



## Renalytix Reports Full Year Fiscal 2023 Results

September 28, 2023

LONDON and SALT LAKE CITY, Sept. 28, 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, reports its financial results for the fiscal year ended June 30, 2023.

### Recent Highlights (including post period events)

#### Regulatory & Reimbursement

- Achieved FDA De Novo marketing authorization for KidneyIntelX.dkd to assess risk of progressive kidney function decline in adults with diabetes and early-stage kidney disease.
- Secured additional key insurance coverage contracts for KidneyIntelX including:
  - EmblemHealth, covering over three million lives in New York Tri-state region
  - CareFirst BlueCross BlueShield, the largest health care plan in the U.S. Mid-Atlantic region
  - Texas Blue Cross Blue Shield and Parkland Community Health Plan covering over seven million lives
- Since announcement of FDA authorization in June 2023, engagement with various parties regarding benefits of KidneyIntelX technology has expanded
- Inclusion of KidneyIntelX in draft Kidney Disease Improving Global Outcomes (KDIGO) 2023 Clinical Practice Guideline for Evaluation and Management of Chronic Kidney Disease (KDIGO 2023 Guideline)
- Continuing to maintain contracted pricing at or over the Medicare Clinical Laboratory Fee Schedule (CLFS) of \$950 per reportable test result
- Medicare payments for KidneyIntelX received
  - Claims submitted through the individual claims review (ICR) process paid effective July 1, 2022
  - Local Coverage Determination (LCD) evaluation underway with two Medicare Administrative Contractors supported by new published real-world utility evidence
- Executed over 40 commercial payor contracts and enrolled as a provider in 35 state Medicaid programs to date
- Milestone achievement converting payment to full, long-term commercial insurance billing model at Mount Sinai Health System
  - Insurance payment now available for over 90% of KidneyIntelX eligible Mount Sinai patients
  - Reduction in Mount Sinai test volumes during commercial insurance billing transition in the second half of fiscal 2023; order mechanisms now restored and commercial testing has resumed

#### Commercial & Partnerships

- Appointed senior diagnostics executive Howard Doran to lead global commercial sales beginning with direct to physician salesforce in New York, Illinois, North Carolina, Florida and Texas
- Full Epic electronic health record system integration with Atrium / Wake Forest proceeding with launch expected before end of calendar 2023
- Selected EVERSANA® to supplement identification and training of sales personnel in select U.S. regions
  - Accelerates deployment of KidneyIntelX across key U.S. regions with high rates of diabetic kidney disease and established insurance coverage
- Agreement with Veterans Affairs (VA) to integrate KidneyIntelX testing with Veterans Health Administration electronic health record system
- Core participant in consortium granted \$10 million by Horizon Europe Grant to advance personalized medicine in treating chronic kidney disease
- Increasing diversity of commercially billable testing volume, particularly among primary care physician practices ordering through the MyIntelX portal

#### Clinical & Validation

- Studies regarding KidneyIntelX clinical utility and health economics presented in multiple scientific venues:
  - American Society of Nephrology Kidney Week 2022
  - National Kidney Foundation Spring Clinical Meeting 2023
  - American Diabetes Association 83rd Scientific Session in June 2023

- American Association of Nurse Practitioners Annual Meeting in June 2023
- Key takeaways:
  - A model that estimated the incremental cost-effectiveness of KidneyIntelX compared to risk stratification using eGFR and UACR, with a lifetime horizon from both a public and private payer perspective, predicted that the average Medicare and commercial patient would experience fewer dialysis starts and kidney transplants while experiencing an increased life span and quality-adjusted life span by using KidneyIntelX compared to the standard of care.
  - Deployment and risk stratification by KidneyIntelX was associated with escalation in clinical actions taken to optimize cardio-metabolic-kidney health including medications and referrals.
  - KidneyIntelX classified more Black vs. non-Black patients as high risk for progression of diabetic kidney disease, and this was associated with increased prescription of SGLT2-inhibitor drug therapy post-testing, contributing to elimination of racial disparity in SGLT2i usage.
- Data includes studies from Wake Forest real world cohort, Mount Sinai real world cohort, Mount Sinai BioMe Biobank, UPenn Medicine Biobank, the CANVAS clinical trial cohort, and the Veterans Affairs Database
- Publications:
  - Real-world evidence in Journal of Primary Care and Community Health in which KidneyIntelX resulted in a 4.5-fold increase in new drug prescriptions (for SGLT2 inhibitors) for high-risk compared to low-risk patients; early evidence suggested that the introduction of SGLT2i contributed to an observed reduction in HbA1c levels most notably in high-risk patients, and a more than a 20% change in dose or type of antihypertensive therapeutic prescriptions in high vs. low-risk patients
  - Patient case studies in the journal Diabetic Nephropathy demonstrated how KidneyIntelX can optimize clinical management in early-stage kidney disease across multiple physician specialties
  - New validation data for KidneyIntelX.dkd, the FDA approved version of KidneyIntelX, in the journal Diabetes, Obesity, and Metabolism. Using data from two independent cohorts and a clinical trial population, it was demonstrated that the updated KidneyIntelX test significantly enhanced risk stratification for progressive decline in kidney function, independent from known risk factors for progression.

## Finance & Operations

- Completed \$20.3 million equity financing led by new institutional investors in February 2023
- Reduced annual operating expenses by over \$11 million versus the prior year with additional cost reduction initiatives underway to extend cash runway while preserving revenue generating activity
- Over 5,000 KidneyIntelX tests performed in fiscal year 2023, up 55% from the prior year
- Expanded board of directors with addition of financial executive Catherine Coste

Investors are advised to read the results for the 12 months ended 30 June 2023, which have been filed with the U.S. Securities and Exchange Commission on Form 10-K concurrently with this results announcement.

## Analyst Conference Call

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/bmrco2si>

**For further information, please contact:**

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James McCullough, CEO

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**Via Walbrook PR**

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### CapComm Partners

**About Renalytix**

Renalytix (LSE: REXX) (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](http://www.kidneyintelx.com)). For more information, visit [www.renalytix.com](http://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, and our expectations and guidance related to partnerships, testing volumes and revenue for future periods. 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 our most recent Annual Report on Form 10-K, 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.

**Chairman & CEO's Joint Statement**

This has been a highly productive year for Renalytix. We have crossed major thresholds in reimbursement, outcomes and utility data and received FDA De Novo marketing authorization for KidneyIntelX.dkd. Our progress was furthered amplified by inclusion of KidneyIntelX in the draft of the leading kidney clinical guidelines, KDIGO, for 2023. It is rare to see all of these milestones pass in a short period of time and we believe they are significant for broader adoption and clinical acceptance of KidneyIntelX testing for risk assessment of patients with type 2 diabetes and early-stage kidney disease in the United States and abroad.

Kidney disease remains one of the costliest and most widespread unmet medical needs of our time. In the United States alone, there are approximately 14 million adults with diabetic kidney disease, which is the intended use population authorized by FDA for KidneyIntelX.dkd. Our goal is to make the benefits of early prognosis from KidneyIntelX technology accessible to as many of these individuals as possible at an early stage when the benefits of treatment strategies and new drug therapies have the greatest chance of success, before the disease irreversibly damages the kidneys.

Importantly, post FDA authorization, we have reviewed our operating cost basis with a view to meaningfully reduce our quarterly cash burn rate. This reduction in cash burn should become apparent in the remainder of our 2024 fiscal year and is being undertaken without compromising our sales and marketing efforts focused on growing testing volume and revenue. These reductions are on top of our recent year over year operating expense reduction of \$11 million. Post FDA authorization, we will also evaluate potential international licensing opportunities and strategic partnerships, both of which could provide sources of non-dilutive capital and expanded revenue opportunities for Renalytix.

