



## **Results for First Quarter of Fiscal Year 2023**

November 30, 2022

RNS Number : 00371

Renalytix PLC

30 November 2022

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

**Renalytix Reports Financial Results for First Quarter of Fiscal Year 2023**

**LONDON and SALT LAKE CITY, November 30, 2022** - Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, announces its financial results for the fiscal first quarter ended September 30, 2022.

**Recent Highlights (including post period events)**

- New commercial coverage for KidneyIntelX; now 30 private insurance and network provider contracts executed to date including:
  - o Largest private payer in Illinois with 8.1 million members
  - o Largest independent provider network in the tristate North Carolina, South Carolina and Virginia, with over 100,000 health care providers in-network
- Over 1,200 KidneyIntelX tests performed in the first quarter of fiscal 2023, a record, of which over 80% were billable, yielding approximately \$1.0 million revenue
- 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
- 33 state Medicaid programs contracted to date
- Publication of new real-world evidence in *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, observed reduction of HbA1c levels in highest risk patients who were prescribed SGLT2 inhibitors, and more than a 20% increase in antihypertensive therapeutic prescriptions in high-risk patients
- Continued data generation and analysis reinforcing the benefits of KidneyIntelX as part of collaborative De Novo process with the FDA, with anticipation that the agency's review is nearing completion. Data supports significant breakthrough in risk stratification for patients with diabetic kidney disease
- KidneyIntelX clinical utility and health economics validated in multiple data releases at American Society of Nephrology
- Data results published in *American Journal of Managed Care* supporting adoption and clinical utility of KidneyIntelX; 98% of 401 primary care physicians surveyed confirmed KidneyIntelX has value as a risk decision tool

**First Quarter 2023 Financial Results**

During the three months ended September 30, 2022, the Company recognized \$1.0 million of revenue (Q1 FY22: \$0.5 million). Cost of revenue for the three months ended September 30, 2022 was \$0.7 million (Q1 FY22: \$0.2 million).

Operating expense for the three months ended September 30, 2022 was \$12.0 million compared with \$12.1 million during the prior year period. As stated in August, we have taken action to lower annual expenditures by over \$12 million through program, vendor and employee reductions, with additional opportunities to reduce expenditures under review.

Within operating expenses, research and development expenses were \$3.8 million for the three months ended September 30, 2022, a decrease of \$0.2 million, from \$4.0 million for the three months ended September 30, 2021. The decrease was primarily due to a \$0.2 million decrease in employee related expenses.

General and administrative expenses were \$8.2 million for the three months ended September 30, 2022, increasing by \$0.1

million from \$8.1 million for the three months ended September 30, 2021. The increase was primarily due to a \$0.6 million increase in employee related expenses, which included \$0.3 million of severance expense offset by a \$0.5 million decrease in insurance expense.

Net loss was \$12.0 million for the three months ended September 30, 2022 compared with \$10.1 million for the prior year period.

Cash and cash equivalents totaled \$31.0 million as of September 30, 2022.

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 processes, at 8:30 a.m. (ET) / 1:30 p.m. (GMT).

**Conference Call Details:**

To participate in the live conference call via telephone, please register [here](#). 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/88vepbze>

*For further information, please contact:*

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**About Renalytix**

Renalytix (LSE: RENX) (NASDAQ: RNLX) is the global founder and leader in the new field of bioprognosis™ for kidney health. The company has engineered a new solution that enables early-stage chronic kidney disease progression risk assessment. The Company's lead product, KidneyIntelX™, has been granted Breakthrough Designation by the U.S. Food and Drug Administration and is designed to help make significant improvements in kidney disease prognosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery (visit [www.kidneyintelx.com](http://www.kidneyintelx.com)). For more information, visit [www.renalytix.com](http://www.renalytix.com).

**Forward-Looking Statements**

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, our expectations regarding 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, and our expectations and guidance related to partnerships, testing volumes and revenue for future periods. 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.

## RENALYTIX PLC

### Operational Update and Financial Results for the three months ended September 30, 2022

*Unless otherwise indicated, all references in this report, to the terms "Renalytix," "Renalytix plc," "the company," "we," "us" and "our" refer to Renalytix plc together with its subsidiaries. We recommend that you read the discussion below together with our audited financial statements and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended June 30, 2022, filed with the Securities and Exchange Commission on October 31, 2022 (our "Annual Report").*

*The statements in this discussion regarding our expectations regarding our market opportunity, partnerships, reimbursement, regulatory approval, cash runway, revenue guidance, capital requirements and future performance, as well as all other non-historical statements are forward-looking statements. Forward-looking statements involve known and unknown risks and uncertainties that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. These risks and uncertainties include, but are not limited to, the risks and uncertainties set forth in the "Risk Factors" section of our Annual Report and any subsequent reports that we file with the SEC. See also the section titled "Forward-Looking Statements" above.*

#### **OPERATIONAL REVIEW**

##### *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.

##### *About 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 past year, KidneyIntelX expanded within the Mount Sinai Health System and launched at Wake Forest Baptist Health, Capital District Physicians' Health Plan (CDPHP), veterans' affairs (VA) medical centers and among independent primary care physicians.

A full electronic health record (EHR) integrated deployment of KidneyIntelX with population health support in the Mount Sinai Health System has now yielded actionable reports for approximately 5,000 patients. Utility results from our first real-world deployment at scale is yielding key evidence of the benefits of KidneyIntelX, particularly at the all-important primary care level. Patients and doctors are now clearly seeing benefits in the short-term from advanced risk assessment and follow-on action early in the disease cycle. Our experience with our physician-led health insurance partner, CDPHP, in upstate New York has been equally robust.

