



## Half-year Report

March 2, 2021

RNS Number : 8349Q

Renalytix AI PLC

02 March 2021

### **Renalytix AI plc ("RenalytixAI", the "Company" or the "Group")**

#### **Half-year Report**

Renalytix AI plc (LSE: RENX) (NASDAQ: RNLX), ("RenalytixAI" or the "Company"), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported its unaudited interim results for the six months ended December 31, 2020.

#### **Recent Highlights**

- Accelerated pathway for reimbursement coverage of KidneyIntelX with the finalization of the Medicare Coverage of Innovation Technology (MCIT) rule; national Medicare coverage upon FDA clearance of KidneyIntelX, which we anticipate in calendar 2021
- Issued the first KidneyIntelX test reports to primary care and specialist physicians in the Mount Sinai network, completing the first instance of fully integrated electronic health record (EHR) ordering and score reporting; physician practice participation increasing with revenue recognition from Mount Sinai expected to begin in the fiscal third quarter of 2021
- Confirmed plans to expand the indicated use of KidneyIntelX for individuals with general chronic kidney disease, including the underserved African ancestry and Hispanic population groups. New indicated use, if approved, expected to increase U.S. total addressable market for KidneyIntelX to an estimated 37 million patients
- Announced partnership with DaVita enabling 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
- Announced partnership with the University of Utah to implement KidneyIntelX and advanced clinical management system-wide at University of Utah Health enabling integrated EHR for 1,700 clinicians across six states
- Continued building KidneyIntelX study data with key findings to be presented at World Congress of Nephrology, American Diabetes Association and Healthcare Information and Management Systems Society in 2021. Findings include further validation in large international trial cohort, monitoring therapeutic response and impact in clinical decision

making/therapy management

### **Financial highlights**

During the six months ended December 31, 2020 the Company recognized \$0.4 million of pharmaceutical services revenue. Cost of revenue for the six months ended December 31, 2020 was \$0.2 million.

Operating expense for the six months ended December 31, 2020 was \$14.0 million compared to \$5.0 million during the six months ended December 31, 2019.

General and administrative expenses increased for the six months ended December 31 2020 due to a \$2.8 million increase in compensation and related benefits including share based compensation due to increased headcount, \$2.2 million increase in insurance costs, \$1.6 million increase in legal and accounting fees due to Securities and Exchange Commission ("SEC") filings and U.S. public listing compliance, \$0.4 million increase in consulting and professional fees, \$0.3 million increase in recruiting expense, and an increase of \$0.2 million in marketing, facility and other operating expenses.

Research and development related expenses increased by \$1.5 million due to increased headcount and the associated compensation and related benefits, including share-based payments as the Company continues to develop its core technology and prepares for expanded clinical operations with Mount Sinai and additional health care system partnership programs, and two development studies focused on long-term effects of COVID-19 on kidney health.

Net loss before tax was \$16.2 million for the six months ended December 31, 2020, including one-time charges and extraordinary expenses, compared to \$6.3 million for the six months ended December 31, 2019.

Cash, cash equivalents and short-term investments were \$74.5 million as of December 31, 2020.

### **Commenting on the outlook for RenalytixAI, James McCullough, chief executive officer of Renalytix said:**

*"Our path to establishing advanced precision prognostics to guide and inform population-wide kidney health continues to become clearer. The January finalization of the Medicare Coverage of Innovative Technology rule provides the foundation to achieve broad insurance coverage for KidneyIntelX. With our newly announced partnerships with University of Utah and DaVita, we are on track to exceed our goal of implementing KidneyIntelX across at least three major healthcare networks before our fiscal year ends in June. We expect to announce additional partnerships in 2021 that will further set the foundation for direct access to KidneyIntelX in advance of Medicare coverage by large groups of primary care and specialist clinicians treating early stage diabetic kidney disease patients."*

Investors are advised to read the results for the 3 months ended 31 December 2020 which have been released alongside these results.

***For further information, please contact:***

**Renalytix AI plc**

James McCullough, CEO

[www.renalytixai.com](http://www.renalytixai.com)

Via Walbrook PR

**Stifel (Nominated Adviser & Joint Broker)**

Alex Price / Nick Moore

**Tel: 020 7710 7600**

**Investec Bank plc (Joint Broker)**

Gary Clarence / Daniel Adams

**Tel: 020 7597 4000**

**Walbrook PR Limited**

**Tel: 020 7933 8780** or [renalytix@walbrookpr.com](mailto:renalytix@walbrookpr.com)

Paul McManus / Lianne Cawthorne

Mob: 07980 541 893 / 07584 391 303

**About Kidney Disease**

Kidney disease is now recognised as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD\*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.

\* <https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html>

**About RenalytixAI**

RenalytixAI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. RenalytixAI's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit [www.renalytixai.com](http://www.renalytixai.com).

**CHAIRMAN'S BUSINESS REVIEW**

I am delighted to present the interim report for the six months ended 31 December 2020 for Renalytix AI plc.

**Company Overview**

We are an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs. KidneyIntelX, our first-in-class diagnostic platform, employs a proprietary artificial intelligence-

enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from electronic health record ("EHR") systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease ("CKD") allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk. CKD affects approximately 37 million individuals in the United States, significantly impacting their quality of life and, according to the United States Renal Data System's 2019 Annual Data Report, resulting in Medicare spending of over \$120 billion per year. In response to this substantial kidney disease burden, a U.S. Presidential Executive Order on Advancing American Kidney Health was issued in July 2019 to support change in kidney disease care. We believe we are well-positioned to help meet this urgent medical need with KidneyIntelX, a laboratory developed test, initially indicated for adult patients with type 2 diabetes and existing CKD, which is referred to as diabetic kidney disease ("DKD"). KidneyIntelX has already been granted a common procedural terminology ("CPT code"), national Medicare pricing and a positive coverage determination from a regional, private physician-led health insurance payor. Further, it has been granted breakthrough device designation from the U.S. Food and Drug Administration (the "FDA"). Building on these significant reimbursement and regulatory milestones, we believe our population health-based business model, which includes partnerships with healthcare systems, such as Mount Sinai Health System, will help facilitate commercial adoption of KidneyIntelX in the United States.

