



Half Year Report

February 15, 2024

RNS Number : 2070D

Renalytix PLC

15 February 2024

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

Half Year Report

LONDON and SALT LAKE CITY, February 15, 2024 - Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported financial results for the six months ended December 31, 2023. The Company plans to issue another announcement following today's report of financial results regarding the date and time of its conference call and webcast to discuss second quarter financial results and other key events.

The Company made significant progress during the quarter in revenue generation, reimbursement coverage, the publication of real-world evidence and operating cost management, setting the stage for potential future growth. Highlights include:

- During the three months ended December 31, 2023, we recognized \$0.7 million of revenue related to sales of KidneyIntelX, compared to the previous quarter reported revenue of \$0.5 million.
- KidneyintelX.dkd, the first U.S. Food and Drug Administration ("FDA"), authorized in vitro prognostic test that uses an artificial intelligence-enabled algorithm to aid in assessment of the risk of progressive decline in kidney function, officially included in the lab fee schedule by Centers for Medicare & Medicaid Services (CMS) at \$950 per test.
- KidneyIntelX™ and kidneyintelX.dkd included in the proposed Local Coverage Determination (LCD) published by National Government Services (NGS) on February 8, 2024, and on the agenda for the LCD open public meeting on February 29, 2024.
- NGS has resumed consistent payment for tests under individual claims review (ICR), allowing revenue recognition of 318 tests billed to Medicare (including prior period tests). Total billable volume of 734 tests during the second quarter (representing 69% of all tests in the period, including non-billable study tests).
- Real-world evidence continues to demonstrate the benefits of KidneyIntelX early risk assessment as published in the *Journal of Primary Care and Community Health*, in which 12 months of care following

KidneyIntelX prognostic testing was associated with clinical actions that led to significant improvement in care and outcomes including a 61% increase in kidney protective drug prescriptions among patients in the high-risk group.

Operating cost reductions commenced during the fiscal second quarter continued with a fiscal third quarter cash burn target approximately 33% less than in the prior quarter and approximately 50% less than in the first quarter of fiscal 2024.

Second Quarter 2024 Financial Results

During the six months ended December 31, 2023, we recognized \$1.2 million of revenue related to sales of KidneyIntelX. During the six months ended December 31, 2022, we recognized \$2.0 million revenue related to sales of KidneyIntelX and \$0.2 million of revenue of pharmaceutical services revenue related to services performed for AstraZeneca. The \$0.8 million decrease in revenue was primarily driven by a \$1.0 million decrease in KidneyIntelX billable testing volumes due to the transition to a commercial billing structure under our arrangement with Mount Sinai and a decrease of \$0.2 million of pharmaceutical services revenue.

Administrative expenses for the six months ended December 31, 2023 were \$18.4 million, compared to \$22.4 million for the six months ended December 31, 2022. We have taken significant actions to lower annual expenditures with a targeted annualized cash burn rate of under \$23 million within our fiscal third quarter of 2024 (down from \$37 million in the 2023 fiscal year), while preserving revenue generating activity.

The major items of expenditure were general and administrative costs of which included \$7.2 million in employee-related costs (HY23: \$11.5 million), \$3.8 million in subcontractors, legal, accounting, and other professional fees (HY23: \$4.6 million), \$3.7 million in external R&D Services, lab supplies and lab services (HY23: \$1.8 million), \$1.1 million in depreciation and amortisation (HY23: \$1.0 million), \$0.7 million in insurance (HY23: \$1.3 million), \$0.6 million in IT related costs (HY23: \$0.7 million), \$0.5 million in marketing and public relations (HY23: \$0.6 million), \$0.3 million in impairment loss on property and equipment (HY23: nil), \$0.2 million in office related expenses including rent (HY23: \$0.1 million), and \$0.3 million in other expenses (HY23: \$0.8 million).

Net loss was \$19.3 million for the six months ended December 31, 2023, compared to a net loss of \$22.6 million for the six months ended December 31, 2022.

Cash and cash equivalents totaled \$5.6 million as of December 31, 2023.

For further information, please contact:

Renalytix plc

James McCullough, CEO

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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.

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, the Company's expectations regarding the timing and outcome of regulatory and reimbursement decisions, the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes, the Company's expectations and guidance related to partnerships, testing volumes and revenue for future periods, the Company's expectations regarding the Company's ability to obtain and maintain intellectual property protection for its diagnostic products and the Company's ability to operate its business without infringing on the intellectual property rights of others, and the forecast of the Company's cash runway and the implementation and potential for additional financing activities and cost-saving initiatives. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. The Company may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on the Company's 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; the Company has only recently commercially launched KidneyIntelX; and risks relating to the impact on the Company's business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in the Company's filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of its annual report on Form 10-K filed with the SEC on September 28, 2023, the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2023 filed with the SEC on November 14, 2023 and other filings the Company makes with the SEC from time to time. All information in this press release is as of the date of the release, and the Company undertakes 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 MEMBERS OF RENALYTIX PLC

This has been a productive period for Renalytix and our lead artificial intelligence enabled prognostic test despite the challenging capital markets environment. When we formed Renalytix, our goals were clear for what we called the three legs of the stool: comprehensive insurance reimbursement, regulatory approval and clear outcomes and benefits data; all of which we have achieved. For the coming quarters, we are now focused on testing volume growth under a significantly streamlined cost structure.