Implementing with the VA medical system has been slower than planned due to the complexities in introducing a new test and integrating its use into the VA system. However, we have now begun to overcome implementation hurdles and are beginning to see an increasing number of orders and corresponding testing volumes. We remain convinced that KidneyIntelX will play an important role nationally in the VA system which serves an estimated one million veterans with diabetes and kidney disease. Again, insurance coverage remains in place with a nationwide 10-year government insurance contract for KidneyIntelX payment throughout the VA system.

Expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website: [www.kidneyintelx.com](http://www.kidneyintelx.com). We believe our education and support program will be an important resource to help inform and improve care for early-stage DKD patients and support future hospital system deployments of KidneyIntelX, which we believe could be achieved more rapidly as a result of the knowledge we have derived from our hospital system implementations to date.

#### *Current outlook*

Building KidneyIntelX into a standard of care in the United States and a global market with 850 million people with chronic kidney disease requires extensive data production, regulatory approvals, physician and patient education, and of course, comprehensive reimbursement. While it sometimes seems this set of milestones takes a long time to accomplish, we are reminded that Renalytix is still a young company that received its first funding four years ago. To have achieved real insurance coverage for KidneyIntelX testing in the complex U.S. market in such a short time we believe is extraordinary. We believe that since the data is comprehensive and showing clear benefit, acceleration of adoption is likely to continue to occur. The social need could not be higher to establish innovative preventative medicine strategies such as KidneyIntelX at the front-end of diabetes and kidney disease.

Operational progress continued into the first quarter of fiscal 2023 with over 1,200 tests performed. More than 80% of these were billable, yielding about \$1.0 million revenue for the quarter. These are record amounts for us in quarterly testing volumes and revenue.

## **FINANCIAL REVIEW**

### **Financial review of the three-month period ended September 30, 2022 and comparison to prior year period**

Our operating loss for the three months ended September 30, 2022, was \$11.7 million (September 30, 2021: \$11.8 million).

#### ***Revenue***

During the three months ended September 30, 2022, we recognized \$1.0 million of revenue related to KidneyIntelX testing. There was \$0.5 million of revenue related to KidneyIntelX testing for the three months ended September 30, 2021.

#### ***Cost of Revenue***

During the three months ended September 30, 2022, cost of revenue consisted of \$0.7 million primarily attributable to KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. There was \$0.2 million of cost of revenue for the three months ended September 30, 2021.

#### ***Research and Development Costs***

Research and development expenses decreased by \$0.2 million, from \$4.0 million for the three months ended September 30,

2021 to \$3.8 million for the three months ended September 30, 2022. The decrease was primarily due to a \$0.2 million decrease in employee related expenses.

#### ***General and Administrative Costs***

General and administrative expenses increased by \$0.1 million, from \$8.1 million for the three months ended September 30, 2021 to \$8.2 million for the three months ended September 30, 2022. The increase was primarily due to a \$0.6 million increase in employee related expenses, which included \$0.3 million of severance expense offset by a \$0.5 million decrease in insurance expense. As stated in August, we have taken action to lower annual expenditures by over \$12 million through program, vendor and employee reductions, with additional opportunities to reduce expenditures under review.

#### ***Foreign Currency gain***

During the three months ended September 30, 2022, we recorded an unrealized foreign exchange gain of \$1.7 million primarily attributable to cash balances denominated in currencies other than the functional currency. We recorded an unrealized foreign currency gain of \$2.3 million during the three months ended September 30, 2021.

#### ***Fair Value Adjustments to VericiDx Investment***

The Company accounts for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During the three months ended September 30, 2022, we recorded a loss of \$0.9 million to adjust the VericiDx investment to fair value. We recorded a loss of \$0.6 million during the three months ended September 30, 2021.

#### ***Fair value adjustment on convertible notes***

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount \$21.2 million due in April 2027 (the "Bonds"). We elected to account for the bonds at fair value with qualifying changes in fair value recognized through the statements of operations until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. For the three months ended September 30, 2022, we recorded a loss of \$1.2 million to adjust the bonds to fair value. There was no fair value adjustment for the three months ended September 30, 2021 as we had not issued convertible debt at that time.

#### ***Other income***

During the three months ended September 30, 2022, we realized \$0.1 million of other income from Kantaro for additional services performed outside the scope of the operating agreement. During the three months ended September 30, 2021, we received \$0.01 million of interest income as a result of interest earned on cash deposits.

#### ***Liquidity and Capital Resources***

Since our inception, we have incurred net losses. As of September 30, 2022, we had an accumulated deficit of \$144.7 million.

We expect to incur additional losses in the near future, and we expect our expenses to increase in connection with our ongoing activities, particularly as we continue to commercialize and scale KidneyIntelX, particularly as we conduct our ongoing and planned clinical utility and other studies for KidneyIntelX for its commercial launch, develop and refine our artificial intelligence technology platform, seek regulatory clearances or approvals for KidneyIntelX or any other product we develop, establish and maintain partnerships with healthcare systems, pursue our coverage and reimbursement strategy and continue to invest in our infrastructure to support our manufacturing and other activities. In addition, we expect to continue to incur additional costs associated with operating as a public company in the United States. The timing and amount of our operating expenditures will depend largely on:

- the cost, progress and results of our ongoing and planned validation studies and health economic studies;
- the cost, timing and outcome of entering into and maintaining partnership agreements with healthcare systems for the commercial sale of KidneyIntelX;
- the cost of manufacturing clinical and commercial supply of KidneyIntelX;
- the cost, timing and outcome of regulatory review of KidneyIntelX, including any post-marketing studies that

could be required by regulatory authorities;

- the cost, timing and outcome of identified and potential future commercialization activities, including manufacturing, marketing, sales and distribution, for KidneyIntelX;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of future revenue, if any, received from commercial sales of KidneyIntelX;
- the sales price and availability of adequate third-party coverage and reimbursement for KidneyIntelX;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, such as Kantaro, although we currently have no other commitments or agreements to complete any such transactions.