KidneyIntelX.dkd is now the only prognostic in vitro diagnostic test for assessment of chronic kidney disease progression with FDA authorization, with claims reimbursed by a broad array of insurance companies including Blue Cross Blue Shield groups, Medicare, and Medicaid, and real-world evidence demonstrating improved outcomes in both diabetes and kidney health in the short-term.

Repeated publication of both outcomes and utility data underpin successful diagnostic launches and the establishment of new standards of care. At Renalytix, we have invested heavily in and emphasized real-world evidence since we began full operations in late 2018. We were excited to present KidneyIntelX outcomes data that has exceeded our expectations by showing that use of KidneyIntelX was associated with clinical actions that in less than 12 months led to observed changes in the core measure for diabetes health, as measured by A1C reductions, and kidney health, as measured by eGFR slope improvement. We expect more data from our real-world evidence studies over coming months.

Raising funds to fuel these clear commercial opportunities is essential, particularly now that we have reduced risks associated with a successful service product launch and adoption. Toward that end, to maximize our flexibility to fund the business growth, we plan to file an S-3 shelf registration statement to give us the ability to source capital at the right time. We will continue to explore less dilutive and non-dilutive capital funding sources, particularly now that we have a unique product proposition post-FDA authorization.

On behalf of everyone at Renalytix, we would like to thank you for your continued support.

**About Renalytix**

At Renalytix, we are introducing more accurate prognosis and effective care management for the estimated 850 million people worldwide with chronic kidney disease. In the United States alone, chronic kidney disease affects about 37 million people and is responsible for one of the largest cost drivers in the national medical system. Early identification, prognosis and treatment beginning with primary care is essential if we are to stem the growing social cost and suffering associated with kidney disease.

With our lead product, KidneyIntelX, the goal is to drive the focus from kidney disease treatment to kidney health management through a more accurate understanding of a patient's risk for kidney failure before it happens. KidneyIntelX leads development in the new field of bioprognosis, a biology driven approach to risk assessment that integrates information from a simple blood draw and a patient's health record to produce an accurate

picture of kidney health. A doctor can use KidneyIntelX results to act on patients at high risk of kidney disease progression or failure at an early stage where active management and therapeutics have the best opportunity to impact outcomes and cost before it is too late.

### **KidneyIntelX™**

**Our novel platform, KidneyIntelX, uses a machine-learning enabled algorithm to process predictive blood biomarkers with key features from a patient's health record to generate an early and accurate kidney health risk score. The score identifies those patients at the most risk for kidney disease progression and/or failure and further guides ongoing clinical decisions.**

KidneyIntelX is initially indicated for use with adults who have diagnosed kidney disease and type 2 diabetes – diabetic kidney disease or DKD. Future KidneyIntelX products in development intend to expand the indicated uses to include broader chronic kidney disease, health equity strategies and kidney health monitoring through treatment. Diabetes is the leading cause of chronic kidney disease, representing nearly 40% of its cases, and DKD patients are the highest contributors to emergency room dialysis starts. Unfortunately, many DKD patients are unaware that their kidney disease has been progressing, often uncontrolled, for many years and now find themselves making difficult decisions about late-stage treatments.

KidneyIntelX was designed as an expandable platform able to add indicated uses and a monitoring capability, all within CLIA and FDA regulated insurance reimbursable framework.

### **Intellectual Property**

The U.S. Patent and Trademark Office allowed claims extending the use of one of KidneyIntelX's primary blood biomarkers, sTNFR1, to all patients with diabetes to determine an increased risk of developing progressive kidney disease or kidney failure. We have also completed rights to additional patent applications for use with KidneyIntelX. We continue to build out our intellectual property portfolio and are actively evaluating in-licensing opportunities that will enhance our competitive product positioning.

### **Current Trading & Outlook**

We believe FDA authorization, positive utility and outcomes data, our physician and patient education programs, and comprehensive reimbursement puts us on a path towards KidneyIntelX.dkd becoming broadly used across the United States among the 14 million Americans with diabetic kidney disease, and ultimately within the global market of 850 million people with chronic kidney disease. We are proud of the rapid pace of these achievements just five years from our company's inception.

Our real-world evidence data is comprehensive and shows clear benefit. With FDA De Novo marketing authorization in June, KidneyIntelX.dkd will become available commercially later in this fiscal year and we expect to see growth in adoption. The social need could not be higher to establish the innovative preventative medicine strategies that KidneyIntelX technology enables at the front-end of diabetes and kidney disease.

During fiscal 2023 over 5,000 KidneyIntelX tests were performed, which was up 55% from the prior year. We expect a meaningful increase in total tests during the remainder of fiscal 2024, building on quarterly test volumes of about 1,200 during fiscal 2023 and through first quarter of 2024. More than half of these during the first quarter of 2024 thus far are revenue generating, with a set of the Mount Sinai clinical trial tests no longer billable following last spring's transition to full commercial payment at the hospital system. We are encouraged by the continued adoption by physicians beyond Mount Sinai, and expect that with the launch of the FDA-authorized KidneyIntelX.dkd later this fiscal year, in conjunction our direct to physician sales force coming on-line, and with new hospital partners such as Atrium / Wake Forest commencing commercial testing before year-end as well, we will see accelerating billable volume growth.

### **Financial Review**

The results presented cover FY23. The presentational currency for Renalytix plc and its subsidiaries (together, the "Group") is the United States Dollar.

#### **INCOME STATEMENT**

##### *Revenue*

The Group recognized a total of \$3.4 million in revenue in the financial year ended 30 June 2023 ("FY23") which was comprised of \$3.1 million in revenue related to testing services as well as \$0.3 million related to pharmaceutical services revenue.

##### *Cost of Sales*

The cost of sales associated with the services performed and commercial testing revenue was \$2.7 million for FY23.

##### *Administrative Costs*

During FY23, administrative expenses totaled \$43.1 million (financial year ended 30 June 2022 ("FY22"): \$58.3 million). The major items of expenditure were general and administrative costs of which included \$21.0 million in employee-related costs (FY22: \$27.6 million), \$5.9 million in subcontractors, legal, accounting, and other professional fees (FY22: \$12.9 million), \$8.0 million in external R&D Services, lab supplies and lab services (FY22: \$6.4 million), \$2.7 million in insurance (FY22: \$4.6 million), \$2.1 million in depreciation and amortisation (FY22: \$2.1 million), \$1.3 million in marketing and public relations (FY22: \$1.9 million), \$1.3 in IT related costs (FY22: \$1.7million), \$0.4 million in office related expenses including rent (FY22: \$0.5 million), \$0.1 million in stock exchange listing and filing fees (FY22: \$0.3 million) and \$0.3 million in other expenses (FY22: \$0.3 million).

##### *Gain (loss) on financial assets at fair value through profit or loss*

The Company accounts for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During the year ended 30 June 2023, we recorded a loss of \$1.3 million to adjust the VericiDx investment to fair value. During the year ended 30 June 2022, we recorded a loss of \$5.9 million to adjust the VericiDx investment to fair value.

##### *Fair value adjustment of convertible debt*

We elected to account for the convertible notes at fair value with qualifying changes in fair value recognized through the income statement until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. For the year ended 30 June 2023, we recorded a loss of \$3.1 million to adjust the convertible notes to fair value. For the year ended 30 June 2022, we recorded a gain of \$4.0 million to adjust the convertible notes to fair value.

