Renalytix Reports Full Year Fiscal 2022 Results

October 31, 2022

LONDON and SALT LAKE CITY, Oct. 31, 2022 (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, announces its full year results for the twelve months ended 30 June 2022.

Highlights (includes post-period events):

Regulatory & Reimbursement

- New commercial coverage in fiscal year 2022; 28 private insurance and network provider contracts now executed to date including:
  - Largest private payer in Illinois with 8.1 million members
  - Largest independent provider network in the tristate North Carolina, South Carolina and Virginia area, with over 100,000 health care providers in-network
- Achieved Medicare payment for KidneyIntelX through the individual claims review (ICR) process based on our Medicare clinical lab fee schedule (CLFS) pricing of $950 per test
- 33 state Medicaid programs contracted to date
- Continued data generation and analysis reinforcing the benefits of KidneyIntelX as part of collaborative *De Novo* process with the FDA, with anticipation that the agency's review is nearing completion. Data supports significant breakthrough in risk stratification for patients with diabetic kidney disease

Commercial & Partnerships

- Sales and medical affairs support buildout across core, strategically-focused market channels:
  - Deployed sales directors and representatives targeting large hospital systems, provider networks and independent primary care physicians, and veterans' hospitals
  - Added VP of Medical Affairs to support KidneyIntelX physician onboarding, education, and test ordering
  - Deployed market access and health systems partnership personnel to drive expansion
  - Developed comprehensive physician and patient marketing and education material
- Launch of myIntelX provider access portal for simplified, decentralized on-line ordering of KidneyIntelX
- Partnered with Singing River Health System to deploy KidneyIntelX informed care management to improve kidney health in individuals across the Mississippi Gulf Coast with type 2 diabetes and early-stage chronic kidney disease
- Partnered with St. Joseph's Health, based in Syracuse, NY and part of the Trinity Health System, for KidneyIntelX deployment and to advance value-based care
- Progressed through layers of vendor approval at several VA hospitals as part of nationwide 10-year payment contract from the U.S. General Services Administration (GSA), with initial test orders and pre-payments received
- Joint program with American Diabetes Association® to improve overall kidney health in patients with type 2 diabetes in the United States
- Kidney disease education programs in partnership with the National Kidney Foundation
- Continued KidneyIntelX testing volume growth
- Growth in number of active physicians ordering KidneyIntelX

Clinical & Validation

- Published data in the *American Journal of Nephrology* in which KidneyIntelX successfully monitored patient response to new drug therapy in 1,325 multinational clinical trial cohort patients
- KidneyIntelX showed ability to assess risk of heart failure hospitalization and death in large international diabetic kidney disease patient cohort (published in *Kidney360*)
- Peer-reviewed publication in *Journal of Medical Economics* supporting payer coverage for early-stage risk assessment and care management in the primary care office; projecting significant five-year savings from KidneyIntelX testing at primary care level
- Data results published in *American Journal of Managed Care* supporting adoption and clinical utility of KidneyIntelX; 98% of 401 primary care physicians surveyed confirmed KidneyIntelX has value as a risk decision tool

- Multiple data presentations at the American Diabetes Association (ADA) 82nd Scientific Sessions® meeting, including one showing KidneyIntelX testing in 1,112 adult diabetic kidney disease (DKD) patients at Mount Sinai Health System showed utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients
- *World Congress of Nephrology* data showing KidneyIntelX predicted the future rate of decline in kidney function compared with current standard diagnostics in patients with early-stage chronic kidney disease and type 2 diabetes
- Ongoing clinical studies at Wake Forest / Atrium Health and Mount Sinai Health System substantiating clinical utility of KidneyIntelX

Finance & Operations

- Commercial development progress with annual revenue growth
- Completion of $30.0 million equity and convertible note financing package ($26.8 million gross proceeds)
- Cost rationalization enacted at end of period reducing annualized spend by over $12 million with review of other cost-savings opportunities ongoing
- Salt Lake and New York laboratories operating to most rigorous audited standards; CLIA, CAP, ISO, and U.S. Food and Drug Administration audit compliant
- The Group had cash on hand of $41.3m (FY21: $65.2m).

Current Quarter

- Operational progress continued into the first quarter of fiscal 2023 with over a record 1,200 tests performed
- More than 80% of these were billable, yielding approximately $1.0 million revenue for the quarter

Investors are advised to read the results for the 12 months ended 30 June 2022, which have been filed with the U.S. Securities and Exchange Commission under Form 20-F concurrently with this results announcement.

Analyst Conference Call
The Company will hold an analyst conference call at 8:30 a.m. (ET) / 1:30 p.m. (BST) on Monday 31 October 2022. James McCullough, CEO and O. James Sterling, CFO will discuss the financial results and key topics including business strategy, partnerships and regulatory and reimbursement processes.