Regarding our three-legged stool, KidneyIntelX is now being paid for by Medicare and several major United States insurance payors including multiple state Blue Cross Blue Shield organizations. Out of the estimated 14 million patients with diabetic kidney disease in the United States, we have now secured insurance coverage for the majority at \$950 per prognostic test. On February 8, 2024, Medicare contractor National Government Services (NGS) published a proposed Local Coverage Determination (LCD) for KidneyIntelX™ and kidneyintelX.dkd (the latter being our FDA-approved version).

In 2023, we also successfully completed a four year Food and Drug Administration (FDA) process with a successful De Novo Marketing Authorization that broke important regulatory ground for prognosing a large population chronic disease.

And equally as important, two groundbreaking peer-review study publications presented long-term utility and outcomes data showing the important effects of KidneyIntelX in helping to improve both kidney and diabetes health in adults.

In a further upside milestone, KidneyIntelX was included in the draft kidney clinical guidelines, KDIGO, which are expected to be finalized by the end of March 2024. It is rare to see all of these key elements come together in a short period of time and we believe they are significant for broader adoption and clinical acceptance of KidneyIntelX across adults with diabetes and early-stage kidney disease in the United States and abroad.

Post FDA authorization, we have reviewed our operating costs with a view to meaningfully reduce quarterly cash burn rate. This reduction in cash burn should become apparent in the remainder of our 2024 fiscal year and is being undertaken without compromising our sales and marketing efforts to grow testing volume and revenue. These reductions are on top of our recent year-over-year operating expense reduction of \$11 million. We will also evaluate potential international licensing opportunities and strategic partnerships, both of which could provide sources of non-dilutive capital and expanded revenue opportunities for Renalytix.

Raising funds to fuel these clear commercial opportunities is essential, particularly now that we have reduced some of the core risks associated with a successful service product launch and adoption. In addition to traditional financing efforts, we will continue to explore less dilutive and non-dilutive capital funding sources, particularly now that we have a unique product proposition post-FDA authorization.

KidneyIntelX prognostic technology provides a powerful tool to front-line physicians and patients to prevent the unnecessary suffering and unsustainable costs associated with kidney decline and dialysis. Innovations like KidneyIntelX are hard won and, if supported properly, can have an enormous impact for the health of millions of people globally with chronic disease. We intend to make sure this happens.

On behalf of everyone at Renalytix, we would like to thank you for your continued support.

Warmest regards,



Christopher Mills

Chairman



James R. McCullough

Chief Executive Officer

Financial Review

The results presented cover the six months ended 31 December 2023 ("HY24"). The presentational currency for Renalytix plc and its subsidiaries (together, the "Group") is the United States Dollar.

INCOME STATEMENT

Revenue

The Group recognized a total of \$1.2 million in revenue in HY24 related to commercial testing, compared to revenue of \$2.2 million in the six months ended 31 December 2022 ("HY23") related to commercial testing and pharmaceutical services performed.

Cost of Sales

The cost of sales associated with the commercial testing revenue was \$1.0 million for HY24, compared to \$1.4 million of cost of sales associated with the commercial testing and services revenue in HY23.

Administrative Costs

During HY24, administrative expenses totaled \$18.4 million (HY23: \$22.4 million). The major items of expenditure were general and administrative costs of which included \$7.2 million in employee-related costs (HY23: \$11.5 million), \$3.8 million in subcontractors, legal, accounting, and other professional fees (HY23: \$4.6 million), \$3.7 million in external R&D Services, lab supplies and lab services (HY23: \$1.8 million), \$1.1 million in depreciation and amortisation (HY23: \$1.0 million), \$0.7 million in insurance (HY23: \$1.3 million), \$0.6 million in IT related costs (HY23: \$0.7 million), \$0.5 million in marketing and public relations (HY23: \$0.6 million), \$0.3 million in impairment loss on property and equipment (HY23: nil), \$0.2 million in office related expenses including rent (HY23: \$0.1 million), and \$0.2 million in other miscellaneous expenses (HY23: \$0.7 million).

Gain (Loss) On Financial Assets At Fair Value Through Profit Or Loss

The Company accounts for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During HY24, we recorded a loss of \$0.2 million to adjust the VericiDx investment to fair value. During HY23, we recorded a loss of \$1.2 million to adjust the VericiDx investment to fair value.

Fair Value Adjustment Of Convertible Debt

We elected to account for the convertible notes at fair value with qualifying changes in fair value recognized through the income statement until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. During HY24, we recorded a loss of \$1.3 million to adjust the convertible notes to fair value. During HY23, we recorded a loss of \$0.8 million to adjust the convertible notes to fair value.

Finance Income (Expense)

During HY24, we recognized a gain of \$0.5 million, which was comprised of \$0.2 million interest income earned on our cash deposits, \$0.2 million of foreign exchange gains and \$0.1 million of grant income. During HY23, we recognized finance income of \$0.9 million mostly related to foreign exchange gains.