##### *Finance Income (Expense)*

During the year ended 30 June 2023, we recognized a gain of \$0.5 million, which was comprised of \$0.2 million of income related to the dissolution of

Kantaro, \$0.3 million of income for refunds from Citibank, \$0.1 million interest income earned on our cash deposits, and offset by \$0.1 million of foreign exchange losses. During the year ended 30 June 2022, we recognized a foreign currency gain of \$9.6 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

## BALANCE SHEET

### Inventory

Inventory consists of consumable materials used by the labs to carry out KidneyIntelX tests. Inventory on hand at 30 June 2023 totaled \$0.7 million (FY22: \$1.2 million). During FY22, inventory levels increased due to purchases as the company prepares for increased KidneyIntelX testing volumes.

### Fixed Assets

Property, plant, and equipment consists of laboratory equipment being used to support testing and product development activities. At 30 June 2023, the company held \$1.0 million in net property, plant, and equipment (FY22: \$1.4 million).

### Intangible Assets

The Group held \$12.5 million net book value of intangible assets held at 30 June 2023 (FY22: \$14.0 million) includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying KidneyIntelX, as well as amounts capitalized as development costs. Intangible assets also include the value of the biomarker business purchased (in exchange for ordinary shares in the Company) from EKF. Intangible assets decreased period over period due to amortisation and the impact of foreign exchange translation at period end.

### Investment in Verici

At the end of FY23 the group held 9,831,681 shares in Verici Dx, the fair value of the investment in Verici Dx was \$1.5 million at 30 June 2023 (FY22: \$2.7 million)

### Convertible Note

In April 2022, the Company issued amortising senior convertible bonds with a principal amount of \$21.2 million in amortising senior convertible bonds due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million. The Company elected to account for the Bonds at fair value. At 30 June 2023, the Bonds had a fair value of \$11.9 million. At 30 June 2022, the Bonds had a fair value of \$12.3 million.

### Cash

The Group had cash on hand of \$24.7 million (FY22: \$41.3 million). Cash and equivalents are held in several deposit accounts in the US (\$14.9 million), UK (\$8.6 million) and IRE (\$1.2 million). Our expenditure plans remain sufficiently adaptable to align with available resources.

## Consolidated Income Statement FOR THE YEAR ENDED 30 JUNE 2023

	<u>Year to 30 June 2023</u>	<u>Year to 30 June 2022</u>
	<u>\$'000</u>	<u>\$'000</u>
<b>Continuing Operations</b>		
Revenue	3,403	2,970
Cost of Sales	(2,702)	(2,052)
<b>Gross profit</b>	<b>701</b>	<b>918</b>
Administrative expenses	(43,056)	(58,290)
<b>Operating loss</b>	<b>(42,355)</b>	<b>(57,372)</b>
Share of Net loss in Associate accounted for using the equity method	(9)	9
Gain (loss) on financial assets at fair value through profit or loss	(1,273)	(5,900)
Fair value adjustment of convertible debt	(3,093)	3,998
Finance (costs) income - net	509	9,637
<b>Loss before tax</b>	<b>(46,221)</b>	<b>(49,628)</b>
Taxation	(2)	(7,104)
<b>Loss for the Period</b>	<b>(46,223)</b>	<b>(56,732)</b>
<b>Earnings per Ordinary share from continuing operations</b>		
Basic	\$ (0.56)	\$ (0.78)
Diluted	\$ (0.56)	\$ (0.82)

## Consolidated Statement of Comprehensive Income FOR THE YEAR ENDED 30 JUNE 2023

	<u>Year to 30 June 2023</u>	<u>Year to 30 June 2022</u>
	<u>\$'000</u>	<u>\$'000</u>
Loss for the period – continuing operations	(46,223)	(56,732)
<b>Other comprehensive income:</b>		
<b>Items that may be subsequently reclassified to profit or loss</b>		
Changes in the fair value of the convertible notes	719	536
Currency translation differences	(337)	(11,742)
<b>Other comprehensive (loss)/income for the period</b>	<b>382</b>	<b>(11,206)</b>
<b>Total comprehensive loss for the period</b>	<b>(45,841)</b>	<b>(67,938)</b>

Items stated above are disclosed net of tax. The income tax relating to each component of other comprehensive income is disclosed in the note.

## Consolidated and Company's Statements of Financial Position

**AS AT 30 JUNE 2023**

	<u>Group As at 30 June 2023</u>	<u>Group As at 30 June 2022</u>
	\$'000	\$'000
<b>Assets</b>		
<b>Non-current assets:</b>		
Property, plant and equipment	1,027	1,368
Right of use asset	194	355
Intangible assets	12,511	14,020
Investment in subsidiaries	-	-
Investments accounted for using the equity method	-	9
Note receivable	-	75
Deferred tax assets	-	-
Other long term assets	51	-
<b>Total non-current assets</b>	<b>13,783</b>	<b>15,827</b>
<b>Current Assets</b>		
Inventory	718	1,160
Security Deposits	132	141
Financial asset at fair value through profit or loss	1,460	2,744
Trade and other receivables	776	901
Due from affiliated company	-	-
Prepaid and other current assets	566	1,152
Cash and cash equivalents	24,682	41,333
<b>Total current assets</b>	<b>28,334</b>	<b>47,431</b>
<b>Total assets</b>	<b>42,117</b>	<b>63,258</b>
<b>Equity attributable to owners of the parent</b>		
Share capital	299	241
Share premium	104,953	85,444
Share-based payment reserve	13,513	11,954
Accumulated other comprehensive income	(1,127)	(1,509)
Retained earnings/(deficit)	(99,184)	(52,961)
<b>Total equity</b>	<b>18,454</b>	<b>43,169</b>
<b>Liabilities</b>		
<b>Current liabilities:</b>		
Trade and other payables	11,514	7,281
Deferred revenue	-	46
Current lease liabilities	156	163
Note payable current	4,463	4,660
Current due to affiliated company	-	55
<b>Total current liabilities</b>	<b>16,133</b>	<b>12,205</b>
<b>Non-current liabilities</b>		
Note payable non-current	7,485	7,682
Non-current lease liabilities	46	202
<b>Total non-current liabilities</b>	<b>7,531</b>	<b>7,884</b>
<b>Total liabilities</b>	<b>23,664</b>	<b>20,089</b>
<b>Total equity and liabilities</b>	<b>42,117</b>	<b>63,258</b>

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the Parent Company income statement. The loss for the Parent Company for the year was (\$15,154,820). (Year ended 30 June 2021: loss of \$7,718,000).

**Consolidated and Company's Statements of Cash Flows  
FOR THE YEAR ENDED 30 JUNE 2023**

	<u>Group As at 30 June</u>	<u>Group</u>
	2023	As at 30 June 2022
	\$'000	\$'000
<b>Cash flows from operating activities:</b>		
Loss before income tax	(46,221)	(49,628)
Adjustments for		