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/y9qtsbmx

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About KidneyIntelX
KidneyIntelX, is a first-of-kind solution that enables early-stage DKD progression risk assessment by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, systems, and employs a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

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 reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. 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 20-F filed with the SEC on October 31, 2022, 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

We are pleased to present our annual report for the twelve months ended 30 June 2022 for Renalytix plc.

Our path to success is focused on five major items:

1. Achieving "super-majority" insurance coverage in key regional markets including New York, Illinois and the Carolinas;
2. Continuing to publish on our growing real-world evidence of KidneyIntelX effectiveness;
3. FDA De Novo marketing authorization for KidneyIntelX;
4. Revenue growth from sequential onboarding of physicians, networks, and hospitals in new locations; and
5. Continuing to lower net expense to maintain cash availability into the first half of fiscal 2024

We are making strong progress and expect to meet or exceed each of these items.

Achieving "super-majority" insurance coverage in key regional markets including New York, Illinois and the Carolinas

We expect to cross the threshold of "super-majority" coverage in different key markets over the next several months. We consider a super-majority as greater than 70% of patients with diabetes and kidney disease having insurance coverage for KidneyIntelX testing in a major population region, such as New York City or metropolitan Chicago. Establishing Medicare and Medicaid payment are two crucial pieces as collectively they provide insurance for an estimated 60-70 percent of the KidneyIntelX eligible patient population. We recently reported that we have secured payment for KidneyIntelX testing by Medicare through claims submitted to National Government Services (NGS), the Medicare Administrative Contractor covering our New York laboratory. This is in addition to KidneyIntelX claims now being paid by Medicare Advantage, Medicaid, Blue Cross Blue Shield and other commercial insurance providers.

The Blue Cross Blue Shield (BCBS) system, covering over 114 million members or 1 in 3 Americans, is also core to our 2023 growth strategy. To date, we are pleased to have KidneyIntelX coverage declared by BCBS Illinois (8.1 million members), and Wellmark BCBS (South Dakota and Iowa with two million members). We have always viewed insurance reimbursement as the most significant hurdle to KidneyIntelX adoption and consider our building success in securing Medicare, Medicaid and BCBS payment to be unusually rapid this early in a company's commercial diagnostic lifecycle. Our expected KidneyIntelX contracted pricing remains at $950, in line with our distinct Medicare CLFS pricing.

Continuing to publish on our growing real-world evidence of KidneyIntelX effectiveness

Published utility study results showed that primary care physicians using KidneyIntelX are six times more likely to prescribe advanced medication to their high-risk patients in early-stage kidney disease where the opportunity to prevent significant kidney damage or kidney failure is greatest. In these studies, the same physician using KidneyIntelX was also three times more likely to make a timely referral to a specialist and three times more likely to initiate more aggressive anti-hypertensive (blood pressure control) strategies.

In other words, these real-world results support that KidneyIntelX is driving behavior change at primary care for high-risk patients – the key to altering the tide on kidney disease progression and reducing dialysis. We expect additional results from our multi-year real-world evidence programs will be in print during the 2nd quarter of fiscal 2023.

FDA De Novo marketing authorization for KidneyIntelX

We continue to work closely and constructively with the FDA on our De Novo Breakthrough Device authorization submission. Notably, we have provided additional comprehensive data which further confirms the performance of KidneyIntelX in risk discrimination for patients with diabetic kidney disease. We now believe we are approaching the completion of the De Novo regulatory process and while there is no guarantee of success until FDA has made its final determination, we are optimistic based on both the quality of analytic and clinical evidence provided and the high level of engagement we have had with the FDA. Our current expectations are for a decision to be made in calendar Q1 2023 but there can be no guarantee on this timescale.

Revenue growth from sequential onboarding of physicians and hospitals in new locations

We expect revenue test volume will continue to increase through the balance of fiscal year 2023 with increased contribution from different market channels. At Mount Sinai Health System alone, we have now generated nearly 5,000 KidneyIntelX patient results including 835 in the quarter ended

June 2022 (Q4 of FY22), and another 974 in the most recent post-period quarter ended September 2022 (Q1 of FY23).

We issued over 1,200 patient KidneyIntelX test reports in the first quarter of fiscal 2023 (ended September 30), which is double the testing rate from a year earlier. With expanded insurance coverage, a growing number of these tests are now billable and revenue recognizable within 30 days.

Continuing to lower net expense

We have continued to reduce Company overhead with a keen eye toward advancing our best commercial opportunities – primarily regions with super-majority insurance coverage in the short term. As stated in August, we have taken action to lower annual expenditures by over $12 million through program, vendor and employee reductions, with additional opportunities to reduce expenditures under review.

In fiscal 2023, the fundamental goals are clear;

- building on diversified testing volume
- securing broad insurance coverage;
- continued evidence of real-world benefit of KidneyIntelX use in the clinic; and
- FDA authorization.

The early-stage kidney health market remains wide open, and we believe Renalytix is in a position to alter the cost landscape and maintain better health for some 15 million Americans with diabetes and kidney disease.