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The National Kidney Foundation estimates that one-third of adults in the United States are at risk of developing kidney disease. Advanced kidney disease is generally not reversible and, once the disease progresses to kidney failure, the only available treatments are long-term dialysis and kidney transplant. In 2016, more than 726,000 patients had end-stage kidney disease ("ESKD"), with more than 500,000 requiring dialysis at least three times a week. More than 100,000 patients begin dialysis each year to treat ESKD. Once on dialysis, patients typically experience a five-year mortality rate of up to 65%, about the equivalent rate for brain cancer. As of July 2019, nearly 100,000 Americans were on the waiting list to receive a kidney transplant and 13 patients die in the United States while waiting for a kidney transplant every day. Moreover, the kidney disease crisis is continuing to grow along with the increased prevalence of contributing risk factors, such as obesity and diabetes.

Managing a CKD population of this scale and associated healthcare costs presents a unique social challenge. The ability to predict which patients will experience progressive kidney function decline, kidney failure, initiation of long-term dialysis or kidney transplant, is critical to changing patient outcomes and health economics. In our clinical validation studies in patients with DKD, we observed that the Kidney Disease: Improving Global Outcomes ("KDIGO") classification system, which is the standard clinical assessment to predict risk for progression of CKD, including DKD, only identified approximately 20% of patients that experienced an adverse kidney outcome as very high-risk patients with the recommendation of referral to a nephrologist, while KidneyIntelX identified nearly half of such patients.

We believe that the utilization of KidneyIntelX across large patient populations will have a significant impact on overall healthcare costs. Health economic benefits are projected to be derived from three key areas: (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. We have partnered with Boston Healthcare Associates ("BHA"), to develop a health economic model analyzing the cost and care pathway for patients with DKD at all stages of the disease and the potential cost savings of implementing and utilizing KidneyIntelX. According to the BHA study, based on the Medicare price of \$950 per reportable test, KidneyIntelX testing would generate a positive return for health insurers in under 24 months and deliver a cost savings of up to \$1.3 billion over five years per 100,000 patients with DKD.

Several federal policy and economic events, including the U.S. Presidential Executive Order on Advancing American Kidney Health issued in July 2019 and recent changes in U.S. reimbursement law, are helping disrupt the kidney disease clinical and commercial environment, highlighting the pressing need for solutions such as KidneyIntelX. We believe these favorable policy trends, which began during the Obama administration, will continue to build under a Biden administration and will support broader commercial adoption of KidneyIntelX and other derivative products contemplated in our diagnostics development planning. In addition, on January 12, 2021, the U.S. Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, finalized the Medicare Coverage of Innovative Technology ("MCIT") rule. We believe that this new CMS rule could have a material positive impact on addressable market population with insurance coverage for KidneyIntelX if we obtain FDA clearance for KidneyIntelX.

MCIT represents the culmination of a sequence of policy steps over the past decade, including finalization of the Protecting Access to Medicare Act in 2018, that have materially altered the pathway for translating innovative diagnostic technology. For emerging growth diagnostic companies such as Renalytix, MCIT can have a substantial effect in achieving comprehensive reimbursement coverage on an accelerated timeline. We believe MCIT represents one of the more significant events in the past several decades to help drive innovation in precision medicine diagnostics/prognostics.

Additionally, we have successfully completed the first stage of our statement of work with AstraZeneca Pharmaceuticals LP ("AstraZeneca") to conduct a feasibility study to determine the impact of the use of our KidneyIntelX platform to optimize utilization of various CKD agents. Further, in December 2020 we entered into a master service agreement with AstraZeneca for future services of this nature. We believe this agreement will define how we can leverage KidneyIntelX to improve the care and outcomes for patients affected by chronic diseases such as kidney disease, diabetes, and cardiovascular disease. Building on our initial success with AstraZeneca, we plan to pursue further collaborations with pharmaceutical companies and make 'Pharmaceutical Services Revenue' a core part of our business going forward with the goal of improving guideline-based standard-of-care for optimal utilization of existing and novel therapeutics using the KidneyIntelX testing platform and proprietary care management software.

### **Reimbursement and Regulatory Pathway**

With the recent finalization of the MCIT rule on January 12, 2021, we now have a clear path to a national Medicare coverage determination for KidneyIntelX testing in the United States. In summary, MCIT provides for an opt-in national Medicare coverage determination for medical devices and diagnostics approved or cleared out of the FDA Breakthrough Device design program. KidneyIntelX was granted breakthrough device designation in May 2019 and is currently under review by the agency as part of this process.

As Medicare beneficiaries make up the majority of individuals with kidney disease in the United States, we believe this represents a critical component in the pursuit of our national commercial strategy.

Pricing for the unique CPT code for KidneyIntelX was finalized by CMS effective January 2020 at \$950 per reportable result, which will be the pricing if KidneyIntelX receives FDA clearance and a positive national Medicare coverage determination. In addition, both coverage and the established pricing for the Medicare patient population in the cleared KidneyIntelX indicated use would apply to the approximately 3,550 Medicare Advantage plans administered by private payors in the United States. Medicare Advantage programs currently cover an estimated 24 million Americans, or 36% of all Medicare beneficiaries.

We are pursuing a comprehensive Medicaid contracting program and, to date, have secured

Medicaid contracts in Arizona, Georgia, Michigan, Montana, North Carolina, Ohio, Oregon, Rhode Island, South Carolina, Utah, Vermont, Wisconsin, and Wyoming with additional state contracts expected throughout the course of fiscal 2021 and 2022. We are also targeting an increase in other private and public insurance and purchasing contracts during the same period.

As reported in August 2020, we submitted the final KidneyIntelX package for FDA consideration under breakthrough device designation. Due to the large influx of COVID-19 related emergency use authorization ("EUA") requests, the FDA has experienced delays in submission processing timing across the diagnostic industry. February 2021, the FDA sent written notification to us stating that it expected the final review process would return to normal no later than April 15, 2021 and did not expect any further delays in process due to the sustained volume of EUA requests in response to the pandemic. While we will continue to decline forecasting specific timing for potential FDA clearance of KidneyIntelX, we view this notification as a positive step in the right direction.

We are continuing to build regulatory expertise through both direct hires and retention of key contracted experts. In January 2021, we retained the services of Dr. Alberto Gutierrez, recently retired Director of the FDA's Office of In Vitro Diagnostics and Radiologic Health, and Dr. Doug Jeffery, recently retired Branch Chief and Acting Deputy Division Director in the FDA's Center for Devices and Radiological Health to support the KidneyIntelX ongoing regulatory strategy and process.

### **Addressable Market and Business Strategy**

One of our top priorities is to build a broad distribution network and increase physician access for KidneyIntelX over the course of 2021 to serve the U.S. diabetic kidney disease population once KidneyIntelX receives FDA clearance and national Medicare coverage.