Depreciation	341	304
Amortisation and impairment charges	2,151	2,309
Share-based payments	1,560	7,010
Share of net (profit)/loss of associate	9	(9)
Reversal of Kantaro Liability	(55)	(295)
Unrealized loss (Gain) on financial asset at fair value through profit or loss	1,273	5,900
Realized foreign exchange loss (gain)	(1,008)	
Fair value adjustment of convertible debt	3,093	(3,998)
Foreign Exchange Loss (Gain)	-	(7,354)
Changes in working capital		
Trade and other receivables	125	(307)
Prepaid assets and other current assets	1,298	(698)
Related party receivable	75	-
Inventory	442	(807)
Security Deposits	141	-
Trade and other payables	4,149	1,904
Deferred Revenue	(46)	(76)
<b>Net cash used in operating activities</b>	<b>(32,674)</b>	<b>(45,745)</b>
<b>Cash flows from investing activities:</b>		
Purchases of property and equipment (PPE)	-	(591)
Purchase of intangibles	-	(103)
Investment in Renalytix Inc	-	-
<b>Net cash generated by/(used in) investing activities</b>	<b>-</b>	<b>(694)</b>
<b>Cash flows from financing activities</b>		
Proceeds from convertible notes	-	18,020
Repayment of convertible notes	(4,288)	-
Payment of debt issuance costs	-	(1,382)
Payments of issuance costs for the Securities Purchase Agreement	-	(218)
Issue of shares (net of issue costs)	19,305	8,804
Proceeds from the issuance of ordinary shares under employee share purchase plan	261	211
Proceeds from exercise of stock options	-	198
Lease payments	(160)	(118)
<b>Net cash generated from financing activities</b>	<b>15,118</b>	<b>25,516</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>(17,556)</b>	<b>(20,924)</b>
Cash and cash equivalents at beginning of period	41,333	65,159
Effect of exchange rate changes on cash	905	(2,902)
<b>Cash and cash equivalents at end of period</b>	<b>24,682</b>	<b>41,333</b>

**Consolidated Statement of Changes in Equity  
FOR THE YEAR ENDED 30 JUNE 2023**

	Share Capital	Share Premium	Share-based payment reserve	Accumulated other comprehensive income	Retained earnings	Total equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>At 30 June 2022</b>	241	85,444	11,954	(1,509)	(52,961)	43,169
Comprehensive income						
Loss for the period	-	-	-	-	(46,223)	(46,223)
<i>Other comprehensive income</i>						
Changes in fair value of convertible notes	-	-	-	719	-	719
Currency translation differences	-	-	-	(337)	-	(337)
<b>Total comprehensive income</b>	<b>-</b>	<b>-</b>	<b>-</b>	<b>382</b>	<b>(46,223)</b>	<b>(45,841)</b>
<b>Transactions with Owners</b>						
Share-based payments	-	-	1,559	-	-	1,559
Shares issues under ESPP	1	260	-	-	-	261
Shares issued under Securities Purchase Agreement	57	19,248	-	-	-	19,305
<b>Total transactions with owners of the parent, recognized directly in equity</b>	<b>58</b>	<b>19,508</b>	<b>1,559</b>	<b>-</b>	<b>-</b>	<b>21,126</b>

## Notes to the Financial Statements

### 1. GENERAL INFORMATION AND BASIS OF PRESENTATION

Renalytix Plc (the "Company") is a company incorporated in the United Kingdom. The Company is a public limited company, which is listed on the AIM market of the London Stock Exchange and Nasdaq global market. The address of the registered office is Finsgate, 5-7 Cranwood Street, London, United Kingdom, EC1V 9EE. The Company was incorporated on 15 March 2018 and its registered number is 11257655.

The principal activity of the Company and its subsidiaries (together "the Group") is as a developer of artificial intelligence- enabled diagnostics for kidney disease.

The financial statements are presented in United States Dollars ("USD") because that is the currency of the primary economic environment in which the Group operates.

### 2. BASIS OF PRESENTATION

The Group and Company's financial statements have been prepared in accordance with UK-adopted International Accounting Standards and with the requirements of the Companies Act 2006.

The unaudited financial information included in this preliminary results announcement for the year ended 30 June 2023 and audited financial information for the year ended 30 June 2022 does not constitute statutory accounts within the meaning of sections 434(3) and 435(3) of the Companies Act 2006 or contain sufficient information to comply with the disclosure requirements in accordance with UK-adopted International Accounting Standards in conformity with the requirements of the Companies Act 2006.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgement in the process of applying the Group's accounting policies.

#### **New Standards, amendments, and interpretations not adopted by the group**

The group did not adopt any new standards, amendments or interpretations in year as they did not have a material impact on the financial statements.

#### **New standards, amendments, and interpretations issued but not effective for the period ended 30 June 2023, and not early adopted**

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning on or after 1 January 2023 and have not been applied in preparing these financial statements. None of these is expected to have a significant effect on the financial statements of the Group or Parent Company.

- Amendments to IAS 1: Presentation of Financial Statements, Disclosure of Accounting Policies
- Amendments to IAS 8: Definition of Accounting Estimates
- Amendments to IFRS 17: Insurance Contracts
- Amendments to IAS 12: Deferred Tax Related to Assets and Liabilities Arising From a Single Transaction
- Amendments to IFRS 16: Leases on Sale and Leaseback
- Amendments to IAS 7 and IFRS 7: Supplier Finance Arrangement

### 3. SIGNIFICANT ACCOUNTING POLICIES

The principal accounting policies applied in the preparation of these financial statements are set out below.

#### **Going concern**

The Group and Company meet their day-to-day working capital requirements through the use of cash reserves.

The Directors have considered the applicability of the going concern basis in the preparation of these financial statements.

The Group and Company have incurred recurring losses and negative cash flows from operations since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of KidneyIntelX or any future products currently in development.

As a result of our losses and our projected cash needs, the Directors have concluded that substantial doubt exists about the Group and Company's ability to continue as a going concern. Substantial additional capital will be necessary to fund the Group and Company's operations, expand its commercial activities and develop other potential diagnostic related products. The Company plans to seek additional funding through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements. The Group and Company may not be able to obtain financing on acceptable terms, or at all, and the Group and Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Group and Company's shareholders. If the Group and Company is unable to obtain funding, the Group and Company could be required to delay, curtail or discontinue research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospect.

The Group and Company's ability to continue as a going concern is contingent upon successful execution of management's intended plan over the next twelve months to improve the Group and Company's liquidity and profitability, which includes, without limitation:

- Seeking additional capital through through public or private equity offerings, debt financings, other collaborations, strategic

alliances and licensing arrangements

- Implementation of various additional operating cost reduction options that are available to the Group and Company
- The achievement of a certain volume of assumed revenue

The consolidated financial statements do not include any adjustments that may result from the outcome of this going concern uncertainty.

#### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and its subsidiary undertakings. The Group controls an entity when the Group is exposed to, or has rights to, variable returns from its involvement with the entity and has the ability to affect those returns through its power over the entity. The existence and effect of potential voting rights that are currently exercisable or convertible are considered when assessing whether the Group controls another entity.

Subsidiaries are fully consolidated from the date on which control is transferred to the Group. They are de-consolidated from the date that control ceases.

The Group uses the acquisition method of accounting to account for business combinations. The consideration transferred for the acquisition of a subsidiary is the fair values of the assets transferred, the liabilities incurred and the equity interests issued by the Group. The consideration transferred includes the fair value of any asset or liability resulting from a contingent consideration agreement. Acquisition related costs are expensed as incurred. Identifiable assets acquired and liabilities and contingent liabilities assumed in a business combination are measured initially at their fair values at the acquisition date.

Inter-company transactions, balances and unrealized gains on transactions between Group companies are eliminated. Unrealized losses are also eliminated. Accounting policies of subsidiaries have been changed where necessary to ensure consistency with the policies adopted by the Group.

Associates are entities over which the Group has significant influence but not control over the financial and operating policies. Investments in associates are accounted for using the equity method of accounting and are initially recognized at cost. The Group's share of its associates' post-acquisition profits or losses is recognized in profit or loss, and its share of post-acquisition movements in reserves is recognized in other comprehensive income. The cumulative post-acquisition movements are adjusted against the carrying amount of the investment.

#### **Foreign currency translation**

##### *(a) Functional and presentational currency*

Items included in the financial statements of each of the Group's entities are measured using the currency of the primary economic environment in which the entity operates (the functional currency). The consolidated financial statements are presented in United States Dollars, which is the Group's presentational currency. The functional currency of the Parent Company is GB Pounds.