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.

Operational Progress
In the year ended 30 June 2022 ("FY22") and the immediate post-period, the Company saw KidneyIntelX expand within the Mount Sinai Health System and launch at Wake Forest Baptist Health, CDPHP, VA medical centers and among independent primary care physicians.

A full electronic health record (EHR) integrated deployment of KidneyIntelX with population health support in the Mount Sinai Health System has now yielded actionable reports on nearly 5,000 patients and growing. Utility results from our first real-world deployment at scale is yielding key evidence of the benefits of KidneyIntelX, particularly at the all-important primary care level. Patients and doctors are now clearly seeing benefits in the short-term from advanced risk assessment and follow-on action early in the disease cycle. Our experience with our physician-led health insurance partner, Capital District Physicians' Health Plan (CDPHP), in upstate New York has been equally robust.

Implementing with the veterans' affairs (VA) medical system has been slower than planned due to the complexities in introducing a new test and integrating its use into the VA system. However, we have now begun to overcome implementation hurdles and are beginning to see an increasing number of orders and corresponding testing volumes. We remain convinced that KidneyIntelX will play an important role nationally in the VA system which serves an estimated one million veterans with diabetes and kidney disease. Again, insurance coverage remains in place with a nationwide 10-year government insurance contract for KidneyIntelX payment throughout the VA system.

Expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website: www.kidneyintelx.com. We believe our education and support program will be an important resource to help inform and improve care for early-stage DKD patients and support future hospital system deployments of KidneyIntelX in the United States and abroad, which we believe could be achieved more rapidly as a result of the knowledge we have derived from our hospital system implementations to date.

Financing
In July 2019, we raised gross proceeds of $17.3 million in a follow-on financing on the AIM market, and in July 2020, we raised an additional $85.1 million in gross proceeds through an offering and concurrent dual-listing on the Nasdaq Global Market in the U.S.

In March 2022, we announced the completion of a financing package yielding $26.8 million in gross proceeds for the Company. The financing included

an $8.8 million equity subscription plus $21.2 million principal amount of convertible bonds (net cash proceeds of $18 million). We are pleased to have achieved the financing in an extremely challenging capital market environment, which we believe illustrates the strength of our kidney disease testing, monitoring and informed care advantages.

Clinical Evidence

Over the past few years, we have published and presented validation, utility and health economics data supporting KidneyIntelX adoption. Of particular note is the growing body of real-world utility evidence building on KidneyIntelX clinical reporting in different institutions through several thousand patients. Examples of published evidence includes:

Initial Forum	Cohort	Findings	Publication
ADA 81st Scientific Sessions 2020	Mount Sinai & UPenn (n=1,146)	KidneyIntelX more accurately predicted progressive kidney function decline and kidney failure than clinical metrics alone	Diabetologia 2021;64, 1504–1515
NKF Spring Clinical Meeting 2020	Simulation in patients with DKD stages 1-3b (n=100,000)	Analyses supported payer coverage for early-stage risk assessment and care management in the primary care office; projects significant savings from KidneyIntelX testing at primary care	Journal of Medical Economics 2021;24:972-982
ADA 82nd Scientific Sessions 2021	CANVAS (n=1,325)	KidneyIntelX algorithm published in Diabetologia and currently deployed commercially accurately predicted progression of DKD in this multinational clinical trial cohort	American Journal of Nephrology 2022;53:21–31
ISN World Congress of Nephrology 2021	CANVAS (n=1,026)	KidneyIntelX can be effective at monitoring therapeutic response and improvements in kidney health over time in adults with type 2 diabetes and DKD	American Journal of Nephrology 2022;53:21–31
NKF Spring Clinical Meetings 2021	PCPs (n=401)	KidneyIntelX test had greater relative importance than albuminuria and eGFR to PCPs in making treatment decisions and was second only to eGFR for nephrologist referrals.	American Journal of Managed Care 2022;28:In Press
ASN Kidney Week 2021	Mount Sinai RWE Cohort	KidneyIntelX testing enhanced patient understanding about kidney disease and revealed substantial motivation to take appropriate actions and receive further education for their kidney health.	Journal of the American Society of Nephrology 32: 2021
ISN World Congress of Nephrology 2022	Sinai/Penn (n=1,146)	KidneyIntelX provided robust prognostic information for future eGFR trajectories and adverse kidney outcomes beyond prior ascertainment of baseline kidney function, injury, or historical kidney function trajectories.	Kidney International Reports 2022; 7, S1–S436
ADA 83rd Scientific Sessions 2022	CANVAS (n=1,325)	KidneyIntelX provided risk stratification for a triple composite end point that included not only the kidney-specific outcome of progression, but also clinically relevant outcomes of hospitalizations for heart failure and all-cause mortality, even after adjusting for several other risk factors for these outcomes.	Kidney360 2022, 3;1599-1602
ADA 83rd Scientific Sessions 2022	Mount Sinai RWE Cohort (n=1,112)	KidneyIntelX showed utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients.	Pending
ASN Kidney Week 2022	Systematic Review and Meta-analysis (n=129 studies)	Systematic review and meta-analysis to summarize the prognostic value of preclinical plasma and urine biomarkers for CKD outcomes (incident CKD, CKD progression, or incident ESKD), including 129 studies in the meta-analysis. Pooled risk ratios (RRs) and 95% confidence intervals (Cis) among some of the most studied CKD biomarkers were 2.17 (1.91 to 2.47) for TNFR1 (31 studies); 2.07 (95% CI, 1.82 to 2.34) for TNFR2 (23 studies); 1.51 (95% CI, 1.38 to 1.66) for KIM-1 (18 studies).	Journal of the American Society of Nephrology 2022, 33:1657-1672
ADA – American Diabetes Association; NKF – National Kidney Foundation; ASN – American Society of Nephrology; ISN – International Society of Nephrology; RWE – Real world evidence; DKD – diabetic kidney disease			

