Renalytix Reports Full Year Fiscal 2021 Results

October 21, 2021

LONDON and SALT LAKE CITY, Oct. 21, 2021 (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 results for the twelve months ended 30 June 2021.

Highlights:

Regulatory & Reimbursement

- Government-wide contract granted by the U.S. General Services Administration for KidneyIntelX™ testing services at $950 per reportable result; applies to more than 140 U.S. government departments, agencies, and affiliates including U.S. Veterans Administration (VA), Department of Defense military branches (Army, Navy, Air Force, and Marines), and Indian Health Services
- Accepted provider in 27 Medicaid state programs (including post-period approvals) with additional applications pending
- Ongoing process with Medicare Contractor organizations for Medicare local coverage
- Positive coverage determinations from 20 regional and local private health insurance payors to date including the first Blue Cross Blue Shield coverage contract and coverage with HealthFirst, one of New York State's largest not-for-profit health insurance companies with over 1.5 million members
- Ongoing process with FDA towards anticipated De Novo marketing authorization under Breakthrough Device designation
- Full CLIA certification of Salt Lake City laboratory facility.

Commercial / Partnerships

- KidneyIntelX launched within the Mount Sinai Health System, validating the electronic health record (EHR) integrated care pathway; subsequent (post-period) volume scale-up announced
- Collaboration with AstraZeneca to develop and launch precision medicine strategies for cardiovascular, renal and metabolic diseases to potentially expand Renalytix's portfolio
  Partnership with Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement advanced clinical care models to improve kidney health and reduce kidney disease progression and kidney failure; expected go-live testing starting in November
- Partnership with the University of Utah to implement KidneyIntelX and advanced clinical management care pathway to reduce the risk of kidney failure
- Collaboration with DaVita to enable first-of-its-kind program combining early risk assessment and comprehensive care management to improve early to late-stage patient outcomes and provide meaningful cost reductions for health care providers
- Exclusive option to license novel biomarkers with Joslin Diabetes Center, which could provide additional clinical utility for understanding early disease progression, risk of kidney failure, therapeutic response, and the mechanistic pathways of kidney disease beyond the markers that are currently captured by KidneyIntelX.

Operations & Finance

- Senior leadership and management hires in preparation for expanded commercialization
- Achieved dual listing on Nasdaq Global Market and associated $85.1 million gross equity financing
- Completed spin-out of Verici Dx; shares in Verici were distributed to Renalytix shareholders, and Verici subsequently listed on the AIM market of the London Stock Exchange
- Cash and equivalents of $65.1 million at 30 June 2021.

Clinical / Validation

- Peer-reviewed publication in Diabetologia demonstrating KidneyIntelX more accurately predicted progressive kidney function decline and kidney failure in a multi-center, diverse cohort of 1,146 type 2 diabetes patients with early-stage (stages 1-3) kidney disease versus the current standard of care
- Data presented at World Congress of Nephrology (WCN) showing that the KidneyIntelX algorithm published in Diabetologia and currently deployed commercially accurately predicted progression of diabetic kidney disease (DKD) in a multinational cohort from the CANagliflozin CardioVAScular Assessment Study (CANVAS) with early-stage DKD (stages 1-3)

- Data presented at the American Diabetes Association (ADA) Annual Scientific meeting from the CANVAS trial demonstrating KidneyIntelX can be effective at monitoring therapeutic response and improvements in kidney health over time in adults with type 2 diabetes
- Peer-reviewed submission accepted by American Journal of Nephrology summarizing the aforementioned findings presented at the WCN and ADA from the analyses in the CANVAS clinical trial cohort.

Post Period End

- Scale-up of Mount Sinai Health System KidneyIntelX population health care-navigated risk assessment program with a target run rate of 300 patient tests per week
- Launch program for KidneyIntelX initiated for Veterans Health Administration with target of 43 sales personnel plus supporting medical science liaison and technical infrastructure
- Achieved first Blue Cross Blue Shield private insurance coverage contract in October 2021
- Welcomed new board members Ann Berman and Daniel Levangie both with extensive backgrounds in healthcare company growth and finance
- 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 savings from KidneyIntelX testing at primary care level.