We are increasingly optimistic about achieving distribution capability under our model of partnering with healthcare networks such as Mount Sinai. In addition to our announced partnership with DaVita Inc. ("DaVita") and University of Utah, we expect to announce additional partnerships during the current fiscal year ending June 30, 2021. We expect to announce five to seven partnerships before the end of calendar 2021. We believe these additional partnerships could materially increase patient and physician access to KidneyIntelX throughout the course of calendar 2021 in advance of broader insurance coverage.

We are also evaluating more aggressive growth strategies to increase distribution, sales and marketing capacities in the United States and global territories. Strategic options may include the hiring of a specialized direct sales force to complement our healthcare systems partnered implementation model.

MCIT may also confer other material advantages including the ability for concurrent deployment of KidneyIntelX over a broader geographic footprint. Given the range of insurance payors that provide coverage in each market, the process of achieving majority population coverage can be laborious, incremental and require considerable time. With a majority of the KidneyIntelX initial indicated use population insured through a national Medicare coverage determination, risk associated with reimbursement in a given major high-concentration geography would be considerably reduced. KidneyIntelX deployment will focus on a region-by-region basis taking into consideration a number of demographic and economic factors in an effort to maximize return on capital and human resource efficiencies.

### **Product Development**

We are continuing development work on expanding the indicated use populations for KidneyIntelX risk assessment to the broader CKD population, which includes the important, underserved

population of kidney disease patients of African and Hispanic ancestry. These populations have been disproportionate sufferers of end stage kidney disease and we intend to provide access to advanced technology embedded in the KidneyIntelX platform to level the playing field in relation to access, knowledge and clinical care through kidney disease prognosis and treatment.

We expect to broaden the indicated use of KidneyIntelX to the larger CKD population as early as calendar 2022.

Due to the large and incremental population groups that would potentially be served by expanding indicated use, we estimate the total addressable market for KidneyIntelX could increase to an estimated 37 million individuals in the United States.

The KidneyIntelX product line is classified as an in vitro prognostic and is anchored by a real-time patient blood draw and biomarker assessment. The biomarker assessment is combined with selected information from a patient's EHR, all processed by a machine-learning enabled algorithm. We believe that to achieve early and accurate disease prognosis, real-time biology accessible through a current blood or urine biomarker assessment is required.

### **Real-world Testing Experience**

During the quarter ended December 31, 2020, we began our clinical testing experience with KidneyIntelX within the Mount Sinai Health System. Despite COVID-19 restrictions, this real-world experience has met or exceeded targeted quality metrics and physician and patient satisfaction measures. To date, KidneyIntelX has been ordered by and test reports have been delivered to over 25 primary care and specialist physicians in the Mount Sinai network. Concurrently, we performed services for Mount Sinai to support establishing a care navigation function based on early stage DKD risk assessment, including physician and practice education, physician and patient materials, electronic order integration and care navigation deployment. We expect to start recognizing revenue from our work with Mount Sinai in the quarter ending March 31, 2021. We also anticipate expanding clinical testing deployment to additional physicians' practices in the Mount Sinai Health System through the remainder of fiscal 2021.

The KidneyIntelX software platform has been designed with a number of significant features to ensure efficient clinical testing implementation and, we believe, provides an outstanding platform for future feature development. KidneyIntelX cloud computing architecture couples data control and encryption protocols and has been verified to high standards. These standards ensure secure and timely access to the order information and data necessary to execute the test in accordance with all applicable regulatory requirements. Working collaboratively with an extended team of information technology professionals, we have developed a robust data pipeline that can provide access to KidneyIntelX for all clinicians across the Mount Sinai Health System and allows the creation of a rich database (using de-identified data) for ongoing product development and shared value generation through advanced data analytics. Key features of the platform such as the patient test report incorporating health system specific care pathways are uniquely developed to be translatable to other health systems and EHR platforms.

We have continued building KidneyIntelX study data with key findings to be presented at World Congress of Nephrology, American Diabetes Association and Healthcare Information and Management Systems Society in 2021. Findings include further validation in large international trial cohort, monitoring therapeutic response and impact in clinical decision making/therapy management.

### **COVID Effects**

COVID-19 has provided a challenge to our business, particularly during the high-intensity first deployment of KidneyIntelX in the Mount Sinai Health System. During our fiscal second quarter both New York State and Mount Sinai reinstated COVID-19 surge protocols which set specific guidelines for prioritization of resources and introducing restrictions to combat infection spread. We have also seen potential KidneyIntelX patients hesitate to visit treating clinicians and blood collection stations necessary to conduct testing.

Fortunately, with vaccinations now underway, we anticipate that these restrictions will be temporary with impact on business operations declining over the next several months.

We have approximately doubled the size of our employee headcount since our listing on Nasdaq in July 2020. Many key personnel have been hired using only Zoom conference with no in-person interviews. These personnel have continued to work remotely through the course of the first KidneyIntelX implementation and expanding deployment. While we believe our team has performed admirably and maintained a high level of productivity, the ultimate effects of virtual operation remain unknown. We have elected to participate in the social security deferral program offered under the Coronavirus Aid, Relief, and Economic Security Act, whereby we can defer payment of the employer portion of all social security taxes that would otherwise be payable from April 15, 2020 through December 31, 2020. Payment of the deferred amount is due 50% on December 31, 2021 and 50% on December 31, 2022.

We anticipate COVID-19 will have substantially less impact on our ability to scale KidneyIntelX implementation and testing in fiscal 2022 as compared to fiscal 2021.

### **Additional Business**

The Renalytix/Mount Sinai joint venture, Kantaro Biosciences LLC ("Kantaro"), has made material business progress with its quantitative COVID-19 serologic antibody testing program. Kantaro has achieved key milestones including 1) FDA Emergency Use Authorization, 2) obtaining a CE Mark, which is a mandatory conformance mark that certifies the product has met EU consumer, health and environmental requirements, 3) entering into a scaled production and distribution agreement with Bio Techne Corporation (NASDAQ: TECH), and 4) a UK/European sales and marketing agreement with EKF Diagnostics Holdings plc (LSE: EKF). Kantaro has started to generate revenue and our share of the equity method investment in Kantaro is reflected within the financial statement line item Equity Losses in Affiliate. We are exploring the possibility of broadening the product technology and intellectual property portfolio of Kantaro.

