

RNS Number : 7000U Renalytix PLC 30 March 2023

> Renalytix plc ("Renalytix" or the "Company")

Half Year Report

LONDON and SALT LAKE CITY, March 30, 2023 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX), reports its financial results for the six months ended December 31, 2022.

Recent Highlights (Including post period events)

- Expanded insurance coverage for KidneyIntelX including:
 - One of the largest not-for-profit health insurers covering over three million lives in the Northeast U.S.
 - Largest private payer in Illinois with over eight million members
 - o 35 state Medicaid plans including recent additions of Texas and Florida
- Achieved Medicare payment for KidneyIntelX through the individual claims review (ICR) process based on our
 Medicare clinical lab fee schedule (CLFS) pricing of \$950 per test
- Over 2,500 KidneyIntelX tests performed in the first half year of fiscal 2023 of which over 80% were billable
- Increasing diversity of commercially billable testing volume, particularly among primary care physician practices ordering through the MyIntelX portal
- Continued progress with FDA De Novo authorization review; FDA has indicated a target date for completion in the second calendar quarter of 2023
- Completed \$20.3 million equity financing led by new institutional investors
- Core participant in \$10 million Horizon Europe Grant to advance personalized medicine in treating chronic kidney disease
- Agreement with Veterans Administration to integrate KidneyIntelX testing with VA hospital electronic health
 record systems
- Publication of new real-world evidence in *Journal of Primary Care and Community Health* in which KidneyIntelX resulted in a 4.5-fold increase in new drug prescriptions (for SGLT2 inhibitors) for high-risk compared to low-risk patients; early evidence suggested that the introduction of SGLT2i contributed to an observed reduction in HbA1c levels most notably in high-risk patients, and a more than a 20% change in dose or type of antihypertensive therapeutic prescriptions in high vs. low-risk patients

 KidneyIntelX clinical utility and health economics validated in multiple data releases at American Society of Nephrology Kidney Week 2022, and multiple presentations on clinical utility data accepted for presentation at National Kidney Foundation Spring Clinical Meeting 2023, American Diabetes Association 83rd Scientific Session, and American Association of Nurse Practitioners Annual Meeting, including data from Wake Forest, Mount Sinai, UPenn, and CANVAS cohorts

Financial Results

During the six months ended December 31, 2022, the Company recognized \$2.2 million of revenue (HY22: \$1.3 million). Cost of revenue for the six months ended December 31, 2022, was \$1.4 million (HY22: \$0.8 million).

Administrative expense for the six months ended December 31, 2022, was \$22.4 million compared to \$27.5 million during the prior year period. The decrease in administrative expenses was driven by previously mentioned cost reduction initiatives resulting in a \$1.9 million decrease in contract labour, \$1.8 million decrease in professional fees and \$1.4 million reduction in other expenses including, insurance, marketing, IT and other miscellaneous expenses.

Net loss before tax was \$22.7 million for the six months ended December 31, 2022, compared to \$26.8 million for the prior year period.

Cash and cash equivalents totaled \$23.8 million as of December 31, 2022, compared to \$41.3 million as of June 30, 2022.

Investors are advised to read the results for the three months ended 31 December 2022 under U.S. GAAP which have been released alongside these results.

The Company will host a corresponding conference call and live webcast today to discuss the financial results and key topics including business strategy, partnerships and regulatory and reimbursement process, at 08.30 a.m. (EDT) / 1.30 p.m. (BST).

Conference Call Details:

To participate in the live conference call via telephone, please register <u>here</u>. Upon registering, a dial-in number and unique PIN will be provided in order for interested parties to join the conference call.

Webcast Registration link:

https://edge.media-server.com/mmc/p/oub5knjk

This announcement contains inside information for the purposes of Article 7 of Regulation (EU) 596/2014 (MAR).

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About Kidney Disease

Kidney disease is a public health epidemic affecting over 850 million people globally.¹ The Centers for Disease Control and Prevention estimates that 15% of U.S. adults, or approximately 37 million people², have chronic kidney disease (CKD). Nearly 95% of people with CKD are in early stages 1-3³. Despite its magnitude, early-stage (1-3) CKD is underdiagnosed and undertreated, largely because it's asymptomatic at this time in the disease. As many as 9 in 10 adults with CKD, and about 2 in 5 adults with severe CKD do not know they have the condition.³

About Renalytix

Renalytix (NASDAQ: RNLX) (LSE: RENX) is an in-vitro diagnostics and laboratory services company that is the global founder and leader in the new field of bioprognosis[™] for kidney health. The leadership team, with a combined 200+ years of healthcare and in-vitro diagnostic experience, has designed its KidneyIntelX laboratory developed test to enable risk assessment for rapid progressive decline in kidney function in adult patients with T2D and early CKD (stages 1-3). We believe that by understanding how disease will progress, patients and providers can take action early to improve outcomes and reduce overall health system costs. For more information, visit www.renalytix.com.

About KidneyIntelX[™]

KidneyIntelX[™] is a laboratory developed test demonstrated to be a reliable, bioprognostic[™] methodology that yields a simple-to-understand, custom risk score, enabling prediction of which adult patients with T2D and early CKD (stages 1-3) are at low, intermediate or high risk for rapid progressive decline in kidney function. By combining information from KidneyIntelX with newer cardio- and reno-protective therapies, doctors will have more information in determining which patients are at higher versus lower risk for rapid disease progression and may be able to more appropriately target resources and guideline-recommended treatments to advance kidney health. KidneyIntelX is supported by a growing body of clinical, utility and health economic studies (including a validation study of two large cohorts) and has demonstrated a 72% improvement in predicting those patients who are at high risk for rapid progressive decline in kidney function versus the current standard of care (eGFR and UACR). KidneyIntelX has received Breakthrough Device Designation from the U.S. Food and Drug Administration, and Renalytix has submitted for De Novo marketing authorization. To learn more about KidneyIntelX and review the evidence, visit www.kidneyintelx.com.

Sources

1 <u>https://www.theisn.org/blog/2020/11/27/more-than-850-million-worldwide-have-some-form-of-kidney-disease-help-raise-awareness/</u>

2 https://www.cdc.gov/kidneydisease/publications-resources/ckd-national-facts.html

3 https://www.cdc.gov/kidneydisease/basics.html

Forward Looking Statements

Statements contained in this report regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the potential benefits, including economic savings, of KidneyIntelX, the future impact of KidneyIntelX on clinical decision-making and outcomes, the potential for KidneyIntelX to receive regulatory approval from the FDA, the commercial prospects of KidneyIntelX, if approved, including whether and to what extent KidneyIntelX will be successfully adopted by physicians and distributed and marketed, expectations regarding insurance and covered lives, our expectations regarding reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery, address systemic inequalities and improve patient outcomes. The results presented in this press release are interim results; subsequent interim results and full results may vary and may not be consistent with these interim results. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance, or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our annual report on Form 20-F filed with the SEC on October 31, 2022, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

Chairman & CEO's Joint Statement

TO THE SHAREHOLDERS OF RENALYTIX PLC

We are pleased to present the half year report for the six months ended December 31, 2022 for Renalytix plc ("Renalytix" or the "Company").