To date, we have primarily financed our operations through equity and debt financings. As of September 30, 2022, we had cash and cash equivalents of \$31.0 million. We believe that our existing cash will enable us to fund our current operating plan for at least the next 12 months. Such expectation is based, in part, on the achievement of certain assumed revenue; however, there is no guarantee we will achieve this amount of revenue during the time period we assume. Management assesses that various operating cost mitigation options are available to the Company if needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

### ***Cash Flows***

#### *Net cash used in operating activities*

During the three months ended September 30, 2022, net cash used in operating activities was \$7.1 million and was primarily attributable to our \$12.0 million net loss including a \$1.7 million net change in our operating assets and liabilities and \$3.1 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to a \$1.7 million increase in accounts payable and accrued expenses and other current liabilities. Noncash charges were primarily related to \$0.8 million in share-based compensation, \$0.9 million fair value adjustment of our VericiDx securities, \$0.9 million fair value adjustment of our convertible debt, \$0.5 million unrealized foreign exchange loss and \$0.1 million of depreciation and amortization.

During the three months ended September 30, 2021, net cash used in operating activities was \$10.5 million and was primarily attributable to our \$10.1 million net loss including \$0.3 million in noncash charges and a \$0.1 million net change in our operating assets and liabilities.

#### *Net cash used in investing activities*

During the three months ended September 30, 2022, no cash was used for investing activities.

During the three months ended September 30, 2021, net cash used in investing activities was \$0.3 million, primarily attributable to a \$0.2 million for purchases of lab and office equipment.

#### *Net cash used in financing activities*

During the three months ended September 30, 2022, net cash used in financing activities was \$0.9 million and was primarily attributable to \$1.0 million in cash used to pay down the principal of the convertible debt, offset by \$0.1 million in proceeds from the issuance of ordinary shares under our employee stock purchase program.

During the three months ended September 30, 2021, net cash provided by financing activities was \$0.2 million and was primarily attributable to \$0.1 million in proceeds from the issuance of ordinary shares under employee stock purchase program as well as \$0.1 million in proceeds from the exercise of stock options.

#### **Cash and Cash Equivalents**

We had cash and cash equivalents of \$31.0 million as of September 30, 2022, which decreased from \$41.3 million as of June 30, 2022 due to normal operations as we continue to commercialize KidneyIntelX and grow our business.

#### **Critical accounting policies and significant judgments and estimates**

Our management's discussion and analysis of our financial condition and results of operations is based on our unaudited condensed consolidated financial statements, which we have prepared in accordance with generally accepted accounting principles in the United States, "U.S. GAAP". The preparation of our unaudited condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our unaudited condensed consolidated financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions.

There have been no material changes to our critical accounting policies from those described in "Management's Discussion and Analysis of Financial Condition and Results of Operations" included in our Annual Report.

#### **Recent accounting pronouncements**

See Note 3 to our financial statements found elsewhere in this report for a description of recent accounting pronouncements applicable to our financial statements.

#### **JOBS Act transition period**

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. An emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards and, as a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates. We are in the process of evaluating the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we may rely on certain of these exemptions, including without limitation exemptions to the requirements for (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (1) following the fifth anniversary of the completion of our U.S. IPO, (2) in which we have total annual gross revenues of at least \$1.235 billion or (3) in

which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our ordinary shares and ADSs that are held by non-affiliates exceeds \$700.0 million as of the prior December 31, or (b) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

RENALYTIX PLC CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(in thousands, except share and per share data)	<b>September 30,</b>	
	<b>2022</b>	<b>June 30, 2022</b>
<b>Assets</b>		
<b>Current assets:</b>		
Cash and cash equivalents	\$ 31,040	\$ 41,333
Accounts receivable	1,223	901
Prepaid expenses and other current assets	2,075	2,445
Note receivable from Kantaro	75	75
Receivable from affiliates	13	-
Total current assets	<u>34,426</u>	<u>44,754</u>
Property and equipment, net	2,348	2,558
Right of use asset	239	-
Investment in VericiDx	1,700	2,744
Investment in Kantaro	-	9
Total assets	<u>\$ 38,713</u>	<u>\$ 50,065</u>
<b>Liabilities and Shareholders' Equity</b>		
<b>Current liabilities:</b>		
Accounts payable	1,892	\$ 1,376
Accounts payable - related party	2,370	1,083
Accrued expenses and other current liabilities	2,873	3,060
Accrued expenses - related party	1,516	1,496
Deferred revenue	39	46
Current lease liability	128	-
Convertible notes-current	4,473	4,660
Payable to affiliate - current	43	55
Total current liabilities	<u>13,334</u>	<u>11,776</u>
Convertible notes-noncurrent	6,408	7,682
Noncurrent lease liability	128	-
Total liabilities	<u>19,870</u>	<u>19,458</u>
<b>Commitments and contingencies (Note 10)</b>		
<b>Shareholders' equity:</b>		
Ordinary shares, £0.0025 par value per share: 79,411,245 shares authorized; 74,891,844 and 74,760,432 shares issued and outstanding at September 30, 2022 and June 30, 2022, respectively	229	228
Additional paid-in capital	164,890	164,012
Accumulated other comprehensive income	(1,605)	(915)
Accumulated deficit	(144,671)	(132,718)
Total shareholders' equity	<u>18,843</u>	<u>30,607</u>
Total liabilities and shareholders' equity	<u>\$ 38,713</u>	<u>\$ 50,065</u>

The accompanying notes are an integral part of these condensed consolidated financial statements.