In July 2020, we spun out Verici Dx Limited ("VericiDx"), which was subsequently admitted for trading on the AIM market of the London Stock Exchange in November 2020. The successful listing and associated financing of VericiDx have now provided VericiDx with capital to drive its portfolio of kidney transplant products to validation and subsequent commercialization beginning as early as calendar year 2022. We believe VericiDx's unique technology and published data represent a step-change forward in kidney transplant that can drive improvements in patient quality of life, standard of treatment, cost savings and long-term viability of transplanted organs. Renalytix holds a 6.94% equity stake in VericiDx.

### **Current outlook**

We view fiscal 2021 as our business launch year and one with the following objectives: 1) increasing visibility to distribution to primary care and specialist clinicians through partnered deployment with at least three health care providers and payors; 2) continuing to generate validating health economics, real-world evidence utility and performance data for submission to peer-reviewed



publication; 3) increasing insurance coverage; and 4) establishing sequential quarter revenue growth for the December, March and June reporting periods.

For the six months ending December 31, 2020, we are reporting revenue of \$0.4 million and net loss of \$16.2 million before tax. Our balance sheet remains strong for all planned growth activities with a cash balance of \$74.5 million as of December 31, 2020.

We continue to expand our business to accommodate multiple revenue pathways from KidneyIntelX testing sales, pharma driven development programs and other strategic partnership initiatives including our recently announced partnership with DaVita (NASDAQ DVA). However, given the early stage nature of our commercial business and the challenges operating in a COVID-19 restricted environment, we do not expect any material revenue for the 12 months ended June 30, 2021 as we continues to focus on ensuring that all necessary regulatory and commercial building blocks are in place to enable us to scale rapidly.

For fiscal 2022, we expect a material inflection point for revenue growth to occur if KidneyIntelX receives FDA clearance and concurrent opt-in for national Medicare coverage, and an easing of COVID restrictions due to broad population vaccination uptake. We are targeting a blended gross margin across all lines of KidneyIntelX testing of greater than 70% as our commercial program scales in fiscal 2022. We look forward to the future with confidence.

We view fiscal 2022 as a year in which we plan to validate our ability to grow significant market share and revenue from KidneyIntelX testing, and pharmaceutical and other strategic partnerships. In addition, we expect our total addressable market will increase materially with the introduction of subsequent KidneyIntelX versions and potentially expanded indications.

## **Financial review**

The results presented cover the six-month period from 1 July 2020 to 31 December 2020 ("H1 FY21"). The Group's presentational currency is the United States Dollar.

### ***Income statement***

#### ***Revenue***

In H1 FY21, \$0.4m in revenue was generated through services provided as part of our SOW with Astra Zeneca, of which \$0.2m was booked as cost of goods sold, yielding a gross margin of \$0.2m.

#### ***Administrative costs***

In H1 FY21, administrative expenses totalled \$14.0m (H1 FY20: \$5.0m). The major items of expenditure were general and administrative expenses of \$9.6m (H1 FY19: \$4.2m) which included \$4.1 million of compensation and related benefits including share based compensation due to increased headcount, \$2.2 million in insurance costs, \$1.7 million in legal and accounting fees due to Securities and Exchange Commission ("SEC") filings and U.S. public listing compliance, \$0.6 million in recruiting expense, \$0.3 million in consulting and professional fees, and of \$0.6 million in marketing, facility and other operating expenses.

#### ***Finance income/costs***

Finance expense of \$2.3m during H1 FY21 (H2 FY20: \$1.2m expense) relates to unrealized foreign exchange losses off set by an increase in the fair value of our equity interest in VericiDx.

#### ***Net loss***

Net loss after tax during H1 FY21 of \$14.0m (H2 FY20: \$5.6m), is in line with expectations. Excluding share-based payments, depreciation, amortisation and deferred tax, H1 FY21 net loss was \$14.5m (H2 FY20: \$4.6m).

### ***Balance sheet***

At 31 December 2020, the Company held \$112.7m in total assets (30 June 2020: \$41.3m), and shareholders' equity totalled \$108.2m (30 June 2020: \$35.9m).

### ***Inventory***

At 31 December 2020, the Company held \$0.5m of inventory. At 30 June 2020, the Company held \$0.3m in inventory on hand. During the period, the Company purchased \$0.2m of consumable assay materials to be used in the processing of tests to be sold.

### ***Fixed assets***

At 31 December 2020, the Company held \$1.3m in net book value of equipment (30 June 2020: \$0.6m). The increase in fixed assets was driven by the build out of our testing lab in Utah.

### ***Intangible assets***

\$18.1m net book value of intangible assets held at 31 December 2020 (20 June 2020: \$17.1m) includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying *KidneyIntelX™*, amounts capitalised as development costs, and also intangible assets representing the value of the biomarker business purchased (in exchange for ordinary shares in the Company) from EKF. The increase from prior period was driven by development costs capitalized over the period.

### ***Deferred tax***

At 31 December 2020, a deferred tax asset of \$4.5m had been estimated (30 June 2020: \$2.3m) based on the accumulated tax losses in the US.

### ***Cash and equivalents***

The Group had cash on hand at 31 December 2020 of \$74.5m (30 June 2020: \$13.3m). Cash and equivalents are held in several deposit accounts in the US (\$58.3m), IRE (\$0.4m) and UK (\$15.8m). Our expenditure plans remain sufficiently adaptable to align with available resources.

### ***Borrowings***

On April 29, 2020, the Company entered into an original loan agreement with Fortis Private Bank as the lender ("Lender") for a loan in an aggregate principal amount of \$255,000 (the "Loan") pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. In June 2020, the Paycheck Protection Program Flexibility Act was enacted, which among other things, extended the deferral period for loan payments to either (1) the date that SBA remits the borrower's loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, ten months after the end of the borrower's loan forgiveness covered period. The Loan matures in two years and bears interest at a rate of 1% per year, with all payments deferred through August 15, 2021. Principal and interest are payable monthly commencing on August 15, 2021 and may be prepaid by the Company at any time prior to maturity without penalty. The Company may apply for forgiveness of amounts due under the Loan, with the amount of potential loan forgiveness to be calculated in accordance with the requirements of the PPP based on payroll costs, any mortgage interest payments, any covered rent payments and any covered utilities payments during the 8-24 week period after the origination date of the Loan. The Company utilized the proceeds of the Loan for payroll and other qualifying expenses, but there can be no assurances that any portion of the Loan will be forgiven.

Other than the loan, the Company has no long-term debt outstanding as of 30 June 2020.