ABOUT RENALYTIX

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

With our lead product, KidneyIntelX, the goal is to drive the focus from kidney disease treatment to kidney health management through a more accurate understanding of a patient's risk for kidney failure before it happens. KidneyIntelX leads development in the new field of bioprognosis, a biology driven approach to risk assessment that integrates information from a simple blood draw and a patient's health record to produce an accurate picture of kidney health. A doctor can use KidneyIntelX results to act on patients at high risk of kidney disease progression or failure at an early stage where active management and therapeutics have the best opportunity to impact outcomes and cost before it is too late.

KIDNEYINTELX™

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

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

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

OPERATIONAL PROGRESS

Over the last several months, we have made continued progress in establishing the commercial foundation for KidneyIntelX.

Commercial Development

Progressing towards majority insurance coverage in multiple regional markets with large prevalence of diabetes and kidney disease

We are demonstrating payment success across a diverse cohort of insurance entities including individual state Blue Cross Blue Shield and Medicaid plans, Medicare Advantage, and other large for-profit and not-for profit insurance plans. Together with the recently awarded individual claim review payment from Medicare contractor National Government Services, this growing diversity in payment is providing us with the basis to expect that KidneyIntelX will continue to achieve majority coverage in markets with large populations of diabetes and kidney disease patients during calendar 2023. As a result, we are now able to concentrate resources and focus on building sales, marketing, and customer service functions to support test adoption in regions with comprehensive insurance coverage.

Establishing comprehensive insurance in metropolitan New York has allowed us to proceed with the important milestone of converting to a long term, commercial reimbursement model with Mount Sinai Health System in our fiscal third quarter of this year (quarter ending March 31, 2023). As discussed below, this conversion from Mount Sinai as the sole payor of tests performed under the real-world evidence program begun in 2021 is timely in the March quarter.

The Centers for Medicare & Medicaid Services set the price for KidneyIntelX at \$950 in 2019. To date, we have matched or exceeded the Medicare price when negotiating commercial insurance coverage contracts. To broaden access, we maintain a robust patient assistance program for those patients who have limited insurance coverage and for whom KidneyIntelX is indicated as a test. We are particularly conscious of the health inequity which is pervasive among diabetes and kidney disease populations and endeavor to expand access to the advanced prognosis benefits of KidneyIntelX wherever possible and permitted under the law.

We believe the diversity and depth of established insurance payment remains critical to establishing long-term testing adoption and revenue growth and is a unique feature of our business strategy in a relatively short time period since commercial testing launch.

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

We continue to accumulate longitudinal data from our real-world evidence program leading to further peer-reviewed support of the positive impact of KidneyIntelX. Published utility study results in the *Journal of Primary Care Community Health* on November 28, 2022 on 1,686 patients showed that primary care physicians using KidneyIntelX were 4.5 times more likely to prescribe advanced medication to their high-risk patients in early-stage kidney disease, where the opportunity to prevent significant kidney damage or kidney failure is greatest, as compared to their low-risk patients. Additionally, providers were nearly 2.5 times more likely to make a timely referral to a specialist in high-risk patients compared to low-risk patients, and 20% more likely to initiate more adaptive and aggressive anti-hypertensive (blood pressure control) strategies in these high risk patients. Notable clinical observations from this study showed improvements in HbA1C levels for diabetes glucose control in the high-risk group in the first six months, most likely the result of both increased patient engagement combined with appropriate medication changes. There was also a 15% improvement in UACR (urine albumin to creatinine ratio), an important indicator of kidney health, at the six-month mark in the low- and intermediate-risk groups.

This evidence builds on a previously published study in the American Journal of Managed Care (AJMC) that indicated that 98% of PCPs were somewhat, very or extremely likely to use KidneyIntelX to predict which of their patients with DKD will experience rapid progressive decline in their kidney function. We believe this investment in real-world evidence is driving positive insurance reimbursement decisions, and will eventually help support inclusion of KidneyIntelX in key clinical guidelines for diabetes and kidney health.

We are also pleased to be a core member of a consortium of industry, academic and clinical research leaders awarded a \$10 million Horizon Europe Grant to advance personalized medicine in treating chronic kidney disease. The consortium, PRIME-CKD, aims to validate and implement in clinical practice, novel biomarker-based tests that predict response to existing drugs used by patients with chronic kidney disease (CKD). PRIME-CKD is funded by Horizon Europe, the European Union's key funding program for research and innovation. The total budget of the project is \$10 million over a projected five-year period, with approximately 10% of the budget targeted for commercial translation activities to be undertaken by Renalytix. The project is closely aligned with Renalytix's objective of expanding the clinical utility of the KidneyIntelX platform beyond prognosis to prediction and monitoring of drug response.

Pursuing Food and Drug Administration (FDA) De Novo marketing authorization for KidneyIntelX

We continue to make progress toward De Novo marketing authorization of KidneyIntelX with the Food and Drug Administration. While there are no guarantees, we remain optimistic and are working diligently with the FDA towards a successful outcome. FDA has indicated they are working towards a decision by the end of second calendar quarter of 2023. As part of the De Novo process, and pending a successful outcome of the review, the FDA will prepare a reclassification order and pursue certain internal processes for this class of test prior to communicating the final decision. The comprehensive data dossier submitted and detailed review process by the FDA is reflective of the breakthrough nature of this novel test.

Mount Sinai billing transition

In our fiscal third quarter (quarter ending March 31, 2023) we completed the milestone of transitioning to a long-term commercial insurance payment model for patients tested at the Mount Sinai Health System. This transition is taking place with the completion of the applicable portion of the 2018 license agreement under which Mount Sinai covered the cost of the first six million dollars of KidneyIntelX testing as part of a real-world evidence study.

Our ability to secure diversity of commercial insurance for KidneyIntelX for a significant portion of the diabetes and kidney disease population in New York City would not be possible without established payment from Medicare, Medicare Advantage and other large New York City concentrated payors. This includes a recently disclosed coverage contract with the second largest non-profit payer in the United States with 3.2 million members and another coverage contract secured with a large value-based care insurer covering 1.8 million members. We are now experiencing a high-rate of payment across both public and private insurance carriers in the New York region at or above our established Medicare pricing of \$950 per reportable result.