BALANCE SHEET

Inventory

Inventory consists of consumable materials used by the labs to carry out KidneyIntelX tests. Inventory on hand at 31 December 2023 totaled \$0.5 million (FY23: \$0.7 million). During FY23, inventory levels decreased due to usage in KidneyIntelX testing.

Fixed Assets

Property, plant, and equipment consists of laboratory equipment being used to support testing and product development activities. At 31 December 2023, the company held \$0.6 million in net property, plant, and equipment (FY23: \$1.0 million).

Intangible Assets

The Group held \$11.6 million net book value of intangible assets at 31 December 2023 (FY23: \$12.5 million) which 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 amortisation and the impact of foreign exchange translation at period end.

Investment in Verici

At the end of HY24, the group held 9,831,681 shares in Verici Dx, the fair value of the investment in Verici Dx was \$1.2 million at 31 December 2023 (FY23: \$1.5 million).

Convertible Note

In April 2022, the Company issued amortising senior convertible bonds with a principal amount of \$21.2 million due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million. The Company elected to account for the Bonds at fair value. At 31 December 2023, the Bonds had a fair value of \$8.4 million (FY23: \$11.9 million).

Cash

The Group had cash on hand of \$5.6 million (FY23: \$24.7 million). Cash and equivalents are held in several deposit accounts in the US (\$2.5 million), UK (\$2.4 million) and IRE (\$0.7 million).

FINANCIAL STATEMENTS

Unaudited Consolidated Income Statement

FOR THE PERIOD ENDED 31 DECEMBER 2023

	\$'000	\$'000
Continuing Operations		
Revenue	1,168	2,161
Cost of Sales	(954)	(1,410)
Gross profit	214	751
Administrative expenses	(18,395)	(22,360)
Operating loss	(18,181)	(21,609)
Share of Net loss in Associate accounted for using the equity method	-	(9)
Gain (loss) on financial assets at fair value through profit or loss	(244)	(1,190)
Fair value adjustment of convertible debt	(1,320)	(750)
Finance income - net	459	910
Loss before tax	(19,286)	(22,648)
Taxation	-	1
Loss for the Period	(19,286)	(22,647)
Earnings per Ordinary share from continuing operations		
Basic	\$ (0.20)	\$ (0.30)
Diluted	\$ (0.20)	\$ (0.30)

Unaudited Consolidated Statement of Comprehensive Income

FOR THE PERIOD ENDED 31 DECEMBER 2023

	\$'000	\$'000
Loss for the period - continuing operations	<u>(19,286)</u>	<u>(22,647)</u>
Other comprehensive income:		
Items that may be subsequently reclassified to profit or loss		
Changes in the fair value of the convertible notes	75	(523)
Currency translation differences	<u>(281)</u>	<u>(492)</u>
Other comprehensive (loss)/income for the period	<u>(206)</u>	<u>(1,015)</u>
Total comprehensive loss for the period	<u>(19,492)</u>	<u>(23,662)</u>

Unaudited Consolidated Statements of Financial Position

AS AT 31 DECEMBER 2023

	\$'000	\$'000
Assets		
Non-current assets:		
Property, plant and equipment	570	1,027
Right of use asset	113	194
Intangible assets	11,563	12,511
Other long term assets	161	51
Total non-current assets	12,407	13,783
Current Assets		
Inventory	512	718
Security Deposits	132	132
Financial asset at fair value through profit or loss	1,220	1,460
Trade and other receivables	1,370	776
Prepaid and other current assets	614	566
Cash and cash equivalents	5,619	24,682
Total current assets	9,467	28,334
Total assets	21,874	42,117
Equity attributable to owners of the parent		
Share capital	318	299
Share premium	108,162	104,953
Share-based payment reserve	13,954	13,513
Accumulated other comprehensive income	(1,297)	(1,127)
Retained earnings/(deficit)	(118,470)	(99,184)
Total equity	2,667	18,454
Liabilities		
Current liabilities:		
Trade and other payables	10,716	11,513
Current lease liabilities	118	156
Note payable current	3,063	4,463
Total current liabilities	13,897	16,132
Non-current liabilities		
Note payable non-current	5,310	7,485
Non-current lease liabilities	-	46
Total non-current liabilities	5,310	7,531
Total liabilities	19,207	23,663
Total equity and liabilities	21,874	42,117

The notes on pages 1 to 14 are an integral part of these financial statements.