### *Capitalisation*

In July 2020, we completed a dual listing on the Nasdaq Global Market through the issuance of American Depositary Shares under ticker symbol "RNLX," expanding our institutional investor base and raising net capital of approximately \$76.1 million after commissions, fees and offering expenses. We maintain our listing on the AIM market of London Stock Exchange plc under the symbol "RENX."

Christopher Mills

**Non-executive Chairman**

2 March 2021

### **CONSOLIDATED INCOME STATEMENT FOR THE PERIOD ENDED 31 December 2020**

	<b>Unaudited Period to 31 December 2020 \$'000</b>	<b>Unaudited (Restated) Period to 31 December 2019 \$'000</b>
Pharmaceutical Services Revenue	400	-
Cost of Revenue	<u>(234)</u>	<u>-</u>
<b>Gross Profit</b>	166	-
Administrative expenses	<u>(14,009)</u>	<u>(4,998)</u>
<b>Operating loss</b>	<b>(13,843)</b>	<b>(4,998)</b>
Share of net Profit (Loss) of associates and joint ventures accounted for using the equity method	(221)	-
Finance income - net	<u>(2,093)</u>	<u>(1,263)</u>
<b>Loss before tax</b>	<b>(16,157)</b>	<b>(6,261)</b>
Taxation	<u>2,121</u>	<u>626</u>
<b>Loss for the period</b>	<b><u>(14,036)</u></b>	<b><u>(5,635)</u></b>
<b>Earnings per Ordinary share from continuing operations</b>		

Basic and diluted	\$ (0.20)	\$ (0.10)
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**CONSOLIDATED STATEMENT OF COMPREHENSIVE  
INCOME  
FOR THE PERIOD ENDED 31 December 2020**

	<b>Unaudited Period to 31 December 2020 \$'000</b>	<b>Unaudited (Restated) Period to 31 December 2019 \$'000</b>
Loss for the period - continuing operations	(14,036)	(5,635)
<b>Other comprehensive income:</b>		
<b>Items that may be subsequently reclassified to profit or loss</b>		
Currency translation differences	9,495	1,964
<b>Other comprehensive loss for the period</b>	<b>(4,541)</b>	<b>(3,671)</b>
<b>Total comprehensive loss for the period</b>	<b>(4,541)</b>	<b>(3,671)</b>

**CONSOLIDATED AND COMPANY'S STATEMENT OF  
FINANCIAL POSITION  
AS AT 31 December 2020**

	<b>Unaudited As at 31 December 2020 \$'000</b>	<b>Audited (Restated) As at 30 June 2020 \$'000</b>
<b>Assets</b>		
<b>Non-current assets</b>		
Property, plant and equipment	1,315	580
Right of use asset	341	365
Intangible assets	18,103	17,118
Investment in Kantaro	1,716	1,937
Investment in Verici	7,852	-
Note receivable - Kantaro	-	83

Deferred tax assets	4,526	2,319
<b>Total non-current assets</b>	<b>33,853</b>	<b>22,402</b>
<b>Current Assets</b>		
Inventory	494	326
Security deposits	86	71
Assets held for sale	-	1,705
Note Receivable Kantaro	167	
Trade and other receivables	158	18
Prepaid and other current assets	3,005	2,501
Accounts Receivable	400	-
Financial assets	-	982
Cash and cash equivalents	74,532	13,293
<b>Total current assets</b>	<b>78,842</b>	<b>18,896</b>
<b>Total assets</b>	<b>112,694</b>	<b>41,298</b>
<b>Equity attributable to owners of the parent</b>		
Share capital	232	192
Share premium	76,020	-
Share-based payment reserve	3,595	2,833
Foreign currency reserves	7,580	(1,915)
Retained earnings/(deficit)	20,816	34,852
<b>Total equity</b>	<b>108,243</b>	<b>35,962</b>
<b>Liabilities</b>		
<b>Current liabilities</b>		
Trade and other payables	2,798	2,899
Lease liabilities	86	92
SBA PPP Funding - short-term	141	121
Payables due to associates	824	271
<b>Total current liabilities</b>	<b>3,849</b>	<b>3,383</b>
<b>Non-current liabilities</b>		
SBA PPP Funding - long-term	114	134
Lease Liabilities	256	275
Payables due to associates	231	1,544
<b>Total non-current liabilities</b>	<b>601</b>	<b>1,953</b>
<b>Total liabilities</b>	<b>4,450</b>	<b>5,336</b>
<b>Total equity and liabilities</b>	<b>112,694</b>	<b>41,298</b>

**CONSOLIDATED AND COMPANY'S STATEMENT OF CASH FLOWS  
FOR THE PERIOD ENDED 30 JUNE 2020**

<b>Unaudited</b>	<b>Unaudited (Restated)</b>
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	Period to 31 December 2020	Period to 31 December 2019
	\$'000	\$'000
<b>Cash flow from operating activities</b>		
Loss before income tax	(16,157)	(6,261)
<i>Adjustments for</i>		
- Depreciation	88	43
- Amortisation and impairment charges	702	524
- Gain on Deconsolidation of VericiDx	(481)	-
- Fair Value Adjustment to Verici DX Investment	(5,018)	(0)
- Unrealized foreign exchange loss	4,744	1,850
- Share of net loss of associate	221	-
- Share-based payments	916	1,083
<i>Changes in working capital</i>		
- Trade and other receivables	-	-
- Accounts Receivable	-	-
- Prepaid assets and other current assets	(134)	(134)
- Inventory	(435)	(435)
- Security Deposits	(29)	(29)
- Trade and other payables	321	321
- Accrued Expenses and other current liabilities	-	-
<b>Cash used in operations</b>	(15,262)	(3,038)
Interest Received/(paid)	-	-
<b>Net cash used in operating activities</b>	<b>(15,262)</b>	<b>(3,038)</b>
<b>Cash flow from investing activities</b>		
Investment in subsidiary	-	-
Purchase of property, plant and equipment (PPE)	(723)	(102)
Software Development Costs	(603)	(1,036)
Change in capital lease	(50)	(410)
Proceeds from short-term investments	1,000	(7,917)
<b>Net cash generated by/(used in) investing activities</b>	<b>(376)</b>	<b>(9,465)</b>
<b>Cash flow from financing activities</b>		
Gross Proceeds from issuance of ordinary shares	79,182	-
Gross Proceeds from issuance of ordinary shares, net offering costs		16,123
Proceeds from loans	-	-
Payment of offering costs	(2,305)	-
<b>Net cash generated from financing activities</b>	<b>76,877</b>	<b>16,123</b>
<b>Net increase/(decrease) in cash and cash equivalents</b>	<b>61,239</b>	<b>3,620</b>
Cash and cash equivalents at beginning of period	13,293	9,288
<b>Cash and cash equivalents at end of period</b>	<b>74,532</b>	<b>12,908</b>