The transition to commercial payment for testing at Mount Sinai will have a short-term adverse impact on testing volumes, predominantly in the month of March. Further, as is customary when diagnostic products move to broad-scale commercial billing, the average selling price for KidneyIntelX will now include a minority percentage of discounted testing for patients qualifying for financial assistance and out-of-network testing.

Further, we have begun to experience the validatory effects of establishing commercial pay after extensive real-world experience with a system as large and influential as Mount Sinai with other key insurers and health systems looking to adopt a KidneyIntelX guided clinical management program for patients with diabetes and kidney disease.

Other commercial market development

Continued diversity of insurance coverage, successful real-world evidence and a positive FDA decision will be important factors in the quarters ahead to drive testing adoption and revenue growth. We are pleased to begin seeing a more diverse group of physicians in different locations in the United States ordering KidneyIntelX. We are assessing more focused hiring of primary care sales and medical science liaison personnel for deployment in areas with established insurance payment.

We entered into an agreement with the Veterans Administration to install the KidneyIntelX solution inside the VA Health System's cloud infrastructure and interface it with the VA electronic health record systems. This marks a significant milestone in ultimately enabling providers at VA Medical Centers and outpatient clinics to order and receive test results in a seamless manner, and eventually make KidneyIntelX accessible to large numbers of veterans with diabetic kidney disease.

Financing

In March of last year, we announced the completion of a financing package yielding \$26.8 million in gross proceeds for the Company. The financing included an \$8.8 million equity subscription plus \$21.2 million principal amount of convertible bonds (net cash proceeds of \$18 million).

In February 2023, post period end, the Company raised an additional \$20.3 million gross proceeds in a private placement of ordinary shares and American Depositary Shares.

We are pleased to have achieved such financings during this challenging capital market environment, which we believe illustrates the strength of our kidney disease testing, monitoring and informed care advantages. In these rounds, we have welcomed substantial new institutional investors alongside participation by longstanding shareholders.

Clinical Evidence

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

Initial Forum	Cohort	Findings	Publication
ADA 81 st Scientific Sessions 2020	Mount Sinai & UPenn (n=1,146)	KidneyIntelX more accurately predicted progressive kidney function decline and kidney failure than clinical metrics alone	Diabetologia 2021;64, 1504-1515
NKF Spring Clinical Meeting 2020	Simulation in patients with DKD stages 1-3b (n=100,000)	Analyses supported payer coverage for early-stage risk assessment and care management in the primary care office; projects significant savings from KidneyIntelX testing at primary care	Journal of Medical Economics 2021;24:972-982
ADA 82 nd Scientific Sessions 2021	CANVAS (n=1,325)	KidneyIntelX algorithm published in Diabetologia and currently deployed commercially accurately predicted progression of DKD in this multinational clinical trial cohort	American Journal of Nephrology 2022;53:21-31
ISN World Congress of Nephrology 2021	CANVAS (n=1,026)	KidneyIntelX can be effective at monitoring therapeutic response and improvements in kidney health over time in adults with type 2 diabetes and DKD	American Journal of Nephrology 2022;53:21-31
NKF Spring Clinical Meetings 2021	PCPs (n=401)	KidneyIntelX test had greater relative importance than albuminuria and eGFR to PCPs in making treatment decisions and was second only to eGFR for nephrologist referrals.	American Journal of Managed Care 2022;28:In Press
ASN Kidney Week 2021	Mount Sinai RWE Cohort	KidneyIntelX testing enhanced patient understanding about kidney disease and revealed substantial motivation to take appropriate actions and receive further education for their kidney health.	Journal of the American Society of Nephrology 32: 2021
ISN World Congress of Nephrology 2022	Sinai/Penn (n=1,146)	KidneyIntelX provided robust prognostic information for future eGFR trajectories and adverse kidney outcomes beyond prior ascertainment of baseline kidney function, injury, or historical kidney function trajectories.	Kidney International Reports 2022; 7, S1-S436

ADA 83 rd Scientific Sessions 2022	CANVAS (n=1,325)	KidneyIntelX provided risk stratification for a triple composite end point that included not only the kidney-specific outcome of progression, but also clinically relevant outcomes of hospitalizations for heart failure and all-cause mortality, even after adjusting for several other risk factors for these outcomes.	Kidney360 2022, 3;1599-1602
ADA 83 rd Scientific Sessions 2022	Mount Sinai RWE Cohort (n=1,112)	KidneyIntelX showed utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients.	Pending
ASN Kidney Week 2022	Systematic Review and Meta-analysis (n=129 studies)	Systematic review and meta-analysis to summarize the prognostic value of preclinical plasma and urine biomarkers for CKD outcomes (incident CKD, CKD progression, or incident ESKD), including 129 studies in the meta-analysis. Pooled risk ratios (RRs) and 95% confidence intervals (Cis) among some of the most studied CKD biomarkers were 2.17 (1.91 to 2.47) for TNFR1 (31 studies); 2.07 (95% Cl, 1.82 to 2.34) for TNFR2 (23 studies); 1.51 (95% Cl, 1.38 to 1.66) for KIM-1 (18 studies).	Journal of the American Society of Nephrology 2022, 33:1657-1672
ASN Kidney Week 2022	Simulation in patients with DKD stages 1-3b (n=100,000)	Analyses demonstrated that population-based KidneyIntelX testing for the prognosis of progression in a DKD G1-G3b population is a dominant strategy for both Medicare and commercial populations in comparison to prognosis relying on eGFR and UACR alone.	Pending
N/A	Review article and Case Series	Review entitled: "The need for risk stratification in type 2 diabetes and chronic kidney disease: Proposed clinical value of KidneyIntelX"	Diabetic Nephropathy, vol.3, no.1, 2023, pp.1-9
NKF Spring Clinical Sessions 2023	Wake Forest RWE (n=590)	KidneyIntelX was successfully deployed in a diverse health care system, and was associated with a near doubling of SGLT2i use in higher risk-categories, including Blacks, in accordance with guideline recommendations.	Pending

Numerous additional publications and presentations are upcoming in the months ahead, including presentations at NKF, ADA and the American Association of Nurse Practitioners (AANP)

Current Trading and Outlook

Our fundamental goals remain clear:

- · Build testing adoption on a regional basis;
- · Continue to secure diversified, long-term insurance coverage;
- · Continue building evidence of real-world benefit of KidneyIntelX use; and
- · Obtain FDA marketing authorization

We believe the early-stage kidney health market remains largely un-tapped and open for innovation. Renalytix is in a position to alter both the fundamental cost of care in the short and long-term, maintain better health for millions of Americans with diabetes and kidney disease, and reduce the threat of unexpected kidney failure and dialysis. With the World Obesity Federation reporting in March that 51% of the global population, or more than 4 billion people, are expected to be overweight or obese by 2035, kidney disease and diabetes which run in parallel will remain significant threats to the global health care system. Now more than ever, we will need a way to understand who is at risk for advancing kidney disease (and importantly who is not), and to whom new effective medication should be given and how they respond. Without a KidneyIntelX-like prognosis available at the front end of chronic kidney disease, easily implemented and understood by primary care physicians, it will be very challenging to allocate medical resource efficiently, and alert patients and their doctors to preventive measures to preserve health.