Investors are advised to read the results for the 12 months ended 30 June 2021, 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. (EDT) / 1:30 p.m. (BST) on Thursday 21 October 2021. 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:
US/Canada Participant Toll-Free Dial-In Number: (833) 614-1551
US/Canada Participant International Dial-In Number: (914) 987-7290
United Kingdom International Dial-In Number: 0800 0288 438
United Kingdom Local Dial-In Number: 0203 1070 289
Conference ID:6364722

Webcast Registration link: https://edge.media-server.com/mmc/p/r4ezp7bk

For further information, please contact:

Renalytix plc — www.renalytix.com
James McCullough, CEO — **Via Walbrook PR**

Stifel (Nominated Adviser, Joint Broker) — **Tel: 020 7710 7600**
Alex Price / Nicholas Moore

Investec Bank plc (Joint Broker) — **Tel: 020 7597 4000**
Gary Clarence / Daniel Adams

Walbrook PR Limited — **Tel: 020 7933 8780** or renalytix@walbrookpr.com
Paul McManus / Lianne Applegarth — Mob: 07980 541 893 / 07584 391 303

CapComm Partners — **Tel: 415-389-6400** or investors@renalytix.com
Peter DeNardo

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 (NASDAQ: RNLX) (LSE: RENX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that successfully 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 21, 2021, 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.

INTERIM CHAIRMAN & CEO'S JOINT REVIEW

We are delighted to present preliminary results for the twelve months ended 30 June 2021 for Renalytix plc.

About Renalytix

At Renalytix, we are helping lead the charge to introduce simple, 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 close to an estimated 40 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 physicians is essential if we are to stem the growing social cost and suffering associated with kidney disease.

With our lead product, KidneyIntelX, our goal is to continue shifting the conversation from kidney disease to kidney health through a more accurate understanding of patient risk early on. With KidneyIntelX deployment this year, Renalytix is the global leader in the new field of bioprognosis, a biology-driven approach to risk assessment that relies on integrating 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.

We have crossed key data, reimbursement and regulatory hurdles during a relatively short time-period since we opened our doors in 2018 through a public listing on AIM, a market of the London Stock Exchange. We subsequently expanded our capital base by raising an additional $85 million through a listing on the Nasdaq Global Market in July 2020. The commercial roll-out of our kidney health solution, KidneyIntelX, is underscored by:

- A 10-year government-wide contract by the U.S. General Services Administration at $950 per test
- Hiring of sales, medical science liaison, and customer service support for national coverage
- The Centers for Medicare & Medicaid Services awarding a national price of $950 per test
- 27 state Medicaid program authorization contracts
- Partnerships announced with the Mount Sinai Health System, University of Utah, Atrium Health, Wake Forest Baptist Health, and Capital District Physicians' Health Plan (CDPHP)
- New York State Department of Health approval
- A distinct Common Procedural Terminology (CPT) Code for reimbursement granted by the American Medical Association
- Over 17 private payor coverage determinations
- Multi-center, peer reviewed clinical studies that found KidneyIntelX is 72% more effective than the current standard of care in identifying early-stage patients at high risk for kidney disease progression and failure

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 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. We believe this predicament is largely avoidable and have built the KidneyIntelX care model to ultimately equip the estimated 210,000 primary care physicians in the United States with a comprehensive suite of information and guidelines driven follow-on action.

KidneyIntelX was designed as an expandable platform which is able to add indicated uses and a monitoring capability, all within an FDA regulated framework. Expansion may include extending into additional populations of CKD patients beyond those with diabetes, including patients of African ancestry with the APOL1 high-risk genotype. We also intend to develop solutions for use in other large chronic disease patient populations, like cardiovascular disease.

Operational Progress

In the year ended 30 June 2021 ("FY21") and the immediate post-period, the Company expanded its announced partnership base to include the University of Utah Health System, Atrium Health and Wake Forest Baptist Health. In September 2021, Mount Sinai Health System and Renalytix announced a scale-up of the KidneyIntelX care program to a targeted run-rate of 300 tests per week. Renalytix testing is fully covered at $950 per test under the Mount Sinai real-world evidence program and we expect an estimated 6,000 tests to be completed by the end of fiscal 2022. We expect that Atrium Health, Wake Forest Baptist Health and University of Utah will be running live testing as early as December 2021.

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 diabetic kidney disease ("DKD") patients and support future hospital system deployments of KidneyIntelX in the United States and abroad.

The Company also continues to execute on a number of key operational items including (1) growing our world-class employee base and leadership team to manage U.S. national commercial expansion, (2) developing expanded products which will add to the KidneyIntelX clinical use cases and addressable market, (3) adding laboratory services capacity with our facility in Salt Lake City, Utah, and (4) generating additional utility and validation data to build-out our peer-reviewed performance data dossier.

Reimbursement and Regulatory

We have achieved full insurance coverage for U.S. government physicians ordering of KidneyIntelX through our granted General Services Administration (GSA) and are moving assertively to activate our VA Health System sales strategy. We estimate there is full coverage available at $950 per test to an estimated 400,000 DKD patients in the VA Health System alone.

Under our agreement with the Mount Sinai Health System, we receive payment for KidneyIntelX testing at $950 per reportable result through the first approximately 6,000 patients tested under a real-world evidence development program. In October, this program was expanded system-wide and Mount Sinai is working to achieve a weekly testing run rate of 300 patients.