RENALYTIX PLC CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS  
(UNAUDITED)

(in thousands, except share data)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021
Revenue	\$ 969	\$ 482
Cost of revenue	696	227
Gross profit	273	255
Operating expenses:		
Research and development	3,757	3,998
General and administrative	8,250	8,132
Performance of contract liability to affiliate	(12)	(61)
Total operating expenses	11,995	12,069
Loss from operations	(11,722)	(11,814)
Equity in net (losses) earnings of affiliate	(9)	-
Foreign currency gain, net	1,730	2,303
Fair value adjustment to VericiDx investment	(854)	(607)
Fair value adjustment to convertible notes	(1,213)	-
Other income, net	114	12
Net loss before income taxes	(11,954)	(10,106)
Income tax expense	1	-
Net loss	(11,953)	(10,106)
Net loss per ordinary share-basic and diluted	\$ (0.16)	\$ (0.14)
Weighted average ordinary shares-basic and diluted	74,804,712	72,230,803
Other comprehensive income (loss):		
Changes in the fair value of the convertible notes	397	-
Foreign exchange translation adjustment	(1,087)	(2,585)
Comprehensive loss	(12,643)	(12,691)

The accompanying notes are an integral part of these condensed consolidated financial statements.

RENALYTIX PLC CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity
	Shares	Amount				
	Balance at July 1, 2022	74,760,432				
Shares issued under the employee share purchase program	131,412	1	115	-	-	\$ 116
Stock-based compensation expense	-	-	763	-	-	\$ 763
Currency translation adjustments	-	-	-	(1,087)	-	\$ (1,087)
Changes in the fair value of the convertible notes at fair value	-	-	-	397	-	\$ 397
Net loss	-	-	-	-	(11,953)	\$ (11,953)
Balance at September 30, 2022	74,891,844	229	164,890	(1,605)	(144,671)	18,843

RENALYTIX PLC CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity
	Shares	Amount				
	Balance at July 1, 2021	72,197,286				
Shares issued under the employee share purchase plan	10,920	-	120	-	-	120
Exercise of stock options	32,500	-	86	-	-	86
Stock-based compensation expense	-	-	997	-	-	997
Currency translation adjustments	-	-	-	(2,585)	-	(2,585)
Net loss	-	-	-	-	(10,106)	(10,106)
Balance at September 30, 2021	72,240,706	\$ 220	\$ 151,610	\$ 5,691	\$ (97,548)	\$ 59,973

The accompanying notes are an integral part of these condensed consolidated financial statements.

## RENALYTIX PLC CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)	Three Months Ended September 30, 2022	Three Months Ended September 30, 2021
Cash flows from operating activities:		
Net loss	\$ (11,953)	\$ (10,106)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	130	119
Stock-based compensation	767	997
Equity in losses of affiliate	9	-
Reduction of Kantaro liability	(12)	-
Fair value adjustment to VericiDx investment	854	607
Unrealized foreign exchange (gain) loss	456	(2,058)
Fair value adjustment to convertible debt	921	-
Changes in operating assets and liabilities:		
Accounts receivable	(322)	242
Prepaid expenses and other current assets	312	(431)
Receivable from affiliates	(13)	(28)
Accounts payable	555	(646)
Accounts payable - related party	1,287	510
Accrued expenses and other current liabilities	(125)	14
Accrued expenses - related party	22	383
Deferred revenue	(7)	(32)
Payable to affiliate - current	-	(61)
Other liabilities	-	-
Net cash used in operating activities	<u>(7,119)</u>	<u>(10,490)</u>
Cash flows from investing activities:		
Purchases of property and equipment	-	(224)
Software development costs	-	(33)
Net cash used in investing activities	<u>-</u>	<u>(257)</u>
Cash flows from financing activities:		
Payment of convertible notes principal	(1,060)	-
Proceeds from the issuance of ordinary shares under employee share purchase plan	116	120
Proceeds from exercise of stock options	-	86
Net cash provided by financing activities	<u>(944)</u>	<u>206</u>
Effect of exchange rate changes on cash	(2,230)	(261)
Net (decrease) in cash and cash equivalents	(10,293)	(10,802)
Cash and cash equivalents, beginning of period	41,333	65,128
Cash and cash equivalents, end of period	<u>\$ 31,040</u>	<u>\$ 54,326</u>
Supplemental noncash investing and financing activities:		
Cash Paid for interest on convertible debt	\$ 292	\$ -
Software development costs in accounts payable and accrued expenses	\$ -	\$ 19

Purchase of property and equipment in accounts payable and accrued expenses	\$	-	\$	15
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The accompanying notes are an integral part of these condensed consolidated financial statements.