Unaudited Consolidated Statements of Cash Flows

FOR THE PERIOD ENDED 31 DECEMBER 2023

	\$'000	\$'000
Cash flows from operating activities:		
Loss before income tax	(19,286)	(22,647)
Adjustments for		
Depreciation	152	152
Amortisation	1,102	1,056
Impairment of property and equipment	306	-
Share-based payments	620	1,239
Share of net (profit)/loss of associate	-	9
Reversal of Kantaro Liability	-	(55)
Unrealized loss (gain) on financial asset at fair value through profit or loss	244	1,199
Fair value adjustment of convertible debt	1,058	750
Foreign Exchange loss (gain)	(1,008)	(52)
Changes in working capital		
Trade and other receivables	(594)	292
Prepaid assets and other current assets	684	180
Inventory	206	243
Security Deposits	-	141
Trade and other payables	(831)	2,259
Deferred Revenue	-	(46)
Net cash used in operating activities	(17,347)	(15,280)
Cash flows from investing activities:		
Payment for long term deferred expense	-	(64)
Net cash generated by/(used in) investing activities	-	(64)
Cash flows from financing activities		
Repayment of convertible notes	(1,660)	(1,648)
Payment of costs	(5)	-
Proceeds from the issuance of ordinary shares under employee share purchase plan	93	116
Lease payments	(81)	(82)
Net cash generated from financing activities	(1,653)	(1,614)
Net increase/(decrease) in cash and cash equivalents	(19,000)	(16,958)
Cash and cash equivalents at beginning of period	24,682	41,333
Effect of exchange rate changes on cash	(63)	(559)
Cash and cash equivalents at end of period	5,619	23,816

Unaudited Consolidated Statement of Changes in Equity

FOR THE PERIOD ENDED 31 DECEMBER 2023

	\$'000	\$'000	\$'000	\$'000	\$'000	\$'000
At 30 June 2022 and 1 July 2022	241	85,444	11,954	(1,509)	(52,961)	43,169
<i>Comprehensive income</i>						
Loss for the period	-	-	-	-	(22,647)	(22,647)
<i>Other comprehensive income</i>						
Changes in fair value of convertible notes	-	-	-	(523)	-	(523)
Currency translation differences	-	-	-	(492)	-	(492)
Total comprehensive income	-	-	-	(1,015)	(22,647)	(23,662)
Transactions with Owners						
Issuance of Ordinary Shares in US	-	-	-	-	-	-
Less issue costs	-	-	-	-	-	-
Share-based payments	-	-	1,181	-	-	1,181
Shares issues under ESPP	1	116	-	-	-	117
Exercise of Stock Options	-	-	-	-	-	-
Total transactions with owners of the parent, recognized directly in equity	1	116	1,181	-	-	1,298
At 31 December 2022 and 1 January 2023	242	85,560	13,135	(2,524)	(75,608)	20,805
<i>Comprehensive income</i>						
Loss for the period	-	-	-	-	(23,576)	(23,576)
<i>Other comprehensive income</i>						
Changes in fair value of convertible notes	-	-	-	1,242	-	1,242
Currency translation differences	-	-	-	155	-	155
Total comprehensive income	-	-	-	1,397	(23,576)	(22,179)
Transactions with Owners						
Share-based payments	-	-	378	-	-	378
Shares issues under ESPP	-	144	-	-	-	144
Shares issued under Securities Purchase Agreement	57	20,240	-	-	-	20,297
Less issue costs	-	(991)	-	-	-	(991)
Total transactions with owners of the parent, recognized directly in equity	57	19,393	378	1,397	(23,576)	(2,351)
At 30 June 2023 and 1 July 2023	299	104,953	13,513	(1,127)	(99,184)	18,454
<i>Comprehensive income</i>						
Loss for the period	-	-	-	-	(19,286)	(19,286)
<i>Other comprehensive income</i>						
Changes in fair value of convertible notes	-	-	-	75	-	75
Currency translation differences	-	-	(2)	(279)	-	(281)
Total comprehensive income	-	-	(2)	(204)	(19,286)	(19,492)
Transactions with Owners						

Share-based payments	-	-	620	-	-	620
Shares issues under ESPP	-	93	-	-	-	93
Shares issued for repayment of convertible bond	18	2,978	-	-	-	2,996
Vesting RSUs	1	138	(143)			(4)
Total transactions with owners of the parent, recognized directly in equity	19	3,209	477	-	-	3,705
At 31 December 2023	318	108,162	13,988	(1,331)	(118,470)	2,667

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 intelligence-enabled diagnostics for kidney disease.

The financial statements are presented in United States Dollars ("USD") because that is the currency of the primary economic environment in which the Group operates.

2. BASIS OF PRESENTATION

The Group and Company's financial statements have been prepared in accordance with UK-adopted International Accounting Standards and with the requirements of the Companies Act 2006.

The preparation of financial statements in conformity with IFRS requires the use of certain critical accounting estimates. It also requires management to exercise its judgment 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 2023, 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 2023 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 IAS 1: Presentation of Financial Statements, Disclosure of Accounting Policies
- Amendments to IAS 8: Definition of Accounting Estimates
- Amendments to IFRS 17: Insurance Contracts
- Amendments to IAS 12: Deferred Tax Related to Assets and Liabilities Arising From a Single Transaction
- Amendments to IFRS 16: Leases on Sale and Leaseback
- Amendments to IAS 7 and IFRS 7: Supplier Finance Arrangement
- Amendments to IAS 21: Lack of Exchangeability

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.

The Group and Company have incurred recurring losses and negative cash flows from operations since inception. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of KidneyIntelX or any future products currently in development.

As a result of our losses and our projected cash needs, the Directors have concluded that substantial doubt exists about the

Group and Company's ability to continue as a going concern. Substantial additional capital will be necessary to fund the Group and Company's operations, expand its commercial activities and develop other potential diagnostic related products. The Company plans to seek additional funding through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements. The Group and Company may not be able to obtain financing on acceptable terms, or at all, and the Group and Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Group and Company's shareholders. If the Group and Company is unable to obtain funding, the Group and Company could be required to delay, curtail or discontinue research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospect.