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

Building KidneyIntelX into a standard of care in the United States and a global market with 850 million people with chronic kidney disease requires extensive data production, regulatory approvals, physician and patient education, and of course, comprehensive reimbursement. While it sometimes seems this set of milestones takes a long time to accomplish, we are reminded that Renalytix is still a young company that received its first funding less than four years ago. To have achieved real insurance coverage for KidneyIntelX testing in the complex U.S. market in such a short time we believe is extraordinary. We believe that since the data is comprehensive and showing clear benefit, acceleration of adoption is likely to continue to occur. The social need could not be higher to establish innovative preventative medicine strategies such as KidneyIntelX at the front-end of diabetes and kidney disease.

Operational progress continued into the first quarter of fiscal 2023 with over 1,200 tests performed. More than 80% of these were billable, yielding

about $1.0 million revenue for the quarter. These are record amounts for us in quarterly testing volumes and revenue.

We greatly appreciate the patience and continued support of our shareholders through these unusual times.

Financial Review

The results presented cover FY22. 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 $2.9 million in revenue in the financial year ended 30 June 2022 (“FY22”) which was comprised of $2.7m in revenue related to testing services as well as $0.2 million related to pharmaceutical services revenue.

Cost of Sales

The cost of sales associated with the services performed and commercial testing revenue was $2.1 million for FY22.

Administrative Costs

During FY22, administrative expenses totaled $58.3 million (financial year ended 30 June 2021 (“FY21”): $33.3 million). The major items of expenditure were general and administrative costs of which included $27.6 million in employee- related costs (FY21: $13.8 million), $12.9 million in subcontractors, legal, accounting, and other professional fees (FY21: $9.1 million), $6.4 million in external R&D Services, lab supplies and lab services(FY21: $1.4 million), $4.6 million in insurance (FY21: $4.6 million), $2.1 million in depreciation and amortization (FY21: $2.1 million), $1.9 million in marketing and public relations (FY21: $0.9 million), $1.7 in IT related costs (FY21: $0.6 million), $0.5 million in office related expenses including rent(FY21: $0.3 million), $0.3 million in stock exchange listing and filing fees (FY21: $0.2 million) and $0.3 million in other expenses (FY21: $0.3 million.

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

The Company accounts for the investment in Verici Dx equity securities at fair value, with changes in fair value recognized in the income statement. During the year ended 30 June 2022, we recorded a loss of $5.9 million to adjust the Verici Dx investment to fair value. During the year ended 30 June 2021, we recorded a gain of $6.5 million to adjust the Verici Dx 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 statements of operations 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 2022, we recorded a gain of $4.0 million to adjust the convertible notes to fair value. There was no fair value adjustment for the year ended 30 June 2021 as we had not issued convertible debt at that time.

Finance Income (Expense)

Finance income (expense) consists of foreign exchange gains or 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. During the year ended 30 June 2021, we recognized foreign currency losses of $8.8 million.

Balance Sheet

Inventory

Inventory consists of consumable materials used by the labs to carry out KidneyIntelX tests. During FY22, inventory levels increased due to purchases as the Company prepares for increased KidneyIntelX testing volumes. Inventory on hand at 30 June 2022 totaled $1.2 million (FY21: $0.4 million).

Fixed Assets

Property, plant, and equipment consists of laboratory equipment being used to support testing and product development activities. At 30 June 2022, the Company held $1.3 million in net property, plant, and equipment (FY21: $1.1 million).

Intangible Assets

The Group held $14.0 million net book value of intangible assets held at 30 June 2022 (FY20: $18.0 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 increased period over period due to capitalized software and the impact of foreign exchange translation at period end.