## RENALYTIX PLC NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

### 1. Business and risks

Renalytix and its wholly-owned subsidiaries, Renalytix AI, Inc. and Renalytix AI Limited, (collectively, "Renalytix", or the "Company") is an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and significantly lower healthcare costs. KidneyIntelX, the Company's first-in-class diagnostic platform, employs a proprietary artificial intelligence-enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from EHR systems, to generate a unique patient risk score. Additionally, the Company has successfully completed the first stage of a statement of work with AstraZeneca Pharmaceuticals LP ("AstraZeneca") to conduct a feasibility study to determine the impact of the use of the Company's KidneyIntelX platform to optimize utilization of various CKD agents. Further, in December 2020 the Company entered into a master service agreement with AstraZeneca for future services of this nature. As a result of the initial success with AstraZeneca the Company plans to pursue further collaborations with pharmaceutical companies and make 'Pharmaceutical Services Revenue' a core part of the business going forward with the goal of improving guideline-based standard-of-care for optimal utilization of existing and novel therapeutics using the KidneyIntelX testing platform and proprietary care management software.

In August 2020, the Company created a wholly-owned subsidiary of Renalytix AI plc, Renalytix AI Limited ("Limited") to facilitate operations in Ireland.

Since inception in March 2018, the Company has focused primarily on organizing and staffing the Company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting its intellectual property portfolio and commercial laboratory operations, pursuing regulatory clearance and developing a reimbursement strategy. The Company has funded its operations primarily through equity and debt financings.

The Company is subject to risks and uncertainties common to early-stage companies in the diagnostics industry, including, but not limited to, ability to secure additional capital to fund operations, compliance with governmental regulations, development by competitors of new technological innovations, dependence on key personnel and protection of proprietary technology. To achieve widespread usage, KidneyIntelX and additional diagnostic products currently under development will require extensive clinical testing and validation prior to regulatory approval and commercialization. These efforts require significant amounts of additional capital, adequate personnel, and infrastructure and extensive compliance-reporting capabilities.

## **2. Liquidity and Going Concern**

The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of \$144.7 million as of September 30, 2022. 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. Management believes its cash and cash equivalents of \$31.0 million as of September 30, 2022, are sufficient to fund the projected operations for at least the next twelve months from the issuance date of these financial statements. Such expectation is based, in part, on the achievement of a certain volume of assumed revenue; however, there is no guarantee we will achieve this amount of revenue during the time period we assume. Management assessed various additional operating cost reduction options that are available to the Company and would be implemented, if assumed levels of revenue are not achieved and additional funding is not obtained.

Substantial additional capital will be necessary to fund the 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 Company may not be able to obtain financing on acceptable terms, or at all, and the 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 Company's shareholders. If the Company is unable to obtain funding, the 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.



### **3. Basis of presentation and summary of significant accounting policies**

The accompanying unaudited interim condensed consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2022 and its results of operations for the three months ended September 30, 2022 and 2021 and cash flows for the three months ended September 30, 2022 and 2021. Operating results for the three months ended September 30, 2022, are not necessarily indicative of the results that may be expected for the year ending June 30, 2023. The unaudited interim condensed consolidated financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended June 30, 2022.

#### ***Principles of consolidation***

The unaudited interim condensed consolidated financial statements include the accounts of Renalytix plc, and its wholly-owned subsidiaries, Renalytix AI, Inc. and Renalytix AI Limited. All inter-company balances and transactions have been eliminated in consolidation. The Company accounts for investments in which it has significant influence but not a controlling financial interest using the equity method of accounting.

#### ***Use of estimates***

The preparation of the consolidated financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements and reported amounts of expenses during the reporting period. Actual results could differ from those estimates. Due to the uncertainty of factors surrounding the estimates or judgments used in the preparation of the consolidated financial statements, actual results may materially vary from these estimates.

Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the consolidated financial statements in the period they are determined to be necessary. Significant areas that require management's estimate include the assumptions used in determining the fair value of share-based awards, determining the fair value of the bonds, recording the prepaid/accrual and associated expense for research and development activities performed for the Company by third parties, determining useful lives of property and equipment and capitalized software, the assessment of noncontrolling interest and equity method investments.

#### ***Segment information***

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is to make significant improvements in kidney disease diagnosis and prognosis, clinical care, patient stratification for drug clinical trials, and drug target discovery.

#### ***Foreign currency***

The Company's consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The functional currency of Renalytix plc and Renalytix AI Limited is GB Pounds. The functional currency of Renalytix AI, Inc. is the U.S. dollar. Assets and liabilities of Renalytix plc and Renalytix AI Limited are translated at the rate of exchange at period-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies

other than the functional currency are included in income in the period in which the change occurs and reported in the consolidated statements of operations and comprehensive loss.

#### ***Concentrations of credit risk and major customers***

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash and accounts receivable balances. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and are not exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships and has not experienced any losses on such accounts.

The Company's accounts receivable are derived from revenue earned from customers located in the U.S. All of the Company's revenue has been generated from seven customers for the three months ended September 30, 2022, and two customers for the three months ended September 30, 2021. The Company performs initial and ongoing credit reviews on customers, which involve consideration of the customers' financial information, their location, and other factors to assess the customers' ability to pay.

#### ***Fair value of financial instruments***

At September 30, 2022 and June 30, 2022, the Company's financial instruments included accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature. The convertible notes are recorded at its estimated fair value.

#### ***Fair value option***

Under the Fair Value Option Subsections of ASC subtopic 825-10, *Financial Instruments - Overall*, the Company has the irrevocable option to report most financial assets and financial liabilities at fair value on an instrument-by-instrument basis, with changes in fair value reported in earnings (see Note 5). The Company has elected to measure and record the convertible notes at their estimated fair value.