We believe we are in the process of validating a new standard with KidneyIntelX that can be used by any physician in any healthcare environment for preventative medicine, with high-quality standards verified by third-party experts and regulatory agencies, tested extensively in the real-world and, of course, covered by a diverse set of insurance payors.

As discussed earlier in this section, during the current third fiscal quarter of 2023, we have secured important new commercial insurance coverage for KidneyIntelX, held constructive interactions with the FDA regarding our De Novo application, enhanced our balance sheet with new funding, and executed an important transition at Mount Sinai to third-party commercial billing.

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

Christophe Mills

Christopher Mills Chairman

James R. McCullough Chief Executive Officer

Financial Review

The results presented cover the six months ended 31 December 2022 ("HY22"). 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 \$2.2 million in HY23 related to commercial testing as well as pharmaceutical services performed, compared to revenue of \$1.3 million in HY22 related to commercial testing and pharmaceutical services performed.

Cost of Sales

The cost of sales associated with the commercial testing and services revenue was \$1.4 million for HY23, compared to \$0.8 million for HY22.

Administrative Costs

During HY23, administrative expenses totaled \$22.4 million (six months ended 31 December 2021 ("HY22"): \$27.5 million). Administrative expenses decreased as a result of the previously mentioned cost reduction initiatives. Major items of expenditure were employee related expenses of \$11.5 million (HY22: \$11.3 million) due to continued hiring of key corporate and commercial personnel. Professional fees of \$4.6 million (HY22: \$6.4 million). Contract labour of \$1.4 million (HY22: \$3.3 million) which include expenses related to R&D efforts such as the utility studies at Mount Sinai and Wake Forest. Depreciation and amortization of \$1.0 million (HY22: \$1.1 million), laboratory supplies of \$0.4 million (HY22: \$0.4 million) and other expenses of \$3.3 million (HY22: \$5.0 million) including \$1.3 million of insurance expense, \$0.6 million of marketing expense, \$0.7 million of IT related expenses and \$0.7 million of miscellaneous expenses.

Gain on financial assets at fair value through profit or loss

During HY23 the group recorded mark to market adjustments related to the Verici securities which resulted in an unrealized loss of \$1.2 million (Six months ended 31 December 2021 ("HY22"): \$2.0 million gain).

Fair value adjustment of convertible debt

We elected to account for the convertible notes at fair value with qualifying changes in fair value recognized through the income statement until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. For the six months ended 31 December 2022, we recorded a loss of \$0.8 million to adjust the convertible notes to fair value. There was no fair value adjustment for the six months ended 31 December 2021 as we had not issued convertible debt at that time.

Finance Income (Expense)

Finance income totaled \$0.9 million during HY23 (HY22: \$2.2 million expense) related to unrealized foreign exchange losses.

BALANCE SHEET

Inventory

Inventory consists of consumable materials used by the labs to carry out KidneyIntelX tests. During HY23, inventory levels decreased due to increased KidneyIntelX testing volumes. Inventory on hand as at 31 December 2022 totaled \$0.9 million (FY22: \$1.2 million).

Fixed Assets

Property, plant, and equipment consists of laboratory equipment being used to support testing and product development

activities. As at 31 December 2022, the company held \$1.2 million in net property, plant, and equipment (FY22: \$1.4 million).

Intangible Assets

The Group held \$13.0 million net book value of intangible assets as at 31 December 2022 (FY22: \$14.0 million) includes payments made primarily to Mount Sinai for license and patent costs for the intellectual property underlying KidneyIntelX, as well as amounts capitalized as development costs. Intangible assets also include the value of the biomarker business purchased (in exchange for ordinary shares in the Company) from EKF. Intangible assets decreased period over period due to amortization and the impact of foreign exchange translation at period end.

Investment in Verici

At the end of HY23 the group held 9.8 million shares in Verici Dx. The fair value of the investment in Verici Dx was \$1.5 million as at 31 December 2022 (FY22: \$2.7 million).

Trade and Other Receivables

As at 31 December 2022, the company held \$0.8 million of trade and other receivables (FY22: \$0.9 million). During HY23, trade and other receivables decreased slightly due to timing of payments.

Prepaid and Other Current Assets

As at 31 December 2022, the company held \$1.0 million of prepaid and other current assets. (FY22: \$1.2 million). During HY23, prepaid and other current assets increased due to prepaid insurance as well as upfront payments associated with studies and other administrative expenses.

Convertible Note

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount of \$21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million. The Company elected to account for the Bonds at fair value. At 31 December 2022, the Bonds had a fair value of \$11.9 million. At 30 June 2022, the Bonds had a fair value of \$12.3 million.

Cash

The Group had cash on hand of \$23.8 million (FY22: \$41.3 million). Cash and cash equivalents are held in several deposit accounts in the US (\$11.1 million), UK (\$10.8 million) and IRE (\$1.9 million). Our expenditure plans remain sufficiently adaptable to align with available resources.

Unaudited Consolidated Income Statement FOR THE PERIOD ENDED 31 DECEMBER 2022

	UNAUDITED Period to 31 December 2022	UNAUDITED Period to 31 December 2021
	\$'000	\$'000
Continuing operations		
Revenue	2,161	1,327
Cost of Sales	(1,410)	(808)
Gross Profit	751	519
Administrative expenses	(22,360)	(27,465)
Operating loss	(21,609)	(26,946)
Share of Net loss in Associate accounted for using the equity	(9)	37
method		
Gain / (Loss) on financial assets at fair value through profit or	(1,190)	(2,021)
loss		
Fair value adjustment of convertible debt	(750)	-
Finance (costs) income - net	910	2,154
Loss before tax	(22,648)	(26,776)
Taxation	1	3,791
Loss for the period	(22,647)	(22,985)
Earnings per Ordinary share from continuing		
operations		
Basic and diluted	\$ (0.30)	\$ (0.32)

Unaudited Consolidated Statement of Comprehensive Income FOR THE PERIOD ENDED 31 DECEMBER 2022

	UNAUDITED Period to 31 December 2022	UNAUDITED Period to 31 December 2021
	\$'000	\$'000
Loss for the period - continuing operations	(22,647)	(22,985)
Other comprehensive income:		
Items that may be subsequently reclassified to profit or		
loss		
Changes in the fair value of the convertible notes	(523)	-
Currency translation differences	(492)	(3,073)
Other comprehensive loss for the period	(1,015)	(3,073)
Total comprehensive loss for the period	(23,662)	(26,058)

Items stated above are disclosed net of tax. The income tax relating to each component of other comprehensive income is disclosed in note 12.