#### CONSOLIDATED

#### STATEMENT OF CHANGES

#### IN EQUITY

**FOR THE PERIOD ENDED 31  
December 2020**

	Share Capital	Share Premium	Share-based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
<b>At 30 June 2019 (Restated)</b>	175	34,032	1,137	(599)	(6,578)	28,167
<b>Comprehensive income</b>	-	-	-	-	-	-
Loss for the period	-	-	-	-	(5,635)	(5,635)
<b>Other comprehensive income</b>						
Currency translation differences	-	-	-	1,964	-	1,964
<b>Total comprehensive income</b>	175	34,032	1,137	1,365	(12,213)	24,496
<b>Transactions with owners</b>			1,094			
Issue of shares	17	17,193	-	-	-	17,210
Less issue costs	-	(596)	-	-	-	(596)
Share-based payments	-	-	1,094	-	-	1,094
<b>Total transactions with owners of the parent, recognised directly in equity</b>	17	16,597	1,094	-	-	17,708
<b>At 31 December 2019 (Restated)</b>	192	50,629	2,231	1,365	(12,213)	42,204
<b>Comprehensive income</b>						
Loss for the period	-	-	-	-	(3,615)	(3,615)
<b>Other comprehensive income</b>						
Currency translation differences	-	-	-	(3,229)	-	(3,229)
<b>Total comprehensive income</b>	192	50,629	2,231	(1,864)	(15,828)	35,360
<b>Transactions with owners</b>						
Issue of shares	-	-	-	-	-	-
Less issue costs	-	-	-	-	-	-
Share-based payments	-	-	602	-	-	602

Reduction of Capital	-	(50,629)	-	(51)	50,680	-
<b>Total transactions with owners of the parent, recognised directly in equity</b>	-	(50,629)	602	(51)	50,680	602
<b>At 30 June 2020</b>	192	-	2,833	(1,915)	34,852	35,962
<b>Comprehensive income</b>						
Loss for the period	-	-	-	-	(14,036)	(14,036)
<b>Other comprehensive income</b>						
Currency translation differences	-	-	-	9,495	-	9,495
<b>Total comprehensive income</b>	192	-	2,833	7,580	20,816	31,421
<b>Transactions with owners</b>						
Distribution of Verici Shares at Par Value		(75)				(75)
Issue of shares	40	79,181	-	-	-	79,221
Less issue costs	-	(3,087)	-	-	-	(3,087)
Share-based payments	-	-	762	-	-	762
<b>Total transactions with owners of the parent, recognised directly in equity</b>	40	76,020	762	-	-	76,822
<b>At 31 December 2020</b>	232	76,020	3,595	7,580	20,816	108,243

## NOTES FORMING PART OF THE INTERIM FINANCIAL STATEMENTS

### 1. General information and basis of presentation

Renalytix AI plc is a public limited company incorporated in the United Kingdom (Registration Number **11257655**). The address of the registered office is Avon House, 19 Stanwell Road, Penarth, CF64 2EZ. The Company's shares are traded on the AIM market of the London Stock Exchange.

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

The financial information in these interim results is that of the holding company and its subsidiary. It has been prepared in accordance with the recognition and measurement requirements of International Financial Reporting Standards as adopted for use in the EU (IFRSs), IFRS IC interpretations, and the Companies Act 2006 applicable to companies reporting under IFRS. The accounting policies applied by the Group in this financial information are the same as those applied by the Group in its financial statements for the period ended 30 June 2020 and which will form the basis of the 2020/21 financial statements except for a number of new and amended standards which



have become effective since the beginning of the previous financial year. These new and amended standards are not expected to materially affect the Group.

Certain statements in this announcement constitute forward-looking statements. Any statement in this announcement that is not a statement of historical fact including, without limitation, those regarding the Company's future expectations, operations, financial performance, financial condition and business is a forward-looking statement. Such forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially. These risks and uncertainties include, amongst other factors, changing economic, financial, business or other market conditions. These and other factors could adversely affect the outcome and financial effects of the plans and events described in this announcement and the Company undertakes no obligation to update its view of such risks and uncertainties or to update the forward-looking statements contained herein. Nothing in this announcement should be construed as a profit forecast.

The financial information presented herein does not constitute full statutory accounts under Section 434 of the Companies Act 2006 and was not subject to a formal review by the auditors. The financial information in respect of the period ended 30 June 2020 has been extracted from the statutory accounts which have been delivered to the Registrar of Companies. The Group's Independent Auditor's report on those accounts was unqualified, did not include references to any matters to which the auditor drew attention by way of emphasis without qualifying their report and did not contain a statement under section 498(2) or 498(3) of the Companies Act 2006. The financial information for the half years ended 31 December 2020 and 31 December 2019 is unaudited and the period to 30 June 2020 is audited.

These interim accounts have not been prepared in accordance with IAS 34.

## **2. Significant accounting policies**

### **Going concern**

The Group meets its 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 interim 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 should be able to operate within the level of its current funding arrangements

The Directors believe that the Company and the Group 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 interim financial statements.

### **Basis of consolidation**

The consolidated financial statements incorporate the financial statements of the Company and its subsidiary undertaking. Subsidiaries are all entities over which the Group has the power to govern their financial and operating policies generally accompanying a shareholding of more than fifty per cent of the voting rights. 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 an acquisition by acquisition basis, the Group recognises any non-controlling interest in the acquiree either at fair value or at the non-controlling interest's proportionate share of the acquiree's net assets.

The excess of the consideration transferred, the amount of any non-controlling interest in the acquiree and the acquisition date fair value of any previous equity interest in the acquiree over the fair value of the Group's share of the identifiable net assets acquired is recorded as goodwill. If this is less than the fair value of the net assets of the subsidiary acquired in the case of a bargain purchase, the difference is recognised directly in the income statement.

Inter-Company transactions, balances and unrealised gains on transactions between Group companies are eliminated. Unrealised gains and 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.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the foreign entity and translated at the closing rate.

### **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:

Plant and machinery      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, currently 5 to 10 years. 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.

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.

