

# Renalytix plc Annual Report and Financial Statements

FOR THE YEAR ENDED 30 JUNE 2021

## : Index

STRATEGIC REPORT	4-23
Chairman & CEO's Joint Statement	4
Company Overview	9
Operational and Financial Highlights	10
Product Overview and Strategy	12
Financial Review	15
Risk Management Approach	17
Section 172 Statement	21
Corporate Social Responsibility Review	23
CORPORATE GOVERNANCE	24-53
Board of Directors	24
Directors' Report	27
Corporate Governance Statement	31
Directors' Remuneration Report and Policy	34
Independent Auditors' Report	49
FINANCIAL STATEMENTS	54-88
Consolidated Income Statement	54
Consolidated Statement of Comprehensive Income	55
Consolidated and Company's Statements of Financial Position	56
Consolidated and Company's Statements of Cashflows	58
Consolidated Statement of Changes in Equity	60
Company's Statement of Changes in Equity	62
Notes to the Financial Statements	64
Additional Financial Information	86

## STRATEGIC REPORT

## Chairman & CEO's Joint Statement

## TO THE MEMBERS OF RENALYTIX AI PLC

We are delighted to present the annual report for the twelve months ended 30 June 2021 for Renalytix plc ("Renalytix" or the "Company").

### **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<sup>TM</sup>**

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 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 repeal of 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.

Christophe Mills

Christopher Mills

Chairman

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James R. McCullough Chief Executive Officer

## Company Overview

## PIONEERING NEXT-GENERATION TECHNOLOGY SOLUTIONS FOR KIDNEY HEALTH

Renalytix is the global founder and leader in the new field of bioprognosis<sup>™</sup> 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.

Renalytix is focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs. KidneyIntelX, our first-in-class in vitro diagnostic platform, employs a proprietary algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from electronic health record, or EHR, systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

## ON A MISSION TO COMBAT A DEVASTATING AND COSTLY DISEASE

Kidney disease is a public health epidemic affecting over 850 million people globally. Managing a CKD population of this scale and the associated healthcare spending presents a unique healthcare system challenge, requiring a solution that provides a clearer understanding of clinical risk tied to specific guideline-driven clinical recommendations. The ability to predict which patients will experience progressive kidney function decline, which includes rapid kidney function decline, or RKFD, sustained significant decline in kidney function, kidney failure, initiation of long-term dialysis or kidney transplant, is critical to changing patient outcomes and health economics. Current methods for risk stratification of patients with CKD lack sufficient precision in predicting progressive kidney function decline, especially at earlier stages of the disease. This can exacerbate the occurrence of unexpected and expensive clinical events. In fact, up to 38% of patients with CKD initiate dialysis with little or no prior clinical specialist consultation, and up to 63% of patients with CKD initiate dialysis in an unplanned fashion with a central venous catheter and/or during emergency hospitalization, which we refer to as "dialysis crash." This highlights the need for an early mechanism to identify potential instances of rapidly progressing CKD before it becomes critical to the patient's health and costly to healthcare providers. In our clinical validation studies in patients with DKD, KidneyIntelX more accurately identified and segmented patients into three risk categories (low, intermediate and high) when compared to clinical models, including the current standard of care, the KDIGO risk stratification algorithm. When guideline-recommended urine albumin to creatinine ratio testing was performed, the positive predictive value (PPV) for progressive decline in kidney function was 69% for those scored as high-risk by KidneyIntelX versus the 40% identified as highest-risk by KDIGO categorization. This is a 72% improvement compared to standard of care. In addition, only 7% of those scored as low-risk by KidneyIntelX experienced progression (i.e., negative predictive value of 93%). Lack of ability to accurately predict which patients are at higher risk has led to strained clinician resources, inadequate referrals to clinical specialists and suboptimal treatment of DKD, resulting in significant patient suffering and diminished quality of life.

We believe that the KidneyIntelX platform will be central to managing CKD, helping to identify which patients could benefit from clinical interventions at earlier stages of CKD before significant and irreversible kidney damage has taken place. For patients with CKD as a result of diabetes, obesity or other factors, early intervention can lower the risk of progressing to lifealtering advanced disease, kidney failure, dialysis and diminished quality of life. For primary care physicians and specialists, KidneyIntelX provides an easy-to-understand, reportable patient risk score integrated with specific guideline-driven clinical recommendations designed to maximize patient treatment and compliance outcomes. For insurance payors, KidneyIntelX can help drive health economics gains over time. For population health and clinical medicine departments, KidneyIntelX provides a powerful prognostic tool to stratify CKD populations into low-, intermediate- and high-risk categories applied to a continuous scale, enabling physicians to optimize the choice of treatment and allocation of clinical resources to benefit patient outcomes and health economics. In our clinical validation studies to date, involving stored specimens from over 1,500 patients with DKD, KidneyIntelX demonstrated the ability to more accurately identify which patients would experience progressive kidney function decline over current clinical practice. We believe early risk stratification, using advanced technology implemented in partnership with healthcare systems and insurance payors, can help support a fundamental shift towards optimal treatment for the over 850 million people suffering from kidney disease worldwide.

## **Operational and Financial Highlights**

## **REGULATORY & REIMBURSEMENT HIGHLIGHTS**

- Government-wide contract granted by the U.S. General Services Administration for KidneyIntelX<sup>TM</sup> 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 HIGHLIGHTS

- 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

## **CLINICAL & VALIDATION HIGHLIGHTS**

- 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.

## FINANCIAL HIGHLIGHTS

- 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 \$65.2 million at 30 June 2021

### POST-PERIOD END DEVELOPMENTS

- 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

## Product Overview and Strategy

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.

## **OUR STRATEGY**

Our goal is to lower healthcare costs and improve patient quality of life by transforming the paradigm for kidney disease risk assessment and clinical management through our KidneyIntelX platform. To achieve this goal, we plan to:

- Continue to Build Integrated Partnerships with Healthcare Systems on a Population Health Basis. We are focused on building partnerships with healthcare systems and the engagement and support of their clinical leadership teams, which will enable us to efficiently initiate and deploy our solution to patient populations with DKD. A key aspect of this is technical integration of the KidneyIntelX software platform with healthcare systems' EHR systems and clinical workflow. In September 2020, we announced the launch of our partnership with Mount Sinai Health System, including initiation of patient testing. Integrated partnerships such as this are designed to allow KidneyIntelX to be deployed directly to patient populations and their treating clinicians in a cost-efficient and timely manner. We are engaging with multiple healthcare institutions and national payors regarding additional partnership opportunities.
- Actively Market KidneyIntelX in Veterans Health Administration. Following our 10-year government-wide contract provided in April 2021 by the U.S. General Services Administration for KidneyIntelX testing services at \$950 per reportable result, we are now staffing sales and support teams and establishing enabling infrastructure to deploy KidneyIntelX at Veterans Health Administration. The Veterans Health Administration is America's largest integrated health care system, providing care at 1,293 health care facilities, including 171 medical centers and 1,112 outpatient sites, serving nine million enrolled veterans each year. The veteran population has an approximately one-third higher chronic kidney disease and DKD prevalence than the general population, which has been attributed to the significant multimorbidity and higher mean age in this group. The economic costs for providing healthcare for Veterans with kidney disease are high and are increasing at a rapid rate. Excluding costs associated with dialysis, \$17.9 billion was spent on care for Veterans with CKD in 2014. New VHA Directive 1053, distributed on March 17, 2020, established policy to improve prevention, early recognition, and management of CKD in VA medical facilities. An update to the VA/DoD Clinical Practice Guideline for the Management of CKD released in 2019 identified the need for accurate risk assessment in patients with early-stage kidney disease. KidneyIntelX and associated care management tools provide information that is essential to realizing the directive's goals for appropriate pharmacy management, promoting communication and collaboration between care providers, particularly between nephrologists and primary care physicians and developing a patient-centered plan for treatment and education about kidney disease.
- Further Expand Insurance Payor Coverage. We believe that the potential of KidneyIntelX to improve patient outcomes and promote benefits in health economics for patients, physicians and payors provides a strong foundation for our reimbursement strategy. Moreover, early and ongoing engagement with insurance payors will be key to supporting the deployment of KidneyIntelX. In October 2019, Capital District Physicians' Health Plan, Inc., a physician-led health insurance payor in New York, adopted coverage determination policies that provide insurance for certain patients with DKD who are tested with KidneyIntelX. We are working with additional private insurance payors and healthcare providers to expand insurance coverage for KidneyIntelX nationwide, which we believe will be accelerated by our recent achievement of a CPT code and national Medicare pricing.
- **Continue to Pursue Medicare Coverage.** Following the receipt of national Medicare pricing at \$950 per reportable test for KidneyIntelX in January 2020, we are actively pursuing multiple distinct pathways for Medicare coverage, which would expedite the claims payment process. We estimate that Medicare currently provides insurance coverage for approximately 14 million patients with CKD, an estimated 40% of which have DKD.

In January 2021, the U.S. Centers for Medicare & Medicaid Services (CMS) announced the Medicare Coverage of Innovative Technologies, or MCIT, rule, which could have accelerated national Medicare coverage under certain conditions. Following a subsequent delay in the implementation of the final rule, CMS issued a proposal to repeal the final rule prior to implementation on December 15, 2021. CMS stated that it believes there are other ways to achieve the goal of providing innovation and access to important new technologies including future policies and potential rulemaking. CMS is now reviewing comments received during the open public comment period. Independent of MCIT, Renalytix has continued to develop clinical evidence to support Medicare coverage at the local level from a Medicare Administrative Contractor (MAC), which it could receive as early as mid-calendar 2022. Coverage from a MAC would allow for Medicare reimbursement at \$950 for any Medicare beneficiary in the United States receiving KidneyIntelX testing.

- Obtain FDA Clearance of KidneyIntelX to Further Drive Commercial Adoption in the United States. While not required for commercialization as an LDT, we are seeking marketing authorization from the FDA through the De Novo pathway as part of our strategy to produce a product capable of becoming the new, long-term standard of care for patients with CKD. We have designed KidneyIntelX under a quality-controlled product development process to support our FDA clearance application, and to take advantage of the dynamic capability of machine learning applied to large datasets through regulated, versioned product releases. KidneyIntelX was granted breakthrough device designation from the FDA in May 2019. In addition, we believe that preparing for and potentially obtaining FDA clearance could support our eventual efforts to obtain regulatory approvals of KidneyIntelX in the United Kingdom, European Union, China and other major global market territories, provide support for the adoption of KidneyIntelX across clinical disciplines and assist with the establishment of private third-party and government-based reimbursement.
- Build Substantial Repository of Kidney Disease-Related Data. We are building a repository of kidney disease-related data for the development of progressive KidneyIntelX product versions and additional artificial intelligence-powered clinical applications. We are designing applications to examine disease patterns in large patient populations and to optimize clinical care navigation and management effectiveness. These developments are underpinned by the goals of driving patient and physician behavior changes and ultimately improving patient outcomes. Access to current and historical patient data, combined with the ability to analytically and clinically validate study results in a quality-controlled framework, provides us with a powerful product development platform. Moreover, the depth, specificity and quality of data is of paramount importance to developing solutions with demonstrated clinical utility across a range of practice specialties and patient demographics, and securing access to this data is central to our strategy of demonstrating both short- and long-term impact on patient outcomes and health economics. We have tested this capability in our clinical validation studies involving stored specimens from over 1,500 patients with DKD from the Mount Sinai Health System and University of Pennsylvania Health System biobanks. As we continue to build our data repository, we believe our predictive capabilities will continue to improve, and we expect that we will have the most comprehensive kidney disease data repository geared toward early identification of high- risk patients and optimization of care pathways.
- Expand Our Product Portfolio. We believe there are significant opportunities to expand our technology platform through incremental version releases of KidneyIntelX as well as through extending the KidneyIntelX platform into new applications into additional populations of CKD patients beyond those with diabetes, including repeat testing to monitor changes in risk and therapeutic response and other CKD subtypes, 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 CKD associated 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.
- **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 of demonstrating 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 a vast 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, kidney disease associated 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.

• Launch in Major International Markets. We plan to pursue the launch of KidneyIntelX in major medical markets outside of the United States, including in the United Kingdom, European Union and China, which have large and growing populations of CKD patients and are facing cost and clinical management challenges similar to the United States. According to a recent report published by NHS Kidney Care, in the United Kingdom, treatment for CKD costs more than breast, lung, colon and skin cancer combined. We plan to pursue foreign regulatory approval pathways, continue data accumulation and study development with ex-U.S. clinical investigators and seek integrated medical center opportunities for addressing CKD patient populations outside of the United States, subject to obtaining the required marketing authorizations.

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 results presented cover FY21. 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 \$31.2m (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 \$7.95m during FY21 (FY20: \$0.5m income) related to unrealized foreign exchanges losses offset by 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: \$0.3m).

#### **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 \$1.1m in net property, plant, and equipment (FY20: \$0.6m).

#### **Intangible Assets**

The Group held \$18.0m 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 capitalized as development costs. Intangible assets also include the value of the biomarker business purchased (in exchange for ordinary shares in the Company) from EKF. Intangible assets increased period over period due to capitalized software and the impact of foreign exchange translation at period end.

#### **Deferred** Tax

A deferred tax asset totaling \$7.1m (FY20: \$2.3m) has been calculated based on the unused 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.

## Risk Management Approach

We recognize that effective risk management is essential to the successful delivery of the Group's strategy. As we grow our business, we believe it is important to develop and enhance our risk management processes and control environment on an ongoing basis and ensure it is fit for purpose by identifying and managing risks across the Group in a consistent and robust manner.

Below we describe our risk management approach, the principal risks and uncertainties faced by the Group and the controls in place to manage them.

## OVERVIEW OF RISK MANAGEMENT APPROACH

The key principles that guide the Group's risk management approach are outlined below:

- It is the employees' responsibility to ensure they understand and comply with the Risk Management Policy and their defined risk management roles and responsibilities.
- There is a defined risk management governance structure with clear accountabilities.
- A consistent risk management approach is used throughout the Group to identify and manage risks posed in the AI and life sciences industries.
- Risk management is embedded in all key processes and decision-making within the Group (including strategy setting, budgeting, planning and day-to-day operations and activities).

A risk register is maintained and updated periodically. The register includes the risk description, risk owner, mitigation/control description and risk profile.

### PRINCIPAL RISKS AND UNCERTAINTIES

Set out below are the principal risks which we believe could materially affect the Group's ability to achieve its financial and operating objectives and control or mitigating activities adopted to manage them. The risks are not listed in order of significance.

## THE GROUP IS DEPENDENT UPON ITS STRATEGIC COLLABORATION WITH THIRD PARTY PARTNERS

The Group is working to develop and commercialize its products in close collaboration with strategic partners. The Group is dependent upon third parties for resources and revenue. Failure by these strategic partners to meet its key contractual obligations or to purchase KidneyIntelX tests, for whatever reason, would likely have a material adverse effect on the Group and its ability to achieve its commercial objectives, potentially including the attainment of sales volumes leading to profitability, and may ultimately result in the Group becoming unviable.

### **REGULATORY RISK**

There can be no guarantee that any of the Group's products will be able to obtain or maintain the necessary regulatory approvals in any or all of the territories in respect of which applications for such approvals are made. Where regulatory approvals are obtained, there can be no guarantee that the conditions attached to such approvals will not be considered too onerous by the Group or its partners in order to be able to market its products effectively.

The Group seeks to reduce this risk by seeking advice from regulatory advisers, consultations with regulatory approval bodies and by working with experienced partners.

#### **REIMBURSEMENT LEVELS**

There is no guarantee that the Company will be able to continue to sell its products or services profitably if the reimbursement level from third party payers, including government and private health insurers, is limited or subsequently withdrawn. Third party payers are increasingly attempting to contain health care costs through measures that could impact the Company including challenging the prices charged for health care products and services, limiting both coverage and the amount of

reimbursement for new diagnostics products and services, and denying or limiting coverage for products that are approved by the regulatory agencies but are considered experimental by third party payers.

The Company understands that due to third party dependency it is extremely difficult to eradicate this risk. However, the Company manages this risk with constant dialogue and educating the third-party payers on the Group's products and also developing new technologies in order to seek additional reimbursements.

### **KEY EMPLOYEES**

The Company's future development and prospects depend to a significant degree on the continuing contribution of key members of its Board, Senior Management and Scientific Advisory Board. As a small organization, the Company relies on a core team of staff and is therefore exposed to any significant departures of key personnel. In particular, the Company's performance depends significantly on the continuing contribution of its CEO, James McCullough, its President, Thomas McLain, its CTO, Fergus Fleming, its CFO, O. James Sterling and its CMO, Michael Donovan.

The Group operates in a highly competitive field and the expertise and skills of key individuals are also applicable in a number of other fields and industries. The high level of demand for such expertise and skills means that there is increasingly intense competition for talent. The departure of any of the key members to pursue other opportunities or because they are no longer able to continue to perform their roles (for whatever reason) could have a negative impact on its operations and could affect the Group's ability to execute the Group's business strategy.

To seek to mitigate the potential risk of departures, the Company has adopted a competitive remuneration structure, which includes share-based incentives. The Company has also taken out key- man insurance on James McCullough. However, there can be no assurance that this insurance will be adequate or continue to be available on appropriate terms or at all.