Unaudited Consolidated Statement of Financial Position

AS AT 31 DECEMBER 2022

	UNAUDITED As at 31 December	AUDITED As at 30 June 2022
	2022	
	\$'000	\$'000
Assets		
Non-current assets		
Property, plant and equipment	1,196	1,368
Right of use asset	275	355
Intangible assets	12,991	14,020
Note Receivable	75	75
Investment accounted for using the equity method	-	9
Other long term assets	64	-
Total non-current assets	14,601	15,827
Current Assets		
Inventory	917	1,160
Security deposits	-	141
Financial asset at fair value through profit	1,487	2,744
or loss		
Trade and other receivables	820	901
Prepaid and other current assets	973	1,152
Cash and cash equivalents	23,816	41,333
Total current assets	28,013	47,431
Total assets	42,614	63,258
Equity attributable to owners of the parent		
Share capital	242	241
Share premium	85,560	85,444
Share-based payment reserve	13,135	11,954
Accumulated other comprehensive income	(2,524)	(1,509)
Retained earnings/(deficit)	(75,608)	(52,961)
Total equity	20,805	43,169

	UNAUDITED	AUDITED
	As at 31 December 2022	As at 30 June 2022
Liabilities		
Current liabilities		
Trade and other payables	9,547	7,281
Deferred Revenue	-	46
Current lease liabilities	4,590	163
Note payable current	166	4,660
Current due to affiliated company	-	55
Total current liabilities	14,303	12,205
Non-current liabilities		
Note payable non-current	7,388	7,682
Non-current lease liabilities	118	202
Total non-current liabilities	7,506	7,884
Total liabilities	21,809	20,089
Total equity and liabilities	42,614	63,258

The notes are an integral part of these financial statements.

Unaudited Consolidated Statement of Cash Flows FOR THE PERIOD ENDED 31 DECEMBER 2022

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Cash flow from operating activities		
Loss before income tax	(22,647)	(26,776)
Adjustments for		
Depreciation	152	136
Amortization and impairment charges	1,056	1,145
Share-based payments	1,239	2,288
Reversal of Kantaro Liability	(55)	(131)
Unrealized loss (Gain) on financial asset at fair value through profit or loss	1,199	2,021
Unrealized foreign exchange loss (Gain)	(52)	(1,867)
Equity in (net earnings) losses of affiliate	9	(37)
Fair value adjustments for convertible debt	750	-
Changes in working capital		
Trade and other receivables	292	(229)
Prepaid assets and other current assets	180	(2,192)
Inventory	243	(383)
Security Deposits	141	-
Trade and other payables	2,248	1,650
Accrued Expenses and other current liabilities	11	
Deferred Revenue	(46)	(55)
Cash used in operations	(15,280)	(24,430)
Interest paid	-	(1)
Net cash used in operating activities	(15,280)	(24,431)
Cash flow from investing activities		
Purchase of property, plant and equipment (PPE)	-	(538)
Software development costs	-	(103)
Payment for long term deferred expense	(64)	-
Net cash generated by/ (used in) investing activities	(64)	(641)

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
Cash flow from financing activities		
Repayment of convertible notes principal and interest	(1,648)	-
Proceeds from the issuance of ordinary shares under employee share purchase		
plan	116	120
Proceeds from exercise of stock options	-	197
Lease Payments	(82)	(53)
Net cash generated from financing activities	(1,614)	264
Effect of exchange rate changes on cash	(1,147)	(423)
Net increase/(decrease) in cash and cash equivalents	(17,517)	(25,231)
Cash and cash equivalents at beginning of period	41,333	65,159
Cash and cash equivalents at end of period	23,816	39,928

Unaudited Consolidated Statement of Changes in Equity FOR THE PERIOD ENDED 31 DECEMBER 2022

				Accumulated		
	Share Capital	Share Premium	Share-based payment reserve	other comprehensive income	Retained earnings	Total equity
	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
At 30 June 2021 and 1 July	233	76,457	4,940	9,701	3,771	95,102
2021						
Comprehensive income						
Loss for the period	-	-	-	-	(22,985)	(22,985)
Other comprehensive						
income						
Currency translation	-	-	(1)	(3,072)	-	(3,073)
differences						
Total comprehensive	-	-	(1)	(3,072)	(22,985)	(26,058)
income						
Transactions with						
owners						
Share-based payments	-	-	2,288	-	-	2,288
Shares issued under ESPP	-	86	-	-	-	86
Exercise of stock options	-	233	-	-	-	233
Total transactions with owners	-	319	2,288	-	-	2,607
At 31 December 2021 and 1	233	76,776	7,227	6,629	(19,214)	71,651
January 2022						
Comprehensive income						
Loss for the period	-	-	-	-	(33,747)	(33,747)
Other comprehensive income						
Changes in fair value of	-	-	-	536	-	536
convertible notes						
Currency translation	-	-	5	(8,674)	-	(8,669)
differences						
Total comprehensive income	-	-	5	(8,138)	(33,747)	(41,880)

				Accumulated		
	Share Capital	Share Premium	Share-based payment reserve	other comprehensive income	Retained earnings	Total equity
Transactions with				income		
Issuance of Ordinary Shares in US	8	8,796	-	-	-	8,804
Less issue costs	-	(218)	-	-	-	(218)

Share-based payments	-	-	4,722	-	-	4,722
Shares issued under ESPP	-	90	-	-	-	90
Exercise of stock options	-	-	-	-	-	-
Total transactions with owners	8	8,668	4,722	-	-	13,398
At 30 June 2022 and 1 July	241	85,444	11,954	(1,509)	(52,961)	43,169
2022						
Comprehensive income						
Loss for the period	-	-	-	-	(22,647)	(22,647)
Other comprehensive income						
Changes in the fair value of the	-	-	-	(523)	-	(523)
convertible notes at fair value						
through other comprehensive						
income						
Currency translation differences	-	-	-	(492)	-	(492)
Total comprehensive income	-	-	-	(1,015)	(22,647)	(23,662)
Transactions with owners						
Share-based payments	-	-	1,181	-	-	1,181
Shares issued under ESPP	1	116	-	-	-	117
Total transactions with owners	1	116	1,181	-	-	1,298
At 31 December 2022	242	85,560	13,135	(2,524)	(75,608)	20,805

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 financial statements for the period ended 31 December 2022 have been prepared in accordance with UK-adopted International Financial Reporting Standards (IFRS). The standards that have been adopted by the Group are those that are effective for financial years beginning on or after 1 January 2022.