The Group and Company's ability to continue as a going concern is contingent upon successful execution of management's intended plan over the next twelve months to improve the Group and Company's liquidity and profitability, which includes, without limitation:

- Seeking additional capital through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements
- Implementation of various additional operating cost reduction options that are available to the Group and Company
- The achievement of a certain volume of assumed revenue

The consolidated financial statements do not include any adjustments that may result from the outcome of this going concern uncertainty.

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 2023.

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.

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.

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.

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 17);

- Share based payments (note 24).
- Convertible debt recorded at fair value through profit or loss (note 26).

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 2023, the Company recognized \$1.2 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. There was \$2.0 million of testing services revenue recognized in the period ended 31 December 2022.

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 2023, there was no pharmaceutical services revenue recognized. There was \$0.2 million of pharmaceutical services revenue recognized in the period ended 31 December 2022.

9. EXPENSES - ANALYSIS BY NATURE

	\$'000	\$'000
Employee benefit expense	7,174	11,546
Contract labour	1,589	1,423
Depreciation and amortisation	1,060	1,029
Professional fees	5,381	4,641
Laboratory supplies	301	386
Impairment loss on property and equipment	306	-
Other expenses	2,584	3,335
Total administration expenses	18,395	22,360

10. EMPLOYEE BENEFIT EXPENSE

	\$'000	\$'000
Wages, salaries and Bonus	4,919	7,870
Social security costs and Benefits	1,635	2,444
Share based payment expenses	620	1,232
Total	7,174	11,546

11. FINANCE INCOME AND COSTS

\$'000	\$'000
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Finance costs:		
Interest expense	(1)	(2)
Finance income:		
Interest income	153	58
Gain/(Loss) on Foreign Exchange	200	700
Other Income	109	154
Net finance income/(loss)	461	910

12. INCOME TAX

No deferred asset is calculated on losses in FY23 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 25%.

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. Effective 1 April 2023, the main rate increased from 19% to 25%.

13. EARNINGS PER SHARE

Basic net loss per ordinary share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during each period. Diluted net loss per ordinary share includes the effect, if any, from the potential exercise or conversion of securities, such as options which would result in the issuance of incremental ordinary shares. Potentially dilutive securities outstanding as of December 31, 2023 have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of ordinary shares outstanding as they would be anti-dilutive:

Stock options to purchase ordinary shares	7,259,741	4,554,901
Restricted stock units	11,105	-
Conversion of convertible note	4,625,019	-
	<u>11,895,865</u>	<u>4,554,901</u>

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.

14. DIVIDEDS

No dividends were declared for the period ended 31 December 2023 or 31 December 2022.

15. PROPERTY, PLANT AND EQUIPMENT

	\$'000
Cost	
At 1 July 2022	1,877
Additions	-
At 31 December 2022	<u>1,877</u>
Depreciation	
At 1 July 2022	509
Charge for the period	172
At 31 December 2022	<u>681</u>
Net book value at 31 December 2022	<u>1,196</u>

Cost	
At 1 January 2023	1,877
Additions	-
At 30 June 2023	1,877
Depreciation	
At 1 January 2023	681
Charge for the period	169
At 30 June 2023	850
Net book value at 30 June 2023	1,027
Cost	
At 1 July 2023	1,877
Additions	-
Impairment	(308)
At 31 December 2023	1,569
Depreciation	
At 1 July 2023	850
Charge for the period	149
At 31 December 2023	999
Net book value at 31 December 2023	570

The depreciation charge of \$149k related to Property, Plant and Equipment has been charged to administration expenses (\$132k) and cost of goods sold (\$17k).

16. LEASES

· Amounts recognized in the statement of financial position

The balance sheet shows the following amounts relating to leases:

	\$'000	\$'000
Right-of-use assets		
Properties	113	194
Total right-of-use assets	113	194
Lease liabilities		
Current	118	156
Non-current	-	46
Total lease liabilities	118	202

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.

· Amounts recognized in the Statement of Comprehensive income

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

	\$'000	\$'000
Depreciation charge - Right-of-use assets		
Properties	81	126
Total right-of-use assets	81	126
Interest expense (included in finance cost)	1	2

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

	\$'000	\$'000	\$'000	\$'000
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
Amortisation				
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 at 31 December 2022	5,013	4,850	3,128	12,991
Cost				
At 1 January 2023	9,254	6,258	4,046	19,558
Additions	-	-	-	-
Foreign translation	406	275	153	834
At 30 June 2023	9,660	6,533	4,199	20,392
Amortisation				
At 1 January 2023	4,241	1,408	918	6,567
Charge for the period	473	320	220	1,013
Foreign Translation	197	69	36	302
At 30 June 2023	4,911	1,797	1,174	7,881
Net book value at 30 June 2023	4,750	4,736	3,025	12,511
Cost				
At 1 July 2023	9,660	6,533	4,199	20,392
Additions	-	-	-	-
Foreign translation	74	50	28	152
At 31 December 2023	9,734	6,583	4,227	20,545
Amortisation				
At 1 July 2023	4,911	1,797	1,174	7,881
Charge for the period	479	324	223	1,025
Foreign Translation	46	19	10	75
At 31 December 2023	5,435	2,140	1,407	8,982
Net book value at 31 December 2023	4,299	4,444	2,820	11,563

The amortisation charge of \$1,025k related to Intangibles has been charged to administration expenses (\$963k) and cost of goods sold (\$62k).