## **OBSOLESCENCE OF GROUP'S PRODUCTS**

Demand for the Group's products could be adversely impacted by the development of alternative technology and alternative medicines specifically intended for the identification, stratification and/ or treatment of CKD patients. There can be no assurance that the technology and products currently being developed by the Group will not be rendered obsolete. New AI technology may continue to emerge and develop. As a result, there is the possibility that new technology may be superior to, or render obsolete, the technology that the Group currently is developing. Any failure of the Company to ensure that its technology platform and products remain up to date with the latest technology may have a material adverse impact on the Company's competitiveness and financial performance. The Group's success will depend, in part, on its or its partners' ability to develop and adapt to these technological changes and industry trends.

## THE GROUP IS SUBJECT TO INCREASINGLY STRINGENT PRIVACY AND DATA SECURITY LEGISLATION

Regulatory, legislative or self-regulatory/standard developments regarding privacy and data security matters could adversely affect the Group's ability to conduct the Group's business. The Group is subject to laws, rules, regulations and industry standards related to data privacy and cyber security, and restrictions or technological requirements regarding the collection, use, storage, protection, retention or transfer of data.

For the foreseeable future, the Group will only process data relating to patients in the US and will therefore be subject to various rules and regulations, including those promulgated under the authority of the US Department of Health and Human Services, the Federal Trade Commission, and state cybersecurity and breach notification laws, as well as regulator enforcement positions and expectations.

If the Company begins processing personal data in the context of an establishment in a country that is subject to the GDPR or if it offers products or services to residents of an EU country, it will have to comply with various robust obligations.

Globally, governments and agencies have adopted and could in the future adopt, modify, apply or enforce laws, policies, regulations, and standards covering user privacy, data security, technologies that are used to collect, store and/or process data, marketing online, the use of data to inform marketing, the taxation of products and services, unfair and deceptive practices, and the collection (including the collection of information), use, processing, transfer, storage and/or disclosure of data associated with unique individual internet users. New regulation or legislative actions regarding data privacy and security (together with applicable industry standards) may increase the costs of doing business and could have a material adverse impact on the Group's operations and cash flows.

Despite the Group's ongoing efforts to ensure practices are compliant, the Group may not be successful either due to various factors within the Group's control, such as limited financial or human resources, or other factors outside the Group's control. It is also possible that local data protection authorities may have different interpretations of the GDPR, leading to potential inconsistencies amongst various EU member states.

### COMPETITION

The markets in which the Group operates, which include the markets for laboratory developed tests, clinical diagnostic support tools and clinical AI solutions, are potentially highly competitive and rapidly changing.

Competitors may have access to considerably greater financial, technical and marketing resources. The availability and price of the Group's competitors' clinical AI development services could limit the demand, and the price the Group is able to charge, for its services. New competing products may enter the market and make the Group's discoveries and the products developed from those discoveries obsolete.

Alternatively, a competitor's products may be more effective, cheaper or more effectively marketed than the products developed by the Group, which could have a material adverse effect on the Group's profitability and/or financial condition.

Technological competition from medical device companies, life science companies, universities and academic medical centers is intense and can be expected to increase. Many competitors and potential competitors of the Group have substantially greater product development capabilities and financial, scientific, marketing and human resources than the Group. The future success of the Group depends, in part, on its ability to maintain a competitive position, including an ability to further progress through the necessary preclinical and clinical trials to support commercialization, marketing authorization where necessary, and coverage and reimbursement. Other companies may succeed in commercializing products earlier than the Group or in developing products that are more effective than those which may be produced by the Group. While the Group will seek to develop its capabilities in order to remain competitive, there can be no assurance that research and development by others will not render the Group's products obsolete or uncompetitive.

### RESEARCH AND DEVELOPMENT RISK

The Group operates in the life sciences sector and will look to exploit opportunities within that sector. The Group is involved in complex clinical development processes and industry experience indicates that there may be a very high incidence of delay or failure to produce the desired results. The Group may not be able to develop new products or to identify specific market needs that can be addressed by technology solutions developed by the Group. The ability of the Group to develop new technology relies, in part, on the recruitment of appropriately qualified staff as the Group grows. The Group may be unable to find a sufficient number of appropriately highly trained individuals to satisfy its growth rate which could affect its ability to develop as planned.

Product development timelines are at risk of delay, particularly since it is not always possible to predict the rate of patient recruitment into clinical trials. There is a risk therefore that product development could take longer than presently expected by the Board. If such delays occur, the Group may require further working capital. The Board shall seek to minimize the risk of delays by careful management of projects.

In addition, research and development may be subject to various requirements, such as research subject protection for individuals participating in clinical evaluations of new laboratory developed tests and products, institutional review board oversight, regulatory authorizations, and design control requirements for FDA and EU-regulated products. Failure to comply with requirements could result in penalties, delay, or prevent commercialisation of products.

## FINANCIAL REPORTING AND DISCLOSURE

Due to the nature of the Group there is a requirement to report accurate financial information in compliance with accounting standards and applicable legislation.

This risk is mitigated through the Group's internal controls over the financial information and reporting, overseen by the local financial heads and then reviewed by the central finance team, including the Chief Financial Officer. The annual financial statements are also subject to audit by the Group's external auditors.

## CYBER SECURITY RISK

The Group uses computers extensively in its operations and has an online presence but does not trade online. It is at risk of attack through hacking or other methods. This risk is mitigated by the use of robust security measures, staff training, and back-up systems.

## INTELLECTUAL PROPERTY RISK

The commercial success of the Group and its ability to compete effectively with other companies depends, amongst other things, on its ability to obtain and maintain patents sufficiently broad in scope to provide protection for the Group's intellectual property rights against third parties and to exploit its products. The absence of any such patents may have a material adverse effect on the Group's ability to develop its business.

The Group mitigates this risk by developing products where legal advice indicates patent protection would be available, seeking patent protection for the Group's products, maintaining confidentiality agreements regarding Group know-how and technology and monitoring technological developments and the registration of patents by other parties. The commercial success of the Group also depends upon not infringing patents granted, now or in the future, to third parties who may have filed applications or who have obtained, or may obtain, patents relating to business processes which might inhibit the Group's ability to develop and exploit its own products.

### PANDEMIC RISK

The COVID-19 pandemic has created uncertainty in the market. The eventual severity and length of the economic disruption is impossible to forecast. We believe we still have a robust plan in place to mitigate the effect of the disruption on the business including taking the following actions (amongst others):

- Organizing for as many staff as possible to work from home
- · Improving our computer networking to facilitate remote working
- Gaining designation as a company essential to basic medical care which allows our premises to remain open even in a lockdown
- Improved social distancing by limiting physical meetings, expanding flexible working, and altering production practices
- Preparing requests for support for short time working with local authorities in case this becomes necessary
- Banning international travel and limiting domestic travel
- Increasing supplier and customer contact so as to be able to anticipate issues and react quickly

We have insurance cover in place in case there is a loss of business, although it cannot be guaranteed that cover will be sufficient to protect against all eventualities.

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. However, at this stage, it is difficult to assess reliably whether there will be any material disruption in the future. We have modelled a number of scenarios covering reductions in revenue of 10% and 50%, without taking into account the potential benefits of any mitigation strategies such as potential cost savings or insurance claims. We have also modelled out 100% reductions in revenue with cost savings within our control. While the eventual severity and length of the economic disruption stemming from the pandemic is impossible to forecast these models give the Directors reasonable confidence that the business has sufficient resources to continue as a going concern for at least the next 12 months.

## Section 172 Statement

The Directors are required by law to act in good faith to promote the success of the Company for the benefit of the shareholders as a whole and are also required to have regard to the following:

- the likely long-term consequences of any decision;
- the interests of the Company's employees;
- the need to foster the Company's business relationships with suppliers, customers and others;
- the impact of the Company's operations on the community and the environment;
- the desirability of the Company maintaining a reputation for high standards of business conduct; and
- the need to act fairly as between shareholders of the Company.

Please see the Corporate Governance Statement in the Directors' Report for an overview of the Company's corporate governance arrangements.

The Chairman and Chief Executive Officer's joint statement and the section headed "Product Overview and Strategy" in this Strategic Report describes the Group's activities, strategies and future prospects, including the considerations for long-term decision making. In particular, the Group has made significant progress towards its operational, regulatory and reimbursement goals and is now engaged in commercial roll-out of its lead product, KidneyIntelX in the United States. In addition, the Group is seeing an increase in strategic partnering activities which will continue to build on the validation and commercial use cases for KidneyIntelX.

The Board has a good relationship with the Group's employees. The Board maintains constructive dialogue with employees through the Chief Executive Officer and other members of the executive team. Appropriate remuneration and incentive schemes are maintained to align employees' objectives with those of the Group. See further under Employees in the section headed "Corporate Social Responsibility" below.

The Group endeavors to maintain good relationships with its suppliers by contracting on fair business terms, paying within agreed timeframes, and responding promptly to inquiries.

The Group's operations have minimal environmental impact. Please see Environment in the section headed "Corporate Social Responsibility" below for more details.

The Board recognizes the Group's duty to be a good corporate citizen. See Social, community and human rights in the section headed "Corporate Social Responsibility" below for more details.

The Board recognizes the importance of maintaining high standards of business conduct. The Group operates a Code of Business Conduct and Ethics applicable to its employees, independent contractors, executive officers and directors. A current copy of the Code of Business Conduct and Ethics is available on our website, which is located at www.renalytixai.com.

The Board endeavors to maintain good relationships with its shareholders and treat them equally. This is described in more detail in the Corporate Governance Statement under the heading "Relations with Shareholders."

There were a number of initiatives and strategic actions undertaken during FY21 which the Directors believe were in the best interests of the Company and all its stakeholders as follows:

- Achieved dual listing on Nasdaq Global Market and associated \$85.1 million gross equity financing
- Government-wide contract granted by the U.S. General Services Administration for KidneyIntelX<sup>™</sup> 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
- Full CLIA certification of Salt Lake City laboratory facility
- 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
- Welcomed new board members Ann Berman and Daniel Levangie both with extensive backgrounds in healthcare company growth and finance

## Corporate Social Responsibility

## **ENVIRONMENT**

The Directors consider that the nature of the Group's activities is not inherently detrimental to the environment. The Group is committed to identifying and minimizing any effect on the environment caused by its operations. As a minimum standard, we will fully comply with all relevant legislation and, wherever possible, look for opportunities to make a positive contribution to the environments in which we operate.

## **EMPLOYEES**

The Group places great value on the involvement of its employees and they are regularly briefed on the Group's activities. The Group closely monitors staff attrition rates which it seeks to keep at low levels and aims to structure staff compensation levels at competitive rates in order to attract and retain high calibre personnel.

### DISABLED EMPLOYEES

Applications for employment by disabled persons are always fully considered, bearing in mind the specific aptitudes of the applicant involved. It is the policy of the Group that the training, career development and promotion of disabled persons, as far as possible, be identical to that of other employees.

## SOCIAL, COMMUNITY AND HUMAN RIGHTS

The Board recognizes that the Group has a duty to be a good corporate citizen and to respect and comply with laws, regulations, and where appropriate the customs and culture of the territories in which it operates. The Group encourages employees to take part in charitable activities which are related to our business areas or customers. It contributes as far as is practicable to the local communities in which it operates and takes a responsible and positive approach to employment practices.

## CORPORATE GOVERNANCE

## **Board of Directors**



#### **Christopher Mills**

Non-Executive Chairman (Aged 68)

Christopher Mills has served as a member of the Renalytix Board since its inception. Christopher founded Harwood Capital Management in 2011, a successor to its former parent company, J.O. Hambro Capital Management, which he co-founded in 1993. He is Chief Executive and Investment Manager of North Atlantic Smaller Companies Investment Trust plc and Chief Investment Officer of Harwood Capital LLP. He is a Non-executive Director of a number of companies, including EKF Diagnostics. Christopher was a Director of Invesco MIM, where he was Head of North American Investments and Venture Capital, and of Samuel Montagu International.



#### James McCullough

#### Chief Executive Officer and Director (Aged 53)

James McCullough has served as Renalytix's co-founder and Chief Executive Officer since its inception. James has leadership experience building emerging technology companies in both the public and private sectors with specific expertise in the life-sciences industry. James was most recently Chief Executive Officer of Exosome Diagnostics, a venture-backed personalized medicine company developing non-invasive liquid biopsy diagnostics in cancer, which was recently acquired by Bio-Techne Corporation. James is also a managing partner of Renwick Capital, LLC, a management consulting firm specializing in assisting emerging healthcare technology companies with strategic planning and business execution, and was a co-founder of PAIGE.AI, a computational pathology spin-out from the Memorial Sloan Kettering Cancer Center. James received his B.A. from Boston University and an M.B.A. from Columbia Business School. James is currently Chairman of BalletNext, a performing arts company in New York City.



#### **Fergus Fleming**

#### Chief Technical Officer and Director (Aged 54)

Fergus Fleming has served as Renalytix's Chief Technical Officer since its inception. Fergus is managing director of FF Consulting Limited and Head of Business Development for Oncomark Limited. Fergus has over 25 years' experience in the life sciences sector, including leadership positions with Baxter Healthcare, Boston Scientific, Trinity Biotech plc, and EKF Diagnostics. Fergus has extensive experience in the design and manufacture of medical device software, in vitro diagnostics instruments and reagents, and electromechanical devices. He has extensive experience managing global projects, including clinical research collaborations, product development, acquisition integration, and manufacturing site transfers.



#### Erik Lium Ph.D.

#### Non-Executive Director (Aged 53)

Erik Lium, Ph.D., has served as a member of the Renalytix Board since November 2018. Dr. Lium is the executive vice president of Mount Sinai Innovation Partners and is responsible for advancing Mount Sinai's research, instruction, and public service missions through strategic research partnerships with industry, the management, transfer and commercialisation of technologies, and fostering the development of start- ups and joint ventures to advance promising early-stage technologies. Dr. Lium also serves as a director of Amathus Therapeutics and as a member of the Investment Review Committee for the Accelerate NY Seed Fund.

Prior to joining Mount Sinai, Dr. Lium served as the assistant vice chancellor of Innovation, Technology & Alliances at the University of California, San Francisco (UCSF), and the UCSF Principal Investigator for the Bay area National Science Foundation I-Corps node. He held previous positions at UCSF, including assistant vice chancellor of Research and director of Industry Contracts, and director of Business Development for the Diabetes Center & Immune Tolerance Network. Dr. Lium served as president of LabVelocity Inc., an Information Services Company focused on accelerating research and development in the life sciences prior to its acquisition in 2004. He pursued post-doctoral research at UCSF, and earned a PhD with honours from the Integrated Program in Cellular, Molecular and Biophysical Studies at Columbia University. Dr. Lium holds a BS in Biology from Gonzaga University.

### Chirag R. Parikh, Ph.D., M.D.

Non-Executive Director (Aged 48)

Chirag R. Parikh, Ph.D., M.D., has served as a member of the Board since October 2019. Since July 2018, Dr. Parikh has served as a Professor of Medicine and the Division Director of Nephrology at Johns Hopkins University. Dr. Parikh also served as a faculty member at Yale University where he directed the Program of Applied Translational Research. Dr. Parikh's research focuses on the translation and validation of novel biomarkers for the diagnosis and prognosis of kidney diseases. He has assembled multi-centre longitudinal prospective cohorts for translational research studies across several clinical settings of acute kidney injury and chronic kidney disease for the efficient translation of novel biomarkers. Dr. Parikh received his medical degree from Seth G.S. Medical College and KEM Hospital in Mumbai, India, and subsequently completed his Nephrology fellowship and a Ph.D. in Clinical Investigation at the University of Colorado Health Sciences Center.



#### Ann Berman

#### Non-Executive Director (Aged 69)

Ann E. Berman joined our board of directors in 2021. She is a former chief financial officer of Harvard University, where she was responsible for financial strategy, policy and planning, financial reporting and operations, treasury and risk management, and various audit functions. She served on the board of Harvard Management Company, the investment management firm for Harvard University's endowment.

Ms. Berman currently serves on the board of directors of Loews Corporation (NYSE: L) as well as the board of Immuneering Corporation where she chairs the audit committee. She is a member of the board of trustees of Beth Israel Deaconess Medical Center, where she is the chair of the compliance and risk committees. She is a certified public accountant with experience overseeing audit-related matters, enterprise risk management, internal audit, cybersecurity, and compliance. Ms. Berman was previously a partner with Richard A. Eisner & Co., an accounting firm,



and began her career at Price Waterhouse & Co. She holds a B.A. from Cornell University and M.B.A. from the University of Pennsylvania's Wharton School of Business.



#### Daniel J. Levangie

Non-Executive Director (Aged 71)

Daniel J. Levangie was appointed to the Company's board of directors in August 2021. He is an experienced executive and long-serving board director in the diagnostics and medical devices industry. Mr. Levangie is co-founder and manager of ATON Partners, a private investment firm, and president and CEO of CereVasc, LLC, a medical device company. He has also served on the board of directors of Exact Sciences Corporation since 2010. From 2013 through January 2017, Mr. Levangie served as president of Insulet Drug Delivery Systems and served as a lead director of Insulet Corporation. From 2011 through 2013, Mr. Levangie was chief executive officer of Dune Medical Devices, Inc., and co-founder and managing partner of Constitution Medical Investors, Inc., a Boston-based private investment and product development firm acquired by Roche Diagnostics Corporation in 2013. Previously, he held executive management positions with Cytyc Corporation including executive vice president and chief operating officer, chief executive officer and president until the acquisition of Cytyc by Hologic, in 2007. He served on the board of Hologic from 2007 to 2009. Mr. Levangie holds a B.S. in Pharmacy from Northeastern University.