The consolidated financial statements have been prepared under the historical cost convention except for certain financial assets measured at fair value. They cover the period to 31 December 2022. The comparatives cover the period ended 31 December 2021 and the year ended 30 June 2022.

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 31 December 2022, and not early adopted

A number of new standards and amendments to standards and interpretations are effective for annual periods beginning on or after 1 January 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.

- Amendments to IFRS 3: Business Combination
- Amendments to IFRS 16: Property, Plant and Equipment
- Amendments to IFRS 37: Provisions, Contingent Liabilities and Contingent Assets

3. SIGNIFICANT ACCOUNTING POLICIES

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.

The Directors believes that Group's and Company's cash and cash equivalents of \$23.8 million as December 31, 2022, combined with proceeds from a \$20.3 million gross financing completed in February 2023, are sufficient to fund the projected operations for at least the next twelve months from the issuance date of these financial statements. For this reason, they have adopted the going concern basis in the preparation of the financial statements.

Accounting policies

The same accounting policies, presentation and methods of computation have been followed in these condensed interim financial statements as were applied in the preparation of the company's annual financial statements for the year ended 30 June 2022.

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

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 period ended 31 December 2022, the Company recognized \$2.0 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. During the period ended 31 December 2021, the Company recognized \$1.1 million of testing services revenue.

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 period ended 31 December 2022, the Company recognized \$0.2 million of pharmaceutical services revenue. There was \$0.2 million of pharmaceutical services revenue recognized in the period ended 31 December 2021.

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:

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Balance, beginning of period	45	122
Deferral of revenue	-	67
Revenue recognized	(45)	(122)
Balance, end of period	-	67

9. EXPENSES - ANALYSIS BY NATURE

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Employee benefit expense	11,546	11,284
Contract labor	1,423	3,266

Total administration expenses	22,360	27,465
Other expenses	3,335	4,951
Laboratory supplies	386	487
Professional fees	4,641	6,342
Depreciation and amortization	1,029	1,135

10. EMPLOYEE BENEFIT EXPENSE

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Wages, salaries and Bonus	7,870	7,231
Social security costs and	2,444	1,766
Benefits		
Share based payment expenses	1,232	2,287
Total	11,546	11,284

11. FINANCE INCOME AND COSTS

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Finance costs:		
Interest expense	(2)	(1)
Finance income:		
Interest income	58	12
Gain/(Loss) on Foreign Exchange	700	2,143
Other income	154	2,143
Net finance income/(loss)	910	2,154

12. INCOME TAX

No deferred asset is calculated on losses in FY22 as the probability of future utilization is considered too remote.

Factors affecting the future tax charge

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

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

13. 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.

	UNAUDITED	UNAUDITED
	Period to 31 December 2022	Period to 31 December 2021
	\$'000	\$'000
Loss attributable to owners of the parent	(22,648)	(22,985)
Weighted average number of ordinary shares in	74,848,278	72,258,372
issue		
Basic and diluted loss per share	\$ (0.30)	\$ (0.32)

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 three categories of dilutive potential ordinary share, being share options, RSUs and convertible debt. The potential shares were not dilutive the period and prior period as the Group made a loss and the impact of the share options, RSUs or convertible debt would be anti-dilutive. No dividends were declared for the period ended 31 December 2021 or 31 December 2020.

15. PROPERTY, PLANT AND EQUIPMENT

	UNAUDITED
	Fixtures and fittings
	\$'000
Cost	
At 1 July 2021	1,286
Additions	538
At 31 December 2021	1,824
Depreciation	
At 1 July 2021	205
Charge for the period	136
At 31 December 2021	341
Net book value at 31 December 2021	1,483
Cost	
At 1 January 2022	1,824
Additions	53
Foreign translation	-
At 30 June 2022	1,877
Depreciation	
At 1 January 2022	341
Charge for the period	168
At 30 June 2022	509
Net book value at 30 June 2022	1,368
Cost	
At 1 July 2022	1,877
Additions	-
At 31 December 2022	1,877
Depreciation	
At 1 July 2022	509
Charge for the period	172
Foreign translation	-
At 31 December 2022	681
Net book value at 31 December 2022	1,196

The depreciation charge of \$172k related to Property, Plant and Equipment has been charged to administration expenses (\$152k) and cost of goods sold (\$20k).

16. LEASES

$(i)\ {\rm Amounts}\ {\rm recognized}\ {\rm in}\ {\rm the}\ {\rm statement}\ {\rm of}\ {\rm financial}\ {\rm position}$

The balance sheet shows the following amounts relating to leases:

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Right-of-use assets		
Properties	275	355
Total right-of-use assets	275	355
Lease liabilities		
Current	166	163
Non-current	118	202
Total lease liabilities	284	365

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:

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Depreciation charge - right-of-use assets		
Properties	80	126
Total right-of-use	80	126
Interest expense (included in finance cost)	2	2

(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.

17. INTANGIBLE FIXED ASSETS

	Trademarks, Trade		Development Costs	
	Names & Licenses	Trade Secrets		Total
	\$'000	\$'000	\$'000	\$'000
Cost				
At 1 July 2021	10,553	7,136	4,429	22,118
Additions	-	-	103	103
Foreign translation	(233)	(157)	(84)	(474)
At 31 December 2021	10,320	6,979	4,448	21,747
Amortization				
At 1 July 2021	3,254	535	308	4,097
Charge for the period	521	352	229	1,102
Foreign translation	(77)	(15)	(8)	(100)
At 31 December 2021	3,698	872	529	5,099
Net book value				
At 31 December 2021	6,622	6,107	3,919	16,648
Cost				
At 1 January 2022	10,320	6,979	4,448	21,747
Additions	-	-	-	-
Foreign translation	(1,041)	(704)	(393)	(2,138)
At 30 June 2022	9,279	6,275	4,055	19,609
Amortization				
At 1 January 2022	3,698	872	529	5,099
Charge for the period	497	336	230	1,063
Foreign translation	(406)	(110)	(57)	(573)
At 30 June 2022	3,789	1,098	702	5,589
Net book value				
At 30 June 2022	5,490	5,177	3,353	14,020
Cost				
At 1 July 2022	9,279	6,275	4,055	19,609
Additions	-	-	-	-
Foreign translation	(25)	(17)	(9)	(51)
At 31 December 2022	9,254	6,258	4,046	19,558
Amortization				
At 1 July 2022	3,789	1,098	702	5,589
Charge for the period	450	304	212	966
Foreign translation	2	6	4	12
At 31 December 2022	4,241	1,408	918	6,567
Net book value				
	5,013			

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 \$3,618,204 and net value of \$3,127,979, these projects were placed into service in FY22.