The recent government proposal to repeal the Medicare Coverage of Innovative Technologies (MCIT) rule was disappointing. However, the earlier delay of MCIT implementation from May to December 2021 had already decreased the rule's potential value to Renalytix given the existing planning for a local Medicare coverage determination which was underway before MCIT was announced in January 2021. Ultimately, we do not see a material impact on our business plan if MCIT is ultimately repealed and believe Medicare payment for KidneyIntelX at $950 per reportable result can be achieved by the summer of 2022. We estimate that over four million DKD patients are covered under Medicare and, in certain metro markets such as our New York City launch market, Medicare represents a majority of insured DKD patients.

As we have previously reported, KidneyIntelX has achieved both a distinct Common Procedural Terminology ("CPT") reimbursement code 0105U and inclusion in the final 2020 Clinical Laboratory Fee Schedule ("CLFS") by CMS which set a national price for KidneyIntelX at $950 per reportable test result.

As has been experienced broadly across the diagnostics industry, KidneyIntelX has had a prolonged review since our De Novo submission in August of 2020 due to FDA staffing challenges and continued prioritization of a significant number of COVID-19 related Emergency Use Authorization submissions. Across a number of applications, the FDA is not currently meeting ITS 150-day De Novo review goal in MDUFA IV due to "considerable increases in COVID-19 activities" and this is not unique to Renalytix. We are committed to working collaboratively and expeditiously with the FDA and continue to provide additional information, clarification and supplemental analyses related to our novel KidneyIntelX design as requested. While we will continue to decline to forecast projecting a definitive timeline for De Novo marketing authorization, we are confident that KidneyIntelX will receive FDA De Novo marketing authorization given interactive dialogue and data requirements to date and that Fiscal 2022 commercial objectives are on track.

Strategic Collaborations

An innovative partnership with AstraZeneca (LSE/STO/NYSE: AZN) was secured in the period to develop and launch precision medicine strategies for cardiovascular, renal and metabolic diseases. The first stage in the collaboration is examining the uptake of, and patient adherence to, treatments for diabetes as well as common complications of CKD, including hyperkalemia and anemia. This will provide key insights into the impact of the KidneyIntelX platform to optimize utilization of therapeutics in CKD under current standard of care protocols. Importantly, this collaboration extends the potential impact of KidneyIntelX to populations beyond the first indicated use, DKD, that is approved with New York State and under breakthrough review with the FDA.

In January 2021, we entered into a partnership with DaVita (NYSE: DVA) for a program aimed at slowing disease progression and improving health outcomes in CKD patients by enabling earlier intervention for patients with early-stage kidney disease through actionable risk assessments and end-to-end care management. After risk stratification using KidneyIntelX, program patients identified as intermediate- and high-risk are expected to receive care management support through DaVita's integrated kidney care program.

In February 2021, we entered into a partnership with the University of Utah to implement KidneyIntelX in combination with a range of advanced clinical management solutions to optimize patient care and drive towards improved outcomes system-wide at University of Utah Health, which serves millions of patients in six states. Core to this partnership is the implementation of care navigation and pharmacy programs, behavioral and health economic assessments, together with data-driven analytics. KidneyIntelX will be deployed directly into the EHR system at University of Utah Health, enabling access to more than 1,700 clinicians for seamless test ordering and patient risk score reporting as part of the standard clinical workflow.

In May 2021, we entered into a partnership with Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement an advanced clinical care model to improve kidney health and reduce kidney disease progression and kidney failure. Through these partnerships, KidneyIntelX access will be enabled to primary care physicians, endocrinologists, nephrologists and care teams in 37 hospitals and more than 1,350 care locations across the Carolinas and Georgia.

Financing

Renalytix has continued to benefit from the participation of a growing investor base. In July 2019, we raised gross proceeds of $17.3 million in a following-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. The Directors believe our company is now well positioned to build on our competitive advantages.

In November 2020, the Company completed a spin-out of Verici Dx (previously known as FractalDx). Shares in Verici were distributed to Renalytix shareholders in July, 2020, and Verici subsequently listed on the AIM market of the London Stock Exchange in November, 2020. Renalytix retains a minority equity interest in Verici.