#### Barbara Murphy M.D.

Non-Executive Director - Deceased on 29 June 2021 (Aged 54)

#### **Julian Baines MBE**

Non-Executive Chairman - Resigned on 16 July 2020 (Aged 57)

#### **Richard Evans**

Non-Executive Director - Resigned on 16 July 2020 (Aged 64)

This report was approved by the Board on 19 November 2021 and signed on behalf of the Board by:

Christophe Mull

Christopher Mills Chairman

## Directors' Report

The Directors present their annual report on the affairs of the Group, together with the consolidated financial statements and auditor's report for the year ended 30 June 2021. The Corporate Governance Statement set out on pages 31 to 33 forms part of this report.

## CORPORATE DETAILS

Renalytix plc is a public limited company incorporated in the under the laws of England & Wales (Registration Number 11257655). The address of the registered office is Finsgate, 5-7 Cranwood Street, London EC1V 9EE. On 25 June 2021 the company changed its name from RenalytixAI plc to Renalytix plc.

## DIRECTORS

The Directors, who served in office during the year and as date of signing these financial statements were as follows:

- Christopher Mills
- James McCullough
- Erik Lium
- Fergus Fleming
- Chirag Parikh
- Ann Berman (appointed on 28 July 2021)
- Daniel Levangie (appointed on 31 August 2021)
- Barbara Murphy (Deceased on 29 June 2021)
- Julian Baines (resigned on 16 July 2020)
- Richard Evans (resigned on 16 July 2020)

Details of the Directors' membership of committees is shown on page 32. The Company Secretary is Salim Hamir.

## **PRINCIPAL ACTIVITIES**

The principal activity of the Group is the development of artificial intelligence-enabled clinical diagnostic solutions for kidney disease.

## **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 the 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. However, at this stage, it is difficult to assess reliably whether there will be any material disruption in the future. In addition, the Directors have considered the potential effects of the COVID-19 pandemic as laid out in the Strategic Report. We have modelled a number of scenarios covering reductions in revenue of 10% and 50%, without taking into account the potential benefits of any mitigation strategies such as potential cost savings or insurance claims. We have also modelled out 100% reductions in revenue with cost savings within our control. While the eventual severity and length of the economic disruption stemming from the pandemic is impossible to forecast these models give the Directors reasonable confidence that the business has sufficient resources to continue as a going concern for at least the next 12 months.

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.

## FUTURE DEVELOPMENTS AND RESEARCH AND DEVELOPMENT ACTIVITIES

Future developments and research and development activities are discussed in the Strategic Report on pages 4 to 23.

### **RESULTS AND DIVIDENDS**

The Group recorded a loss for the year of \$31.0 million (FY20: \$9.3 million). When it is commercially prudent to do so and subject to the availability of distributable reserves, the Board may approve the payment of dividends. However, at present, the Directors consider that it is more prudent to retain cash to fund the development of the Group and, as a result, feel it is inappropriate to give an indication of the likely level or timing of any future dividend payment. The Directors do not recommend payment of a dividend in respect of FY21 (FY20: nil).

### FINANCIAL RISK MANAGEMENT

Financial risk management is discussed in Note 4 of the financial statements.

### EMPLOYEE POLICIES

Employee policies are discussed in the Strategic Report on page 23.

### POLITICAL CONTRIBUTIONS AND CHARITABLE CONTRIBUTIONS

Neither the Company nor any of its subsidiaries made any political donations or incurred any political expenditure during the year ended 30 June 2021 (FY20: nil).

## **DIRECTORS' INTERESTS**

The interests in the share capital of the Company of those Directors serving at 30 June 2021 and as at the date of signing of these financial statements, all of which are beneficial, were as follows:

	On 30 June 2021 Ordinary Shares of 0.25p each	On 30 June 2020 Ordinary Shares of 0.25p each
Christopher Mills	9,174,401	9,197,501
James McCullough	2,740,110	2,870,110
Erik Lium	-	-
Fergus Fleming	569,481	584,481
Chirag Parikh	-	-
Ann Berman	-	-
Daniel Levangie	-	-

Christopher Mills' shareholding includes shares held through North Atlantic Smaller Companies Investment Trust plc and Oryx International Growth Fund Limited. Christopher Mills is a partner and Chief Investment Officer of Harwood Capital LLP. Harwood Capital LLP is investment manager to North Atlantic Smaller Companies Investment Trust plc and investment adviser to Oryx International Growth Fund Limited.

## SUBSTANTIAL SHAREHOLDINGS

As at 12 November 2021, the following interests in 3% or more of the issued Ordinary Share capital had been notified to the Company:

Shareholder	Number of Shares	Percentage of Issued Share Capital
Icahn School of Medicine at Mount Sinai	10,750,926	14.9%
Christopher Mills	9,174,401	12.7%
Gilder Gagnon Howe and Co LLC	6,042,634	8.4%
James McCullough	2,740,110	3.8%
Amati Global Investors	2,455,247	3.4%
Fidelity Investment International	2,173,851	3.0%

## STATEMENT OF DIRECTORS' RESPONSIBILITIES IN RESPECT OF THE FINANCIAL STATEMENTS

The Directors are responsible for preparing the Annual Report and the financial statements in accordance with applicable law and regulation.

Company law requires the Directors to prepare financial statements for each financial year. Under that law the Directors have prepared the group financial statements in accordance with International Financial Reporting Standards (IFRSs) in conformity with the requirements of the Companies Act 2006 and parent company financial statements in accordance with International Financial Reporting Standards (IFRSs) in conformity with the requirements of the Companies Act 2006. Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and parent company and of the profit or loss of the Group for that period. In preparing the financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- state whether applicable IFRSs in conformity with the requirements of the Companies Act 2006 have been followed for the group financial statements and IFRSs in conformity with the requirements of the Companies Act 2006 have been followed for the parent company financial statements, subject to any material departures disclosed and explained in the financial statements;
- make judgements and accounting estimates that are reasonable and prudent; and
- prepare the financial statements on the going concern basis unless it is inappropriate to presume that the group and parent company will continue in business.

The Directors are also responsible for safeguarding the assets of the Group and parent company and hence for taking reasonable steps for the prevention and detection of fraud and other irregularities.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Group and parent company's transactions and disclose with reasonable accuracy at any time the financial position of the Group and parent company and enable them to ensure that the financial statements comply with the Companies Act 2006.

The Directors are responsible for the maintenance and integrity of the parent company's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

The Directors consider that the annual report and accounts, taken as a whole, is fair, balanced and understandable and provides the information necessary for shareholders to assess the Group and parent company's performance, business model and strategy.

Each of the Directors, whose names and functions are listed in the Report of the Directors confirm that, to the best of their knowledge:

- the parent company financial statements, which have been prepared in accordance with IFRSs in conformity with the requirements of the Companies Act 2006, give a true and fair view of the assets, liabilities, financial position and loss of the Company;
- the Group financial statements, which have been prepared in accordance with IFRSs in conformity with the requirements of the Companies Act 2006, give a true and fair view of the assets, liabilities, financial position and loss of the Group; and
- the Strategic Review includes a fair review of the development and performance of the business and the position of the Group and parent company, together with a description of the principal risks and uncertainties that it faces.

### DIRECTORS' INDEMNITIES

The Company has entered into deeds of indemnity for the benefit of each Director of the Company in respect of liabilities to which they may become liable in their capacity as Director of the Company and of any Company in the Group. Those indemnities are qualifying third party indemnity provisions for the purposes of section 234 of the Companies Act 2006 and have been in force during the whole of the financial period and up to the date of approval of the financial statements.

## INDEPENDENT AUDITORS

PKF Littlejohn LLP has expressed their willingness to continue in office as auditors and a resolution to reappoint them will be proposed at the forthcoming Annual General Meeting.

## DISCLOSURE OF INFORMATION TO THE AUDITORS

The Directors who hold office at the date of approval of this report confirm that so far as they are each aware, there is no relevant audit information of which the Company's auditors are unaware, and each Director has taken all the steps that they ought to have taken as a Director in order to make themselves aware of any relevant audit information and to establish that the Company's auditors are aware of that information.

## CORPORATE GOVERNANCE

The Company's statement of corporate governance can be found in the Corporate Governance Statement on pages 24 to 26 of these financial statements. The Corporate Governance Statement forms part of this Report of the Directors and is incorporated into it by cross-reference.

## ANNUAL GENERAL MEETING

The resolutions to be proposed at the forthcoming Annual General Meeting are set out in a separate notice sent to the shareholders.

### RECOMMENDATION

The Board considers that the resolutions to be proposed at the Annual General Meeting are in the best interests of the Company and it is unanimously recommended that shareholders support these proposals as the Board intends to do in respect of their own holdings.

This report was approved by the Board on 19 November 2021 and signed on behalf of the Board by:

Christophe Mills

**Christopher Mills** 

Chairman

## Corporate Governance Statement

## COMPLIANCE

The Company recognizes the value of good corporate governance in every part of its business. The Board has adopted the corporate governance principles of the 2018 Quoted Companies Governance Code (the "QCA Code") and the Company has continued to comply with the QCA Code throughout the reporting period. The Board believes that this corporate governance framework is appropriate for the Company, having regard to its size and nature. Details of the QCA Code can be obtained from the Quoted Companies Alliance's website (www.theqca.com).

Details of how the Group seeks to address the principles underlying the QCA Code and how it leverages its principles to support the long-term success of the Group can be found on the Company's website.

## BOARD COMPOSITION AND RESPONSIBILITY

The Board currently comprises two Executive Directors and four Non-Executive Directors.

It is the Board's opinion that the Barbara Murphy was independent has been independent in character and judgement and that there were no relationships or circumstances which could materially affect or interfere with the exercise of her independent judgement during the course of FY21. Since the passing away of Barbara Murphy the Board have appointed two independent two Non-Executive Directors, Ann Berman and Daniel Levangie.

All Directors are subject to election by Shareholders at the first Annual General Meeting after their appointment, and are subject to re-election at least every three years. Non-Executive Directors are appointed for a specific term of office which provides for their removal in certain circumstances, including under section 168 of the Companies Act 2006. The Board does not automatically re-nominate Non-Executive Directors for election by Shareholders. The terms of appointment of the Non-Executive Directors can be obtained by request to the Company Secretary.

The Board's primary objective is to generate value for the Group by identifying and assessing business opportunities and ensuring that potential risks are identified, monitored and controlled. Matters reserved for Board decisions include strategic long-term objectives and the capital structure of major transactions. The implementation of Board decisions and day to day operations of the Group are delegated to senior management.

There is a division of responsibilities between the Non-Executive Chairman, who is responsible for the overall strategy of the Group and running the Board, and the Chief Executive Officer, who is responsible for implementing the strategy and day to day running of the Group. He is assisted by the Chief Technical Officer, who is a Board member, and Chief Financial Officer who is not a Board member.

## **BOARD MEETINGS**

Eighteen Board meetings were held during the year. The Directors' attendance record during their period of office is as follows:

Christopher Mills (Non-Executive Chairman)	17/18
James McCullough (Chief Executive Officer)	18/18
Erik Lium (Non-Executive Director)	17/18
Fergus Fleming (Chief Technology Officer)	18/18
Chirag Parikh (Non-Executive Director)	16/18
Barbara Murphy (Non-Executive Director)	10/16
Julian Baines (Non-Executive Chairman)	1/1 (Resigned on 16 July 2020)
Richard Evans (Non-Executive Director)	1/1 (Resigned on 16 July 2020)

During the year, the Board conducted an evaluation of the performance of the Board and that of the Chairman, as well as the effectiveness of the Board Committees. The Board intends to develop further its evaluation of the performance of the Board and Committees on an annual basis. The evaluation will include Board composition, experience, dynamics and the Board's role and responsibilities for strategy, risk review and succession planning. The evaluations will involve a detailed questionnaire and individual discussions between the Non-Executive Chairman and the Directors. The Board is considering overhauling its evaluations process now it has listed at Nasdaq.

### AUDIT COMMITTEE

The Audit Committee comprises of Ann Berman, who acted as chair, Daniel Levangie and Erik Lium. The Audit Committee, among other things, determines and examines matters relating to the financial affairs of the Company including the terms of the engagement of the Company's auditors and, in consultation with the auditors, the scope of the audit. It receives and reviews the reports from management and the Company's auditors relating to the half yearly and annual forward statements and the accounting and the internal control systems in use throughout the Company.

The committee has met formally once during the year ended 30 June 2021. There have been no significant matters communicated to the Committee by the auditors and no interaction with the Financial Reporting Council.

Before the appointment of Ann Berman and Daniel Levangie, the composition of the Audit Committee was Erik Lium, acting as chair, Barbara Murphy and Christopher Mills.

## **REMUNERATION COMMITTEE**

The Remuneration Committee comprised Daniel Levangie, who acted as chair, and Chirag Parikh. The Remuneration Committee reviews and makes recommendations in respect of the Executive Directors' remuneration and benefits packages, including share options and the terms of their appointment. The Remuneration Committee also make recommendations to the Board concerning the allocation of share options to employees under the intended share option schemes.

The Committee has met three time during the year ended 30 June 2021.

## NOMINATION COMMITTEE

The Nomination Committee comprised Ann Berman, who acted as chair, and Christopher Mills. The Nomination Committee reviews and recommends nominees as new Directors to the Board.

## INTERNAL CONTROL

The Directors are responsible for ensuring that the Group maintains a system of internal control to provide them with reasonable assurance regarding the reliability of financial information used within the business and for publication and that the assets are safeguarded. There are inherent limitations in any system of internal control and accordingly even the most effective system can provide only reasonable, but not absolute, assurance with respect to the preparation of financial reporting and the safeguarding of assets.

The Group, in administering its business, has put in place strict authorization, approval and control levels within which senior management operates. These controls reflect the Group's organizational structure and business objectives. The control system includes clear lines of accountability and covers all areas of the organization. The Board operates procedures which include an appropriate control environment through the definition of the above organization structure and authority levels and the identification of the major business risks.

## INTERNAL FINANCIAL REPORTING

The Directors are responsible for establishing and maintaining the Group's system of internal reporting and as such have put in place a framework of controls to ensure that on-going financial performance is measured in a timely and correct manner and that risks are identified as early as is practicably possible. There is a comprehensive budgeting system and monthly management accounts are prepared which compare actual results against both the budget and the previous year. They are reviewed and approved by the Board and revised forecasts are prepared on a regular basis.

## **RELATIONS WITH SHAREHOLDERS**

The Company reports to Shareholders twice a year. The Company dispatches the notice of its Annual General Meeting, together with a description of the items of special business, at least 21 clear days before the meeting. Each substantially separate issue is the subject of a separate resolution and all Shareholders have the opportunity to put questions to the Board at the Annual General Meeting.

The Chair(s) of the Audit and Remuneration Committees normally attend the Annual General Meeting and will answer questions which may be relevant to their work. However, due to the ongoing COVID-19 pandemic, the Committee Chairs will not be in attendance at this year's Annual General Meeting. The Chairman advises the meeting of the details of proxy votes cast on each of the individual resolutions after they have been voted on in the meeting. The Chairman and the Non-Executive Directors intend to maintain a good and continuing understanding of the objectives and views of the Shareholders.

#### Shareholders May Contact the Company as Follows:

Tel: +44 (0)20 7933 8790 (from USA: +1-646-217-4999) Email: investors@renalytix.com

## CORPORATE SOCIAL RESPONSIBILITY

The Board recognizes that the Group has a duty to be a good corporate citizen and is conscious that its business processes minimize harm to the environment, that it contributes as far as is practicable to the local communities in which it operates and takes a responsible and positive approach to employment practices. The Group is subject to the requirements of the Modern Slavery Act 2015 and published the required statement on its website. The directors consider that the nature of the Group's activities is not inherently detrimental to the environment. The Group is committed to minimizing any effect on the environment caused by its operations.

The Corporate Governance Statement was approved by the Board on 19 November 2021 and signed on its behalf by:

Salim Hamir

**Company Secretary** 

## Director's Remuneration Report and Policy

#### For the Period Ended 30 June 2021

## STATEMENT OF COMPLIANCE

This report does not constitute a Directors' Remuneration Report in accordance with the Large and Medium-sized Companies and Groups (Accounts and Reports) (Amendment) Regulations 2013, the Companies (Miscellaneous Reporting) Regulations 2018, and the Companies (Directors' Remuneration Policy and Directors' Remuneration Report) Regulations 2019 which do not apply to the Company as it was not a quoted company (as defined in the Companies Act 2006) as at the end of the financial year. This report sets out the Group policy on Directors' remuneration, including emoluments, benefits and other share-based awards made to each Director.

## REMUNERATION COMMITTEE REPORT DR. ERIK LIUM CHAIR OF THE REMUNERATION COMMITTEE

#### Dear shareholder,

As the Chair of the Remuneration Committee (the "Committee"), I am pleased to present, on behalf of the board of directors (the "Board") of Renalytix PLC (the "Company" or "Renalytix"), the Directors' remuneration report for the year ended 30 June 2021 (the "Directors' Remuneration Report").

The Company's Annual Report and Accounts, along with the Directors' Remuneration Report, will be subject to an advisory vote at the forthcoming Annual General Meeting on 17 December 2021 (the "AGM") and the remuneration policy section of the Directors' Remuneration Report will be subject to a binding vote at the AGM.