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 amortisation 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 20%. 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 \$4,226,826 and net value of \$2,819,866. These projects were placed into service in FY21.

18. INVENTORY

	\$'000	\$'000
Finished Goods	512	718

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 \$Nil (31 December 2022: \$Nil).

The cost of inventories recognized as expense and included in 'cost of sales' amounted to \$90k (Year to 31 December 2022: \$158k).

19. FINANCIAL INSTRUMENTS

Assets at amortised cost

	\$'000	\$'000
Assets as per balance sheet		
Security deposits	132	132
Cash and cash equivalents	5,619	24,682
Total	5,751	24,814

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

Assets at fair value

	<u>\$'000</u>	<u>\$'000</u>
Assets as per balance sheet		
Investment in Verici Dx	1,220	1,460
Total	<u>1,220</u>	<u>1,460</u>

Fair value for the investment in Verici Dx was determined by reference to their published price quotation in an active market (classified as level 1 in the fair value hierarchy).

Liabilities at amortised cost

	<u>\$'000</u>	<u>\$'000</u>
Liabilities as per balance sheet		
Accounts payable	2,816	2,936
Accrued expenses	7,900	8,568
Lease Liabilities	118	202
Total	<u>10,834</u>	<u>11,706</u>

Liabilities at fair value

	<u>\$'000</u>	<u>\$'000</u>
Liabilities as per balance sheet		
Note payable	8,373	11,948
Total	<u>8,373</u>	<u>11,948</u>

The note payable relates to our convertible debt instrument and is classified as Level 3 in the fair value hierarchy.

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 2023, 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:

	<u>\$'000</u>	<u>\$'000</u>
AA+	5,619	24,682
Total	<u>5,619</u>	<u>24,682</u>

20. TRADE AND OTHER RECEIVABLES

	\$'000	\$'000
Trade Receivables	1,370	776
Due from affiliates	-	-
Total	1,370	776

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

	\$'000	\$'000
Prepays	557	538
Other Current Assets	57	27
Prepays and Other Current Assets	614	566

22. CASH AND CASH EQUIVALENTS

	\$'000	\$'000
Cash at Bank	5,619	24,682
Cash and cash equivalents	5,619	24,682

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

23. SHARE CAPITAL

15-Mar-18	Formation	50,000	50,000	66	-	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	6,547	6,596
6-Nov-18	Placing & offer (listing on AIM)	18,388,430	53,816,134	60	27,485	27,545
At 30 June 2019			53,816,134	175	34,032	34,207
29-Jul-19	Placing & Secondary Offering (AIM)	5,600,000	59,416,134	17	16,597	-
15-May-20	Cancellation of Share premium	-	59,419,134	-	(50,629)	-
At 30 June 2020			59,416,134	192	-	192
17-Jul-20	Placing & Offering (Nasdaq)	12,613,500	72,029,634	40	76,094	76,134
4-Mar-21	Shares issued under the ESPP	17,652	72,047,286	-	111	111
25-Jun-21	Exercise of Stock Options	150,000	72,197,286	1	252	253
At 30 June 2021			72,197,286	233	76,457	76,690
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
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
12-Sep-22	Shares issues under ESPP	131,412	74,891,844	-	116	116
8-Feb-23	Private Placement	18,722,960	93,614,804	57	19,249	19,306
7-Mar-23	Shares issues under ESPP	166,674	93,781,478	1	144	145
At 30 June 2023			93,781,478	299	104,953	105,252
17-Jul-23	Shares issued for repayment of convertible bond	1,052,422	94,833,900	3	1,049	1,052
4-Aug-23	Vesting of RSUs	185,540	95,019,440	1	138	139
6-Oct-23	Shares issues under ESPP	75,328	95,094,768	-	93	93
19-Oct-23	Shares issued for repayment of convertible bond	2,335,388	97,430,156	7	1,272	1,279
21-Dec-23	Shares issued for repayment of convertible bond	2,500,000	99,930,156	8	657	665
At 31 December 2023			99,930,156	318	108,162	108,480

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 AI plc Share Option Plan (the "Plan") and a U.S. Sub-Plan and Non-Employee Sub-Plan. In July 2020, the Company's board of directors adopted and the Company's shareholders approved the 2020 Equity Incentive Plan (the "EIP"), which superseded the 2018 Share Option Plan. The equity incentive 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 December 31, 2023, there were 12,179,489 shares available for future issuance under the EIP.

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.