##### *(b) Transactions and balances*

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions where items are re-measured. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at year-end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognized in the income statement within 'administrative expenses'.

##### *(c) Group companies*

The results and financial position of all the Group entities that have a functional currency different from the presentational currency are translated into the presentational currency as follows:

- assets and liabilities for each balance sheet presented are translated at the closing rate at the date of that balance sheet;
- income and expenses for each income statement are translated at average exchange rates; and
- all resulting exchange differences are recognized in other comprehensive income.

On consolidation, exchange differences arising from the translation of the net investment in foreign operations are taken to other comprehensive income. When a foreign operation is partially disposed of or sold, exchange differences that were recorded in equity are recognized in the income statement as part of the gain or loss on sale.

#### **Segmental reporting**

Operating segments are reported in a manner consistent with the internal reporting provided to the chief operating decision-maker. The chief operating decision-maker, who is responsible for allocating resources and assessing performance of the operating segments, has been identified as the Executive Directors who make strategic decisions. At present the Directors consider the business to operate in a single segment.

#### **Property, plant and equipment**

Property, plant and equipment are stated at historical cost less accumulated depreciation and any provision for impairment. Historical cost includes expenditure that is directly attributable to the acquisition of the asset and bringing the asset to its working condition for its intended use.

Subsequent costs are included in the asset's carrying amount or recognized as a separate asset, as appropriate, only where it is probable that future economic benefits associated with the asset will flow to the Group and the cost of the asset can be measured reliably. The carrying amount of the replaced part is derecognized. All other repairs and maintenance are charged to the income statement during the financial period in which they are incurred.

Depreciation on assets is calculated using the straight-line method to allocate their cost to their residual values over their estimated useful lives, as follows:

Fixtures and fittings 20%

The assets' residual values and useful economic lives are reviewed regularly, and adjusted if appropriate, at the end of each reporting period.

An asset's carrying value is written down immediately to its recoverable amount if the asset's carrying amount is greater than its estimated recoverable amount.

Gains and losses on the disposal of assets are determined by comparing the proceeds with the carrying amount and are recognized in administration expenses in the income statement.

### **Intangible assets**

#### **(a) Trademarks, trade names and licenses**

Separately acquired trademarks and licenses are shown at historical cost. Trademarks and licenses acquired in a business combination are recognized at fair value at the acquisition date. Trademarks and licenses have a finite useful life and are carried at cost less accumulated amortisation. Amortisation is calculated using the straight-line method to allocate the cost of trademarks and licenses over the contractual license period of 10 to 15 years and is charged to administrative expenses in the income statement.

#### **(b) Development costs and trade secrets**

Development costs have a finite useful life and are carried at cost less accumulated amortisation.

Expenditure incurred on the development of new or substantially improved products or processes is capitalized, provided that the related project satisfies the criteria for capitalisation, including the project's technical feasibility and likely commercial benefit. All other research and development costs are expensed to profit or loss as incurred.

Development costs are amortised over the estimated useful life of the products with which they are associated. amortisation commences when a new product is in commercial production. The amortisation is charged to administrative expenses in the income statement. The estimated remaining useful lives of development costs are reviewed at least on an annual basis.

The carrying value of capitalized development costs is reviewed for potential impairment at least annually and if a product becomes unviable and an impairment is identified the deferred development costs are immediately charged to the income statement. Amortisation has not yet commenced.

Trade secrets, including technical know-how, operating procedures, methods and processes, are recognized at fair value at the acquisition date. Trade secrets have a finite useful life and are carried at cost less accumulated amortisation. amortisation has not yet commenced.

### **Impairment of non-financial assets**

Assets that have an indefinite life or where amortisation has not yet commenced are tested annually for impairment. Assets that are subject to amortisation are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the carrying amount exceeds its recoverable amount.

The recoverable amount is the higher of an asset's fair value less costs to sell and value in use. In assessing value in use, the estimated future cash flows are discounted to their present value using a pre-tax discount rate that reflects current market assessments of the time value of money and the risks specific to the asset for which the estimates of future cash flows have not been adjusted.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows. Impairment losses recognized for cash-generating units, to which goodwill has been allocated, are credited initially to the carrying amount of goodwill. Any remaining impairment loss is charged pro rata to the other assets in the cash-generating unit.

Where an impairment loss subsequently reverses, the carrying amount of the asset (cash-generating unit) is increased to the revised estimate of its recoverable amount, but so that the increased carrying amount does not exceed the carrying amount that would have been determined had no impairment loss been recognized for the asset (cash-generating unit) in the prior period. A reversal of an impairment loss is recognized in the income statement immediately. If goodwill is impaired however, no reversal of the impairment is recognized in the financial statements.

### **Financial assets**

#### **Classification**

The Company classifies its financial assets in the following categories: loans and receivables at amortised cost and financial assets at fair value through profit or loss. The classification depends on the purpose for which the financial assets were acquired and management determines the classification of its financial assets at initial recognition.

#### **(a) Loans and receivables**

Financial assets are classified as at amortised cost only if both of the following criteria are met: the asset is held within a business model whose objective is to collect contractual cash flows, and the contractual terms give rise to cash flows that are solely payments of principal and interest. Loans and receivables are non-derivative financial assets with fixed or determinable payments that are not quoted on an active market. They are included in current assets, except for maturities greater than 12 months after the balance sheet date. These are classified as non-current assets. The Company's loans and receivables comprise 'trade and other receivables' and cash and cash equivalents in the balance sheet.

#### **(b) Financial assets at fair value through profit or loss**

The Group classifies the following financial assets at fair value through profit or loss ("FVPL"):

- equity investments that are held for trading, and
- equity investments for which the entity has not elected to recognize fair value gains and losses through Other Comprehensive Income.

*(c) Financial assets at fair value through other comprehensive income*

Financial assets at fair value through other comprehensive income comprise equity securities that are not held for trading and which the Group has irrevocably elected at initial recognition to recognize in this category. The Group considers this category to be more relevant for assets of this type.

*(d) Financial liabilities at fair value through profit or loss*

The Group classifies the following financial assets at fair value through profit or loss ("FVPL"):

- Convertible debt recorded at fair value through profit or loss.

**Cash and cash equivalents**

Cash and short-term deposits in the balance sheet comprise cash at bank and in hand and short-term deposits with an original maturity of three months or less.

For the purposes of the cash flow statements, cash and cash equivalents consist of cash and short-term deposits as defined above.

**Share capital and premium**

Ordinary Shares are classified as equity. Proceeds in excess of the nominal value of shares issued are allocated to the share premium account and are also classified as equity. Incremental costs directly attributable to the issue of new Ordinary Shares or options are deducted from the share premium account.

**Other reserves - equity**

The share-based payment reserve is used to recognize the fair value of equity settled share-based payment transactions.

Foreign currency reserve is used to record the exchange differences on translation of entities in the Group which have a functional currency different to the presentation currency.

Retained earnings includes all current and prior period results as disclosed in the income statement.

**Trade and other payables**

Trade payables are obligations to pay for goods or services that have been acquired in the ordinary course of business from suppliers. Accounts payable are classified as current liabilities if payment is due within one year or less (or in the normal operating cycle of the business if longer). If not, they are presented as non-current liabilities. Trade payables are recognized initially at fair value and subsequently measured at amortised cost using the effective interest method.

**Current and deferred income tax**

Income tax comprises current and deferred tax. Tax is recognized in the income statement, except to the extent that it relates to items recognized in other comprehensive income where the associated tax is also recognized in other comprehensive income.

