



Renalytix Reports Financial Results for First Quarter of Fiscal Year 2024

November 14, 2023

LONDON and SALT LAKE CITY, Nov. 14, 2023 (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 first quarter ended September 30, 2023.

Recent Highlights (including post period events)

- Financing discussions in process with goal to provide operating runway through at least early calendar 2026, enabled by cost reductions and sales growth from adoptions by new hospital systems and independent physicians
- Cost cutting initiative projected to reduce payroll expense by over 35% and total SG&A by over 30% year-over-year. Now with FDA authorization of kidneyintelX.dkd, real-world outcomes data published, and anticipation of inclusion in final medical guidelines, personnel have been realigned to focus on sales
- KidneyIntelX EPIC-integrated commercial roll-out progressing at Atrium Health with expected integration completion in December 2023
- Additional Illinois hospital system launch expected December 2023 to highlight health equity benefits of KidneyIntelX guided care pathway in diabetes
- Long-term Medicare reimbursement process advanced with August independent Clinical Advisory Committee meeting for Local Coverage Determination (LCD), and submission of application for National Coverage Determination (NCD)
- Second Medicare contractor, First Coast Options, now paying for billed KidneyIntelX tests
- Additional key commercial payer coverage achieved, including contracts with:
 - BlueCross and BlueShield of Texas, the largest statewide health care plan serving 7,000,000 members
 - Parkland Community Health Plan (PCHP), a Dallas-based insurance plan with over 300,000 covered lives
 - Provider Network of America (PNOA) a PPO plan contracted with 525,000 physicians, 27,500 hospitals and membership of over 8 million patients across all 50 states
- Evidence from 12 months of care following KidneyIntelX prognostic testing released at American Diabetes Association demonstrated clinical actions that led to improvement in both diabetes (A1C reductions) and kidney health (eGFR slope improvement) in patients with type 2 diabetes and chronic kidney disease; detailed results paper submitted for publication
- Senior executive Howard Doran appointed as chief business officer, leading global sales effort with full direct-to-physician sales force expected to be in field by January 2024
- Testing volumes in fiscal first quarter:
 - Total tests of 1,297 of which 56% were billable, compared to 1,232 (57% billable) in the prior quarter and 1,252 (82% billable) in the prior-year fiscal first quarter. Certain study-related tests at Mount Sinai are no longer billable following transition from Mount Sinai as payor to traditional commercial insurance billing, as previously communicated
 - 699 tests conducted at Mount Sinai (529 were billable)
 - 396 tests conducted at Atrium Health Wake Forest (to date, all non-billable study tests);
 - Remainder mainly direct-to-physician billable commercial testing
- Clinical advisory board featuring multi-disciplinary experts formed to advise on adoption of FDA authorized kidneyintelX.dkd within the 14 million patient addressable market in the U.S.
- Distribution agreement executed to expand availability of kidneyintelX.dkd to an estimated four million diabetic kidney disease (DKD) patients in the Middle East
- Intellectual property:
 - U.S. Patent Office allows patent claims for intellectual property exclusively licensed to Renalytix, specifically biomarkers sTNFR1 and sTNFR2 used in KidneyIntelX technology
 - IP relating to protein biomarker pipeline continues to expand with data presented at American Society of Nephrology Kidney Week from collaborators at Joslin showing potential for expanded indications and utility
- KidneyintelX.dkd recommended for pricing by Centers for Medicare & Medicaid Services (CMS) at \$950 per test, matching the pricing of the pre-FDA authorized version of the prognostic; final decision to be made by the end of December 2023.

First Quarter 2024 Financial Results

During the three months ended September 30, 2023, the Company recognized \$0.5 million of revenue, compared to \$1.0 million for the three months ended September 30, 2022. Cost of revenue for the three months ended September 30, 2023 was \$0.5 million, compared to \$0.7 million for the three months ended September 30, 2022.

Operating expenses for the three months ended September 30, 2023 was \$8.8 million, compared to \$12.0 million for the three months ended September 30, 2022. As previously stated in FY23, we have taken action to lower annual expenditures by over \$11 million with additional cost reduction initiatives underway to extend cash runway while preserving revenue generating activity.

Within operating expenses, research and development expenses were \$2.8 million for the three months ended September 30, 2023, decreasing by \$1.0 million from \$3.8 million for the three months ended September 30, 2022. The decrease was attributable to a \$0.7 million decrease in compensation and related benefits and a \$0.7 million decrease related to external R&D projects and studies with Mount Sinai, Wake Forest and Joslin Diabetes, offset by a \$0.3 million increase related to consulting and professional fees and \$0.1 million increase in other miscellaneous expenses.

General and administrative expenses were \$6.1 million for the three months ended September 30, 2023, decreasing by \$2.2 million from \$8.3 million for the three months ended September 30, 2022. The decrease was driven by our ongoing cost cutting measures, which resulted in a \$1.0 million decrease in compensation and related benefits, including share-based payments, due to decreased headcount, \$0.4 million decrease in consulting and professional fees, \$0.3 million decrease in insurance costs, \$0.2 million decrease in marketing, and \$0.3 million decrease in other operating expenses.