18. INVENTORY

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Finished goods	917	1,160

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 2022: \$0).

The cost of inventories recognized as expense and included in 'cost of sales' amounted to \$158K (Year to 31 December 2021: \$128K).

19. FINANCIAL INSTRUMENTS

(a) Assets at amortized cost

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Assets as per balance sheet		
Security deposits	-	141
Cash and cash equivalents	23,816	41,333
Total	23,816	41,474

$\left(b\right)$ Assets at fair value through profit or loss

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Assets as per balance sheet		
Investment in Verici Dx	1,487	2,744
Total	1,487	2,744

(c) Liabilities at amortized cost

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Liabilities as per balance sheet		
Accounts payable	4,148	2,460
Accrued expenses	5,389	4,821
Lease Liabilities	285	365
Total	9,822	7,646

(d) Liabilities at fair value

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Liabilities as per balance sheet		
Note Payable	11,978	12,342
Total	11,978	12,342

(e) 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 31 December 2022, 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:

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
AA-	23,816	41,333
AA+	-	-
Total	23,816	41,333

20. TRADE AND OTHER RECEIVABLES

	UNAUDITED	AUDITED
	31 December 2021	30 June 2022
	\$'000	\$'000
Trade Receivables	820	901
Due from affiliates	75	75
Total	895	976

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

21. PREPAIDS AND OTHER CURRENT ASSETS

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Prepaids	973	1,116
Deferred offering costs	-	36
Prepaids and Other Current Assets	973	1,152

22. CASH AND CASH EQUIVALENTS

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Cash at Bank	23,816	41,333
Cash and cash equivalents	23,816	41,333

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

23. SHARE CAPITAL

Group and Company	Movement	Total Number of Shares	Ordinary Shar	es Share	Total
			\$'000	Premium	\$'000
				\$'000	
At 30 June 2021		72,197,286	233	76,457	76,500
7-Jul-21 Exercise of Stock Options	27,500	72,224,786	-	46	46
17-Jul-21 Exercise of Stock Options	5,000	72,229,786	-	40	40
31-Aug-21 Shares issued under the ESPP	10,920	72,240,706	-	121	121
1-Nov-21 Exercise of Stock Options	68,224	72,308,930	-	112	112
At 31 December 2021		72,308,930	233	76,776	76,819
31-Mar-22 Shares issued under the ESPP	22,814	72,380,014	-	90	90
6-Apr-22 Private Placement	2,428,688	74,760,432	8	8,578	8,586
At 30 June 2022		74,760,432	241	85,444	85,685
6-Apr-22 Private Placement	2,428,688	74,760,432	1	116	117
At 31 December 2022	131,412	74,891,844	242	85,560	85,802

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

24. SHARE OPTIONS, RESTRICTED STOCK UNITS and SHARE-BASED PAYMENTS

In November 2018, Company established the Renalytix plc Share Option Plan (the "Plan") and a U.S. Sub-Plan and Non-Employee Sub-Plan. The Plans provide for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of December 31, 2022, there were 10,739,229 shares available for future issuance under the Plans.

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 December 31, 2022 consist of 2,299,799 options which vest equally over twelve quarters following the grant date, 962,600 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 immediately and the remainder equally over the remaining eleven quarters, 475,300 which vest 25% on the one year anniversary, 50% on 2nd anniversary and 25% on the third anniversary and 40,000 which vest in eight equal quarterly instalments commencing on the Vesting Commencement date. 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:

	Average exercise price	Number of
General employee share option plan	per share (USD)	Options
As at 30 June 2022	4.00	4,599,899
Granted during the period	1.50	555,300
Exercised	-	-
Forfeited	8.43	(177,500)
Outstanding at 31 December 2022	3.56	4,977,699
Exercisable at 31 December 2022	3.21	3,721,211
Vested and expected to vest at 31 December 2022	3.56	4,977,699

The fair value of each share option granted during the period has been estimated using a Black-Scholes model and is ± 0.94 (\$1.14). The inputs into the model are an exercise price of ± 1.24 (\$1.50), expected volatility of 66.9%, no expected dividend yield, weighted-average term of 6.1 years and weighted-average risk-free interest rate of 3.2%.

The aggregate intrinsic value of options outstanding and options exercisable at 31 December 2022 was \$0. The Group recognized total expenses of \$1.3 million relating to equity-settled share-based payment transactions during the period to 31 December 2022. There was \$5.4 million in unamortized stock based compensation expense as of December 31, 2022. The weighted average remaining contractual term of the options outstanding is 7.2 years.

Activity for restricted stock units for the six months ended December 31, 2022 is as follows:

	Number of	Weighted-average	
	Restricted Stock	Grant Date Fair Value	
	Units	(USD)	
Non-vested balance at 30 June 2022	-	-	
Granted	131,380	1.53	
Vested	(41,400)	1.44	
Forfeited	-	-	
Non-vested balance at 31 December 2022	89,980	1.57	

The total fair value of restricted stock units and performance stock units vested during the six months ended December 31, 2022 was \$0.06 million. There were no vested restricted stock units at December 31, 2021. Restricted stock units vest upon the achievement of time-based service requirements.

At December 31, 2022, total unrecognized compensation expense related to non-vested restricted stock units was approximately \$0.1 million. Unrecognized compensation expense relating to restricted stock units that are deemed probably of vesting is expected to be recognized over a weighted-average period of approximately 1.2 years.

25. TRADE AND OTHER PAYABLES

	UNAUDITED	AUDITED
	31 December 2022	30 June 2022
	\$'000	\$'000
Accounts payable	4,148	2,460
Payroll taxes payable	145	139
Accrued expenses	5,254	4,682
	9,547	7,281

26. CONVERTIBLE DEBT

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount \$21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million and accrue interest at an annual rate of 5.5%, payable quarterly in arrears, in cash or ADSs valued at the ADS Settlement Price at the option of the Company. The principal and interest payments are due in equal quarterly installments starting in July 2022. The Bonds contain various conversion and redemption features. The initial conversion price for the Convertible Bonds of \$8.70 has been set at a 20 per cent. premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance and save in limited circumstances, the Bonds have a hard floor in the conversion price of \$7.25. Between amortization dates, the Convertible Bond Investor retains the right to advance future amortization payments, provided that (a) there shall be no amortization advancements during the first 12 months, (b) no more than 2 amortization advancements may occur in any 12 month period, and (c) no more than 1 amortization advancement may occur in any 3 month period.