The current income tax charge is calculated on the basis of the tax laws enacted or substantively enacted at the balance sheet date in the countries where the Company and its subsidiary operate and generate taxable income. Management evaluates positions taken in tax returns with respect to situations in which applicable tax regulation is subject to interpretation and establishes provisions where appropriate on the basis of amounts expected to be paid to the tax authorities.

Deferred tax is recognized, using the liability method, on all temporary differences at the balance sheet date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes. Deferred tax liabilities are recognized in respect of all temporary differences except where the deferred tax liability arises from the initial recognition of goodwill in business combinations.

Deferred tax assets are recognized for all deductible temporary differences, carry-forward of unused tax assets and tax losses, to the extent that they are regarded as recoverable. They are regarded as recoverable where, on the basis of available evidence, there will be sufficient taxable profits against which the future reversal of the underlying temporary differences can be deducted.

The carrying value of the amount of deferred tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all, or part, of the tax asset to be utilized.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realized or the liability is settled, based on the tax rates (and tax laws) that have been substantively enacted at the balance sheet date.

Deferred income tax assets and liabilities are offset when there is a legally enforceable right to offset current tax assets against current tax liabilities and when the deferred income tax assets and liabilities relate to income taxes levied by the same taxation authority on either the taxable entity or different taxable entities where there is an intention to settle the balances on a net basis.

**Leases**

Leases are recognized as a right-of-use asset and a corresponding lease liability at the date on which the leased asset is available for use by the Group.

Assets and liabilities arising from a lease are initially measured on a present value basis. Lease liabilities include the net present value of the following lease payments:

- fixed payments (including in-substance fixed payments), less any lease incentives receivable
- variable lease payment that are based on an index or a rate, initially measured using the index or rate as at the commencement date
- amounts expected to be payable by the group under residual value guarantees
- the exercise price of a purchase option if the group is reasonably certain to exercise that option, and
- payments of penalties for terminating the lease, if the lease term reflects the group exercising that option.

Lease payments to be made under reasonably certain extension options are also included in the measurement of the liability.

The lease payments are discounted using the interest rate implicit within the lease. If that rate cannot be readily determined, the Group's incremental borrowing rate is used, being the rate that the Group would have to pay to borrow the funds necessary to obtain an asset of similar value to the right-of-use asset in a similar economic environment with similar terms, security, and conditions.

Where the Group is exposed to potential future increases in variable lease payments based on an index or rate, amounts are not included in the lease liability until they take effect. When adjustments to lease payments based on an index or rate take effect, the lease liability is reassessed and adjusted against the right-of-use asset.

Lease payments are allocated between principal and finance cost. The finance cost is charged to the income statement over the lease period so as to produce a constant periodic rate of interest on the remaining balance of the liability for each period.

Right-of-use assets are measured at cost comprising the following:

- the amount of the initial measurement of lease liability
- any lease payments made at or before the commencement date less any lease incentives received
- any initial direct costs
- restoration costs

Right-of-use assets are generally depreciated over the shorter of the asset's useful life and the lease term on straight line basis. If the Group is reasonably certain to exercise a purchase option, the right-of-use asset is depreciated over the underlying asset's useful life.

### **Revenue Recognition**

The Group recognizes revenue when a customer obtains control of contracted goods or services. The Group records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Group applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Group satisfies each performance obligation.

The Group only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. The Group reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. Certain contracts have options for the customer to acquire additional services. The Group evaluates these options to determine if a material right exists. If, after that evaluation, it determines a material right does exist, it assigns value to the material right based upon the renewal option approach. The Group recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Group uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer occurs at a point in time. Sales tax and other similar taxes are excluded from revenues.

### **Cost of revenue**

Cost of revenue consists of costs directly attributable to the services rendered, including labor costs directly related to revenue generating activities.

### **Employee benefits**

#### **(a) Pension obligations**

The Group makes contributions to defined contribution pension plans. A defined contribution plan is a pension plan under which the Group pays fixed contributions into a separate entity with the pension cost charged to the income statement as incurred. The Group has no further obligations once the contributions have been paid.

#### **(b) Share-based compensation**

The Group operates an equity-settled, share-based compensation plan, under which the Group receives services from employees and others as consideration for equity instruments of the Group. Equity-settled share-based payments are measured at fair value at the date of grant and are expensed over the vesting period based on the number of instruments that are expected to vest. For plans where vesting conditions are based on share price targets, the fair value at the date of grant reflects these conditions. Where applicable the Group recognizes the impact of revisions to

original estimates in the income statement, with a corresponding adjustment to equity for equity-settled schemes. Fair values are measured using appropriate valuation models, taking into account the terms and conditions of the awards.

When the share-based payment awards are exercised, the Company issues new shares. The proceeds received net of any directly attributable transaction costs are credited to share capital (nominal value) and share premium.

#### **National insurance on share options**

To the extent that the share price at the balance sheet date is greater than the exercise price on options granted to UK citizens under unapproved share-based payment compensation schemes, provision for any National Insurance Contributions has been based on the prevailing rate of National Insurance. The provision is accrued over the performance period attaching to the award.

#### **Interest income**

Interest income is accrued on a time basis, by reference to the principal outstanding and at the effective interest rate applicable, which is the rate that exactly discounts estimated future cash receipts through the expected life of the financial asset to that asset's net carrying amount.

#### **Exceptional items**

These are items of an unusual or non-recurring nature incurred by the Group and include transactional costs and one-off items relating to business combinations, such as acquisition expenses.

#### **Assets Classified as Held for Sale**

Assets are classified as held for sale if their carrying amount will be recovered principally through a sale transaction rather than through continuing use and a sale is considered highly probable. They are measured at the lower of their carrying value and fair value less costs to sell. An impairment loss is recognized for any subsequent write-down of the asset to fair value less costs to sell.

### **4. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS**

The Company makes estimates and assumptions regarding the future. Estimates and judgments are continually evaluated based on historical experience and other factors, including expectations of future events that are believed to be reasonable under the circumstances. In the future, actual results may differ from these estimates and assumptions. The estimates and assumptions that have a significant risk of causing a material adjustment to the carrying amounts of assets and liabilities within the next financial year relate to:

- Capitalisation and recoverability of intangible assets
- Share-based payments
- Convertible debt recorded at fair value through profit or loss

### **5. SEGMENTAL REPORTING**

The Group operates as a single segment.

### **6. REVENUE**

#### **Testing services revenue**

Testing services revenue is generated from the KidneyIntelX platform, which provides analytical services to customers. Each individual test is a performance obligation that is satisfied at a point in time upon completion of the testing process (when results are reported) which is when control passes to the customer and revenue is recognized. During the year ended 30 June 2023, the Company recognized \$3.1 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. There was \$2.7 million of testing services revenue recognized in the 2022 accounting period.

During the year ended 30 June 2023, the Company performed testing and provided approved KidneyIntelX risk scores for approximately 100 samples or \$0.1 million of potential revenue where collectability was determined to not be reasonably assured. The Company will continue to assess each contract to determine whether the collectability criterion is met and recognize revenue when collectability is reasonable assured.

#### **Pharmaceutical services revenue**

Pharmaceutical services revenue is generated from the provision of analytical services to customers. Contracts with customers generally include an initial upfront payment and additional payments upon achieving performance milestones. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer which may occur at a point in time or over time depending on the individual contract terms. Sales tax and other similar taxes are excluded from revenues. During the year ended 30 June 2023, the Company recognized \$0.3 million of pharmaceutical services revenue. There was \$0.2 million of pharmaceutical services revenue recognized in the 2022 accounting period.