### **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.

**Inventories**

Inventories and work in progress are stated at the lower of cost and net realisable value. Cost is calculated on a first in and first out basis and includes direct costs and attributable overheads, where appropriate. Net realisable value represents the estimated selling price less all estimated costs of completion and applicable selling costs. Where necessary, provision is made for slow-moving and obsolete inventory. Inventory on consignment and their related obligations are recognised in current assets and payables respectively.

**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 consolidated cash flow statement, cash and cash equivalents consist of cash and short-term deposits as defined above.

**Share capital**

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.

**Revenue**

Revenue is accounted for in accordance with the principles of IFRS 15.

Revenue for the sale of goods and services is measured at the fair value of the consideration received or receivable and represents the invoiced value for the sale of the goods and services net of sales taxes, rebates and discounts. Revenue from the sale of goods and services is recognised when the performance obligation has been satisfied and collectability of the related receivables is reasonably assured. A receivable is recognised when performance obligation related to the goods or services has been satisfied as this is the point in time that the consideration is unconditional because only the passage of time is required before the payment is due. Where contracts contain multiple deliverables, and the volume of each deliverable can be determined with reasonable certainty, then the transaction price will be allocated to each performance obligation based on the expected cost of each item.

*Pharmaceutical services revenue*

Pharmaceutical services revenue is generated from the provision of analytical services to customers. Contracts with customers generally include an initial upfront payment and additional payments upon achieving performance milestones. Revenue is recognized when control of the promised services is transferred to customers and the performance obligation is fulfilled in an amount that reflects the consideration that the Company expects to be entitled in exchange for those services. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer which may occur at a point in time or over time depending on the individual contract terms. Sales tax and other similar taxes are excluded from revenues.

During the six months ended December 31, 2020 the Company recognized \$0.4 million of pharmaceutical services revenue where performance obligations are satisfied at a point in time.

**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.

#### **Performance of contract liability to affiliate**

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement ("Kantaro 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. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. During the three months ended September 30, 2020, the Company recognized \$0.5 million related to the performance of the contract liability with Kantaro. This represents the allocation of costs for performing services on behalf of Kantaro.

#### **Equity Method Investment**

As the Company can exert significant influence over, but does not control, Kantaro's operations through voting rights or representation on Kantaro's board of directors, the Company accounts for the investment using the equity method of accounting. The Company records its share in Kantaro's earnings and losses in the condensed consolidated statement of operations. The Company assesses its investment for other-than-temporary impairment when events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable and recognize an impairment loss to adjust the investment to its then-current fair value.

#### **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.

*(C) Employee Stock Purchase Plan*

The Group's 2020 Employee Share Purchase Plan (the ESPP) became effective on August 17, 2020. The ESPP authorizes the issuance of up to 850,000 shares of the Company's ordinary shares (American Depositary Shares) . The number of shares of the Company's ordinary shares that may be issued pursuant to rights granted under the ESPP shall automatically increase on January 1st of each year, commencing on January 1, 2021 and continuing for ten years, in an amount equal to the lesser of one percent of the total number of shares of the Company's ordinary shares outstanding on December 31st of the preceding calendar year, and 2,000,000 ordinary shares, subject to the discretion of the board of directors or remuneration committee to determine a lesser number of shares shall be added for such year.

Under the ESPP, eligible employees can purchase the Company's ordinary shares through accumulated payroll deductions at such times as are established by the board of directors or remuneration committee. Eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of the Company's ordinary shares on the first day of the offering period or on the purchase date. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not purchase more than \$25,000 worth of the Company's ordinary shares for each calendar year in which such rights is outstanding. Share-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period.

**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.

**3. Segmental reporting**

The Group operates as a single segment.

**4. Income Tax**

Unaudited	Unaudited	Audited
Period ended 31 December 2020	Period ended 31 December 2019	Period ended 30 June 2020

	\$'000	\$'000	\$'000
Deferred tax	4,526	1,585	2,319
<b>Total deferred tax</b>	<b>4,526</b>	<b>1,585</b>	<b>2,319</b>
Income tax credit	4,526	1,585	2,319

## 5. 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 share in issue during the period.

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.

	Unaudited Period ended 31 December 2020	Unaudited Period ended 31 December 2019	Audited Period ended 30 June 2020
	\$'000	\$'000	\$'000
<b>Loss attributable to owners of the parent</b>	(14,036)	(5,635)	(9,250)
Weighted average number of ordinary shares in issue	70,932,808	58,563,960	59,416,134
Basic and diluted loss per share	\$ (0.20)	\$ (0.10)	\$ (0.16)

## 6. Property, Plant and Equipment

	Fixtures and fittings \$'000
<b>Cost</b>	
At beginning of period	309
Additions	471
<b>At 31 December 2019</b>	<b>780</b>
<b>Depreciation</b>	
At beginning of period	31
Charge for the period	27

<b>At 31 December 2019</b>	<b>58</b>
<b>Net book value at 31 December 2019</b>	<b>722</b>
<b>Cost</b>	
At 1 July 2019	780
Additions	391
Verici-Assets held for sale	(522)
Foreign translation	1
<b>At 30 June 2020</b>	<b>650</b>
<b>Depreciation</b>	
At 1 July 2019	58
Charge for the period	47
Verici - Assets Held for Sale Depreciation	(36)
Foreign translation	1
<b>At 30 June 2020</b>	<b>70</b>
<b>Net book value at 30 June 2020</b>	<b>580</b>
<b>Cost</b>	
At 1 July 2020	650
Additions	853
Foreign translation	
<b>At 31 December 2020</b>	<b>1,503</b>
<b>Depreciation</b>	
At 1 July 2020	70
Charge for the period	118
Foreign translation	
<b>At 31 December 2020</b>	<b>188</b>
<b>Net book value at 30 June 2020</b>	<b>1,315</b>

## 7. Intangible Assets

	Trademarks trade names & licences	Trade secrets	Development costs	Total
	\$'000	\$'000	\$'000	\$'000
<b>Cost</b>				
At beginning of period	11,002	6,641	2,732	20,375
Additions	-	-	546	546

