)	588	(359)	(499)
Comprehensive loss	(8,886)	(10,776)	(18,923)	(23,419)

RENALYTIX PLC
CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share data)	December 31, 2023	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 5,619	\$ 24,682
Accounts receivable	1,370	776
Prepaid expenses and other current assets	1,261	1,424
Total current assets	8,250	26,882
Property and equipment, net	576	1,027
Right of Use Asset	102	159
Investment in VericiDx	1,220	1,460
Other Assets	1,128	1,101
Total assets	\$ 11,276	\$ 30,629
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,109	\$ 1,485
Accounts payable – related party	707	1,451
Accrued expenses and other current liabilities	4,259	6,644
Accrued expenses – related party	3,673	1,963
Current lease liability	111	130
Convertible notes-current	3,063	4,463
Total current liabilities	13,922	16,136
Convertible notes-noncurrent	5,310	7,485
Noncurrent lease liability	—	41
Total liabilities	19,232	23,662
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 107,189,897 shares authorized; 99,930,156 and 93,781,478 shares issued and outstanding at December 31, 2023 and June 30, 2023, respectively	305	286
Additional paid-in capital	190,437	186,456
Accumulated other comprehensive loss	(1,734)	(1,450)
Accumulated deficit	(196,964)	(178,325)

Total shareholders' (deficit) equity	(7,956)	6,967
Total liabilities and shareholders' (deficit) equity	<u>\$ 11,276</u>	<u>\$ 30,629</u>

RENALYTIX PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	For the Six Months Ended December 31,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (18,639)	\$ (22,397)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	235	258
Impairment of property and equipment	306	—
Stock-based compensation	909	1,584
Equity in losses of affiliate	—	9
Reduction of Kantaro liability	—	(55)
Fair value adjustment to VericiDx investment	245	1,199
Unrealized foreign exchange gain	—	271
Realized foreign exchange gain	(163)	—
Fair value adjustment to convertible debt, net interest paid	1,059	730
Non cash lease expense	57	52
Changes in operating assets and liabilities:		
Accounts receivable	(594)	81
Prepaid expenses and other current assets	45	494
Receivable from affiliates	—	(22)
Accounts payable	618	2,773
Accounts payable – related party	(744)	(1,083)
Accrued expenses and other current liabilities	(2,465)	1,367
Accrued expenses – related party	1,708	(566)
Deferred revenue	—	(46)
Net cash used in operating activities	<u>(17,423)</u>	<u>(15,351)</u>
Cash flows from investing activities:		
Payment for long term deferred expense	—	(64)
Net cash used in investing activities	<u>—</u>	<u>(64)</u>
Cash flows from financing activities:		
Payment of convertible notes principal	(1,660)	(1,648)
Payment of issuance costs	(5)	—
Proceeds from purchase of ordinary shares under employee share purchase plan	93	116
Net cash used in financing activities	<u>(1,572)</u>	<u>(1,532)</u>
Effect of exchange rate changes on cash	<u>(68)</u>	<u>(570)</u>
Net decrease in cash and cash equivalents	(19,063)	(17,517)
Cash and cash equivalents, beginning of period	24,682	41,333
Cash and cash equivalents, end of period	<u>\$ 5,619</u>	<u>\$ 23,816</u>
Supplemental noncash investing and financing activities:		
Cash paid for interest on convertible debt	\$ 249	\$ —