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

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of September 30, 2022, the Company had a cash balance of \$31.0 million. As of June 30, 2022, the Company had a cash balance of \$41.3 million.

#### ***Accounts receivable***

Accounts receivable are recorded at the invoice amount and are non-interest bearing. The Company considers receivables past due based on the contractual payment terms. The Company reserves specific receivables if collectability is no longer reasonably assured. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations, historical payment patterns, and individual customer circumstances. No reserves have been recorded as of September 30, 2022 or June 30, 2022.

#### ***Property and equipment***

Property and equipment are recorded at cost. Depreciation is determined using the straight-line method over the estimated useful lives ranging from three to ten years. Expenditures for maintenance and repairs are expensed as incurred while renewals and betterments are capitalized. When property and equipment are sold or otherwise disposed of, the cost and related accumulated depreciation are eliminated from the accounts and any resulting gain or loss is reflected in operations.

#### ***Leases***

Effective July 1, 2022, the Company adopted Accounting Standards Codification ("ASC"), Topic 842, Leases ("ASC 842"),

using the required modified retrospective approach and utilizing the effective date as its date of initial application.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. Most leases with a term greater than one year are recognized on the balance sheet as right-of-use assets, lease liabilities and, if applicable, long-term lease liabilities. The Company has elected not to recognize on the balance sheet, leases with terms of one year or less. Operating lease liabilities and their corresponding right-of-use assets are recorded based on the present value of lease payments over the expected remaining lease term. However, certain adjustments to the right-of-use asset may be required for items such as incentives received, initial direct costs, or prepayments. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rates, which are the rates incurred to borrow on a collateralized basis over a similar term an amount equal to the lease payments in a similar economic environment.

In accordance with the guidance in ASC 842, components of a lease should be split into three categories: lease components (e.g., land, building, etc.), non-lease components (e.g., common area maintenance, consumables, etc.), and non-components (e.g., property taxes, insurance, etc.). Then the fixed and in-substance fixed contract consideration (including any related to non-components) must be allocated based on the respective relative fair values to the lease components and non-lease components.

Although separation of lease and non-lease components is required, certain practical expedients are available. Entities may elect the practical expedient to not separate lease and non-lease components. Rather, they would account for each lease component and the related non-lease component together as a single component. Upon adoption, the Company elected the package of practical expedients and the hindsight practical expedient but did not elect the easement practical expedient which is not applicable to the Company as the Company does not have any ground leases. In accordance with the package of practical expedients, the Company has not reassessed any of their existing or expired contracts or any other agreements that were previously concluded to not contain a lease for the following practical expedient guidance: (1) whether the arrangement is or contains a lease, (2) lease classification and (3) whether previously capitalized costs continue to qualify as initial direct costs.

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

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement ("Kantaro Operating Agreement") to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which is designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. During the three months ended September 30, 2022, the Company recognized \$0.01 million, related to the performance of the contract liability with Kantaro. During the three months ended September 30, 2021, the Company recognized \$0.06 million, related to the performance of the contract liability with Kantaro. This represents the allocation of costs for performing services on behalf of Kantaro.

#### ***Equity method investments***

The Company accounts for equity investments where it owns a non-controlling interest, but has the ability to exercise significant influence, under the equity method of accounting. Under the equity method of accounting, the original cost of the investment is adjusted for the Company's share of equity in the earnings of the equity investee and reduced by dividends and distributions of capital received, unless the fair value option is elected, in which case the investment balance is marked to fair value each reporting period and the impact of changes in fair value of the equity investment are reported in earnings.

#### ***Kantaro Biosciences LLC***

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

then-current fair value. The Company owned 25% of the membership equity units in Kantaro at September 30, 2022 and June 30, 2022.

#### ***Impairment assessment***

The Company evaluates its investments that are in unrealized loss positions, if any, and equity method investments for other-than-temporary impairment on a quarterly basis (see note 3). Such evaluation involves a variety of considerations, including assessments of the risks and uncertainties associated with general economic conditions and distinct conditions affecting specific issuers or investees. Factors considered by the Company include (i) the length of time and the extent to which an investment's fair value has been below its cost; (ii) the financial condition, credit worthiness, and near-term prospects of the issuer; (iii) the length of time to maturity; (iv) future economic conditions and market forecasts; (v) the Company's intent and ability to retain its investment for a period of time sufficient to allow for recovery of market value; (vi) an assessment of whether it is more likely than not that the Company will be required to sell its investment before recovery of market value; and (vii) whether events or changes in circumstances indicate that the investment's carrying amount might not be recoverable.

#### ***Software development costs***

The Company follows the provisions of ASC 985, Software, which requires software development costs for software to be marketed externally to be expensed as incurred until the establishment of technological feasibility, at which time those costs are capitalized until the software is available for general release and amortized over its estimated useful life of ten years. Technological feasibility is established upon the completion of a working model that has been validated.

#### ***Revenue recognition***

The Company accounts for revenue under ASC 606 - *Revenue from Contracts with Customers* ("ASC 606"). Pursuant to ASC 606, the Company recognizes revenue when a customer obtains control of promised goods or services. The Company records the amount of revenue that reflects the consideration that it expects to receive in exchange for those goods or services. The Company applies the following five-step model in order to determine this amount: (i) identification of the promised goods or services in the contract; (ii) determination of whether the promised goods or services are performance obligations, including whether they are distinct in the context of the contract; (iii) measurement of the transaction price, including the constraint on variable consideration; (iv) allocation of the transaction price to the performance obligations; and (v) recognition of revenue when (or as) the Company satisfies each performance obligation.