Transfer to Assets Held for Sale	(1,261)	-	-	(1,261)
Foreign translation	(275)	(239)	(55)	(569)
<b>At 30 June 2020</b>	<b>9,466</b>	<b>6,402</b>	<b>3,223</b>	<b>19,091</b>
<b>Amortisation</b>				
At beginning of period	1,620	-	-	1,620
Charge for the period	584	-	-	584
Transfer to Assets Held for Sale	(114)	-	-	(114)
Foreign translation	(117)	-	-	(117)
<b>At 30 June 2020</b>	<b>1,973</b>	<b>-</b>	<b>-</b>	<b>1,973</b>
<b>Net book value</b>				
<b>At 30 June 2020</b>	<b>7,493</b>	<b>6,402</b>	<b>3,223</b>	<b>17,118</b>
<b>Cost</b>				
At beginning of period	9,466	6,402	3,223	19,091
Additions	-	-	488	488
Foreign translation	739	342	84	1,165
<b>At 31 December 2020</b>	<b>10,205</b>	<b>6,744</b>	<b>3,795</b>	<b>20,744</b>
<b>Amortisation</b>				
At beginning of period	1,973	-	-	1,973
Charge for the period	510	-	-	510
Foreign translation	158	-	-	158
<b>At 31 December 2020</b>	<b>2,641</b>	<b>-</b>	<b>-</b>	<b>2,641</b>
<b>Net book value</b>				
<b>At 31 December 2020</b>	<b>7,564</b>	<b>6,744</b>	<b>3,795</b>	<b>18,103</b>

## 8. Dividends

No dividends to shareholders of the holding company were provided or paid during the six months to 31 December 2020 (six months to 31 December 2019 and period to 30 June 2020: both nil). The Board's policy is to enhance shareholder value mainly through the growth of the Group, which is currently in the early stages of its development. The Board will however consider the payment of dividends if and when appropriate.

### Additional Financial Information: IFRS to US GAAP reconciliation

Since RenalytixAI's initial listing on Nasdaq, the Company has followed accounting principles generally accepted in the United States of America ('US GAAP'), both for internal as well as external purposes. Renalytix's Q2 6-k, which is based on US GAAP, contains differences from its Half Year report, which

is based on IFRS. Both the Form 6-K and Half Year Report are 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 information, Renalytix has provided, on a voluntary basis, a reconciliation from IFRS to U.S. GAAP as follows:

## Balance Sheet

	GAAP	IFRS		
	December 30,		GAAP vs IFRS	
	2020	2020	Difference	
<b>Assets</b>				
Current assets:				
Cash	\$ 74,532	\$ 74,532		
Short-term investments	-	-		
Accounts Receivable	400	400		
Prepaid expenses and other current assets	3,587	3,585	2	( a )
Note Receivable - Kantaro	167	167		
Related-party receivable	158	158		
<b>Total current assets</b>	<b>78,844</b>	<b>78,842</b>		
Property and equipment, net	2,603	1,315	1,288	( b )
Intangibles, net	-	18,103	(18,103)	( c )
Deferred tax assets	-	4,526	(4,526)	( d )
Investment in Verici	7,852	7,852		
Investment in Kantaro	1,716	1,716		
Right of use asset	-	341	(341)	( e )
<b>Total assets</b>	<b>\$ 91,015</b>	<b>\$ 112,695</b>		
<b>Liabilities and stockholders' equity</b>				
Current liabilities:				
Note payable - current	141	141		
Accounts payable	864	2,798	(43)	( f )
Accrued expenses and other current liabilities	1,608	-		
Accrued expenses - related party	283	-		
Current lease liability	-	86	(86)	( g )
Payable to Kantaro - current	824	824		
<b>Total current liabilities</b>	<b>3,720</b>	<b>3,849</b>		
Note payable - Noncurrent	114	114		
Payable to Kantaro - noncurrent	231	231		
Non-current lease liabilities	-	256	(256)	( h )
Other liabilities	53	-		

<b>Total liabilities</b>	<b>4,118</b>	<b>4,450</b>		
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	219	232	13	( i )
Additional paid-in capital	148,408	79,615	(68,793)	( j )
Accumulated other comprehensive (loss) income	7,116	7,580	464	( k )
Accumulated deficit	(68,846)	20,816	89,662	( l )
<b>Total stockholders' (deficit) equity</b>	<b>86,897</b>	<b>108,243</b>		
<b>Total liabilities and stockholders' (deficit) equity</b>	<b>\$ 91,015</b>	<b>\$ 112,693</b>		

- (a) Immaterial difference
- (b) Differences is attributable to \$1.2 million of 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, \$1.2 million of capitalized software costs which are recorded as property and equipment under US GAAP and Intangibles under IFRS.
- (d) 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. Under U.S. GAAP, a full valuation allowance has been applied. Under IFRS, a partial valuation allowance has been applied.
- (e) Represents the adoption of IAS 17 in connection with the Company's commercial laboratory in Utah. he Comapny has deferred the adoption of ASC 842 under U.S. GAAP until July 1, 2022.
- (f) Accounts payable and other current liabilities are presented in the aggregate within the Half Year report while broken out separately on the US GAAP 6-k. Difference represents other immaterial audit adjustments.
- (g) Represents the adoption of IAS 17 in connection with the Company's commercial laboratory in Utah. he Comapny has deferred the adoption of ASC 842 under U.S. GAAP until July 1, 2022.
- (h) Represents the adoption of IAS 17 in connection with the Company's commercial laboratory in Utah. he Comapny has deferred the adoption of ASC 842 under U.S. GAAP until July 1, 2022.
- (i) Represents other immaterial audit adjustments.
- (j) Represents cancellation of share premium account and reduction in accumulated deficit under IFRS in anticipation of a distribtuion of FractalDx net assets to the shareholders of Verici. In addition, stock based compensation is recognized on a straight line basis under U.S. GAAP and a graded vesting basis under IFRS.
- (k) Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
- (l) Represents cancellation of share premium and reduction in accumulated deficit under IFRS in anticipation of a distribtuion of FractalDx net assets to the shareholders of Verici and differences noted within the Company's consolidated statement of operations and comprehensive loss.

## Income Statement

### *Reconciliation of Net Loss*

(\$ thousands)	December 30, 2020
<b>Net loss in accordance with IFRS</b>	<b>(14,036)</b>
(a) <i>Deferred tax assets</i>	(2,121)
(b) <i>Stock compensation expense</i>	(107)
(c) <i>Amortization of intangibles</i>	667
(d) <i>Verici transaction</i>	(434)
(e) <i>Other adjustments</i>	(98)
Total adjustments	(2,093)
<b>Net loss in accordance with US GAAP</b>	<b>(16,129)</b>

- (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. Under U.S. GAAP, a full valuation allowance has been applied. Under IFRS, a partial valuation allowance has been applied.
- (b) Stock based compensation is recognized on a straight line basis under U.S. GAAP and a graded vesting basis under IFRS.
- (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) 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) The remaining difference of \$0.1 million represents other immaterial audit adjustments and small accounting differences.

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