#### Introduction

During the period covered by this Directors' Remuneration Report, we maintained the remuneration programs and policies that the Committee established during the financial year 2021 and implemented strategic compensation initiatives designed to incentivise and retain key employees in the Company.

As we move into 2022 and beyond, the Committee's role will be to ensure that Directors and senior executives at Renalytix are appropriately compensated and incentivised to deliver growth to shareholders in a long-term and sustainable manner. The Committee seeks to accomplish this by establishing remuneration programs that are grounded in market practice, are effective at driving proper management behaviors, clearly link pay and performance and are cost efficient overall.

#### **Corporate Governance Standards**

As a public company, we are subject to corporate governance standards and regulations applicable in the United States and the United Kingdom.

#### The Global Marketplace for Talent

Renalytix is a biopharmaceutical company with operations in Europe and the United States. The Company plans to expand its operations in both geographic regions in line with the growth of its clinical and manufacturing activities and its plans to commercialize its products in these geographies. Given that the market for experienced directors and biopharmaceutical executive management talent, particularly in the United States, is very competitive, the Committee references the US market as the leading indicator for remuneration levels and practices. This will help attract and retain directors and motivate the superior executive management talent needed to successfully manage the Company's complex global operations. Being consistent in this market view of the United States as the primary benchmark for remuneration practices for directors and executive directors (CEO and CTO) is key for the Company as it builds its global operations in a manner designed to deliver sustainable long-term growth and shareholder value.

Committee decisions have been taken in light of the extensive benchmarking for director and executive director compensation conducted in 2021, which included a review of compensation practices of comparable companies to Renalytix in the US and

Europe. In taking any actions, the Committee is mindful of the general UK compensation framework, including investor bodies' guidance, and the UK Corporate Governance Code, and has incorporated these into its remuneration programs, policies and decisions where it believes they best serve the long-term interests of shareholders.

#### **Remuneration Program Highlights**

While I recommend that you carefully read the disclosure on our programs and policies that follows this letter to help with the understanding of our approach to director compensation, I want to highlight the following aspects of our program below:

- **Pay for Performance** We believe that a significant portion of remuneration of our directors and our executive directors (CEO & CTO) should be based on achieving objectives designed to create inherent value in the Company, and ultimately on achieving value creation for our shareholders. In line with this belief, the compensation of our CEO includes a significant performance-based cash bonus opportunity and a large equity incentive component. Further, our directors receive equity incentives designed to reward long-term value creation for our shareholders.
- Shareholding requirements for Executive Directors We believe having these requirements encourages executive directors to build meaningful shareholding positions and furthers alignment of their interests with those of shareholders.
- 2021 Remuneration Outcome As outlined above, a core principle in Renalytix's remuneration program is the linkage between pay and performance. In financial year 2021, the annual bonus of James McCullough our CEO and Fergus Fleming our CTO, our executive directors were based on a combination of corporate and personal objectives. The Committee of the Board determined that the Company achieved 100% of its annual corporate objectives, bonuses for company executives are still being finalized and are expected to be paid in Q2 financial year 22. This outcome was based on achievements versus goals in the following key areas: EHR Integration, FDA Submission, healthcare/commercial partnerships, coverage agreements, regulatory compliance and attracting and retaining top talent.
- **Major Decisions and Substantial Changes regarding Directors' Remuneration** During financial year 2021, there were no major decisions or substantial changes on our directors' remuneration scheme however the company did engage remuneration consultants in financial year 2020 to advise the Committee on all aspects of senior executive remuneration. The remuneration consultant's findings were relied upon when approving salary increases for financial year 2021.

#### Conclusion

The Committee believes the proposals put forth in this report will properly motivate our directors and our CEO to deliver sustainable growth and shareholder value over the long term and do so in a responsible and cost efficient manner.

I hope that you find the information in this report helpful, and look forward to the AGM, where we hope to have your support.

#### **Dr. Erik Lium**<sup>1</sup>

Chair of the Remuneration Committee

19 November 2021

<sup>1.</sup> Dr. Erik Lium served as Chair of the Remuneration Committee for the entirety of the year ended 30 June 2021 and was replaced on 12 October 2021 when Daniel Levangie was appointed Chair of the Remuneration Committee.

## DIRECTORS' REMUNERATION POLICY

This part of the Directors' remuneration report sets out the Directors' remuneration policy for the Company's directors and executive directors and has been prepared in accordance with the Large and Medium-sized Companies and Groups (Accounts and Reports) (Amendment) Regulations 2013.

The remuneration policy will be put forward for approval by shareholders in a binding vote at the forthcoming AGM on 17 December 2021.

If approved, it is intended that the remuneration policy will take effect from the date of approval and apply for a maximum period of three years (or until a revised policy is approved by shareholders).

Renalytix's remuneration policy has been designed to:

- align to the Company's strategy and business model;
- attract, retain and motivate high calibre individuals who have the potential to support the growth of the Company;
- be competitive against appropriate market benchmarks, focusing particularly on the US bio-technology sector; and
- take account of good governance and promote the long-term success of the Company.

## EXECUTIVE DIRECTOR REMUNERATION POLICY TABLE

The table below sets out, for each element of pay, a summary of how remuneration of executive directors is structured and how it supports the Company's strategy.

Executive Directors									
Purpose and Link to Strategy	Operation	Maximum Opportunity	Performance Metrics						
	BASE SALARY								
To attract, retain and motivate executive directors of the highest calibre who are capable of delivering the Company's strategic objectives, reflecting the individual's experience and role within the Company. Base salary is designed to provide an appropriate level of fixed income to avoid an over- reliance on variable pay elements that could encourage excessive risk taking.	<ul> <li>Salaries are normally reviewed annually, and changes are generally effective from 1 October.</li> <li>The annual salary review of the Executive Directors takes into consideration a number of factors, including: <ul> <li>scope of the individual's responsibilities;</li> <li>abilities, experience and performance of the individual;</li> <li>business performance;</li> <li>salary increases awarded to the overall employee population;</li> <li>market competitiveness and US and UK market practice; and</li> <li>the underlying rate of inflation.</li> </ul> </li> </ul>	Executive Director level salaries are determined considering industry benchmarking data. There is no prescribed maximum annual salary or salary increase. Base salary increases are awarded at the discretion of the Committee; however, the Committee is guided by the general increase for the broader employee population but may decide to award a lower increase for Executive Directors or exceed this to recognize, for example, an increase in the scale, scope or responsibility of the role and/or take account relevant market movements. Salary increases will normally Executive Director level salaries are approved by the Board in line with corporate performance and are consistent with positions held.	No formal metrics, although any increases take account of Company performance and the individual performance of the Executive Director.						
BENEFITS									
Benefits in kind offered to Executive Directors are provided on a market- competitive basis, to assist with their recruitment and retention.	The Company aims to offer benefits that are in line with the Executive Directors' local market and those offered to the wider workforce.	There is no defined maximum value for benefits, but the Committee will consider the aggregate value of any such benefits when determining what should be offered.	Not performance related.						
	Executive	Directors							
--	---	--	---	--	--	--	--	--	--
Purpose and Link to Strategy	Operation	Maximum Opportunity	Performance Metrics						
PENSION									
The Company aims to provide a contribution towards life in retirement.	Depending on their location and comparable benefits offered to local employees, Executive Directors may be eligible to receive employer contributions to a defined contribution pension scheme or a cash supplement in lieu of such contributions, or a mixture of both.	The maximum employer pension contribution or cash in lieu amount will be a percentage of annual base salary aligned with that provided to other senior executives in the Executive Director's location.	Not performance related.						
	ANNUAI	L BONUS							
An annual bonus rewards the achievement of objectives that support the Company's corporate goals and delivery of the business strategy	Bonuses are determined based on objectives that are agreed with the Committee, and the Board, at the start of each financial year although the Committee retains the discretion to amend objectives during the year if it considers that objectives are no longer appropriate. Different performance measures and weightings may be used each year, as agreed with the Committee, to take into account changes in the business strategy. Bonuses are normally paid in cash (but may be paid in the form of an equity award, at the	Executive Director level bonuses are approved by the Board in line with corporate performance and are consistent with positions held.	Performance measures are determined by the Committee each year and may vary to ensure that they promote the Company's business strategy and shareholder value. The annual bonus will be based on corporate measures, including, but not limited to, financial and/or strategic measures. Bonus measures are reviewed at least annually and the Committee has the discretion to change the measures or to introduce new measures when it deems appropriate.						
	discretion of the Committee).	TIVE DI ANI ('EID')							
To attract, motivate, retain	EQUITY INCENT Equity awards granted to	TVE PLAN ('EIP') There is no maximum	Vesting of equity awards is						
and reward for long-term, sustainable performance linked to corporate strategy and provide alignment with shareholders' interests.	Executive Directors may take the form of options, restricted shares, performance share units, restricted share units, or other forms of awards granted in accordance with the discretionary EIP that may be in place from time to time. The Executive Directors received a grant under the EIP's predecessor plan upon listing on AIM and it is intended that top- up awards shall be issued under the EIP from time to time in the discretion of the Committee.	opportunity for equity incentives. However, the Committee will generally assess the position at similar sized comparator companies prior to making any award to ensure that any awards are aligned to the market.	generally subject to continued employment and may also be subject to the achievement of performance conditions aligned with the Company's strategic plan. Measures, their weightings and the period over which performance is tested will be determined by the Committee. The Committee will select the most appropriate form of EIP for awards each year and/or each individual grant. Vesting of equity awards may						
	discretion of the committee.		be accelerated in part or in full in connection with certain corporate events such as a change of control.						
	ALL EMPLOYEE	EQUITY PLANS							
Encourages employee share ownership and therefore increases alignment of interests with shareholders.	The Company may, from time to time, operate tax-advantaged share plans for which Executive Directors would be eligible on the same basis as all other eligible employees.	Within the limits of the relevant legislation.	Not performance related.						

# Notes to the Executive Director Remuneration Policy Table

### Legacy arrangements

For the duration of this Remuneration Policy, the Company will honour any commitments made in respect of current or former Directors before the date on which either: (i) the Remuneration Policy becomes effective; or (ii) an individual becomes a Director, even where not consistent with the Remuneration Policy set out in this report or prevailing at the time such commitment is fulfilled. For the avoidance of doubt, all outstanding historic awards that were granted in connection with, or prior to, our IPO on NASDAQ remain eligible to vest based on their original or modified terms.

### Clawback Provisions

The Company does not currently have a policy on recoupment and clawback, but the Committee will keep this under review.

### Shareholding Requirements

Executive directors are not currently required to build and retain a shareholding, but the Committee will keep this under review.

# NON-EXECUTIVE DIRECTOR REMUNERATION POLICY TABLE

The table below sets out, for each element of pay, a summary of how remuneration of non-executive directors is structured and how it supports the Company's strategy.

Chair and Non-Executive Directors								
Purpose and Link to Strategy	Operation	Maximum Opportunity	Performance Metrics					
CASH FEES AND BENEFITS								
Set at a level that is sufficient to attract and retain high calibre non- executives who contribute to the business.	The Chair and the Non- Executive Directors receive fees paid in cash. Fees are paid and reviewed annually. Non-Executive Directors ordinarily do not participate in any pension, bonus or performance-based share incentive plans. Travel, accommodation and other business-related expenses incurred in carrying out the role as well as fees for tax advice associated with completion of international tax returns will be paid by the Company including, if relevant, any gross- up for tax and/or social security contributions. Tax equalization and/or relocation benefits may be provided to Non-Executive Directors who are required to relocate or become tax resident in a new jurisdiction.	When reviewing fee levels and benefits, account is taken of market movements in the fees and benefits of Non-Executive Directors, Board Committee responsibilities and ongoing time commitments. Actual fee levels are disclosed in the annual Directors' Remuneration Report for the relevant financial year.	Not performance related.					

Chair and Non-Executive Directors								
Purpose and Link to Strategy	Operation	Maximum Opportunity	Performance Metrics					
EQUITY-BASED AWARDS								
To facilitate share ownership and provide alignment with shareholders.	Non-Executive Directors may receive equity awards under any equity incentive plan operated by the Company from time to time which permits their participation with careful consideration being given to ensuring their independence. Non-Executive Directors may receive an initial equity award upon appointment or election. Initial equity awards will normally vest over a specified period of time, subject generally to continued service. Vesting of equity awards may be accelerated in part or in full in connection with certain corporate events such as a change of control. In addition, Non-Executive Directors may be granted an equity award each year which may vest in full upon grant or over time subject to continued service. If a new Non-Executive Director joins the Board following the date of grant of this annual grant in any calendar year, such Non-Executive Director may be granted a pro rata portion of the next annual grant to reflect his or her service during the relevant part of the relevant year.	There is no maximum number of equity incentive awards that may be awarded to individuals each year. However, when reviewing award levels, account is taken of market movements in equity incentive awards, Board committee responsibilities, ongoing time commitments and the general economic environment.	Non-executive directors do not participate in performance based equity incentives.					

# **REMUNERATION FOR NEW APPOINTMENTS**

Where it is necessary to appoint or replace an Executive Director, the Committee has determined that the new Executive Director will receive a compensation package in accordance with the provisions of the approved remuneration policy in force at the time of appointment but focusing on the objective of appointing the most appropriate person in the right geography.

In setting base salaries for new Executive Directors, the Committee will consider the existing salary package of the new Director, the individual's skills, level of experience and the market rate for the role.

In setting the annual performance bonus, the Committee may wish to set different performance metrics (to those of other Executive Directors) in the first year of appointment. Where it is appropriate to offer a below-median salary on initial appointment, the Committee will have the discretion to allow phased salary increases over a period of time for a newly appointed Director as the Executive gains experience in their new role, even though this may involve increases in excess of inflation and the increases awarded to the wider workforce.

Benefits and pensions will be in line with those offered to other executive directors, taking account of local market practice with relocation expenses provided at the discretion of the Committee if necessary. Tax equalization may also be considered if an executive is adversely affected by taxation due to their employment with the Group. Legal fees and other costs incurred by the individual may also be met by the Company.

The ongoing incentive opportunity offered to new recruits will be in line with that offered to existing Directors. Different measures and targets under the bonus plan or the Company's equity incentive arrangements may be set initially taking

account of the responsibilities of the individual and the point in the financial year at which they join. A new employee may be granted normal annual equity awards in the first year of employment in addition to any awards made with respect to prior employment being forfeited, which shall be excluded from any annual maximum on the size of awards.

To enable the recruitment of exceptional talent, the Committee may determine that the buy-out of remuneration forfeit from a prior employer is necessary. Where possible, any replacement remuneration will be offered on a like-for-like basis with the forfeited awards and may be in the form of cash or shares and depending whether the award forgone has similar performance conditions, may or may not be subject to performance conditions. The value of any buy-out will be limited to the value of remuneration forfeit. Where appropriate, such awards will be granted under existing share plans, however, the Committee will have discretion to make standalone awards where appropriate.

In respect of internal appointments, any commitments entered into in respect of a prior role, including variable pay elements, may be allowed to pay out according to their prior term, adjusted as relevant to take into account the appointment.

The terms of appointment for a new Non-Executive Director would be in accordance with the remuneration policy for Non-Executive Directors in force at that time.

# EXECUTIVE DIRECTORS' SERVICE CONTRACTS

James McCullough (Chief Executive Officer) is currently employed at-will pursuant to an employment agreement entered into with Renalytix AI, Inc, dated 2 November 2018 but effective on 1 November 2018. His employment may be terminated by either party at any time for any or no reason, with or without notice. Severance payments no more generous than those described in this policy will be payable to him on termination. Upon termination of his employment agreement, our Chief Executive Officer is required to resign from all other positions within the Company's group. Following termination of his employment, our Chief Executive Officer will be bound by certain post-termination covenants.

As is customary for US executives, our Chief Executive Officer's remuneration is subject to a "best-after-tax" cutback for excise tax calculations under section 280G of the US Internal Revenue Code of 1986, with no tax gross-up.

Fergus Fleming (Chief Technology Officer) is currently employed on an indefinite term pursuant to an employment agreement entered into with the Company dated 1 November 2018. His employment may be terminated by either party on 12 months written notice.

At its discretion, upon receipt of his written notice, or as an alternative to providing notice, terminate the employment with immediate effect and make a payment in lieu of notice, comprising base salary only, for the notice period (or remainder thereof, should notice have been given). In the event of a breach of service agreement or other summary termination of employment, no such payments will be made.

A copy of these contracts may be viewed at the Company's head office or may be requested from the Company Secretary at the annual general meeting.

# NON-EXECUTIVE DIRECTORS' TERMS OF ENGAGEMENT

All Non-Executive Directors, including the Chair, have specific terms of engagement which may be terminated on not less than six months' notice by either party.

The remuneration of Non-Executive Directors is determined by the Board within the limits set by the Company's articles of association and based on a review of fees and equity-based remuneration paid to Non-Executive Directors of similar companies.

A Board evaluation has been performed and the results of this exercise confirmed that all Non-Executive Directors were independent.

# TERMINATION AND LOSS OF OFFICE PAYMENTS

Depending on market practice in the jurisdiction in which an Executive Director is employed, exit payments shall depend on the circumstances of termination and may be made by reference to a notice period (including a payment in lieu of notice) or employment "at-will" together with a severance payment. Where a notice period applies, this will not exceed 12 months but may be accompanied by additional severance entitlements where applicable.