With respect to the options outstanding as of December 31, 2023:

- 5,968,095 options vest equally over twelve quarters following the grant date;
- 777,521 options vest 25% on the one year anniversary of the grant date and the remaining 75% equally over twelve quarters following the one year anniversary of the grant date;
- 301,625 options vest 25% on the one year anniversary of the grant date, 50% on the two year anniversary of the grant date, and 25% on the three year anniversary;
- 190,000 options vest one third on the one year anniversary of the grant date and the remaining two thirds equally over eight quarters following the one year anniversary of the grant date;
- 12,500 options vest quarterly over two years following the grant date; and
- 10,000 options vested 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:

Outstanding at June 30, 2022	4,968,576	\$	4.50	6.7
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Granted	2,673,296	\$	1.93	
Exercised	-	\$	-	
Forfeited	(380,568)	\$	5.48	
Expired	(1,563)	\$	6.68	
Outstanding at December 31, 2023	<u>7,259,741</u>	\$	3.29	7.3
Exercisable at December 31, 2023	<u>4,452,018</u>	\$	4.29	6.0
Vested and expected to vest at December 31, 2023	<u>7,259,741</u>	\$	3.29	7.3

The weighted average fair value of each share option granted has been estimated using a Black-Scholes model and is \$0.76 (\$0.96), exercise price of \$1.04 (\$1.32), expected volatility of 74.3%, no expected dividend yield, weighted-average term of 6.4 years and weighted-average risk-free interest rate of 4.3%. None of the granted stock options were exercised in the period ended 31 December 2023.

The aggregate intrinsic value of the outstanding options is \$0. The Group recognized total expenses of \$619,757 (\$406,582 within G&A expense, \$207,646 within R&D expense and \$5,529 within COGS expense) relating to equity-settled share-based payment transactions during the period to 31 December 2023. The weighted average remaining contractual term of the options is 6.7 years.

Activity for restricted stock units for the period ended December 31, 2023 is as follows:

Non-vested balance at June 30, 2022	-	\$	-
Granted	-	\$	-
Vested	20,150	\$	2.10
Forfeited	(9,045)	\$	1.69
Non-vested balance at December 31, 2023	<u>11,105</u>	\$	0.63

The total fair value of restricted stock units vested during the period ended December 31, 2023 was \$0.01 million. There were no vested restricted stock units at December 31, 2022. Restricted stock units vest upon the achievement of time-based service requirements.

At December 31, 2023, total unrecognized compensation expense related to non-vested restricted stock units was approximately \$0.01 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 1.0 years.

25. TRADE AND OTHER PAYABLES

	\$'000	\$'000
Accounts payable	2,816	2,935
Payroll taxes payable	97	128
Accrued expenses	<u>7,803</u>	<u>8,450</u>
Total	<u>10,716</u>	<u>11,513</u>

26. CONVERTIBLE DEBT

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") to Heights Capital Ireland LLC (the "Convertible Bond Investor"). 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 American Depositary Shares ("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 Bonds of \$8.70 has been set at a 20 percent premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance, and the Bonds have a hard floor in the conversion price of \$7.25. As a result of the February 2023 private placement and pursuant to conditions of the bond agreement, the conversion price was adjusted to \$8.2508 (previously \$8.70) and the floor price was adjusted to \$6.8757 (previously \$7.25). Further, pursuant to conditions of the agreement, effective April 7, 2023, the conversion price was adjusted from \$8.2508 to \$7.7924. 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 percent of the nominal amount. In July 2023, 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. Also in July 2023, the Convertible Bond Investor exercised its right to advance an amortization payment and the Company made an accelerated repayment of \$1.06 million through the issuance of 526,211 ADSSs. In October 2023, the Company made an amortization payment of \$1.3 million, which

consisted of \$1.1 million of principal and \$0.2 million of interest, through the issuance of 2,335,388 ordinary shares in the form of 150,000 Ordinary Shares and 1,092,694 ADSs. In December 2023, the Company made an amortization payment of \$1.3 million, which consisted of \$1.1 million of principal and \$0.2 million of interest, through the issuance of 2,500,000 Ordinary Shares and a cash payment of \$0.6 million. As of December 31, 2023, \$13.8 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. The fair value of the Bonds was determined to be \$16.9 million on issuance, which is the principal amount of the Bonds. On issuance, total debt issuance costs of \$1.4 million were immediately expensed as a component of general and administrative expense in the consolidated statement of operations during the year ended June 30, 2022. As of December 31, 2023, the fair value of the Bonds was determined to be \$8.5 million. During the three months ended December 31, 2023 and 2022, the Company recognized no change and a \$0.9 million increase in fair value of the Notes related to the instrument-specific credit risk in comprehensive loss, respectively, and an increase in fair value related to non-instrument specific credit risk of \$0.1 million and \$0.4 million as a loss in the consolidated statement of operations, respectively. During six months ended December 31, 2023 and 2022, the Company recognized a decrease of \$0.1 million and an increase of \$0.5 million in the fair value of the Notes related to the instrument-specific credit risk in comprehensive loss, respectively, and an increase in fair value related to non-instrument specific credit risk of \$1.3 million and \$0.7 million as a loss in the consolidated statement of operations, respectively.