Investment in Verici

At the end of FY22 the Group held 9,831,681 shares in Verici Dx, the fair value of the investment in Verici Dx was $2.7 million at 30 June 2021 (FY20: $9.3 million)

Convertible Note

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount $21.2 million 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 2022, the Bonds had a fair value of $12.3 million.

Cash

The Group had cash on hand of $41.3m (FY21: $65.2m). Cash and equivalents are held in several deposit accounts in the US ($12.7m), UK ($28.3m) and IRE ($0.3m). Our expenditure plans remain sufficiently adaptable to align with available resources.

CONSOLIDATED INCOME STATEMENT
FOR THE YEAR ENDED 30 JUNE 2022

	Note	Year to June 30 2022	Year to June 30 2021

		$'000	$'000
Continuing operations			
Revenue	8	2,970	1,491
Cost of Sales		(2,052)	(804)
Gross Profit		**918**	**687**
Administrative expenses	9	(58,290)	(33,298)
Operating loss		**(57,372)**	**(32,611)**
Share of Net loss in Associate accounted for using the equity method		9	(199)
Impairment of Investment of associate	37	-	(1,913)
Gain (loss) on financial assets at fair value through profit or loss	24	(5,900)	6,483
Gain on distribution of assets classified as held for sale	36	-	402
Fair value adjustment of convertible debt		3,998	-
Finance (costs) income - net	14	9,637	(7,950)
Loss before tax		**(49,628)**	**(35,788)**
Taxation	15	(7,104)	4,778
Loss for the period		**(56,732)**	**(31,010)**
Earnings per Ordinary share from continuing operations			
Basic and diluted	16	$ (0.78)	$ (0.43)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE YEAR ENDED 30 JUNE 2022

	Year to 30 June 2022	Year to 30 June 2021
	$'000	$'000
Loss for the period – continuing operations	(56,732)	(31,010)
Other comprehensive income:		
Items that may be subsequently reclassified to profit or loss		
Currency translation differences	(11,206)	11,616
Other comprehensive loss for the period	**(67,938)**	**(19,394)**
Total comprehensive loss for the period	**(67,938)**	**(19,394)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2022

	Note	Group As at 30 June 2022 $'000	Group As at 30 June 2021 $'000	Company As at 30 June 2022 $'000	Company As at 30 June 2021 $'000
Assets					
Non-current assets					
Property, plant and equipment	18	1,368	1,081	-	-
Right of use asset	19	355	297	-	-
Intangible assets	20	14,020	18,021	13,605	17,524
Investment in subsidiaries	21	-	-	89,112	4,588
Investments accounted for using the equity method		9	-	-	-
Note receivable	22	75	75	-	-
Deferred tax assets	15	-	7,097	-	-
Total non-current assets		**15,827**	**26,571**	**102,717**	**22,112**
Current Assets					
Inventory	23	1,160	353	-	-
Security deposits	24	141	86	-	-
Assets classified as held for sale	36	-	-	-	-
Financial asset at fair value through profit or loss	24	2,744	9,295	2,744	9,295
Trade and other receivables	25	901	594	234	84,686
Prepaid and other current assets	26	1,152	520	299	271

Cash and cash equivalents	27	41,333	65,159	28,313	15,063
Total current assets		**47,431**	**76,007**	**31,590**	**109,315**
Total assets		**63,258**	**102,578**	**134,307**	**131,427**
Equity attributable to owners of the parent					
Share capital	28	241	233	241	233
Share premium	29	85,444	76,457	85,444	76,457
Share-based payment reserve	30	11,954	4,940	11,840	4,940
Foreign currency translation reserve		(1,509)	9,701	(5,119)	9,687
Retained earnings/(deficit)		(52,961)	3,771	23,763	38,917
Total equity		**43,169**	**95,102**	**116,169**	**130,234**
Liabilities					
Current liabilities					
Trade and other payables	31	7,281	6,652	5,796	1,193
Deferred Revenue	8	46	122	-	-
Current lease liabilities	19	163	86	-	-
Current liabilities		-	53	-	-
Note payable current	32	4,660	-	4,660	-
Current due to affiliated company	33	55	350	-	-
Total current liabilities		**12,205**	**7,263**	**10,456**	**1,193**
Non-current liabilities					
Note payable non-current		7,682	-	7,682	-
Non-current lease liabilities	19	202	213	-	-
Non-current due to affiliated company		-	-	-	-
Total non-current liabilities		**7,884**	**213**	**7,682**	**-**
Total liabilities		**20,089**	**7,476**	**18,138**	**1,193**
Total equity and liabilities		**63,258**	**102,578**	**134,307**	**131,427**