The Company's policy on remuneration for Executive Directors who leave the Company is set out below. The Committee will exercise its discretion when determining amounts that should be paid to leavers, taking into account the facts and circumstances of each case.

# **US-BASED EXECUTIVES**

	Termination without cause or with Good Reason <sup>1</sup>	Termination for cause	Termination without cause or with Good Reason <sup>1</sup> in connection with change in control
Salary and benefits	Subject to the executive executing a release: a payment of up to 12 months' salary and benefits including COBRA or other applicable healthcare coverage payable in equal monthly instalments or as a lump sum, at the discretion of the Committee.	No payment.	Subject to the executive executing a release: a payment of up to 18 months' salary and benefits and benefits payable in equal monthly instalments or as a lump sum, at the discretion of the Committee.
Annual bonus	Any earned but unpaid bonus, a pro-rata portion of the bonus that would have been due for any part year worked, plus up to one year's target bonus, or a higher bonus at the discretion of the Committee, payable as a lump sum or on a monthly basis.	No payment.	Any earned but unpaid bonus, a pro-rata portion of the bonus that would have been due for any part year worked, plus up to 1.5 year's target bonus, or a higher bonus at the discretion of the Committee, payable as a lump sum or on a monthly basis.
Equity incentive awards	The Company may accelerate the vesting of the portion of equity held on the termination date that would have vested over the following one year period.	Unvested awards lapse in full.	Full vesting on termination.

1: Includes, among others, a material diminution in role, a material reduction in base salary or mandated relocation, as defined by contract.

# NON-US BASED EXECUTIVES

When calculating termination payments for Non-US based Executives, the Committee will consider a variety of factors, including individual and Company performance, the length of service of the Executive Directors in question and, where appropriate, the obligation for the Executive Directors to mitigate loss. In the event of a change of control and ownership, the Committee may exercise its discretion to provide for additional remuneration and/or benefits for Executive Directors who leave the Company in connection with such change of control, and will take into account all relevant circumstances when making any such determination.

In the case of a 'good leaver' (to be determined at the discretion of the Committee) the following policy will normally apply, although the Committee retains the discretion to make payments which are no more generous than those applicable to a US based Executive Director (as described above), when viewed in the round with notice / payment in lieu of notice entitlements:

- notice period of twelve months or payment in lieu of notice;
- statutory redundancy payments will be made, as appropriate;
- Executive Directors have no entitlement to a bonus payment in the event that they cease to be employed by the Company, however, they may be considered for a pro-rated award by the Committee in good leaver circumstances; and
- any share-based entitlements granted to an Executive Director under the Company's share and individual share contracts or share option plans will be determined based upon the relevant individual share option contracts or plan rules, and performance conditions or hurdles and vesting may be accelerated in the discretion of the Committee.

# ADDITIONAL PAYMENTS

The Committee will make payment of any statutory entitlements as necessary. In addition, the Committee will retain the discretion to make additional payments in settlement of, or to compromise, an actual or potential claim in connection with a termination of any Executive Director as necessary.

The Committee reserves the right to make reasonable legal, relocation and outplacement costs, if deemed necessary.

# **REMUNERATION COMMITTEE (THE "COMMITTEE")**

### Governance

In its decision-making process, the Committee takes account of information from both internal and independent sources and Compensia surveys. Compensia were appointed as remuneration consultants by the Committee based on their expertise in the field via a competitive tender process. Compensia advises the Committee on all aspects of senior executive remuneration. Compensia has kept the Committee up to date on remuneration trends and corporate governance best practice. Compensia does not have any other connection with the Company and is considered to be independent and objective by the Committee. During the year ended 30 June 2021, fees charged by Compensia amounted to approximately USD 16,000 and this was charged on a time spent basis.

The current members of the Committee are Dr. Erik Lium (Chair), Dr. Chirag Parikh, and Daniel Levangie (who became a member of the Remuneration Committee on 30 August 2021 following his appointment as a director of the Company on that date). Each member is deemed to be independent.

### Remuneration Committee report (continued)

The Company's Chief Human Resources Officer provides updates to the Committee, as required, to ensure that the Committee is fully informed about pay and performance issues throughout the Company. The Committee takes these factors into account when determining the remuneration of the Executive Directors and senior executives.

No Executive Director or employee can participate in any discussion directly relating to their own personal conditions of service or remuneration.

No conflicts of interest have arisen during the year and none of the members of the Committee has any personal financial interest in the matters discussed, other than as option holders. The fees of the Non-Executive Directors are approved by the Board on the joint recommendation of the Committee and the Chief Executive Officer.

Director	Meetings attended
Dr. Erik Lium	3
Dr. Chirag Parikh	3

The Committee met three times in the year to 30 June 2021.

### Discretions retained by the Committee

The Committee operates under the powers it has been delegated by the Board. In addition, it complies with rules that require certain matters to be put to either shareholder or Board approval. These rules provide the Committee with certain discretions which serve to ensure that the implementation of the Remuneration Policy is fair, both to the individual director and to the shareholders. The Committee operates the Company's remuneration plans in accordance with their rules from time to time. To maintain an efficient administrative process, the Committee retains the following discretions to apply its judgement in setting remuneration:

- the eligibility to participate in the plans;
- the timing of grant of awards and any payments;
- the size of awards and payments (subject to any maximum limits set out in the policy table above and the respective plan rules);
- the determination of whether the performance conditions have been met;
- determining a good or bad leaver under the terms of the plan and the treatment of such leaver's cash and equity remuneration;

- dealing with a change of control or restructuring of the Group;
- adjustments required in certain capital events such as rights issues, corporate restructuring, events and special dividends and certain other out-of-the-ordinary events;
- the annual review of performance and other vesting conditions for the annual bonus plan and equity awards.

In certain circumstances, such as a material acquisition/divestment of a Group business, which mean the original performance conditions are no longer appropriate, the Committee may adjust the targets, alter weightings or set different measures as necessary, to ensure the conditions achieve their original purpose and are not materially less difficult to satisfy.

The Committee may make minor amendments to the Remuneration Policy (for regulatory, exchange control, tax or administrative purposes or to take account of a change in legislation) without obtaining shareholder approval for that amendment.

# ILLUSTRATION OF APPLICATION OF THE POLICY

### Pay-for-performance scenario analysis

The charts below provide an estimate of the potential future reward opportunities for the Executive Directors, and the potential split between different elements of remuneration under different performance scenarios:

- Minimum fixed pay only.
- Target (performance in line with expectations) fixed pay, plus bonus and equity payouts at threshold level (50% of maximum).
- Maximum (performance meets or exceeds maximum) fixed pay, plus the maximum bonus payout and full vesting of any equity awards, based on grant-date face value of awards to be granted in financial year 2022.

### Fixed pay comprises:

- Salaries salary effective at 1 July 2020.
- Benefits an estimated value of all benefits receivable in the 2022 financial year.
- Pension 5% of salary for the CEO and CTO.



Amounts are shown in thousands (USD).

Values do not include the impact of any share price appreciation over the vesting period. The reporting regulations require the disclosure of maximum total pay including the impact of a 50% increase in share price over the vesting period for equity awards subject to multi-year performance measures which is not applicable to any of our current equity awards. The equity award amounts shown above relate to share options vesting during the year using the Company's AIM closing price at the end of the quarter in which the award vested less associated exercise price.

### Statement of consideration of employees' pay and remuneration conditions elsewhere in the Group

The Company does not formally consult with employees on the matters of Executive Director remuneration. However, the Committee is made aware of employment conditions in the wider Group. The same broad principles apply to the remuneration policy for both Executive Directors and the wider employee population. However, the remuneration for Executive Directors has a stronger emphasis on performance-related pay than for other employees. Salaries, benefits and pensions are compared to appropriate market rates in the jurisdiction in which the Executive Director is employed and is set at an appropriate level with allowance for role, responsibilities and experience.

### Statement of consideration of Shareholders' views

The Committee will consider any Shareholder feedback received at the Annual General Meeting and at meetings throughout the year, when reviewing the overall remuneration policy each year. The guidance from relevant shareholder representative bodies is also considered on an ongoing basis.

More specifically the Committee will consult with major Shareholders when proposing any significant changes to the policy in the future.

# ANNUAL REPORT ON REMUNERATION<sup>1</sup>

This section of the remuneration report provides details of how our remuneration policy was implemented during the financial year ended 30 June 2021, and how it will be implemented during the year ending 30 June 2022.

This report splits certain information into that for Executive Directors and that for Non-Executive Directors.

### Directors' Remuneration – financial year ended 30 June 2021

The total remuneration of the individual Directors who served during the period is shown below. Total remuneration is the sum of emoluments for the period in service as a director plus Company pension contributions, and the value of long-term incentive awards vesting by reference to performance in the twelve months to 30 June 2021.

### Directors' Remuneration – financial year ended 30 June 2021

	Year	Basic Salary (\$000s)ª	Benefits (\$000s)⁵	Bonus (\$000s)⁰	EIP <sup>d</sup>	Pension (\$000s)º	Total Remuneration (\$000s)	Total Fixed Remuneration (\$000s)	Total Variable Remuneration (\$000s)
Executive Directors									
James McCullough	2021	586	62	530	-	15	1,193	663	530
	2020	370	46	471	-	17	904	433	471
Fergus Fleming	2021	366	17	211	2,379	24	2,997	407	2,590
	2020	317	3	180	910	11	1,321	331	910
Non-Executive Directors									
Erik Lium (Mount Sinai representative)1	2021	27	-	-	904	-	931	27	904
	2020	25	-	-	346	-	371	25	346
Christopher Mills	2021	27	-	-	-	-	27	27	-
	2020	25	-	-	-	-	25	25	-
Barbara Murphy²	2021	27	-	-	1,190	-	1,217	27	1,190
	2020	25	-	-	455	-	480	25	455
Chirag Parikh <sup>3</sup>	2021	87	-	-	548	-	635	87	548
	2020	69	-	-	165	-	234	69	165
Ann Berman <sup>4</sup>	2021	-	-	-	-	-	-	-	-
	2020	-	-	-	-	-	-	-	-
Daniel Levangie⁵	2021	-	-	-	-	-	-	-	-
	2022	-	-	-	-	-	-	-	-

### Notes to the remuneration table

- a. All amounts presented were earned in respect of the financial period.
- b. This is the taxable value of benefits paid or payable in respect of the financial period. For Non-Executive Directors, the taxable benefits comprise travel costs (and the gross-up for associated income tax and employees' National Insurance Contributions which will be settled on behalf of the Non-Executive Directors) for attendance at Board meetings. For executive directors, benefits include health, dental, vision, life and long-term disability insurance paid for by the Company
- c. Executive bonuses for financial year 2021 have not been approved by the Committee yet therefore for financial year 2021 this is the total bonus expected to be earned under the annual bonus scheme in respect of the financial year (despite being paid in the following financial year, following determination of final outcomes). The final amounts in respect of such bonuses will be disclosed in next year's report.
- d. The amount shown relates to the market value of the EIP and other equity awards vesting during the year using the Company's AIM closing price at the end of the quarter in which the award vested less associated exercise price.
- e. The amount shown relates to Company contributions to the defined contribution scheme, plus any cash in lieu.
- 1. Dr. Lium sits on our board as a representative of the Icahn School of Medicine at Mount Sinai. This fee is invoiced annually by Mt. Sinai.
- 2. Dr. Murphy passed away on June 29, 2021.
- 3. In addition to \$25,206 in board fees Chirag Parikh's remuneration includes consulting services performed for Renalytix. Chirag received \$500/hr for consulting services in both financial year 2020 and financial year 2021.
- 4. Ann Berman joined the board in July 2021 therefore she did not receive remuneration for the 2020 and 2021 financial years.
- 5. Dan Levangie joined the board in August 2021 therefore he did not receive remuneration for the 2020 and 2021 financial years.

# ANNUAL PERFORMANCE BONUS – 2020/2021 FINANCIAL YEAR

In the 2020 financial year, all employees were eligible for an annual discretionary cash bonus, whereby performance objectives were established at the beginning of the financial year by reference to suitably challenging corporate goals.

For the 2021 financial year, the company refined the annual bonus calculation as annual bonuses for all staff (including Executive Directors) were calculated and achieved by reference to both corporate and individual performance.

The achievement against the scorecard of corporate goals was as follows:

Corporate goals	Weighting %	2021 Achievement %
Achieve first implementation and associated building blocks for future implementations	20%	100%
FDA Submission for KidneyIntelX	20%	100%
Announced Events with Healthcare Systems / Payer Groups	20%	100%
Payor coverage agreements	20%	100%
Pass Regulatory Audits and Certifications	10%	100%
Attract and Retain Top Talent	10%	100%
Total	100%	100%

Specific targets associated with each corporate goal are commercially sensitive and have been omitted to protect competitive information. However, full details of the targets will be disclosed when they are no longer considered commercially sensitive.

Achievement against objectives is given careful consideration by the Committee prior to finalisation of bonus outcomes. The Committee reviewed the formulaic outcome of the scorecard and concluded that 100% of corporate goals were met and the scorecard outcome, as shown above, reflected the performance of the Executive Directors in the year. As a result of corporate performance, the following bonuses were calculated for the Company's executive directors and will be presented to the Board for approval.

	Bonus scorecard Outcome (\$000s)	% of salary	Maximum opportunity Cash amount (\$000s)	% of salary
James McCullough	530	90%	1,060	180%
Fergus Fleming	211	67%	422	133%

During the year ended 30 June 2021, no Executive Directors or non-executive directors were awarded options under the EIP scheme. There was no change in the exercise price or date of existing options.

# EXECUTIVE DIRECTORS' SHARE AWARDS

### Directors' interests in shares at 30 June 2021

Director	Total shares owned outright plus vested options	Shares owned outright	Percentage of issued share capital	Vested but not exercised	Unvested but subject to performance	Unvested and not subjected to performance
Current Directors						
James McCullough <sup>1</sup>	2,740,110	2,740,110	3.8%	-	-	-
Fergus Fleming	1,017,949	569,481	0.79%	448,468	-	89,694
Ann Berman	-	-	-	-	-	-
Mount Sinai (Board Seat)	170,418	-	-	170,418	-	34,084
Christopher Mills <sup>2</sup>	9,174,401	9,174,401	12.7%	-	-	-
Chirag Parikh	92,270	-	-	92,270	-	38,454
Daniel Levangie	-	-	-	-	-	-

1. James McCullough shareholding includes 2,554,398 shares held through his family trust, The McCullough 2020 Irrevocable Trust (the "Trust").

2. Christopher Mills is partner and Chief Investment Officer of Harwood Capital LLP. Harwood Capital LLP is Investment Manager to North Atlantic Smaller Companies Investment Trust plc and investment adviser to Oryx International Growth Fund Limited. Christopher's shareholding is made up of 6,145,001 ordinary shares held by North Atlantic Smaller Companies Investment Trust PLC, 2,780,000 ordinary shares are held by Oryx International Growth Fund Limited and 249,400 ordinary shares are held by Harwood Capital LLP.

# **REMUNERATION COMMITTEE REPORT (CONTINUED)**

# Performance graph and table

The following graph shows Renalytix's cumulative Total Shareholder Return ("TSR") from the Company's November 2018 IPO on AIM relative to the FTSE AIM All Share Index and the Nasdaq Biotech Index. These two indices were chosen due to Renalytix's listing on both exchanges and the sector in which it operates. For the period from 6 November 2018 to 30 June 2021 Renalytix Plc data relates to AIM TSR, and from 17 July 2020 the data relates to Nasdaq TSR (as show by the separate line).

TSR is defined as the return on investment obtained from holding a company's shares over a period. It includes dividends paid, the change in capital value of the shares and any other payment made to or by shareholders within the period.



# ALIGNING PAY WITH PERFORMANCE

# CEO remuneration compared with annual growth in TSR:

The total 2020/21 remuneration figure for the CEO (James McCullough) is shown in the table below, along with the value of bonuses paid in respect of the year, and EIP vesting, as a percentage of the maximum opportunity. As this is the first year reported since listing on Nasdaq and therefore the first year for which this disclosure is required, it is not possible to provide meaningful comparative data. However, full disclosure of the year on year movement will be provided in future remuneration reports.

James McCullough \$000s					
Total remuneration	1,193				
Actual bonus as a % of the maximum	50%				
Actual share award vesting as % of the maximum	-				

# Percentage change in remuneration of the Directors and employees

Set out below is the change over the prior period in base salary, benefits, pension and annual performance bonus for all the directors and the Company's employees.

	Salary % change 2019/20 vs 2020/21	Benefits % change 2019/20 vs 2020/21	Bonus % change 2019/20 vs 2020/21
James McCullough	58%	36%	371%
Fergus Fleming	58%	512%	116%
Ann Berman	-	-	-
Mount Sinai	-	-	-
Christopher Mills	-	-	-
Chirag Parikh	-	-	-
Dan Levangie	-	-	-

# Statement of Implementation of Policy in 2021/22

**Base salary:** There was no change in James McCullough's or Fergus Fleming's base salary for the 2021/2022 financial year. The 2021/2022 target base salary increases for other employees are expected to be in line with market rates for all of eligible employees, being those that had joined the business prior to 1 July 2021.

**Pension and benefits:** In 2021/2022, Executive Directors are eligible for the same benefits as provided to all senior employees. The Executive Directors are each entitled to the maximum employer pension contribution of 5% of their respective base salary which is paid into a defined contribution pension scheme / paid in cash in lieu of pension contributions.