Net loss was \$10.2 million for the three months ended September 30, 2023, compared to a net loss of \$12.0 million for the three months ended September 30, 2022.

Cash and cash equivalents totaled \$13.9 million as of September 30, 2023.

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. (ET) / 1:30 p.m. (GMT).

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/mdveh2i3>

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About Renalytix

Renalytix (LSE: RENX) (NASDAQ: RNLX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that enables early-stage chronic kidney disease progression risk assessment. The Company's lead product, KidneyIntelX™, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit www.kidneyintelx.com). 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, our 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, our expectations and guidance related to partnerships, testing volumes and revenue for future periods, and the forecast of our 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. 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 10-K filed with the SEC on September 28, 2023, 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.

RENALYTIX PLC
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

(in thousands, except share data)	For the Three Months Ended September 30,	
	2023	2022
Revenue	\$ 459	\$ 969
Cost of revenue	502	696
Gross (loss) profit	(43)	273
Operating expenses:		
Research and development	2,787	3,757
General and administrative	6,059	8,250
Performance of contract liability to affiliate	—	(12)
Total operating expenses	8,846	11,995
Loss from operations	(8,889)	(11,722)
Equity in net (losses) earnings of affiliate	—	(9)
Foreign currency gain, net	289	1,730
Fair value adjustment to VericiDx investment	(447)	(854)
Fair value adjustment to convertible notes	(1,207)	(1,213)
Other income, net	100	114
Net loss before income taxes	(10,154)	(11,954)
Income tax benefit	—	1
Net loss	(10,154)	(11,953)
Net loss per ordinary share—basic	\$ (0.11)	\$ (0.16)
Net loss per ordinary share—diluted	\$ (0.11)	\$ (0.16)
Weighted average ordinary shares—basic	94,767,841	74,804,712
Weighted average ordinary shares—diluted	94,767,841	74,804,712
Other comprehensive income (loss):		
Changes in the fair value of the convertible notes	75	397
Foreign exchange translation adjustment	42	(1,087)
Comprehensive loss	(10,037)	(12,643)

RENALYTIX PLC
CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share data)	September 30, 2023	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,891	\$ 24,682
Accounts receivable	1,014	776
Prepaid expenses and other current assets	1,566	1,424
Total current assets	16,471	26,882
Property and equipment, net	944	1,027
Right of Use Asset	131	159
Investment in VericiDx	978	1,460
Other Assets	1,016	1,101
Total assets	\$ 19,540	\$ 30,629
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,715	\$ 1,485
Accounts payable – related party	1,653	1,451

Accrued expenses and other current liabilities	4,566	6,644
Accrued expenses – related party	2,539	1,963
Current lease liability	131	130
Convertible notes-current	4,569	4,463
Total current liabilities	15,173	16,136
Convertible notes-noncurrent	5,848	7,485
Noncurrent lease liability	10	41
Total liabilities	21,031	23,662

Commitments and contingencies (Note 10)

Shareholders' equity:

Ordinary shares, £0.0025 par value per share: 102,537,697 shares authorized; 95,019,440 and 93,781,478 shares issued and outstanding at September 30, 2023 and June 30, 2023, respectively

	290	286
Additional paid-in capital	188,031	186,456
Accumulated other comprehensive loss	(1,333)	(1,450)
Accumulated deficit	(188,479)	(178,325)
Total shareholders' (deficit) equity	(1,491)	6,967
Total liabilities and shareholders' (deficit) equity	\$ 19,540	\$ 30,629

RENALYTIX PLC CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	For the Three Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (10,154)	\$ (11,953)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	127	130
Stock-based compensation	523	767
Equity in losses of affiliate	—	9
Reduction of Kantaro liability	—	(12)
Fair value adjustment to VericiDx investment	447	854
Unrealized foreign exchange loss	—	456
Fair value adjustment to convertible debt, net interest paid	945	921
Non cash lease expense	28	—
Changes in operating assets and liabilities:		
Accounts receivable	(238)	(322)
Prepaid expenses and other current assets	(153)	312
Receivable from affiliates	—	(13)
Accounts payable	250	555
Accounts payable – related party	202	1,287
Accrued expenses and other current liabilities	(2,060)	(125)
Accrued expenses – related party	579	22
Deferred revenue	—	(7)
Net cash used in operating activities	(9,504)	(7,119)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Payment of convertible notes principal	(1,060)	(1,060)
Payment of issuance costs	(5)	—
Proceeds from the issuance of ordinary shares under employee share purchase plan	—	116
Net cash used in financing activities	(1,065)	(944)
Effect of exchange rate changes on cash	(222)	(2,230)
Net decrease in cash and cash equivalents	(10,791)	(10,293)

Cash and cash equivalents, beginning of period	<u>24,682</u>	<u>41,333</u>
Cash and cash equivalents, end of period	<u>\$ 13,891</u>	<u>\$ 31,040</u>
Supplemental noncash investing and financing activities:		
Noncash lease liabilities arising from obtaining right-of-use assets	\$ 4	\$ —
Cash Paid for interest on convertible debt	\$ 249	\$ 292