#### **Deferred revenue**

Deferred revenue represents the allocated transaction price to the material right which will be recognized as revenue when the renewal options are exercised which is expected to occur over the next 24 months.

The following table summarizes the changes in deferred revenue:

<u>Year ended 30 June 2023</u>	<u>Year ended 30 June 2022</u>
\$'000	\$'000

Balance, beginning of period	45	122
Deferral of revenue		150
Revenue recognized	(45)	(227)
Balance, end of period	-	45

## 7. INCOME TAX

Group	Year ended 30 June 2023	Year ended 30 June 2022
	\$'000	\$'000
Deferred tax	-	(7,104)
<b>Total deferred tax</b>	-	<b>(7,104)</b>
Income tax (charge)/credit	-	(7,104)

No deferred asset is calculated on losses in FY23 as the probability of future utilization is considered too remote.

### Factors affecting the future tax charge

The standard rate of corporation tax in the UK is 25%.

Changes to UK Corporation tax rates were enacted as part of The Finance (No.2) Act 2021 which received Royal Assent on 10 June 2021. The main rate will remain at 19% before increasing to 25% from 1 April 2023.

	Year ended 30 June 2023	Year ended 30 June 2022
	\$'000	\$'000
Loss before tax	46,221	49,628
Tax Calculated at domestic tax rates applicable to the UK Standard of tax at 25%	11,555	9,429
Tax effects of:		
Expenses not deductible for tax purposes	(872)	4,490
Losses on which no deferred tax asset is recognized	(85)	(578)
Tax credit for the year	10,598	13,341
Current Year Valuation Allowance	(10,598)	(13,341)
Prior year deferred tax asset	-	7,097
Reversal of tax asset at 30 June	-	(7,097)
Tax expense	(2)	(7)
Total Income Tax (Expense)/Credit	(2)	(7,104)

Net losses can be carried forward indefinitely to offset future taxable profits however management has concluded that the realization of deferred tax assets to be less than probable and recorded a full valuation allowance. No deferred asset is calculated on losses in the UK totaling \$14,389,422 where the probability of future utilization is considered too remote.

## 8. NET LOSS PER SHARE

Basic net loss per ordinary share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during each period. Diluted net loss per ordinary share includes the effect, if any, from the potential exercise or conversion of securities, such as options which would result in the issuance of incremental ordinary shares. Potentially dilutive securities outstanding as of June 30, 2023, have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

For the fiscal year ended June 30, 2022, the diluted net loss per share calculation included the dilutive effect of convertible debt as well as the impact of the \$3.9 million fair value gain related to the convertible debt, which further increase net loss used in the diluted loss per share calculation.

The following is a reconciliation of basic net loss per share to diluted net loss per share for the fiscal years ended June 30, 2023 and 2022.

	Year ended 30 June 2023	Year ended 30 June 2022
Basic earnings per share	\$ (0.56)	\$ (0.78)
Average shares outstanding - basic	82,210,050	72,861,251
Convertible debt shares	-	976,048
Adjusted average shares outstanding - diluted	82,210,050	73,837,496
Diluted earnings per share	\$ (0.56)	\$ (0.82)

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of ordinary shares outstanding as they would be anti-dilutive:

	Year ended 30 June 2023	Year ended 30 June 2022
Stock options to purchase ordinary shares	4,968,576	4,554,901
Restricted stock units	40,340	—
Conversion of convertible note	5,441,199	—
	10,450,115	4,554,901

The Company was incorporated on 15 March 2018 with 50,000 ordinary shares of £1.00 each, and as a result of subdivisions (100:1 on 4 May 2018

and then 4:1 on 24 October 2018), the resulting founding shares became 20,000,000 at £0.0025 each.

## 9. INVESTMENTS IN SUBSIDIARIES

Company	Year ended 30 June 2023	Year ended 30 June 2022
	\$'000	\$'000
At beginning of Period	89,112	4,588
Capital Contribution relating to share based payment	1,511	2,824
Capital Contribution to Subsidiary	27,864	
Conversion of intercompany loan to equity investment	-	81,700
At End of Period	<u>118,487</u>	<u>89,112</u>

Investments in Group undertakings are recorded at cost, which is the fair value of the consideration paid, less any impairment. The Company had the following subsidiaries as of 30 September 2023.

Name of Company	Proportion held	Class of shareholding	Nature of business
Renalytix AI, Inc. <sup>1</sup>	100 %	Ordinary	Developer of artificial intelligence-enabled clinical diagnostic solutions for kidney disease
Renalytix AI Limited <sup>2</sup>	100 %	Ordinary	Developer of artificial intelligence-enabled clinical diagnostic solutions for kidney disease

- Renalytix AI Inc. is incorporated in the United States of America and has their principal place of business at 1460 Broadway, New York, New York 10036. Renalytix AI Inc. is included in the consolidation. The proportions of voting shares held by the parent company do not differ from the proportion of Ordinary Shares held.
- Renalytix AI Limited is incorporated in the Republic of Ireland and has their principal place of business at 29 Lower Patrick Street, Kilkenny, Ireland. Renalytix AI Ltd. is included in the consolidation. The proportions of voting shares held by the parent company do not differ from the proportion of Ordinary Shares held.

## 10. RELATED PARTY TRANSACTIONS

In May 2018, the Company secured its cornerstone license agreement with ISMMS for research and clinical study work and intended commercialization by the Company. As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's IPO in November 2018 and the subsequent sale of ordinary shares in July 2019. As of 30 June, 2023 and 2022, amounts due to ISMMS totaled \$3.4 million and \$2.6 million, respectively. During the years ended 30 June, 2023, 2022, 2021, the Company incurred expenses of \$3.3 million, \$3.1 million and \$1.3 million, respectively.

In connection with the formation of Kantaro, the Company entered into a five-year Advisory Services Agreement ("Advisory Agreement") pursuant to which the Company has agreed to provide certain advisory services to Kantaro. Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to the Company as the sole consideration for the services to be rendered by the Company under the Advisory Agreement. A portion of the Company's units are subject to forfeiture if, prior to December 31, 2021, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services to be provided under the Advisory Agreement was \$2.0 million and the fair value of the Class A units received from Kantaro was \$2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions which include discount rates and future cash flows, among others. As a result of the prior year impairment charge discussed in Note 3, the carrying value of the Kantaro investment was written down to zero.

A contributing factor to the impairment consideration for Kantaro was lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees. Based on these circumstances, the Company adjusted the liability to perform services to Kantaro under the Advisory Agreement during the year ended June 30, 2021. On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the business and unanimously signed a termination agreement. As part of the termination agreement, the members agreed to wind up Kantaro's business and dissolve it reasonably promptly after the effective date of the termination agreement. The termination agreement relieved Renalytix of its obligation to provide services to Kantaro, and the total liability associated with the services was written off.

For the twelve months ended June 30, 2023, the Company recognized \$0.02 million, in the statement of operations related to services performed under the Advisory Agreement. For the twelve months ended June 30, 2023, \$0.01 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.01 million were included in general and administrative expense, respectively. For the twelve months ended June 30, 2022, the Company recognized \$0.1 million statements of operations related to services performed under the Advisory Agreement. For the twelve months ended June 30, 2022, \$0.05 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.07 million were included within general and administrative expense.

In addition to the equity granted at formation, in May 2020 the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of \$0.3 million and an additional \$0.5 million thereafter. The Company committed to lend an initial amount of \$0.08 million and an additional \$0.17 million thereafter. Each loan bears interest at a per year rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to the Company based on each investor's proportionate ownership). The Company loaned

Kantaro \$0.25 million and initially recorded a note receivable. Upon liquidation of the joint venture, Kantaro paid Renalytix \$0.2 million for repayment of the loan. Renalytix recognized a gain of \$0.1 million in the statement of operations as prior to repayment, the loan had a carrying value of approximately \$0.075 million.