**Annual performance bonus:** For 2021/2022, the Executive Directors' annual cash bonus target payouts are still being determined by the Committee as the benchmarking process is ongoing and will be disclosed in next year's report. The Committee considers overall corporate performance and individual performance when determining the final bonus amount to be awarded to an Executive Director. Performance will be tested against targets set by the Committee at the start of the year and will comprise a combination of corporate goals and individual goals for James McCullough and Fergus Fleming.

Specific targets are commercially sensitive and therefore are not disclosed in advance. However, full details of the targets and performance against them will be disclosed when they are no longer considered commercially sensitive.

The Chairman and non-executive directors will continue to be paid their current level of fees.

# Payments for loss of office (audited information)

There were no loss of office payments in 2020/2021.

# Payments to past Directors (audited information)

There were no payments to past directors in 2020/2021.

# Dr. Erik Lium

Chair of the Remuneration Committee

19 November 2021

# Independent Auditor's Report to the Members of Renalytix plc

# OPINION

We have audited the financial statements of Renalytix Plc (the 'parent company') and its subsidiaries (the 'group') for the year ended 30 June 2021 which comprise the Consolidated Income Statement, Consolidated Statement of Comprehensive Income, the Consolidated and Parent Company Statement of Financial Position, the Consolidated and Parent Company Statements of Cash Flows and the Consolidated and Parent Company Statements of Changes in Equity and notes to the financial statements, including significant accounting policies. The financial reporting framework that has been applied in their preparation is applicable law and international accounting standards in conformity with the requirements of the Companies Act 2006 and as regards the parent company financial statements, as applied in accordance with the provisions of the Companies Act 2006.

In our opinion:

- the financial statements give a true and fair view of the state of the group's and of the parent company's affairs as at 30 June 2021 and of the group's loss for the year then ended;
- the group financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006;
- the parent company financial statements have been properly prepared in accordance with international accounting standards in conformity with the requirements of the Companies Act 2006 and as applied in accordance with the provisions of the Companies Act 2006; and
- the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

# **BASIS FOR OPINION**

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the Auditor's responsibilities for the audit of the financial statements section of our report. We are independent of the group and parent company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

# CONCLUSIONS RELATING TO GOING CONCERN

In auditing the financial statements, we have concluded that the director's use of the going concern basis of accounting in the preparation of the financial statements is appropriate. Our evaluation of the directors' assessment of the group's and parent company's ability to continue to adopt the going concern basis of accounting included:

- a consideration of the inherent risks to the group's business model and an analysis of how those risks might affect the group's financial resources or ability to continue operations over the period from the date of signing the financial statements to November 2022.
- Identification of the risks that we considered most likely to affect the group's financial resources or ability to continue operations over this period, which were adverse circumstances impacting growth in revenues, timely conversion of trade receivables to cash, reduction in expenses and operating cash outflows, and access to financial resources in the form of debt facilities if so required. We considered this through a review of the application of reasonably foreseeable downside scenarios.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's or parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

Our responsibilities and the responsibilities of the directors with respect to going concern are described in the relevant sections of this report.

# OUR APPLICATION OF MATERIALITY

The scope of our audit was influenced by our application of materiality. The quantitative and qualitative thresholds for materiality determine the scope of our audit and the nature, timing and extent of our audit procedures. Materiality for the consolidated financial statements was set at \$1,005,000 (2020: \$410,000) based on the group's gross assets with performance materiality for the group set at \$603,000 (2020: \$246,000). Gross assets are considered to be a key benchmark as the group holds product trademarks and licenses and product development costs are capitalised in the group. We have also set a separate, lower, materiality for revenue owing to this being the first period in which revenue is recognised based on revenue for the year. We have determined materiality for revenue as \$32,000 and performance materiality as \$19,200.

Materiality for the parent company financial statements was set at \$470,000 (2020: \$260,000), with Gross assets being used as the benchmark with performance materiality for the parent company set at \$282,000 (2020: \$156,600). Gross assets are considered to be a key benchmark as the parent company holds the product trademarks and licenses and product development costs are capitalised in this company.

For each component in the scope of our group audit, we allocated a materiality that was less than our overall group materiality. Component materiality for significant and/or material subsidiary undertakings ranged from \$603,000 to \$410,000 (2020: \$246,000 to \$240,000).

We agreed with the audit committee that we would report all individual audit differences identified during the course of our group audit in excess of \$50,250 (2020: \$20,500) together with any other audit misstatements below that threshold that we believe warranted reporting on qualitative grounds. For the parent company, this threshold was \$23,500 (2020: \$13,000).

# OUR APPROACH TO THE AUDIT

In designing our audit, we determined materiality and assessed the risks of material misstatement in the financial statements. In particular, we looked at areas involving significant accounting estimates and judgement by the Directors such as the recoverability of intangible fixed assets and eligibility of capitalised development costs, as outlined in the Key Audit Matter section below, and considered events that are inherently uncertain.

We also addressed the risk of management override of controls, including among other matters consideration of whether there was evidence of bias that represented a risk of material misstatement due to fraud. All significant and/or material subsidiary undertakings were audited directly by PKF Littlejohn LLP.

# **KEY AUDIT MATTERS**

Key audit matters are those matters that, in our professional judgment, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) we identified, including those which had the greatest effect on: the overall audit strategy, the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

#### **Key Audit Matter**

# Recoverability of intangible fixed assets and eligibility of capitalised development costs (Note 20)

Intangible assets comprise the following categories as at 30 June 2021 with a total value of \$18,021,000:

- Trademarks, trade names and licenses
- Trade secrets
- Product development costs

Intangible assets that are subject to amortisation are assessed for indicators of impairment.

Estimated recoverable amounts using value in use calculations are subjective due to the inherent uncertainty involved in forecasting and discounting future cash flows. Judgement is also required when estimating useful economic lives.

The eligibility for capitalisation of expenditure is assessed in accordance with the criteria in IAS 38 Intangible Assets. There is a risk that these assets have been capitalised incorrectly and are not recoverable. Given the judgements and estimates involved these were a key focus for our audit. We confirmed the Group held good title to the trademarks, trade names and licenses.

We assessed whether any indicators of impairment (including regulatory issues, progress on obtaining milestones towards commercialisation, development of competing technology and products entering the market) existed which required an impairment charge to be recognised in profit or loss.

We performed substantive testing of additions in all intangible asset categories to supporting documentation. We reperformed the amortisation calculations.

Our testing on the forecasts and value in use calculations included:

- Evaluation and challenge of the key assumptions used by management;
- The performance of a sensitivity analysis on the headroom to reasonably possible changes in key assumptions.

We tested and verified the eligibility for capitalisation of development costs in accordance with the criteria under IAS 38, in particular technical feasibility, the ability to commercialise the asset and the availability of technical and financial resources to complete development.

# **OTHER INFORMATION**

The other information comprises the information included in the annual report, other than the financial statements and our auditor's report thereon. The directors are responsible for the other information contained within the annual report. Our opinion on the group and parent company financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon. Our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the financial statements or our knowledge obtained in the course of the audit, or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether this gives rise to a material misstatement in the financial statements themselves. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

# OPINIONS ON OTHER MATTERS PRESCRIBED BY THE COMPANIES ACT 2006

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the strategic report and the directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the directors' report have been prepared in accordance with applicable legal requirements.

# MATTERS ON WHICH WE ARE REQUIRED TO REPORT BY EXCEPTION

In the light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the strategic report or the directors' report.

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the parent company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

# **RESPONSIBILITIES OF DIRECTORS**

As explained more fully in the statement of directors' responsibilities in respect of the financial statements, the directors are responsible for the preparation of the group and parent company financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the group and parent company financial statements, the directors are responsible for assessing the group and the parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

# AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. The extent to which our procedures are capable of detecting irregularities, including fraud is detailed below:

- We obtained an understanding of the group and parent company and the sector in which they operate to identify laws and regulations that could reasonably be expected to have a direct effect on the financial statements. We obtained our understanding in this regard through discussions with management, and experience of the AI diagnostics sector.
- We determined the principal laws and regulations relevant to the group and parent company in this regard to be those arising from:
  - » Companies Act 2006
  - » AiM listing rules
  - » General Data Protection Regulation
  - » Quoted Companies Alliance compliance
  - » Food and Drug Administration Agency
  - » Local laws and regulations in UK and the USA where the group operates; and
  - » Local tax and employment law where each member of the group operates

- We designed our audit procedures to ensure the audit team considered whether there were any indications of noncompliance by the group and parent company with those laws and regulations. These procedures included, but were not limited to:
  - » Enquires of management
  - » Review of Board minutes
  - » Review of legal expenses
  - » Review of RNS announcements
- We also identified the risks of material misstatement of the financial statements due to fraud. We considered, in addition to the non-rebuttable presumption of a risk of fraud arising from management override of controls, the potential for management bias was identified in relation to the impairment of intangible fixed assets and as noted above, we addressed this by challenging the assumptions and judgements made by management when auditing that significant accounting estimate.
- As in all of our audits, we addressed the risk of fraud arising from management override of controls by performing audit procedures which included, but were not limited to: the testing of journals; reviewing accounting estimates for evidence of bias; and evaluating the business rationale of any significant transactions that are unusual or outside the normal course of business.
- All significant components of the group were audited by PKF Littlejohn LLP. Our work in relation to the points noted above considers all aspects of the group.

Because of the inherent limitations of an audit, there is a risk that we will not detect all irregularities, including those leading to a material misstatement in the financial statements or non-compliance with regulation. This risk increases the more that compliance with a law or regulation is removed from the events and transactions reflected in the financial statements, as we will be less likely to become aware of instances of non-compliance. The risk is also greater regarding irregularities occurring due to fraud rather than error, as fraud involves intentional concealment, forgery, collusion, omission or misrepresentation.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

# USE OF OUR REPORT

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone, other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

David Thompson

(Senior Statutory Auditor)

For and on behalf of PKF Littlejohn LLP Statutory Auditor

15 Westferry Circus Canary Wharf London E14 4HD

19 November 2021

# **FINANCIAL STATEMENTS**

# Consolidated Income Statement

	Note	Year to 30 June 2021	Year to 30 June 2020
		\$'000	\$'000
Continuing operations			
Revenue	8	1,491	-
Cost of Sales		(804)	-
Gross Profit		687	
Administrative expenses	9	(33,298)	(11,078)
Operating loss		(32,611)	(11,078)
Share of Net loss in Associate accounted for using the equity method		(199)	(63)
Impairment of Investment of associate	37	(1,913)	-
Gain on financial assets at fair value through profit or loss	24	6,483	-
Gain on distribution of assets classified as held for sale	36	402	-
Finance (costs) income - net	14	(7,950)	531
Loss before tax		(35,788)	(10,610)
Taxation	15	4,778	1,360
Loss for the period		(31,010)	(9,250)
Earnings per Ordinary share from continuing operations			
Basic and diluted	16	\$ (0.43)	\$ (0.16)

# Consolidated Statement of Comprehensive Income

# FOR THE YEAR ENDED 30 JUNE 2021

	Year to 30 June 2021	Year to 30 June 2020
	\$'000	\$'000
Loss for the period – continuing operations	(31,010)	(9,250)
Other comprehensive income:		
Items that may be subsequently reclassified to profit or loss		
Currency translation differences	11,616	(1,265)
Other comprehensive loss for the period	(19,394)	(10,515)
Total comprehensive loss for the period	(19,394)	(10,515)

Items stated above are disclosed net of tax. The income tax relating to each component of other comprehensive income is disclosed in note 15.

# Consolidated and Company's Statements of Financial Position

# AS AT 30 JUNE 2021

	Notes	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
		\$'000	\$'000	\$'000	\$'000
Assets					
Non-current assets					
Property, plant and equipment	18	1,081	580	-	-
Right of use asset	19	297	365	-	-
Intangible assets	20	18,021	17,118	17,524	16,841
Investment in subsidiaries	21	-	-	4,588	2,264
Investments accounted for using the equity method		-	1,937	-	-
Note receivable	22	75	83	-	2,106
Deferred tax assets	15	7,097	2,319	-	-
Total non-current assets		26,571	22,402	22,112	21,211
Current Assets					
Inventory	23	353	326	-	-
Security deposits	24	86	71	-	-
Assets classified as held for sale	36	-	1,705	-	-
Financial asset at fair value through profit or loss	24	9,295	-	9,295	-
Trade and other receivables	25	594	18	84,686	21,956
Prepaid and other current assets	26	520	2,501	271	2,408
Short term investments	24	-	982	-	-
Cash and cash equivalents	27	65,159	13,293	15,063	2,441
Total current assets		76,007	18,896	109,315	26,805
Total assets		102,578	41,298	131,427	48,016
Equity attributable to owners of the parent					
Share capital	28	233	192	233	192
Share premium	29	76,457	-	76,457	-
Share-based payment reserve	30	4,940	2,833	4,940	2,833
Foreign currency reserves		9,701	(1,915)	9,687	(1,970)
Retained earnings/(deficit)		3,771	34,852	38,917	46,710

	Notes	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
Total equity		95,102	35,962	130,234	47,765
Liabilities					
Current liabilities					
Trade and other payables	31	6,652	2,899	1,193	251
Deferred Revenue	8	122	-	-	-
Current lease liabilities	19	86	92	-	-
Borrowings	32	53	121	-	-
Current due to affiliated company	33	350	271	-	-
Total current liabilities		7,263	3,383	1,193	251
Non-current liabilities					
SBA PPP Funding - long-term		-	134	-	-
Non-current lease liabilities	19	213	275	-	-
Non-current due to affiliated company		-	1,544	-	-
Total non-current liabilities		213	1,953	-	-
Total liabilities		7,476	5,336	1,193	251
Total equity and liabilities		102,578	41,298	131,427	48,016

The notes on pages 62 to 83 are an integral part of these financial statements.

The Company has elected to take the exemption under section 408 of the Companies Act 2006 not to present the Parent Company income statement. The loss for the Parent Company for the year was (\$7,718,000). (Year ended 30 June 2020: loss of \$1,793,000).

The financial statements were approved and authorized for issue by the Board on 19 November 2021 and signed on its behalf by:

Christophe Mills,

**Christopher Mills** 

Chairman

James R. McCullough Chief Executive Officer

Company number: 11257655

# Consolidated and Company's Statements of Cash Flows

	Note	Group Year to 30 June 2021	Group Year to 30 June 2020	Company Year to 30 June 2021	Company Year to 30 June 2020
		\$'000	\$'000	\$'000	\$'000
Cash flow from operating activities					
Loss before income tax		(35,788)	(10,610)	(7,718)	(1,793)
Adjustments for					
Depreciation		138	140	-	25
Amortization 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		2,112	63	-	-
Reversal of Kantaro Liability		(495)	-	-	-
Gain on Sale of assets		(449)	-	-	(270)
Forgiveness of PPP Loan		(255)	-	-	-
Unrealized loss (Gain) on financial asset at fair value through profit or loss		(6,483)	-	(6,483)	-
Foreign Exchange Loss (Gain)		8,832	-	2,939	-
Impairment of Investment in Subsidiary		-	-	517	-
Changes in working capital					
Trade and other receivables		(576)	(18)	(60,624)	(12,756)
Prepaid assets and other current assets		1,981	(2,440)	2,137	(2,378)
Assets classified as available for sale		-	(1,714)	-	-
Inventory		(27)	(326)	-	-
Security Deposits		(15)	(22)	-	-
Trade and other payables		3,753	2,064	943	(188)
Deferred Revenue		122	-	-	-
Payable to affiliated company		(1,623)	-	-	-
Cash used in operations		(24,635)	(10,059)	(66,408)	(16,094)
Interest paid		3	-	2	-
Net cash used in operating activities		(24,632)	(10,059)	(66,406)	(16,094)
Cash flow from investing activities					
Purchase of property, plant and equipment (PPE)		(783)	(359)	-	-
Lease Payments		(93)	(61)	-	-
Purchase of intangibles		(847)	(1,411)	(358)	(1,027)
Proceeds (purchase) of financial assets		982	982	_	-

	Note	Group Year to 30 June 2021	Group Year to 30 June 2020	Company Year to 30 June 2021	Company Year to 30 June 2020
Net cash generated by/(used in) investing activities		(741)	(849)	(358)	(1,027)
Cash flow from financing activities					
Note receivable		-	(83)	-	(161)
Issue of shares (net of issue costs)		76,876	16,678	79,023	16,678
Proceeds from loans		-	255	-	-
Proceeds from the issuance of ordinary shares under employee share purchase plan		111	-	111	-
Proceeds from exercise of stock options		252	-	252	-
Net cash generated from financing activities		77,239	16,850	79,386	16,517
Net increase/(decrease) in cash and cash equivalents		51,866	5,942	12,622	(605)
Cash and cash equivalents at beginning of period		13,293	7,297	2,441	3,045
Cash and cash equivalents at end of period	22	65,159	13,293	15,063	2,441

# Consolidated Statement of Changes in Equity

	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	-	-	-	(1,265)	(9,250)	(10,515)
Transactions with owners						
Issue of shares	17	17,193	-	-	-	17,210
Less issue costs	-	(596)	-	-	-	(596)
Share-based payments	-	-	1,696	-	-	1,696
Reduction of Capital	-	(50,629)	-	(51)	50,680	-
Total transactions with owners of the parent, recognized 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	35,962
Comprehensive income						
Loss for the period	-	-	-	-	(31,010)	(31,010)
Other comprehensive income						
Currency translation differences	-	-	-	11,612	4	11,616
Total comprehensive income	-	-	-	11,612	(31,006)	(19,394)
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,101	-	-	-	85,141
Less issue costs	-	(9,007)	-	-	-	(9,007)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	111	-	-	-	111

	Share Capital	Share Premium	Share-based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
Exercise of Stock Options	1	252	-	-	-	253
Verici Ordinary Share Repurchase	-	-	-	-	(75)	(75)
Total transactions with owners of the parent, recognized directly in equity	41	76,457	2,107	-	(75)	78,530
At 30 June 2021	233	76,457	4,940	9,701	3,771	95,102

# Company's Statement of Changes in Equity

	Share Capital	Share Premium	Share-based payment	Foreign Currency	Retained earnings	Total equity
		Premium	reserve	Reserve	earnings	
	\$'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	-	-	-	(1,309)	(1,974)	(3,283)
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	-		-	-	-	-
Reduction of Capital	-	(50,629)	-	(51)	50,680	-
Total transactions with owners of the parent, recognized 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	-	-	-	-	(7,718)	(7,718)
Other comprehensive income						
Currency translation differences	-	-	-	11,657		11,657
Total comprehensive income	-	-	-	11,657	(7,718)	3,939
Transactions with owners						
Issuance of Ordinary Shares in US IPO	40	85,101	-	-	-	85,141
Less issue costs	-	(9,007)	-	-	-	(9,007)
Share-based payments	-	-	2,107	-	-	2,107
Shares issued under the ESPP	-	111	-	-	-	111

	Share Capital	Share Premium	Share-based payment reserve	Foreign Currency Reserve	Retained earnings	Total equity
Exercise of Stock Options	1	252	-	-	-	253
Verici Ordinary Share Repurchase	-		-	-	(75)	(75)
Total transactions with owners of the parent, recognized directly in equity	41	76,457	2,107	-	(75)	78,530
At 30 June 2021	233	76,457	4,940	9,687	38,917	130,234

# Notes to the Financial Statements

# 1. GENERAL INFORMATION AND BASIS OF PRESENTATION

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

The principal activity of the Company and its subsidiaries (together "the Group") is as a developer of artificial intelligenceenabled 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 2020.