Patient Studies

During fiscal year 2021 and in the post-period, several publications and presentations supporting KidneyIntelX were disseminated, including:

- Peer-reviewed publication in Diabetologia demonstrating KidneyIntelX more accurately predicted progressive kidney

function decline and kidney failure in a multi-center, diverse cohort of 1,146 type 2 diabetes patients with early-stage (stages 1, 2, and 3) kidney disease versus the current standard of care

- Data presented at World Congress of Nephrology (WCN) showing that the KidneyIntelX algorithm published in Diabetologia and currently deployed commercially accurately predicted progression of diabetic kidney disease (DKD) in a multinational cohort from the CANagliflozin CardioVAScular Assessment Study (CANVAS) with early-stage DKD (stages 1-3)
- Data presented at the American Diabetes Association (ADA) Annual Scientific meeting from the CANVAS trial demonstrating KidneyIntelX can be effective at monitoring therapeutic response and improvements in kidney health over time in adults with type 2 diabetes
- Peer-reviewed submission accepted by American Journal of Nephrology summarizing the aforementioned findings presented at the WCN and ADA from the analyses in the CANVAS clinical trial cohort
- Peer-reviewed publication in Journal of Medical Economics supports payer coverage for early-stage risk assessment and care management in the primary care office; projects significant savings from KidneyIntelX testing at primary care level

Intellectual Property

In the period, 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.

Real World Evidence Program

Through our growing number of health system partnerships, pharmaceutical collaborations and payor models, we are creating a comprehensive real-world evidence (RWE) and data generation program including the previously announced programs at Mount Sinai, Wake Forest / Atrium Health and Utah Health. The primary objective is to demonstrate the clinical and economic impact of KidneyIntelX informed care management in large populations and we expect to expand the scale of this program with extensive publication and dissemination of the results.

Additionally, through these Institutional Review Board (IRB)-approved and patient consented studies we will be amassing or have access to a large biorepository of urine, blood and DNA samples (already planned to exceed 10,000 patients) linked to comprehensive longitudinal patient data which will help accelerate the development of diagnostic products and data solutions for kidney disease and related complications and co-morbidities.

Importantly, we are actively pursuing opportunities to leverage the KidneyIntelX platform and this unique RWE program focused on chronic condition management at primary care to other indications, most notably cardiovascular disease, heart failure and liver disease.

A further significant value creation aspect of our RWE program is the enablement and deployment of our comprehensive digital health and data strategy. This program provides an invaluable access to users and insights that inform the features we are building into our digital technology and data platforms.

Additional Business

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS- CoV-2 originally developed by Mount Sinai. Owing to a shift in focus from COVID-19 antibody testing to promoting vaccination in the United States and European Union, Kantaro saw a decrease in demand for COVID-19 antibody testing, lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees.

Expansion of Product Portfolio

We believe there are significant opportunities to expand our technology platform through incremental version releases of KidneyIntelX as well as through extending KidneyIntelX application into additional populations of CKD patients beyond those with diabetes, including patients of African ancestry with the APOL1 high-risk genotype. We also intend to develop solutions for use in other large chronic disease patient populations, like cardiovascular disease. KidneyIntelX has been designed within a regulated, manufacturing-quality environment to allow us to take advantage of the dynamic nature of machine learning to improve product performance through a sequence of controlled version releases. We believe that our product development approach, which is based on a quality systems framework following FDA's Quality System Regulations and the ISO guidelines applicable to medical devices, will enable our KidneyIntelX platform to rapidly generate exponential data growth and new clinical use cases, with a clearer path to achieving the regulated and reimbursed introduction and subsequent product improvements of an artificial intelligence-powered in vitro diagnostic.

Continued Expansion of People

Our executive team has an average of 25 years' experience in professional disciplines including bioinformatics, digital health, data security, market access, commercial operations, medical affairs, insurance reimbursement, FDA regulation and International Organization for Standardization, or ISO, quality management systems, population health, clinical medicine, finance and health economics. We believe the integration of such diverse experience is essential to understanding the complex dynamics of deploying a new technology into the highly regulated world of patient clinical care, and we have assembled our team specifically with this multi-disciplinary approach in mind.

We have continued to invest in key hires on the board and in management to support the commercialization pathway. During FY21, we filled positions including a VP of global quality and regulatory appointment, VP of sales, VP and director of commercial partnerships, VP of marketing, among others. Post period end, we appointed Ann Berman and Daniel Levangie to the board of directors, both bringing extensive commercial operating and leadership experience to the Company. Jed Fulk was appointed as vice president of sales, government accounts to develop and lead a team to support the KidneyIntelX rollout to the VA Health System.

Outlook

We believe KidneyIntelX is a powerful, actionable prognostic tool that can inform clinical pathways to slow the progression of kidney disease and potentially prevent the occurrence of progressive kidney function decline such as kidney failure and the need for long-term dialysis or kidney transplant. We are building a body of evidence through clinical validation studies and patient data generation to demonstrate that accurate and early identification of high-risk patients, coupled with guidelines-driven clinical recommendation designed to maximize patient treatment and compliance,

can have a measurable positive impact on patient quality of life and significantly lower healthcare costs. By involving a broad range of expert clinical opinions, testing a growing number of patient samples, consulting closely with clinical society and patient advocacy organizations, partnering with healthcare systems and payors and developing a detailed understanding of the clinical practice environment, we believe KidneyIntelX will help ease suffering and improve outcomes for patients living with DKD.