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. As of December 31, 2023, amounts due to ISMMS totaled \$4.4 million and are included within accrued expenses and other current liabilities and accounts payable on the balance sheet. During the three and six months ended December 31, 2023, the Company incurred expenses of \$1.1 million and \$2.4 million, respectively, related to its obligations under the ISMMS license agreement. During the three and six months ended December 31, 2022, the Company incurred expenses of \$0.00 million and \$1.40 million, respectively, which are included in research and development expenses in the condensed consolidated statement of operations.

In June 2020, the Company and Mount Sinai entered into a registration rights agreement pursuant to which the Company has 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.

On February 9, 2023, the Company entered into security purchase agreements to sell an aggregate of 3,699,910 Ordinary Shares, and 7,511,525 ADS, at a price of \$2.17 per ADS and £0.90 per Ordinary Share. The private placement generated gross cash proceeds of \$20.3 million, the net proceeds of which will be used for sales and marketing, clinical product development, and corporate support and financing costs. Certain related parties, directors of the company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,382,489 new American Depositary Shares at \$2.17 per ADS. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 346,375 Ordinary Shares at £0.90 per Ordinary Share.

In the year ended June 30, 2022, the Company also entered into a private placement agreement to sell, an aggregate of 2,428,688 shares of common stock (the "PIPE Shares"), for a purchase price of \$3.625 per share and an aggregate purchase price of \$8.8 million. Certain related parties, directors of the company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,103,448 new ordinary shares at \$3.625 per ordinary share. EKF Diagnostics Holdings, subscribed for a total of 137,930 new ordinary shares at \$3.625 per ordinary share. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 551,724 new ordinary shares at \$3.625 per ordinary share. Timothy Scannell, Non-Executive Director, subscribed for a total of 68,964 new ordinary shares at \$3.625 per ordinary share. Thomas McLain, President, subscribed for a total of 55,172 new ordinary shares at \$3.625 per ordinary share.

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

As of December 31, 2023, the Company has accrued for the \$300,000 sales milestone due to Joslin as total net sales of \$2 million were achieved in the year.

29. ULTIMATE CONTROLLING PARTY

The Directors believe there to be no ultimate controlling party.

Additional Financial Information

RECONCILIATION OF IFRS TO US GAAP

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

Renalytix Form 10-Q, which is based on US GAAP, contains differences from its Half-Year Report, which is based on IFRS.

The Form 10-Q and Half-Year 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

	\$'000	\$'000	\$'000	
Assets				
Cash	5,619	5,619	-	
Accounts receivable	1,370	1,370	-	
Prepaid expenses and other current assets	1,261	1,258	3	(a)
Property, plant and equipment, net	576	570	6	(a)
Intangibles, net	-	11,563	(11,563)	(b)
Investment in Verici	1,220	1,220	-	
Right of use asset	102	113	(11)	(c)
Other assets	1,128	161	967	(d)
Total assets	11,276	21,874	(10,598)	
Liabilities and stockholder's equity				
Current Liabilities:				
Note payable - current	3,063	3,063	-	
Accounts payable	2,816	10,716	7,900	(e)
Accrued expenses and other current liabilities	4,259	-	(4,259)	(e)
Accrued expenses - related party	3,673	-	(3,673)	(e)
Current lease liability	111	118	7	(d)
Note payable - non current	5,310	5,310	-	
Noncurrent lease liabilities	-	-	-	
Total Liabilities	19,232	19,207	(25)	
Stockholders' (deficit) equity:				
Ordinary shares	305	318	13	(f)
Additional paid in capital	190,437	122,116	(68,321)	(g)
Accumulated other comprehensive (loss) income	(1,734)	(1,297)	437	(h)
Accumulated deficit	(196,964)	(118,470)	78,494	(i)
Total stockholders' (deficit) equity	(7,956)	2,667	10,623	
Total liabilities and stockholders' (deficit) equity	11,276	21,874	10,598	

a. Represents other immaterial presentation differences between US GAAP & 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 difference in the timing of the adoption of IFRS 16 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.
- d. Difference is attributable to capitalized software costs which are recorded as other assets under U.S. GAAP and Intangibles under IFRS.
- e. Accounts payable and other current liabilities are presented in the aggregate within the Annual report while broken out separately on the US GAAP 10-K. Difference represents other immaterial presentation differences and audit adjustments.
- f. Represents other immaterial audit adjustments.
- g. Represents cancellation of share premium account and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici in prior year. In addition, stock based compensation is recognized on a straight line basis under U.S. GAAP and a graded vesting basis under IFRS which creates timing differences as to when expenses are recorded.
- h. Represents the difference in weighted average foreign exchange rates and spot rates used for translation of financial statements under IFRS and U.S. GAAP.
- i. Represents cancellation of share premium and reduction in accumulated deficit under IFRS in anticipation of a distribution of FractalDx net assets to the shareholders of Verici and differences noted within the Company's consolidated statement of operations and comprehensive loss.

RECONCILIATION OF NET LOSS

	\$'000
Net loss in accordance with IFRS	(19,286)
Stock compensation expense	(274) (j)
Amortisation of intangibles	935 (k)
Other adjustments	(14) (l)
Net loss in accordance with US GAAP	(18,639)

- j. 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.
- k. Amortisation 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.
- l. The remaining difference represents the aggregation of other immaterial audit adjustments and small accounting standard differences.

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