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. Certain contracts have options for the customer to acquire additional services. The Company evaluates these options to determine if a material right exists. If, after that evaluation, it determines a material right does exist, it assigns value to the material right based upon the renewal option approach. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer occurs at a point in time. Sales tax and other similar taxes are excluded from revenues.

#### ***Cost of revenue***

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

#### ***Research and development expenses***

Research and development costs consist primarily of costs incurred in connection with the development of KidneyIntelX and other studies for KidneyIntelX to determine clinical value and performance in different CKD populations. Research and

development costs are expensed as incurred.

### ***Share-based compensation***

The Company measures equity classified share-based awards granted to employees and nonemployees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. The Company accounts for forfeitures as they occur. For share-based awards with service-based vesting conditions, the Company recognizes compensation expense on a straight-line basis over the service period. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company was a privately-held organization prior to November 2018 and has been a publicly-traded company for a limited period of time and therefore lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly-traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is none based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies share-based compensation expense in its condensed consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

### ***Income taxes***

Income taxes are accounted for under the asset and liability method as required by FASB ASC Topic 740, Income Taxes (ASC 740). Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. A reduction in the carrying value of the deferred tax assets is required when it is not more likely than not that such deferred tax assets are realizable.

FASB ASC Subtopic 740-10, Accounting for Uncertainty of Income Taxes(ASC 740-10), defines the criterion an individual tax position must meet for any part of the benefit of the tax position to be recognized in financial statements prepared in conformity with U.S. GAAP. The Company may recognize the tax benefit from an uncertain tax position only if it is more likely than not such tax position will be sustained on examination by the taxing authorities, based solely on the technical merits of the respective tax position. The tax benefits recognized in the financial statements from such a tax position should be measured based on the largest benefit having a greater than 50% likelihood of being realized upon ultimate settlement with the tax authority. In accordance with disclosure requirements of ASC 740-10, the Company's policy on income statement classification of interest and penalties related to income tax obligations is to include such items as part of income tax expense.

### ***Comprehensive loss***

Comprehensive loss includes net loss as well as other changes in shareholders' equity that result from transactions and economic events other than those with shareholders. For the periods presented changes in shareholders' equity includes foreign currency translation as well as changes in fair value of the convertible note due to changes in instrument specific credit risk. The change in instrument specific credit risk was calculated as the change in the risk yield from the convertible debt issuance date to the valuation date. The instrument specific credit risk at issuance date was calibrated such that the fair value of the convertible bond

was equal to the issue price as of the issuance date. The risk yield was adjusted to reflect the change in credit spreads between the issuance date and the valuation date.

#### ***Net loss per ordinary 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 and convertible debt which would result in the issuance of incremental ordinary shares.

The dilutive effect of convertible securities is calculated using the if-converted method. Under the if-converted method, interest charges applicable to the convertible debt as well as nondiscretionary adjustments which include any expenses or charges that are determined based on the income (loss) for the period are added back to net income. The convertible debt is assumed to have been converted at the beginning of the period (or at time of issuance, if later).

For the quarter ended September 30, 2022, the diluted and basic net loss per share calculation excluded 4,519,401 shares related to stock options, as the exercise price of these options was greater than their market value. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

#### ***Emerging growth company***

The Company is an emerging growth company as defined in the Jumpstart Our Business Startups Act of 2012, as amended (the "JOBS Act"). Under the JOBS Act, companies have extended transition periods available for complying with new or revised accounting standards. The Company has elected to avail itself of this exemption and, therefore, while the Company is an emerging growth company it will not be subject to new or revised accounting standards at the same time that they become applicable to other public emerging growth companies that have not elected to avail themselves of this exemption.

#### ***Recently issued accounting pronouncements***

In June 2016, the FASB issued ASU 2016-13, Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments, which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2023. The Company is currently evaluating the impact of adopting this guidance to its consolidated financial statements.

In August 2020, the FASB issued ASU 2020-06, Debt - Debt with Conversion and Other Options (Subtopic 470-20) and Derivatives and Hedging - Contracts in Entity's Own Equity (Subtopic 815-40), Accounting for Convertible Instruments and Contracts in an Entity's Own Equity ("ASU2020-06"). ASU 2020-06 eliminates two of the three models in ASC 470-20 that require issuers to separately account for embedded conversion features and eliminates some of the requirements for equity classification in ASC 815-40-25 for contracts in an entity's own equity. The guidance also requires entities to use the if-converted method for all convertible instruments in the diluted earnings per share calculation and generally requires them to include the effect of potential share settlement for instruments that may be settled in cash or shares. It is effective for annual periods beginning after December 15, 2023, and interim periods therein. The Company evaluated the effect ASU 2020-06 and it is not expected to have a material impact on the consolidated financial statements.

#### 4. 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 three months ended September 30, 2022, the Company recognized \$1.0 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. During the three months ended September 30, 2021, the Company recognized \$0.4 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 three months ended September 30, 2022, the Company recognized \$0.01 million of pharmaceutical services revenue where performance obligations are satisfied over time. During the, the three months ended September 30, 2021 Company recognized \$0.03 million of pharmaceutical services revenue where performance obligations are satisfied over time.

##### *Professional services revenue*

Professional services revenue consists of services related to the creation of a branded care navigation portal/pathway for use with KidneyIntelX. Revenue is recognized when control of the promised services is transferred to customers and the performance obligation is fulfilled in an amount that reflects the consideration that the Company expects to be entitled in exchange for those services.