Financial Review

The preliminary results presented cover the fiscal year ended June 30, 2021 (FY21). Full audited financial results will be included within the company's FY21 Annual Report. The presentational currency for Renalytix plc and its subsidiaries (together, the "Group") is the United States Dollar.

Income Statement

Revenue

The Group recognized revenue of $1.5m in the financial year ended 30 June 2021 ("FY21") related to services performed as well as the successful launch of commercial testing in the second half of the financial year.

Cost of Sales

The cost of sales associated with the services performed and commercial testing revenue was $0.8m for FY21.

Administrative Costs

During FY21, administrative expenses totaled $33.3m (financial year ended 30 June 2020 ("FY20"): $11.1m). The major items of expenditure were general and administrative costs of $22.9m (FY20: $9.9m) which included $13.8m in employee-related costs (FY20: $4.6m), $9.1m in subcontractors, legal, accounting, and other professional fees (FY20: $3.0m), and $8.3m in insurance, marketing, materials, rent, and other administrative costs (FY20: 2.3m). Depreciation and amortization expense totaled $2.1m for the period (FY20: $1.2m).

Finance Income (Expense)

Finance expense totaled $3.2m during FY21 (FY20: $0.5m income) related to unrealized foreign exchanges losses and an impairment of the investment in Kantaro offset by mark to market adjustments related to Verici securities, interest income and other income related to PPP loan forgiveness.

Balance Sheet

Inventory

Inventory consists of consumable materials used by the labs to carry out KidneyIntelX tests. During FY21, inventory levels increased slightly due to purchases as the company prepares for increased KidneyIntelX testing volumes. Inventory on hand at 30 June 2021 totaled $0.4m (FY20: $0.3).

Fixed Assets

Property, plant, and equipment consists of laboratory equipment being used to support testing and product development activities. At 30 June 2021, the company held $1.0m in net property, plant, and equipment (FY20: $0.6m).

Intangible Assets

The Group held $15.8m net book value of intangible assets held at 30 June 2021 (FY20: $17.1m) includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying KidneyIntelX, as well as amounts capitalised 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 amortization.

Deferred Tax

A deferred tax asset totaling $7.1m (FY20: $2.3m) has been calculated based on the accumulated tax losses in the U.S.

Investment in Verici

In the first half of FY21 the Group converted the note receivable into equity in Verici Dx. At the end of FY21 the group held 9,831,681 shares in Verici Dx. The fair value of the investment in Verici Dx was $9.3 million at June 30, 2021.

Cash

The Group had cash on hand of $65.2m (FY20: $13.3m). Cash and equivalents are held in several deposit accounts in the US ($64.0m), UK ($1.1m) and IRE ($0.1m). Our expenditure plans remain sufficiently adaptable to align with available resources.

Borrowings

The Group has no long-term debt outstanding as of 30 June 2021.

CONSOLIDATED INCOME STATEMENT
FOR THE YEAR ENDED 30 JUNE 2021

	Note	Period to 30 June 2021	Period to 30 June 2020
		$'000	$'000
Continuing operations			
Revenue		1,491	-
Cost of Sales		(804)	-
Gross Profit		687	
Administrative expenses		(33,298)	(11,078)
Operating loss		**(32,611)**	**(11,078)**
Share of Net loss in Associate		(199)	

Finance income - net		(2,977)	468
Loss before tax		**(35,787)**	**(10,610)**
Taxation	5	4,778	1,360
Loss for the period		(31,009)	(9,250)
Earnings per Ordinary share from continuing operations			
Basic and diluted	6	$ (0.43)	$ (0.16)

CONSOLIDATED STATEMENT OF COMPREHENSIVE INCOME
FOR THE YEAR ENDED 30 JUNE 2021

	Period to 30 June 2021	Period to 30 June 2020
	$'000	**$'000**
Loss for the period – continuing operations	(31,009)	(9,250)
Other comprehensive income:		
Items that may be subsequently reclassified to profit or loss		
Currency translation differences	9,705	(1,265)
Other comprehensive loss for the period	**(21,304)**	**(10,515)**
Total comprehensive loss for the period	**(21,304)**	**(10,515)**