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 year ended 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 not adopted by the group

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

# New standards, amendments, and interpretations issued but not effective for the period ended 30 June 2021, 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.

- Amendments to IFRS 16: Leases COVID-19 Concessions
- Amendments to IFRS 9, IAS 39, IFRS 7 IFRS 4 and IFRS 16: Interest Rate Benchmark Reform Phase 2

# **3. SIGNIFICANT ACCOUNTING POLICIES**

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

# Going concern

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

The Directors have considered the applicability of the going concern basis in the preparation of these financial statements. This included the review of internal budgets and financial results which show, taking into account reasonably probable changes in financial performance, that the Group and Company should be able to operate within the level of its current funding arrangements.

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

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

### **Basis of consolidation**

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

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

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

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

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

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

### Foreign currency translation

### (a) Functional and presentational currency

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

### (b) Transactions and balances

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

### (c) Group companies

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

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

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

### Segmental reporting

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

# Property, plant and equipment

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

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

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

Fixtures and fittings 20%

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

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

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

# Intangible assets

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

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

### (b) Development costs and trade secrets

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

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

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

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

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

# Impairment of non-financial assets

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

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

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

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

### **Financial assets**

### Classification

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

### (a) Loans and receivables

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

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

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

- debt investments that do not qualify for measurement at either amortized 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 recognize fair value gains and losses through Other Comprehensive Income.

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

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

### Cash and cash equivalents

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

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

### Share capital and premium

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

### Other reserves - equity

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

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

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

# Trade and other payables

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

### Current and deferred income tax

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

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

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

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

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

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

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

### Leases

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

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

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

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

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

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

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

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

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

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

### **Revenue Recognition**

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

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

### Cost of revenue

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

### **Employee benefits**

### (a) Pension obligations

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

### (b) Share-based compensation

The Group operates an equity-settled, share-based compensation plan, under which the Group receives services from employees and others as consideration for equity instruments of the Group. Equity-settled share-based payments are measured at fair value at the date of grant and are expensed over the vesting period based on the number of instruments that are expected to vest. For plans where vesting conditions are based on share price targets, the fair value at the date of grant reflects these conditions. Where applicable the Group recognizes the impact of revisions to original estimates in the income statement, with a corresponding adjustment to equity for equity-settled schemes. Fair values are measured using appropriate valuation models, taking into account the terms and conditions of the awards.

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

### National insurance on share options

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

### Interest income

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

### **Exceptional items**

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

### Assets Classified as Held for Sale

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

# 4. FINANCIAL RISK MANAGEMENT

### **Financial Risk Factors**

The Company's activities expose it to a variety of financial risks. The Company's Board monitors and manages the financial risks relating to the operations of the Company.

### (a) Market Risk

### Foreign Exchange Risk

The Company operates internationally and is exposed to foreign exchange risk primarily with respect to the US Dollar and the Pounds Sterling. Foreign exchange risk arises from future commercial transactions and recognized assets and liabilities.

### (b) Credit Risk

Credit risk relates mainly to cash at bank. The Company only deposits cash with major banks with high quality credit standing and limits exposure to any one counterparty.

### (c) Liquidity Risk

The Company's continued future operations depend on its ability to raise sufficient working capital through the issue of share capital and generate revenue.

# 5. CAPITAL RISK MANAGEMENT

The Company manages its capital to ensure that it will be able to continue as a going concern while maximizing the return to stakeholders. The Company's capital structure primarily consists of equity attributable to the owners, comprising issued capital, reserves and retained losses.

# 6. CRITICAL ACCOUNTING ESTIMATES AND JUDGMENTS

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

- Capitalisation and recoverability of intangible assets (note 20);
- Share based payments (note 30).

# 7. SEGMENTAL REPORTING

The Group operates as a single segment.

# 8. REVENUE

### Testing services revenue

Testing services revenue is generated from the KidneyIntelX platform, which provides analytical services to customers. Each individual test is a performance obligation that is satisfied at a point in time upon completion of the testing process (when results are reported) which is when control passes to the customer and revenue is recognized. During the year ended June 30, 2021, the Company recognized \$0.4 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. There was no testing services revenue recognized in the 2020 and 2019 accounting periods.

### Pharmaceutical services revenue

Pharmaceutical services revenue is generated from the provision of analytical services to customers. Contracts with customers generally include an initial upfront payment and additional payments upon achieving performance milestones. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer which may occur at a point in time or over time depending on the individual contract terms. Sales tax and other similar taxes are excluded from revenues. During the year ended June 30, 2021, the Company recognized \$1.1 million of pharmaceutical services revenue. There was no pharmaceutical services revenue recognized in the 2020 and 2019 accounting periods.

### Deferred revenue

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

The following table summarizes the changes in deferred revenue:

	Year ended 30 June 2021	Year ended 30 June 2022
	\$'000	\$'000
Balance, beginning of period	-	-
Deferral of revenue	250	-
Revenue recognized	(128)	-
Balance, end of period	122	-

# 9. EXPENSES - ANALYSIS BY NATURE

	Year ended 30 June 2021	Year ended 30 June 2020
	\$'000	\$'000
Employee benefit expense	12,416	4,639
Contract labor	3,393	1,376
Depreciation and amortization	2,053	1,244
Professional fees	8,374	1,654
Laboratory supplies	326	366
Other expenses	6,736	1,799
Total administration expenses	33,298	11,078

# **10. AUDITOR'S REMUNERATION**

	Year ended 30 June 2021	Year ended 30 June 2020
	\$'000	\$'000
Fees payable to the Company's auditor for the audit of the parent Company and consolidated financial statements	53	28
Fees payable to the Company's auditor for other services:		
Tax compliance services	-	5
Service for finance related transactions	-	9
Total	53	42

# **11. DIRECTORS' REMUNERATION**

	Year ended 30 June 2021	Year ended 30 June 2020	
	\$'000	\$'000	
Aggregate emoluments	1,832	945	
Share based payments	206	230	
Contribution to defined contribution pension scheme	39	28	
Total	2,077	1,203	

Retirement benefits are accruing to two current executive directors under a defined contribution scheme. See further disclosures within the Remuneration Report on pages 34. The highest paid director received aggregate emoluments, excluding the effect of the share based payments charge, totaling \$1,193,000 (2020: \$904,000).

# **12. EMPLOYEE BENEFIT EXPENSE**

	Group Year ended 30 June 2021	Group Year ended 30 June 2020	Company Year ended 30 June 2021	Company Year ended 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Wages, salaries and Bonus	8,902	2,712	168	215
Social security costs and Benefits	1,334	231	9	-
Share based payment expenses	2,180	1,696	74	172
Total	12,416	4,639	251	387
# 13. MONTHLY AVERAGE NUMBER OF PEOPLE EMPLOYED

The monthly average number of people (including Executive Directors) employed was:

	Group Year ended 30 June 2021	Company Year ended 30 June 2021	Group Year ended 30 June 2020	Company Year ended 30 June 2020
Administration	27	2	6	1
Research and development	20	-	6	1
Total	47	2	12	2

The total number of employees (FTEs) in the Group at 30 June 2021 was 53, and in the Company was 2.

# 14. FINANCE INCOME AND COSTS

	Year ended 30 June 2021	Year ended 30 June 2020	
	\$'000	\$'000	
Finance costs:			
Interest expense	(3)	(2)	
Finance income:			
Interest income	236	194	
Gain on debt forgiveness	255	-	
Reduction in contractual liability	495	-	
Gain/(Loss) on Foreign Exchange	(8,933)	339	
Net finance income/(loss)	(7,950)	531	

### **15. INCOME TAX**

	Year ended 30 June 2021	Year ended 30 June 2020
Group	\$'000	\$'000
Deferred tax	4,778	2,319
Total deferred tax	4,778	2,319
Income tax credit	4,778	2,319

#### Factors affecting the future tax charge

The standard rate of corporation tax in the UK is 19%.

A reduction in the UK corporation tax rate from 19% to 17% effective 1 April 2020 was substantively enacted on 6 September 2016. The March 2020 Budget announced that a rate of 19% would continue to apply with effect from 1 April 2020. An increase in the UK corporate tax rate from 19% to 25% (effective from 1 April 2023) was substantively enacted on 14 May 2021.

	Year ended 30 June 2021	Year ended 30 June 2020
	\$'000	\$'000
Loss before Tax	35,788	10,610
Tax Calculated at domestic tax rates applicable to the UK Standard of tax at 19%	6,800	2,016
Tax effects of:		
Expenses not deductible for tax purposes	(487)	(159)
Losses on which no deferred tax asset is recognized	(1,535)	(501)
Other Movements	-	4
Tax Credit for the Year	4,778	1,360
Prior year Deferred Tax	2,319	959
Deferred tax asset at 30 June 2021	7,097	2,319

Deferred tax assets are recognized based on subsidiary net losses based on the US corporate tax rate of 21%. Net losses can be carried forward indefinitely to offset future taxable profits. No deferred asset is calculated on losses in the UK totaling \$7,718,000 where the probability of future utilization is considered too remote.

### **16. 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	Year ended 30 June 2020
	\$'000	\$'000
Loss attributable to owners of the parent	(31,010)	(9,250)
Weighted average number of ordinary shares in issue	71,484,934	59,079,522
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 and prior period as the Group made a loss.

### **17. DIVIDENDS**

On 7 July 2020 the Board convened and declared a distribution in specie of shares in Verici to trustees on trust for the Company's shareholders (the "Distribution"). The Company's shareholders on the register as at close of business on 9 July 2020 ("Relevant Renalytix Shareholders") will receive one A Share in Verici ("Distribution Shares") for every 1 ordinary share held in the Company. Broadway Nominees Limited, as trustees, will act as legal holder of the Distribution Shares (59,416,134 shares of £0.001 each) during the Lock-Up period. Following the Lock-up Period, Relevant Renalytix Shareholders will receive individual certificates in respect of their Distribution Shares.

# 18. PROPERTY, PLANT AND EQUIPMENT

Group	Fixtures and fittings
	\$'000
Cost	
At 1 July 2019	309
Additions	862
Transfer to Assets held for sale	(522)
Foreign translation	1
At 30 June 2020	650
Depreciation	
At 1 July 2019	31
Charge for the period	74
Transfer to Assets Held for Sale	(36)
Foreign translation	1
At 30 June 2020	70
Net book value at 30 June 2020	580
Cost	
At 1 July 2020	650
Additions	782
Reclass to computer software	(146)
Foreign translation	
At 30 June 2021	1,286
Depreciation	
At 1 July 2020	70
Charge for the period	138
Foreign translation	(3)
At 30 June 2021	205
Net book value at 30 June 2021	1,081

The depreciation charge of \$138k related to Property, Plant and Equipment has been charged to administration expenses (\$126k) and cost of goods sold (\$12k).

### 19. LEASES

#### (i) Amounts recognized in the statement of financial position

The balance sheet shows the following amounts relating to leases:

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Right-of-use assets				
Properties	297	365	-	-
Total right-of-use assets	297	365	-	-
Lease liabilities				
Current	86	92	-	-
Non-current	213	275	-	-
Total lease liabilities	299	367	-	-

Right-of-use assets have been measured at the amount equal to the lease liability.

Lease liabilities were measured at the present value of the remaining lease payments, discounted using the Group's incremental borrowing rate.

#### (ii) Amounts recognized in the Statement of Comprehensive income

The statement of profit or loss shows the following amounts relating to leases:

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Depreciation charge - right-of-use assets				
Properties	155	62	-	-
Total right-of-use	155	62	-	-
Interest expense (included in finance cost)	3	1	-	-

The total cash outflow for leases in the year to 30 June 2021 was \$155k for the Group and \$Nil for the Company.

#### (iii) The group's leasing activities and how these are accounted for

The group leases various offices. Rental contracts for offices are made for fixed periods of between 1 and 5 years, but may have extension options as described below.

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 in the lease. If that rate cannot be readily determined, which is generally the case for leases in the group, the lessee's incremental cash rate is used, being the rate that the individual lessee would forego to release 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.

# **20. INTANGIBLE FIXED ASSETS**

	Trademarks, Trade Names & Licenses	Trade Secrets	Development Costs	Total
	\$'000	\$'000	\$'000	\$'000
Cost				
At 1 July 2019	11,002	6,641	1,740	19,383
Additions	-	-	1,538	1,538
Transfer to assets held for sale	(1,261)	-	-	(1,261)
Foreign translation	(275)	(239)	(55)	(569)
At 30 June 2020	9,466	6,402	3,223	19,091
Amortization				
At July 2019	1,096	-	-	1,096
Charge for the period	1,108	-	-	1,108
Transfer to assets held for sale	(114)	-	-	(114)
Foreign translation	(117)	-	-	(117)
At 30 June 2020	1,973	-	-	1,973
Net book value				
At 30 June 2020	7,493	6,402	3,223	17,118
Cost				
At 1 July 2020	9,466	6,402	3,223	19,091
Additions	-	-	847	847
Foreign translation	1,087	734	359	2,180
At 30 June 2021	10,553	7,136	4,429	22,118
Amortization				
At July 2020	1,973	-	-	1,973
Charge for the period	1,030	529	305	1,864
Transfer to assets held for sale	-	-	-	-
Foreign translation	251	6	3	260
At 30 June 2021	3,254	535	308	4,097
Net book value				
At 30 June 2021	7,299	6,601	4,121	18,021

Amortization expense of \$1,864,016 has been charged to administration costs. Amortization expense of \$1,108,000 was charged in the prior year ended 30 June 2020.

Licenses entail agreements with Icahn School of Medicine at Mount Sinai for rights to intellectual property and data to support the KidneyIntelX diagnostic assay. Trade secrets refer to the Company's acquisition of the biomarker business from EKF, which includes intellectual property licensed from Joslin Diabetes Centre and forms a key component of the KidneyIntelX product. Development costs include proprietary software development and diagnostic assay design for KidneyIntelX.

Assets that are subject to amortization are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount may not be recoverable. An impairment loss is recognized for the amount by which the carrying amount exceeds its recoverable amount.

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

The Group has tested the carrying value for impairment at the balance sheet date. The recoverable amount was assessed in the basis of value in use. The assessed value exceeded the carrying value and no impairment loss was recognized. The key assumptions in the calculation to assess value in use are future revenues and costs and the ability to generate future cash flows. Recent working capital projections approved by the Board were used as well as forecasts for a further four years, followed by an extrapolation of expected cash flows and the calculation of a terminal value. For prudence the expected growth rate used for longer term growth was zero. The projected results were discounted at a rate which is a prudent evaluation of the pre-tax rate which reflects current market assessments of the value of money and the risks specific to the business, reflecting an assessment of the risk-adjusted weighted average cost of capital of 10%. The headroom in the value in use calculation is not sensitive to changes in key assumptions.

For the purposes of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows. Any impairment loss is charged pro rata to the other assets in the cash generating unit.

The remaining average useful lives of the intangible assets is as follows:

Trademarks trade names & licenses	10-15 years
Trade secrets	15 years
Development Costs	15 years

The Company holds capitalized development costs with a cost of \$4,428,786 and net value of \$4,121,372, these projects were placed into service in FY21.