In June 2020, we and Mount Sinai entered into a registration rights agreement pursuant to which we have granted Mount Sinai the following registration rights:

- Demand Registration on Form F-3 – Mount Sinai is entitled to demand registrations on Form F-3, if we are then eligible to register shares on Form F-3, including up to two underwritten offerings in any 12-month period.
- Demand Registration on Form F-1 or Form S-1 – At any time following one year after the completion of the global offering, if we are not eligible to register shares on Form F-3 or S-3, Mount Sinai is entitled to a maximum of one demand registration on Form F-1 or Form S-1 during any 12-month period, subject to specified exceptions.
- Piggyback Registration – Mount Sinai is entitled to certain piggyback registration rights, subject to certain marketing and other limitations in the context of an underwritten offering.
- Expenses – We will pay all registration expenses incident to the performance of our obligations under the registration rights agreement.

Mount Sinai's registration rights will terminate at such time as Rule 144, or another similar exception under the Securities Act, is available for the unlimited public sale of all of Mount Sinai's registrable securities without any volume or manner of sale limitations, subject to specified exceptions.

On February 9, 2023, the Company entered into security purchase agreements to sell an aggregate of 3,699,910 Ordinary Shares, and 7,511,525 ADS, at a price of \$2.17 per ADS and £0.90 per Ordinary Share. The private placement generated gross cash proceeds of \$20.3 million, the net proceeds of which will be used for sales and marketing, clinical product development, and corporate support and financing costs. Certain related parties, directors of the company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,382,489 new American Depositary Shares at \$2.17 per ADS. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 346,375 Ordinary Shares at £0.90 per Ordinary Share.

In the year ended June 30, 2022, the Company also entered into a private placement agreement to sell, an aggregate of 2,428,688 shares of common stock (the "PIPE Shares"), for a purchase price of \$3.625 per share and an aggregate purchase price of \$8.8 million. Certain related parties, directors of the company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,103,448 new ordinary shares at \$3.625 per ordinary share. EKF Diagnostics Holdings, subscribed for a total of 137,930 new ordinary shares at \$3.625 per ordinary share. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 551,724 new ordinary shares at \$3.625 per ordinary share. Timothy Scannell, Non-Executive Director, subscribed for a total of 68,964 new ordinary shares at \$3.625 per ordinary share. Thomas McLain, President, subscribed for a total of 55,172 new ordinary shares at \$3.625 per ordinary share.

## 11. RECONCILIATION OF IFRS TO US GAAP

Since Renalytix's initial listing on Nasdaq, the Company has followed accounting principles generally accepted in the United States of America ('US GAAP'), both for internal as well as external purposes. The information below is unaudited and does not form part of the statutory accounts.

Renalytix Form 10-K, which is based on US GAAP, contains differences from its Annual Report, which is based on IFRS.

The Form 10-K and Annual Report are available on the Company's website ([www.renalytix.com](http://www.renalytix.com)). In order to help readers to understand the difference between the Group's two sets of financial statements, Renalytix has provided, on a voluntary basis, a reconciliation from IFRS to U.S. GAAP as follows:

### BALANCE SHEET

(in thousands)

	GAAP As at 30 June 2023 \$'000	IFRS As at 30 June 2023 \$'000	GAAP vs IFRS Difference \$'000	
<b>Assets</b>				
Cash	24,682	24,682	-	
Accounts receivable	776	776	-	
Prepaid expenses and other current assets	1,424	1,416	8	(a)
Note receivable – Kantaro	-	-	-	
Property, plant and equipment, net	1,027	1,027	-	
Intangibles, net	-	12,511	(12,511)	(b)
Investment in Verici	1,460	1,460	-	
Right of use asset	159	194	(35)	(c)
Other assets	1,101	51	1,050	(d)
<b>Total assets</b>	<b>30,629</b>	<b>42,117</b>	<b>(11,488)</b>	
<b>Liabilities and stockholder's equity</b>				

**Current Liabilities:**

Note payable – current	4,463	4,463	-	
Accounts payable	2,936	11,514	8,578	(e)
Accrued expenses and other current liabilities	6,644		(6,644)	(e)
Accrued expenses – related party	1,963		(1,963)	(e)
Current lease liability	130	156	26	(c)
Deferred Revenue	-	-	-	
Note payable – noncurrent	7,485	7,485	-	
Noncurrent lease liabilities	41	46	5	(c)
<b>Total Liabilities</b>	<b>23,662</b>	<b>23,664</b>	<b>2</b>	

**Stockholders' (deficit) equity:**

Ordinary shares, £0.0025 par value per share: 98,750,054 shares authorized; 93,781,478 and 74,760,432 shares issued and outstanding at June 30, 2023 and June 30, 2022, respectively	286	299	13	(f)
Additional paid in capital	186,456	118,466	(67,990)	(g)
Accumulated other comprehensive (loss) income	(1,450)	(1,127)	323	(h)
Accumulated deficit	(178,325)	(99,184)	79,141	(i)
<b>Total stockholders' (deficit) equity</b>	<b>6,967</b>	<b>18,454</b>	<b>11,487</b>	
<b>Total liabilities and stockholders' (deficit) equity</b>	<b>30,629</b>	<b>42,117</b>	<b>11,488</b>	

- Represents other immaterial presentation differences between US GAAP & IFRS
- Under IFRS, the acquisition of licenses and subsequent development efforts are capitalized and presented as intangible assets. Under U.S. GAAP, such costs are expensed as incurred until technological feasibility has been achieved or the assets are deemed to have future alternative use. In addition to capitalized software costs which are recorded as property and equipment under US GAAP and Intangibles under IFRS.
- Represents differenced in the timing of the adoption of IFRS 16 in connection with the Company's commercial laboratory in Utah. The Company has deferred the adoption of ASC 842 under U.S. GAAP until July 1, 2022.
- Differences is attributable to capitalized software costs which are recorded other assets under U.S. GAAP and Intangibles under IFRS.
- Accounts payable and other current liabilities are presented in the aggregate within the Annual report while broken out separately on the US GAAP 10-K. Difference represents other immaterial presentation differences and audit adjustments.
- Represents other immaterial audit adjustments.
- Represents cancellation of share premium account and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici in prior year. In addition, stock-based compensation is recognized on a straight-line basis under U.S. GAAP and a graded vesting basis under IFRS which creates timing differences as to when expenses are recorded.
- Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
- Represents cancellation of share premium and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici and differences noted within the Company's consolidated statement of operations and comprehensive loss.

**RECONCILIATION OF NET LOSS**

(\$ thousands)

Year ended 30 June 2023

\$'000

<b>Net loss in accordance with IFRS</b>	<b>(46,223)</b>
Stock compensation expense	(1,376) (j)
Amortisation of intangibles	1,963 (k)
Other adjustments	29 (l)
<b>Net loss in accordance with US GAAP</b>	<b>(45,607)</b>

- Stock based compensation is recognized on a straight-line basis under U.S. GAAP and a graded vesting basis under IFRS which creates timing differences as to when expenses are recorded.
- Amortisation expense is higher on the IFRS books as a result of the higher intangible asset balance. Under IFRS, the acquisition of licenses and subsequent development efforts are capitalized and presented as intangible assets. Under U.S. GAAP, such costs are expensed as incurred until technological feasibility has been achieved or the assets are deemed to have future alternative use.
- The remaining difference represents the aggregation of other immaterial audit adjustments and small accounting standard difference.