CONSOLIDATED STATEMENT OF FINANCIAL POSITION
AS AT 30 JUNE 2021

		Group	Group	Company	Company
		As at 30 June 2021	As at 30 June 2020	As at 30 June 2021	As at 30 June 2020
	Notes	$'000	$'000	$'000	$'000
Assets					
Non-current assets					
Property, plant and equipment		1,081	580	-	-
Right of use asset		297	365	-	-
Intangible assets		15,812	17,118	15,314	16,841
Investment in subsidiaries	7	-	1,937	4,588	2,264
Note receivable		75	83	-	2,106
Deferred tax assets	5	7,097	2,319	-	-
Total non-current assets		24,362	22,402	19,903	21,211
Current Assets					
Inventory		353	326	-	-
Security deposits		86	71	-	-
Assets held for sale		-	1,705	-	-
Investment in Verici Dx		9,295	-	9,295	
Trade and other receivables		594	18	84,573	21,956
Prepaid and other current assets		520	2,501	271	2,408
Financial assets		-	982	-	-
Cash and cash equivalents		65,159	13,293	15,063	2,441
Total current assets		76,006	18,896	109,202	26,805
Total assets		100,368	41,298	129,105	48,016
Equity attributable to owners of the parent					

Share capital	233	192	233	192
Share premium	76,457	-	76,346	-
Share-based payment reserve	4,940	2,833	4,940	2,833
Foreign currency reserves	7,790	(1,915)	7,776	(1,970)
Retained earnings/(deficit)	3,772	34,852	38,917	46,710
Total equity	93,192	35,962	128,211	47,765
Liabilities				
Current liabilities				
Trade and other payables	6,474	2,899	894	251
Current lease liabilities	86	92	-	-
Borrowings	53	121	-	-
Current due to affiliated company	350	271	-	-
Total current liabilities	6,963	3,383	894	251
Non-current liabilities				
SBA PPP Funding - long-term	-	134	-	-
Non-current lease liabilities	213	275	-	-
Non-current due to affiliated company		1,544		
Total non-current liabilities	213	1,953	-	-
Total liabilities	7,176	5,336	894	251
Total equity and liabilities	100,368	41,298	129,105	48,016

CONSOLIDATED STATEMENT OF CASH FLOWS
FOR THE YEAR ENDED 30 JUNE 2021

	Note	Group Period to 30 June 2021	Group Period to 30 June 2020	Company Period to 30 June 2021	Company Period to 30 June 2020
		$'000	$'000	$'000	$'000
Cash flow from operating activities					
Loss before income tax		(35,787)	(10,610)	(7,316)	(1,794)
Adjustments for					
- Depreciation		126	140	-	25
- Amortisation and impairment charges		1,958	1,108	1,806	1,094
- Share-based payments		2,180	1,696	75	172
- Share of net loss of associate		1,617	63		
- Gain on Sale of assets		(449)	-	(449)	(270)
- Forgiveness of PPP Loan		(255)	-		
- Unrealized loss (Gain) on equity method investment		(6,483)	-	(6,483)	
- Unrealized foreign exchange loss (Gain)		8,349	-	3,074	
Changes in working capital		-	-	517	
- Trade and other receivables					
- Prepaid assets and other current assets		(576)	(18)	(57,673)	(12,756)
- Assets classified as available for sale		1,981	(2,440)	2,137	(2,378)
- Inventory			(1,714)		
- Security Deposits		(27)	(326)		-
- Trade and other payables		(15)	(22)		-
Cash used in operations		3,575	2,064	643	(188)
Interest paid		(23,806)	(10,059)	(63,669)	(16,095)
Net cash used in operating activities		3	-	3	-
		(23,803)	(10,059)	(63,666)	(16,095)
Cash flow from investing activities					
Investment in subsidiary					
Purchase of property, plant and equipment (PPE)		472	-	(2,324)	-
Purchase of capital lease		(637)	(359)	-	-
Purchase of intangibles		(93)	(61)	-	-

Proceeds (purchase) of financial assets		(1,118)	(1,411)	(840)	(1,027)
Net cash generated by/(used in) investing activities		-	982		-
		(1,377)	(849)	(3,164)	(1,027)
Cash flow from financing activities					
Note receivable					
Issue of shares (net of issue costs)		8	(83)		(161)
Proceeds from loans		76,877	16,678	79,023	16,678
Proceeds from the issuance of ordinary shares under employee share purchase plan		(202)	255	67	-
Proceeds from exercise of stock options		111		111	
Repayment of loans		252		252	
Net cash generated from financing activities		-	-		-
Net increase/(decrease) in cash and cash equivalents		77,046	16,850	79,453	16,517
Cash and cash equivalents at beginning of period		51,866	5,942	12,622	(605)
Cash and cash equivalents at end of period	**22**	13,293	7,297	2,441	3,045
		65,159	13,293	15,063	2,441