### 21. INVESTMENTS IN SUBSIDIARIES

	At 30 June 2021	At 30 June 2020
Company	\$'000	\$'000
At beginning of Period	2,264	771
Capital Contribution relating to share based payment	2,325	1,493
Shares in Verici Dx Ltd	(1)	1
At End of Period	4,588	2,264

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 8 November 2021.

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

- 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.

### 22. NOTES RECEIVABLE

#### Company

In May 2020, the Group's FractalDX related business was sold to Verici DX Limited for consideration totalling \$2m which took the form of secured convertible debt ("the Notes"). The Notes were for a maximum of \$3m to allow for the inclusion of any additional charges. They were secured by a debenture over Verici's assets. The Notes were interest free and were converted into ordinary shares in Verici at the Company's option at the equivalent price to that paid by investors on a fund raising.

### 23. INVENTORY

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Finished goods	353	326	-	-

The Directors are of the opinion that the replacement values of inventories are not materially different to the carrying values stated above. The carrying values above are stated net of impairment provisions of \$0 (30 June 2021: \$0).

The cost of inventories recognized as expense and included in 'cost of sales' amounted to \$60k (Year to 30 June 2020: \$Nil).

The Company held no inventories at 30 June 2020 and 30 June 2021.

# 24. FINANCIAL INSTRUMENTS

#### (a) Assets at amortized cost

	Group 30 June 2021	Group 30 June 2020	Company 30 June 2021	Company 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Assets as per balance sheet				
Security deposits	86	71	-	-
Intragroup receivable	-	-	84,686	21,956
Short Term Investments	-	982	-	-
Cash and cash equivalents	65,159	13,293	15,063	2,441
Total	65,245	14,346	99,749	24,397

Receivables in the analysis above are all categorized as "loans and receivables" for the Group and Company.

#### (b) Assets at fair value

	Group 30 June 2021	Group 30 June 2020	Company 30 June 2021	Company 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Assets as per balance sheet				
Investment in Verici Dx	9,295	-	9,295	-
Total	9,295	-	9,295	-

#### (c) Liabilities at amortized cost

	Group 30 June 2021	Group 30 June 2020	Company 30 June 2021	Company 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Liabilities as per balance sheet				
Accounts payable	1,765	2,245	622	159
Accrued expenses	4,887	654	571	93
SBA PPP Funding	-	255	-	-
Lease Liabilities	299	367	-	-
Total	6,951	3,521	1,193	252

#### (d) Credit Quality of Financial Assets

The Group is exposed to credit risk from its operating activities and from its financing activities, including deposits with banks and financial institutions, foreign exchange transactions and other financial instruments.

The Group's maximum exposure to credit risk, due to the failure of counterparties to perform their obligations as at 30 June 2021, in relation to each class of recognized financial assets, is the carrying amount of those assets as indicated in the accompanying balance sheets.

#### Trade Receivables

The credit quality of trade receivables that are neither past due nor impaired have been assessed based on historical information about the counterparty default rate.

#### Cash at Bank

The credit quality of cash has been assessed by reference to external credit ratings, based on reputable credit agencies' long-term issuer ratings:

	Group At 30 June 2021	Group At 30 June 2020	Company At 30 June 2021	Company At 30 June 2020
	\$'000	\$'000	\$'000	\$'000
AA-	65,159	13,293	15,063	2,441
AA+	-	982	-	-
Total	65,159	14,275	15,063	2,441

### 25. TRADE AND OTHER RECEIVABLES

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Trade Receivables	594	-	-	-
Due from subsidiaries	-	-	84,686	21,956
Due from affiliates	-	18	-	-
Total	594	18	84,686	21,956

Due to their short term nature, the Directors consider that the carrying amount of trade and other receivables approximates to their fair value.

# 26. PREPAIDS AND OTHER CURRENT ASSETS

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Prepaids	520	137	271	44
Deferred Nasdaq Offering Costs	-	2,364	-	2,364
Prepaids and Other Current Assets	520	2,501	271	2,408

# 27. CASH AND CASH EQUIVALENTS

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Cash at Bank	65,159	13,293	15,063	2,441
Cash and cash equivalents	65,159	13,293	15,063	2,441

The Directors consider that the carrying value of cash and cash equivalents approximates to their fair value.

# 28. SHARE CAPITAL

Group and	Company	Movement	Total Number of Shares	\$'000
At 15 March	2018	-	-	-
15-Mar-18	Formation	50,000	50,000	66
4-May-18	100:1 subdivision	-	5,000,000	-
24-Oct-18	4:1 subdivision	-	20,000,000	-
24-Oct-18	Biomarker business acquisition	15,427,704	35,427,704	49
6-Nov-18	Placing & offer (listing on AIM)	18,388,430	53,816,134	60
At 30 June	2019	-	53,816,134	175
29-Jul-19	Placing & Secondary Offering (AIM)	5,600,000	59,416,134	17
At 30 June	2020	-	59,416,134	192
17-Jul-20	Placing & Offering (Nasdaq)	12,613,500	72,029,634	40
4-Mar-21	Shares issued under the ESPP	17,652	72,047,286	0
25-Jun-21	Exercise of Stock Options	150,000	72,197,286	1
At 30 June	2021	-	72,197,286	233

Ordinary Shares have a par value of £0.0025 each. All issued shares are fully paid.

### 29. SHARE PREMIUM ACCOUNT

On May 15, 2020, our shareholders approved at a general meeting the reduction of our share capital by the cancellation of our share premium account in its entirety in order to create realized profits, which was confirmed by the High Court in England and Wales on June 9, 2020. This was necessary to increase our distributable reserves to allow us to implement the distribution in specie for the FractalDx spin-off, whose distribution was declared by our board of directors on July 7, 2020 and distributed on July 10, 2020.

# **30. SHARE OPTIONS AND SHARE-BASED PAYMENTS**

In November 2018, Company established the Renalytix AI plc Share Option Plan (the "Plan") and a U.S. Sub-Plan and Non-Employee Sub-Plan. The Plan provides for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of June 30, 2021, there were 2,937,005 shares available for future issuance under the Plan.

The Plan is administered by the board of directors. The exercise prices, vesting and other restrictions are determined at their discretion, except that all options granted have exercise prices equal to the fair value of the underlying ordinary shares on the date of the grant and the term of stock option may not be greater than ten years from the grant date.

The options granted as of June 30, 2021 vest equally over twelve quarters following the grant date, with the exception of 80,724 options which vested immediately when granted, 582,100 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary and 500,000 which vest 1/12th on the one year anniversary and equally over twelve quarters following the one year anniversary. If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

Details of the share options outstanding during the period are as follows:

General employee share option plan	Average exercise price per share (USD)	Number of Options
As at 30 June 2020	1.95	3,028,858
Granted during the year	10.63	1,387,100
Outstanding at 30 June 2021	4.68	4,415,958
Exercisable at 30 June 2021	2.18	2,495,621
Vested and expected to vest at 30 June 2021	4.68	4,415,958

The fair value of each share option granted has been estimated using a Black-Scholes model and is £3.33 - £7.02 (\$4.36 - \$9.69). The inputs into the model are a weighted average share price of £4.84 (\$6.60), exercise price of £7.79 (\$10.63), expected volatility of 70.23%, no expected dividend yield, weighted-average term of 5.74 years and weighted-average risk free interest rate of 1.7%. As of 30 June 2021 none of the granted stock options have been exercised.

The aggregate fair value of the award is \$13,026,041. The Group recognized total expenses of \$2,109,911 (\$427,003 within R&D expense and \$1,682,911 within G&A expense) relating to equity-settled share-based payment transactions during the period to 30 June 2021. The weighted average remaining contractual term of the options is 8.2 years.

### **31. TRADE AND OTHER PAYABLES**

	Group As at 30 June 2021	Group As at 30 June 2020	Company As at 30 June 2021	Company As at 30 June 2020
	\$'000	\$'000	\$'000	\$'000
Accounts payable	1,765	2,221	623	134
Payroll taxes payable	638	24	-	24
Accrued expenses	4,249	654	571	93
	6,652	2,899	1,194	251

The carrying amount of the trade and other payables balances denominated in GBP are £4k for the Group and Company (2020 - £202k).

## **32. BORROWINGS**

#### Paycheck Protection Program

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 \$0.255 million (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. The Loan matures in two years and bears interest at a rate of 1% per year, with all payments deferred through the six-month anniversary of the date of the Loan. Principal and interest are payable monthly commencing on October 29, 2020 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. The balance on the PPP loan was \$0.255 as of June 30, 2020 and has been classified as a long-term liability in notes payable in the accompanying consolidated balance sheet at June 30, 2020.

On April 28, 2021, the Company received notification that the full amount of the PPP Loan and accrued interest was forgiven.

### 33. 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 Z021.

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.

# **34. CONTINGENT LIABILITIES**

The Group has a contract with Icahn School of Medicine at Mount Sinai which give rise to contingent liabilities:

#### Mount Sinai Collaboration Agreement

The Group is subject to the following one-off milestone payment obligations:

- \$1.5 million once worldwide sales of Licensed Products reach \$50 million; and
- \$7.5 million once worldwide sales of Licensed Products reach \$300 million.

In addition, royalties of 4-5% are payable to Mount Sinai on net sales of KidneyIntelX<sup>™</sup>, and 15% or 25% (depending on timing) of income from sublicensing. The Group is also subject to an annual data transfer fee of \$50,000.

#### Joslin Diabetes Center Agreement

The Group has a contract with Joslin Diabetes Center under which the Group is liable for the following costs and payments:

- 5% royalty on net sales of Joslin Licensed Products and Joslin Licensed Processes;
- 25% of royalties received by the Group from sublicensing;
- A one-off milestone payment of \$300,000 once total net sales reach \$2 million; and
- A one-off milestone payment of \$1 million once total net sales reach \$10 million

### **35. ULTIMATE CONTROLLING PARTY**

The Directors believe there to be no ultimate controlling party.

### 36. ASSETS AND LIABILITIES OF DISPOSAL GROUP CLASSIFIED AS HELD FOR SALE

In April 2020, the Group announced its intentions to pursue a spin-off and potential admission to AIM of Verici Dx Limited in order to secure separate financial and management resources for the FractalDx portfolio with the goal of enabling accelerated development.

On 7th July 2020 the Board declared a distribution in specie of shares in Verici to trustees on trust for the Company's shareholders. The following Assets and liabilities were reclassified as held for sale as of 30 June 2020 as a result of the pending spin off and removed from the balance sheet after the transaction was completed in FY21.

	As at 30 June 2021	As at 30 June 2020
Assets classified as held for sale		
Prepaid Expenses	-	11
Property Plant and Equipment	-	490
Intangible Assets	-	1,204
Total	-	1,705

At the time of distribution the value of the Group's convertible note due from Verici was \$2.1m which resulted in a gain of \$0.4m on distribution of the Verici assets. The note was later converted into ordinary shares in Verici at the equivalent price to that paid by investors on Verici's admission to the AIM market in November 2020.

# **37. EQUITY METHOD INVESTMENTS**

In May 2020, the Group and Mount Sinai entered into the Kantaro Operating Agreement in order to form 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. In connection with the formation of Kantaro, the Group entered into the Advisory Agreement, pursuant to which the Group 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 Group in respect of the services to be rendered by the Group under the Advisory Agreement. A portion of the units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of the uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Group account for the investment in Kantaro using the equity method of accounting as the Group can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, the Group and Mount Sinai each committed to making a loan to Kantaro.

Mount Sinai committed to lend an initial amount of \$250,000 and an additional \$500,000 thereafter. The Group committed to lend an initial amount of \$83,333 and an additional \$166,667 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 us). All services provided by the Group under the Advisory Agreement are subject to the oversight and direction of the board of managers of Kantaro.

Based on sales forecasts, the Company concluded that its equity method investment in Kantaro was impaired due to a shift in focus from COVID antibody testing to promoting vaccination in the United States and European Union. The forecasts indicate there is a prolonged period of time that Kantaro's fair value is below the carrying value of the investment. Accordingly, the Company recorded a \$1.9 million impairment charge within the consolidated income statement.

#### (A) Interest in associates and joint ventures

Set out below are the associates and joint ventures of the Group as of 30 June 2021 which, in the opinion of the directors, are material to the Group. The entities listed below have share capital consisting solely of ordinary shares, which are held directly by the Group. The country of incorporation or registration is also their principal place of business, and the proportion of ownership interest is the same as the proportion of voting rights held.

Name of the Entity	Place of Business/ Country of Incorporation	% of Ownership Interest		Nature of Relationship	Method of Measurement	Quoted Fair Value		Carrying Amount	
		2021	2020			2021	2020	2021	2020
Kantaro Biosciences LLC	USA	25%	25%	Joint Venture	Equity Method	(*)	(*)	-	1,937,000
Total equity accounted investments (*) - Private Entity - No quoted price available	-		-	-	-	-	-	-	1,937,000

#### (B) Interest in associates and joint ventures

	As at 30 June 2021	As at 30 June 2020
Commitments - Joint Ventures	-	-
Commitment to provide additional loan to Kantaro	-	166,667
Total	-	166,667

# Additional Financial Information

# **RECONCILIATION OF IFRS TO US GAAP**

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

Renalytix Form 20-F, which is based on US GAAP, contains differences from its Annual Report, which is based on IFRS. The Form 20-F and Annual Report are available on the Company's website (www.renalytix.com). In order to help readers to understand the difference between the Group's two sets of financial statements, Renalytix has provided, on a voluntary basis, a reconciliation from IFRS to U.S. GAAP as follows:

### **BALANCE SHEET**

(in thousands except share and per share amounts)

	GAAP As at 30 June 2021	IFRS As at 30 June 2021	GAAP vs IFRS Difference	
Assets				
Cash	\$ 65,128	\$ 65,159	\$ -	
Short-term investments	-	-	-	
Accounts Receivable	594	594	-	
Prepaid expenses and other current assets	993	958	35	(a)
Note Receivable - Kantaro	75	75	-	
Related-party receivable	1	1	-	
Property and equipment, net	2,490	1,081	1,409	(b)
Intangibles, net	-	18,021	(18,021)	(c)
Deferred tax assets	-	7,097	(7,097)	(d)
Investment in Verici	9,295	9,295	-	
Investment in Kantaro	-	-	-	
Right of use asset	-	297	(297)	(e)
Total assets	\$ 78,576	\$ 102,578	\$ -	_
Liabilities and stockholders' equity				-
Accounts payable	1,764	6,652	(62)	(f)
Accrued expenses and other current liabilities	4,602	-	-	
Accrued expenses - related party	224	-	-	
Current lease liability	-	86	(86)	(e)
Deferred Revenue	122	122	-	
Payable to Kantaro - current	350	350	-	
Non-current lease liabilities	-	213	(213)	(e)
Other liabilities	53	53	-	
Total liabilities	7,115	7,476	-	
Stockholders' (deficit) equity:				

	GAAP As at 30 June 2021	IFRS As at 30 June 2021	GAAP vs IFRS Difference	
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	220	233	13	(a)
Additional paid-in capital	150,407	81,397	(69,010)	(g)
Accumulated other comprehensive (loss) income	8,276	9,701	1,425	(h)
Accumulated deficit	(87,442)	3,771	91,213	(i)
Total stockholders' (deficit) equity	71,461	95,102		
Total liabilities and stockholders' (deficit) equity	\$ 78,576	\$ 102,578		_

- a. Represents other immaterial presentation differences between US GAAP & IFRS
- b. Differences is attributable to capitalized software costs which are recorded as property and equipment under U.S. GAAP and Intangibles under IFRS.
- c. Under IFRS, the acquisition of licenses and subsequent development efforts are capitalized and presented as intangible assets. Under U.S. GAAP, such costs are expensed as incurred until technological feasibility has been achieved or the assets are deemed to have future alternative use. In addition to capitalized software costs which are recorded as property and equipment under US GAAP and Intangibles under IFRS.
- d. 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. The Company 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 presentation differences and audit adjustments.
- g. Represents cancellation of share premium account and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici in prior year. In addition, stock based compensation is recognized on a straight line basis under U.S. GAAP and a graded vesting basis under IFRS which creates timing differences as to when expenses are recorded.
- h. Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
- i. Represents cancellation of share premium and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici and differences noted within the Company's consolidated statement of operations and comprehensive loss.

# **RECONCILIATION OF NET LOSS**

#### (\$ thousands)

	Year ended June 2021	
Net loss in accordance with IFRS	(31,010)	-
Deferred tax assets	(4,778)	(a)
Stock compensation expense	(483)	(b)
Amortization of intangibles	1,834	(c)
Verici Transaction	(434)	(d)
Other adjustments	(465)	(e)

	Year ended June 2021	
Total adjustments	(4,326)	
Net loss in accordance with US GAAP	(35,336)	

- 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. In addition, stock based compensation is recognized on a straight line basis under U.S. GAAP and a graded vesting basis under IFRS which creates timing differences as to when expenses are recorded.
- c. Amortization expense is higher on the IFRS books as a result of the higher intangible asset balance. Under IFRS, the acquisition of licenses and subsequent development efforts are capitalized and presented as intangible assets. Under U.S. GAAP, such costs are expensed as incurred until technological feasibility has been achieved or the assets are deemed to have future alternative use.
- d. This difference is attributable to the differences in accounting treatment of the distribution in specie of Verici Dx to Renalytix shareholders and subsequent deconsolidation of the Verici entity under IFRS and US GAAP.
- e. The remaining difference represents the aggregation other immaterial audit adjustments and small accounting standard differences.