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 30 JUNE 2022

	Note	Group As at 30 June 2022 $'000	Group As at 30 June 2021 $'000	Company As at 30 June 2022 $'000	Company As at 30 June 2021 $'000
Cash flow from operating activities					
Loss before income tax		(49,628)	(35,788)	(15,154)	(7,718)
Adjustments for					
Depreciation		304	138	-	-
Amortization and impairment charges		2,309	1,958	2,100	1,806
Share-based payments		7,010	2,180	63	75
Share of net loss of associate		(9)	2,112	-	-
Reversal of Kantaro Liability		(295)	(495)	-	-
Gain on Sale of assets		-	(449)	-	-
Forgiveness of PPP Loan		-	(255)	-	-
Unrealized loss (Gain) on financial asset at fair value through profit or loss		5,900	(6,483)	5,900	(6,483)
Fair value adjustment of convertible debt		(3,998)	-	(3,998)	-
Foreign Exchange Loss (Gain)		(7,354)	8,832	-	2,939
Impairment of Investment in Subsidiary		-	-	-	517
Changes in working capital					
Trade and other receivables		(307)	(576)	-	(60,624)
Prepaid assets and other current assets		(698)	1,981	253	2,137
Assets classified as available for sale		-	-	-	-
Inventory		(807)	(27)	-	-

Security Deposits		-	(15)	-	-
Trade and other payables		1,904	3,753	1,417	943
Deferred Revenue		(76)	122	-	-
Payable to affiliated company		-	(1,623)	-	-
Cash used in operations		**(45,745)**	**(24,635)**	**(9,419)**	**(66,408)**
Interest paid		-	3	-	2
Net cash used in operating activities		**(45,745)**	**(24,632)**	**(9,419)**	**(66,406)**
Cash flow from investing activities					
Purchase of property, plant and equipment (PPE)		(591)	(783)	-	-
Lease Payments		-	(93)	-	-
Purchase of intangibles		(103)	(847)	(103)	(358)
Proceeds (purchase) of financial assets		-	982	-	-
Net cash generated by/(used in) investing activities		**(694)**	**(741)**	**(103)**	**(358)**
Cash flow from financing activities					
Proceeds from convertible notes		18,020	-	18,020	-
Payment of debt issuance costs		(1,382)		(1,382)	
Payments of issuance costs for the Securities Purchase Agreement		(218)	-	(218)	-
Issue of shares (net of issue costs)		8,804	76,876	8,804	79,023
Proceeds from the issuance of ordinary shares under employee share purchase plan		211	111	211	111
Proceeds from exercise of stock options		198	252	198	252
Lease payments		(118)	-	-	
Net cash generated from financing activities		**25,515**	**77,239**	**25,633**	**79,386**
Effect of exchange rate changes on cash		(2,902)	-	(2,861)	-
Net increase/(decrease) in cash and cash equivalents		**(23,826)**	**51,866**	**13,250**	**12,622**
Cash and cash equivalents at beginning of period		65,159	13,293	15,063	2,441
Cash and cash equivalents at end of period	22	**41,333**	**65,159**	**28,313**	**15,063**

COMPANY CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 30 JUNE 2022

	Share Capital	Share Premium	Share-based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
	$'000	**$'000**	**$'000**	**$'000**	**$'000**	**$'000**
At 30 June and 1 July 2020	192	-	2,833	(1,915)	34,852	35,962
Comprehensive income						
Loss for the period	-	-	-	-	(31,010)	(31,010)
Other comprehensive income						
Currency translation differences	-	-	-	11,612	4	11,616
Total comprehensive income	**-**	**-**	**-**	**11,612**	**(31,006)**	**(19,394)**
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,101	-	-	-	85,141
Less issue costs	-	(9,007)	-	-	-	(9,007)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	111	-	-	-	111
Exercise of Stock Options	1	252	-	-	-	253
Verici Ordinary Share Repurchase	-	-	-	-	(75)	(75)
Total transactions with owners of the parent, recognized directly in equity	**41**	**76,457**	**2,107**	**-**	**(75)**	**78,530**
At 30 June and 1 July 2021	**233**	**76,457**	**4,940**	**9,697**	**3,771**	**95,098**
Comprehensive income						
Loss for the period	-	-	-	-	(56,732)	(56,732)
Other comprehensive income						
Currency translation differences	-	-	4	(11,206)		(11,202)
Total comprehensive income	**-**	**-**	**4**	**(11,206)**	**(56,732)**	**(67,934)**

Transactions with owners						
Issuance of Ordinary Shares in US IPO	8	8,796	-	-	-	8,804
Less issue costs	-	(218)	-	-	-	(218)
Share-based payments	-	-	7,010	-	-	7,010
Shares issued under the ESPP	-	211	-	-	-	211
Exercise of Stock Options	-	198	-	-	-	198
Total transactions with owners of the parent, recognized directly in equity	**8**	**8,987**	**7,010**	**-**	**-**	**16,005**
At 30 June 2022	**241**	**85,444**	**11,954**	**(1,509)**	**(52,961)**	**43,169**