COMPANY CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 30 JUNE 2021

	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 2019	175	34,032	1,137	(599)	(6,578)	28,167
Comprehensive income						
Loss for the period	-	-	-	-	(9,250)	(9,250)
Other comprehensive income						
Currency translation differences	-	-	-	(1,265)	-	(1,265)
Total comprehensive income	175	34,032	1,137	(1,864)	(15,828)	17,652
Transactions with owners						
Issue of shares	17	17,193	-	-	-	17,210
Less issue costs	-	(596)	-	-	-	(596)
Share-based payments	-	-	1,696	-	-	1,696
Stock reduction	-	(50,629)	-	(51)	50,680	-
Total transactions with owners of the parent, recognised directly in equity	17	(34,032)	1,696	(51)	50,680	18,310
At 30 June and 1 July 2020	192	-	2,833	(1,915)	34,852	35,963
Comprehensive income						
Loss for the period	-	-	-	-	(31,009)	(31,009)
Other comprehensive income						
Currency translation differences	-	-	-	9,705	4	9,709
Total comprehensive income	192	-	2,833	7,790	3,848	14,663
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,141	-	-	-	85,181
Less issue costs	-	(9,047)	-	-	-	(9,047)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	111	-	-	-	111
Exercise of Stock Options	1	252	-	-	-	252
Verici Ordinary Share Repurchase	-		-	-	(75)-	(75)
Total transactions with owners of the parent, recognised directly in equity	41	76,457	2,107	-	(75)-	78,530
At 30 June 2021	233	76,457	4,940	7,790	3,773	93,192

COMPANY CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
FOR THE YEAR ENDED 30 JUNE 2021

	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 2019	175	34,032	1,137	(610)	(2,176)	32,558
Comprehensive income						
Loss for the period	-	-	-	-	(1,794)	(1,794)
Other comprehensive income						
Currency translation differences	-	-	-	(1,309)	-	(1,309)
Total comprehensive income	175	34,032	1,137	(1,919)	(3,970)	29,455
Transactions with owners						
Issue of shares	17	17,193	-	-	-	17,210
Less issue costs	-	(596)	-	-	-	(596)
Share-based payments	-	-	1,696	-	-	1,696
Asset Sale	-		-	-	-	-
Stock reduction	-	(50,629)	-	(51)	50,680	-
Total transactions with owners of the parent, recognised directly in equity	17	(34,032)	1,696	(51)	50,680	18,310
At 30 June and 1 July 2020	192	-	2,833	(1,970)	46,710	47,765
Comprehensive income						
Loss for the period	-	-	-	-	(7,316)	(7,316)
Gain on Verici					(402)	(402)
Other comprehensive income						
Currency translation differences	-	-	-	9,746		9,746
Total comprehensive income	192	-	2,833	7,776	38,992	49,793
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,141	-	-	-	85,181
Less issue costs	-	(9,047)	-	-	-	(9,047)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	-	-	-	-	-
Exercise of Stock Options	1	252	-	-	-	252
Verici Ordinary Share Repurchase	-		-	-	(75)-	(75)
Total transactions with owners of the parent, recognised directly in equity	41	76,346	2,107	-	(75)-	78,419
At 30 June 2021	233	76,346	4,940	7,776	38,917	128,212

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. 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's and Company's financial statements for the year ended 30 June 2021 have been prepared in accordance with International Financial Reporting Standards (IFRS) in conformity with the requirements of the Companies Act 2006. The standards that have been adopted by the Group are those that are effective for financial years beginning on or after 1 January 2019.

The consolidated financial statements have been prepared under the historical cost convention except for certain financial assets measured at fair value. They cover the year to 30 June 2021. The comparatives cover the period from 30 June 2019 to 30 June 2020.

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 issued but not effective for the period ended 30 June 2020, 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 2021, 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.

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 re-organisation, 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 reorganisation 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 unrealised gains on transactions between Group companies are eliminated. Unrealised 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 recognised at cost. The Group's share of its associates' post-acquisition profits or losses is recognised in profit or loss, and its share of post-acquisition movements in reserves is recognised 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 recognised 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 recognised 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 recognised 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 recognised 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 derecognised. 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 recognised in administration expenses in the income statement.

Intangible assets
(a) Trademarks, trade names and licences
Separately acquired trademarks and licences are shown at historical cost. Trademarks and licences acquired in a business combination are recognised at fair value at the acquisition date. Trademarks and licences 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 licences over the contractual licence 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 capitalised, 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 capitalised 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 recognised 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 recognised 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 recognised 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 recognised for the asset (cash-generating unit) in the prior period. A reversal of an impairment loss is recognised in the income statement immediately. If goodwill is impaired however, no reversal of the impairment is recognised 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"):

- debt investments that do not qualify for measurement at either amortised cost or fair value through Other Comprehensive Income;
- 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 recognise in this category. The Group considers this category to be more relevant for assets of this type.