The Convertible Bond Investor is also permitted to defer up to two amortization payments to a subsequent amortization date. The Company retains the option to repay any deferred amortization in cash at 100 per cent. of the nominal amount In July 2022, the Company made a cash amortization payment of \$1.4 million, which consisted of \$1.1 million of principal and \$0.3 million of interest. In October 2022, the company made an interest payment of \$0.3 million. As of December 31, 2022, \$20.1 million of principal was outstanding.

On issuance, the Company elected to account for the Bonds at fair value in accordance with ASC 815, Derivatives and Hedging, with qualifying changes in fair value being recognized through the statements of operations until the Bonds are settled. Changes in fair value related to instrument-specific credit risk are recognized through comprehensive loss until the Bonds are settled. The fair value of the bonds is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders. Significant assumptions used in the fair value analysis include the volatility rate, risk-free rate, dividend yield and risky yield. As of December 31, 2022, the fair value of the Bonds was determined to be \$11.9 million. During the three and six months ended December 31, 2022, the Company recognized a change in fair value of the Notes related to the instrument-specific credit risk of \$0.9 million and \$0.5 million, respectively, in the statement of comprehensive loss. The Company recognized an increase in fair value related to non-instrument specific credit risk of \$0.8 million in the consolidated becember 31, 2022 and a decrease in fair value related to non-instrument specific credit risk of \$0.8 million in the consolidated statement of operations during the six months ended December 31, 2022.

27. 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. On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the business and unanimously signed a termination agreement. As part of the termination agreement, the members agreed to wind up Kantaro's business and dissolve reasonably promptly after the effective date of the termination agreement. As of December 31, 2022, the total liability associated with the services was \$0.0 million, as the termination agreement relieved Renalytix of its obligation to provide services to Kantaro. As of June 30, 2022, the total liability associated with the services was \$0.5 million.

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 30 June 30 2021 and the period ended 31 December 2021.

For the six months ended 31 December 2022, the Company recognized \$0.02 million, in the statement of operations related to services performed under the Advisory Agreement. For the six months ended 31 December 2022, \$0.01 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.01 million were included in general and administrative expense, respectively. For the six months ended 31 December 2021, the Company recognized \$0.1 million in the condensed consolidated statements of operations related to services performed under the Advisory Agreement. For the six months ended 31 December 2021, the company recognized \$0.1 million in the condensed consolidated statements of operations related to services performed under the Advisory Agreement. For the six months ended 31 December 2021, \$0.09 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.05 million were included within general and administrative expense, respectively.

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.

28. 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[™], 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

The company previously accrued for the \$300,000 milestone payment once it became probable that the sales milestone would be reached.

29. ULTIMATE CONTROLLING PARTY

The Directors believe there to be no ultimate controlling party.

30. 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 for the year ended 30 June 2021.

On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the business and unanimously signed a termination agreement. As part of the termination agreement, the members agreed to wind up Kantaro's business and dissolve reasonably promptly after the effective date of the termination agreement. As of December 31, 2022, the total liability associated with the services was \$0.0 million, as the termination agreement relieved Renalytix of its obligation to provide services to Kantaro.

(A) Interest in associates and joint ventures

Set out below are the associates and joint ventures of the Group as of 31 December 2022 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.

	Place of	% of Ow	nership						
Name of the Entity	Business/	Inter	est	Nature of	Method of	Quoted		Carrying Amount	
	Country of			Relationship	Measurement	Fair	r Value	(\$'0	000)
	Incorporation								
		Dec	June			Dec	June	Dec	June
		2022	2022			2022	2022	2022	2022
Kantaro	USA	25%	25%	Joint Venture	Equity Method	(*)	(*)	-	\$9.5
Biosciences LLC									

(*) - Private Entity - No quoted price available

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 6-K, which is based on US GAAP, contains differences from its Half Year Report, which is based on IFRS. The Form 20-F and Annual Report are available on the Company's website (www.renalytix.com). 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	IFRS	GAAP vs IFRS	
	As at	As at	Difference	
	31 December 2022	31 December 2022		
	\$'000	\$'000		
Assets				
Cash at Bank	28,816	28,816	-	
Accounts Receivable	820	820	-	
Prepaid expenses and other current assets	1,868	1,868	-	
Note Receivable - Kantaro	75	75	-	
Related-party receivable	22	22	-	
Property, plant and equipment, net	2,295	1,196	1,099	(a)
Intangibles, net	-	12,991	(12,991)	(b)
Investment in Verici	1,487	1,487	-	
Right of use asset	213	275	(62)	(c)
Other Long term assets	46	46	-	
Total Assets	30,660	42,614		
Liabilities				
Accounts payable	4,148	9,547	21	(d)
Accrued expenses and other current liabilities	4,489	-		
Accrued expenses - related party	931	-		
Current lease liability	129	166	(37)	(c)
Noncurrent lease liability	100	118	(18)	(c)
Note payable - current	4,590	4,590	-	
Note Payable - noncurrent	7,388	7,388	-	
Total Liabilities	21,775	21,809		
Stockholders' equity				
Ordinary shares	229	242	13	(e)
Additional paid-in capital	165,708	98,695	(67,013)	(f)
Accumulated other comprehensive (loss) income	(1,937)	(2,524)	(587)	(g)
Accumulated deficit	(155,115)	(75,608)	79,507	(h)
Total stockholders (deficit) equity	8,885	20,805		
Total liabilities and stockholder's (deficit) equity	30,660	42,614		

- a) Differences is attributable to capitalized software costs which are recorded as property and equipment under U.S. GAAP and Intangibles under IFRS.
- b) 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.
- c) Represents slight differences due to the timing of adoption of IAS 17 in connection with the Company's commercial laboratory in Utah. The Company has adopted ASC 842 under U.S. GAAP in the current year.
- d) Accounts payable and other current liabilities are presented in the aggregate within the Half Year report while broken out separately on the US GAAP 6-k. Difference represents other immaterial audit adjustments.
- e) Represents immaterial audit adjustments.
- f) 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.
- g) Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
- Represents cancellation of share premium and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici and differences noted within the Company's consolidated statement of operations and comprehensive loss.

RECONCILIATION OF NET LOSS

(\$ thousands)

	31 December 2022			
Net loss in accordance with IFRS	(22,647)			
Stock compensation expense	(347)	(a)		
Amortization of intangibles	879	(b)		
License expense	(280)	(c)		
Other adjustments	(3)	(d)		
Net loss in accordance with US GAAP	(22,398)			

- a. 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.
- 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.
- c. Difference represents different 'probability' thresholds used under IFRS and US GAAP to record contingent liabilities, specifically Joslin Sales milestone which was recorded in prior year under IFRS and current year under US GAAP. Generally, US GAAP has a higher recognition threshold than IFRS standards.
- d. The remaining difference represents the aggregation other immaterial audit adjustments and small accounting standard differences

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