COMPANY CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 30 JUNE 2022

	Share Capital	Share Premium	Share-based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
	$'000	**$'000**	**$'000**	**$'000**	**$'000**	**$'000**
At 30 June and 1 July 2020	192	-	2,833	(1,970)	46,710	47,765
Comprehensive income						
Loss for the period	-	-	-	-	(7,718)	(7,718)
Other comprehensive income						
Currency translation differences	-	-	-	11,657		11,657
Total comprehensive income	**-**	**-**	**-**	**11,657**	**(7,718)**	**3,939**
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,101	-	-	-	85,141
Less issue costs	-	(9,007)	-	-	-	(9,007)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	111	-	-	-	111
Exercise of Stock Options	1	252	-	-	-	253
Verici Ordinary Share Repurchase	-		-	-	(75)	(75)
Total transactions with owners of the parent, recognized directly in equity	**41**	**76,457**	**2,107**	**-**	**(75)**	**78,530**
At 30 June 2021	**233**	**76,457**	**4,940**	**9,687**	**38,917**	**130,234**
Comprehensive income						
Loss for the period	-	-	-	-	(15,154)	(15,154)
Other comprehensive income						
Currency translation differences	-	-	-	(14,806)		(14,806)
Total comprehensive income	**-**	**-**	**-**	**(14,806)**	**(15,154)**	**(29,960)**
Transactions with owners						
Issuance of Ordinary Shares in US IPO	8	8,796	-	-	-	8,804
Less issue costs	-	(218)	-	-	-	(218)
Share-based payments	-	-	6,900	-	-	6,900
Shares issued under the ESPP	-	211	-	-	-	211
Exercise of Stock Options	-	198	-	-	-	198
Total transactions with owners of the parent, recognized directly in equity	**8**	**8,987**	**6,900**	**-**	**-**	**15,895**
At 30 June 2022	**241**	**85,444**	**11,840**	**(5,119)**	**23,763**	**116,169**

NOTES FORMING PART OF 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 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 2022, 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 2022 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 IFRS 1, IAS 3, IFRS 17

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. This included the review of internal budgets and financial results which show, taking into account reasonably probable changes in financial performance, that the Group and Company should be able to operate within the level of its current funding arrangements.

We have not yet seen any material disruption to our business as a result of the COVID-19 pandemic and current trading suggests that our base case forecasts are still applicable.

The Directors believe that the Group and the Company have adequate resources to continue in operation for the foreseeable future. For this reason, they have adopted the going concern basis in the preparation of the financial statements.

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.

On 23 October 2018 as part of a pre-admission reorganization, the Company acquired the entire share capital of Renalytix AI, Inc., then a subsidiary of EKF. Given common ownership of the Company and the subsidiary from incorporation up to the date of legal ownership, the transaction has been treated as a group reorganization with no fair value adjustments to assets or liabilities. The subsidiary has been consolidated within the results of the Group from the date of incorporation.

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 licences
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 amortization. Amortization 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 amortization.

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 amortized over the estimated useful life of the products with which they are associated. Amortization commences when a new product is in commercial production. The amortization 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. Amortization 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 amortization. Amortization has not yet commenced.

Impairment of non-financial assets
Assets that have an indefinite life or where amortization has not yet commenced are tested annually for impairment. Assets that are subject to amortization 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 amortized 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 amortized 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 recognise 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 amortized 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. Segmental Reporting

The Group operates as a single segment.

5. Income Tax

	Year ended 30 June 2022	Year ended 30 June 2021
Group	**$'000**	**$'000**
Deferred tax	-	4,778
Total deferred tax	-	4,778
Income tax credit	-	4,778

No deferred asset is calculated on losses in FY22 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 19%.

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 2022	Year ended 30 June 2021
	$'000	**$'000**
Loss before Tax	49,628	35,788
Tax Calculated at domestic tax rates applicable to the UK Standard of tax at 19%	9,429	6,800
Tax effects of:		
Expenses not deductible for tax purposes	4,490	(487)
Losses on which no deferred tax asset is recognized	(578)	(1,535)
Tax Credit for the Year	**13,341**	**4,778**
Current year Valuation Allowance	(13,341)	4,778
Prior year Deferred Tax	7,097	2,319
Reversal of tax asset at 30 June	(7,097)	7,097
Tax Expense	(7)	-
Total Income Tax Expense	**(7,104)**	**7,097**

Deferred tax assets are recognized based on subsidiary net losses based on the US corporate tax rate of 21%. 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 an impaired the deferred tax asset in current year. No deferred asset is calculated on losses in the UK totaling $15,155,000 where the probability of future utilization is considered too remote.

6. Earnings Per Share

Basic earnings per share is calculated by dividing the loss attributable to equity holders of the parent by the weighted average number of ordinary shares in issue during the period.

	Year ended 30 June 2022	Year ended 30 June 2021
	$'000	$'000
Loss attributable to owners of the parent	(56,648)	(31,010)
Weighted average number of ordinary shares in issue	72,836,424	71,484,934
Basic and diluted loss per share	$ (0.78)	$ (0.43)

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.