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 recognise 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 recognised 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 recognised in the income statement, except to the extent that it relates to items recognised in other comprehensive income where the associated tax is also recognised 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 recognised, 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 recognised 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 recognised 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 utilised.

Deferred tax assets and liabilities are measured at the tax rates that are expected to apply to the year when the asset is realised 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 recognised 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 Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company 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 Company satisfies each performance obligation.

The Company 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 Company 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 Company 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 Company 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 Company 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 recognises 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.

4. Segmental reporting

The Group operates as a single segment. The Group is in its initial commercial launch phase and therefore has not yet commenced revenue generation as of the end of FY20.

5. Income Tax

	Period ended 30 June 2021	Period ended 30 June 2020
Group	**$'000**	**$'000**
Deferred tax	7,097	2,319
Total deferred tax	7,097	2,319
Income tax credit	7,097	2,319

The Finance Act 2015 which was substantively enacted in 2015 included legislation to reduce the main rate of UK corporation tax to 19% from 1 April 2017 and the Finance Act 2016 which was substantively enacted in 2016 included legislation to reduce the main rate of UK corporation tax to 17% from 1 April 2020. On 18 November 2019, the government pledged to put the planned corporation tax reduction from 19% to 17% on hold. This was substantively enacted on March 17 2020.

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 2021 $'000	Year ended 30 June 2020 $'000
Loss attributable to owners of the parent	(31,009)	(9,250)
Weighted average number of ordinary shares in issue	71,484,934	59,416,134
Basic and diluted loss per share	$ (0.43)	$ (0.16)

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 one category of dilutive potential ordinary share, being share options. The potential shares were not dilutive in the period as the Group made a loss per share.

7. Investments in Subsidiaries

Company	At 30 June 2021 $'000	At 30 June 2020 $'000
Shares in Renalytix AI, Inc.	4,588	2,264
Shares in Renalytix AI, Ltd.	-	-

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 14 October 2021.

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. Additionally, in December 2018, the Company executed its option with ISMMS for the FractalDx license, which grants rights to technology and patents relating to a series of potential diagnostics and prognostics in the field of kidney transplant and rejection.

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, 2021 to be provided under the Advisory Agreement was $0.4 million and the fair value of the Class A units received from Kantaro was $1.9 million. A loss of $0.1 million was recognized within equity in losses of affiliate in the accompanying consolidated statements of operations and comprehensive loss. As of June 30, 2020, the total liability associated with the services was $.9 million of which $0.3 million is included within accrued expenses and other current liabilities and $1.6 million is within other liabilities.

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, 2021. In addition, the Company recognized losses of $199,000 on their investment in Kantaro during the year ended 30 June 30 2021.

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.

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 ("U.S. GAAP"), both for internal as well as external purposes.

Renalytix Form 20-F, which is based on U.S. 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.renalytixai.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:

Reconciliation of Net Loss

($ thousands)	***30-Jun-21***	***30-Jun-20***
Net loss in accordance with IFRS	**(31,009)**	**(9,250)**
(a) Development expenditures and amortization	1,842	(77)
(b) Deferred tax assets	(4,778)	(1,360)
(c) Stock compensation expense	(483)	537

(d) Verici Transaction	(434)	-
(e) Other Adjustments	(473)	306
Total adjustments	(4,326)	(592)
Net loss in accordance with U.S. GAAP	**(35,336)**	**(9,844)**

(a) *Development expenditures*
Under IFRS, costs relating to development projects are recognised as intangible assets when costs can be measured reliably and the technical feasibility of the product, volumes and pricing support the view that the development expenditure will generate future economic benefits. Under U.S. GAAP, development costs are expensed as incurred. As a result, costs incurred related to development projects that have been capitalised under IFRS are expensed as incurred under U.S. GAAP. Amortization expenses, net result on disposal and impairment charges of previously capitalised development costs recorded under IFRS have been reversed under U.S. GAAP.

(b) *Deferred tax assets*
The Group's policy for accounting for deferred income taxes under IFRS is described in section "Significant accounting policies". This policy is similar to U.S. GAAP which states that a deferred tax asset or liability is recognised for the estimated future tax effects attributable to temporary differences and tax loss carry forwards. Valuation allowances are recorded to reduce deferred tax assets when it is more likely than not that a tax benefit will not be realised based on available evidence.

(c) *Stock compensation expense*
Under IFRS, the Company utilises the graded vesting method to expense stock options whereas the Company has elected to recognise stock compensation expense on a straight-line basis under US GAAP.

(d) *Verici Transaction*
Attributable to the differences in accounting treatment of the Verici Dx transaction specifically the distribution in specie and subsequent deconsolidation of the Verici entity under IFRS vs. US GAAP.

(e) *Other adjustments*
The remaining difference of $0.1 million represents other immaterial audit adjustments and small accounting differences.