The Company has two categories of dilutive potential ordinary share, being share options and convertible debt. The potential shares were not dilutive the period and prior period as the Group made a loss.

7. Investments in Subsidiaries

	At 30 June 2022	At 30 June 2021
Company	$'000	$'000
At beginning of Period	4,588	2,264
Capital Contribution relating to share based payment	2,824	2,325
Conversion of intercompany loan to equity investment	81,700	
Shares in Verici Dx Ltd	-	(1)
At End of Period	89,112	4,588

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 2022.

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

1. 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.
2. 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.

8. 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.

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, 2020, 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 at June 30, 2022, to be provided under the Advisory Agreement was $0.1 million. A gain of $0.01 million was recognized within equity in gain (losses) of affiliate the accompanying consolidated statements of operations and comprehensive loss.

In addition to the equity granted at formation, 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 $83,333 and an additional $0.2 million thereafter. Each loan bears interest at a per annum 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). In the year ended 30 June 2021, the Company loaned Kantaro the full $250,000 however later recorded a reserve of $175,000 based on uncertainty regarding collectability and had a remaining $75,000 note receivable at June 30, 2022.

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.

Additionally, Mount Sinai participated in our April 2022 equity offering and purchased 551,724 ADSs. This purchase was made through the underwriters at the offering price of $7.25 per ADS.

9. Reconciliation of IFRS to U.S. GAAP

Since Renalytix 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 20-F, which is based on US GAAP, contains differences from its Annual Report, which is based on IFRS. The Form 20-F and Annual Report will be available on the Company's website (www.renalytix.com) once filed. 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 except share and per share amounts)

	GAAP As at 30 June 2022	IFRS As at 30 June 2022	GAAP vs IFRS Difference	
Assets				
Cash	$ 41,333	$ 41,333	$ -	
Accounts receivable	901	901	-	
Prepaid expenses and other current assets	2,445	2,453	(8)	(a)
Note receivable – Kantaro	75	75	-	
Property, plant and equipment, net	2,558	1,368	1,190	(b)
Intangibles, net	-	14,020	(14,020)	(c)
Investment in Verici	2,744	2,744	-	
Investment in Kantaro	9	9	-	
Right of use asset		355	(355)	(d)
Total assets	50,065	63,258		
Liabilities and stockholders' equity				
Current Liabilities:				
Note payable – current	4,660	4,660		
Accounts payable	2,459	7,281	(266)	(e)
Accrued expenses and other current liabilities	3,060	-		
Accrued expenses – related party	1,496	-		
Current lease liability	-	163	(163)	(d)
Payable to Kantaro - current	55	55		
Deferred Revenue	46	46		
Total current liabilities	11,776	12,205		
Note payable – noncurrent	7,682	7,682		
Noncurrent lease liabilities	-	202	(202)	(d)
Total Liabilities	19,458	20,089		
Stockholders' (deficit) equity:				
Ordinary shares, £0.10 nominal value: 56,011,831 shares authorized; 20,000,000 and 53,816,134 shares issued and outstanding at June 30, 2018 and 2019, respectively	228	241	13	(f)
Additional paid in capital	164,012	97,398	(66,614)	(g)
Accumulated other comprehensive (loss) income	(915)	(1,509)	(594)	(h)
Accumulated deficit	(132,718)	(52,961)	79,757	(i)
Total stockholders' (deficit) equity	30,607	43,169		
Total liabilities and stockholders' (deficit) equity	50,065	63,258		

(a) Represents other immaterial presentation differences between US GAAP & IFRS
(b) Differences is attributable to capitalized software costs which are recorded as property and equipment under U.S. GAAP and Intangibles under

IFRS.
(c) 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.
(d) Represents the adoption of IAS 17 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.
(e) Accounts payable and other current liabilities are presented in the aggregate within the Annual report while broken out separately on the US GAAP 6-k. Difference represents other immaterial presentation differences and audit adjustments.
(f) Represents other immaterial audit adjustments
(g) 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.
(h) Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
(i) 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 June 2022	
Net loss in accordance with IFRS	**(56,732)**	
Deferred tax assets	7,104	(a)
Stock compensation expense	2,389	(b)
Amortization of intangibles	1,981	(c)
Other adjustments	(18)	(e)
Total adjustments	11,456	
Net loss in accordance with US GAAP	**(45,276)**	

(a) Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realized based on available evidence. Historically, under U.S. GAAP, a full valuation allowance has been applied. Historically, under IFRS a partial valuation allowance was applied however a full valuation allowance was booked in the current year which resulted in the increased tax expense.
(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.
(c) Amortization 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.
(d) This difference is attributable to the differences in accounting treatment of the distribution in specie of Verici Dx to Renalytix shareholders and subsequent deconsolidation of the Verici entity under IFRS and US GAAP.
(e) The remaining difference represents the aggregation other immaterial audit adjustments and small accounting standard difference.