The company did not recognize any professional services revenue during the three months ended September 30, 2022 or during the three months ended September 30, 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 few months.

The following table summarizes the changes in deferred revenue:

(in thousands)	<u>September 30, 2022</u>	<u>June 30, 2022</u>
Balance, beginning of period	\$ 46	\$ 122
Deferral of revenue	\$ -	67
Revenue recognized	(7)	(143)
Balance, end of period	<u>\$ 39</u>	<u>\$ 46</u>



## 5. Fair value measurements and the fair value option

Assets and liabilities recorded at fair value on a recurring basis in the condensed consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

- Level 1 - Quoted prices (unadjusted in active markets for identical assets or liabilities)
- Level 2 - Inputs other than quoted prices in active markets that are observable either directly or indirectly
- Level 3 - Unobservable inputs in which there is little or no market data, which require the Company to develop its own assumptions

This hierarchy requires the use of observable market data when available and to minimize the use of unobservable inputs when determining fair value. The following fair value hierarchy table presents information about the Company's assets measured at fair value on a recurring basis:

(in thousands)	Fair value measurement at reporting date using		
	(Level 1)	(Level 2)	(Level 3)
September 30, 2022			
Assets:			
Available for sale securities	\$ 1,700	\$ -	\$ -
Liabilities:			
Convertible notes	\$ -	\$ -	\$ 10,881
June 30, 2022			
Assets:			
Available for sale securities	\$ 2,744	\$ -	\$ -
Liabilities:			
Convertible notes	\$ -	\$ -	\$ 12,342

As further described in Note 8, in April 2022 the Company issued convertible promissory notes (the "Notes") to various investors. The fair value option, as prescribed by ASC 815, *Derivatives and Hedging*, was elected and applied in connection with the preparation of these consolidated financial statements. The fair value of the Notes 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.

The Company adjusts the carrying value of the Notes to their estimated fair value at each reporting date, with qualifying increases or decreases in the fair value recorded as change in fair value of convertible promissory notes in the statements of operations and comprehensive loss. Changes in the fair value resulting from changes in the instrument-specific credit risk will be presented separately in other comprehensive income.

(in thousands)	September 30, 2022
Balance at July 1, 2022	\$ 12,342
Change in Principal amount	\$ (1,352)
Change in credit risk	\$ (397)
Change in time to maturity, stock price and Risk-Free Rates	\$ 1,213
FX Impact	\$ (925)
Balance at September 30, 2022	\$ 10,881

*Non-financial assets and liabilities*

The Company's non-financial assets, which primarily consist of property and equipment and equity method investments, are not required to be measured at fair value on a recurring basis, and instead are reported at carrying value in its condensed consolidated balance sheet. However, on a periodic basis or whenever events or changes in circumstances indicate that they may not be fully recoverable, the respective carrying value of non-financial assets are assessed for impairment and, if ultimately considered impaired, are adjusted and written down to their fair value, as estimated based on consideration of external market participant assumptions.

## 6. Property and equipment

Property and equipment consists of (in thousands):

(in thousands)	<u>September 30, 2022</u>	<u>June 30, 2022</u>
Lab equipment	\$ 1,143	\$ 1,143
Software	1,380	1,476
Office equipment	124	124
Office furniture	35	35
Leasehold improvements	576	576
Construction in progress	-	-
Total	<u>3,258</u>	<u>3,354</u>
Less accumulated depreciation and amortization	<u>(910)</u>	<u>(796)</u>
	<u>\$ 2,348</u>	<u>\$ 2,558</u>

Depreciation expense was \$0.1 million for the three months ended September 30, 2022, respectively. Depreciation expense was \$0.1 million for the three months ended September 30, 2021, respectively.

As of September 30, 2022 there was \$1.1 million of unamortized capitalized software development costs. Amortization expense related to capitalized software development costs was \$0.04 million and \$0.04 million three months ended September 30, 2022 and 2021 respectively.

As of September 30, 2022, the expected amortization expense for software for the next five years and thereafter is as follows:

(in thousands)	
2023	\$ 125
2024	166
2025	166
2026	128
2027	111
Thereafter	<u>371</u>
	<u>\$ 1,067</u>

## 7. Accrued expenses and other current liabilities

Accrued expenses and other current liabilities consisted of (in thousands):

	September 30, 2022	June 30, 2022
Consulting and professional fees	\$ 446	\$ 551
Research and development	1,008	1,060
Payroll and related benefits	1,092	1,437
License Expense	300	-
Other	27	12
	<u>\$ 2,873</u>	<u>\$ 3,060</u>

## 8. Convertible Notes

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. As of September 30, 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 September 30, 2022, the fair value of the Bonds was determined to be \$10.9 million. The Company recognized a change in fair value of the Notes related to the instrument-specific credit risk of \$0.4 million in the comprehensive loss and a change in fair value related to non-instrument specific credit risk of \$1.2 million in the consolidated statement of operations during the quarter ended September 30, 2022.

## 9. Leases

The Company leases certain office space and laboratory space. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present. The Company does not recognize right-of-use assets or lease liabilities for leases determined to have a term of 12 months or less. Many of the Company's leases contain variable non-lease components such as maintenance, taxes, insurance, and similar costs for the spaces it occupies.

Variable executory costs, as it relates to net leases, are excluded from the calculation of the lease liability. Variable executory costs include costs relating to utilities, repairs, maintenance, insurance, common area expenses, and taxes paid for the leased asset during its economic life. The Company expenses the variable lease payments in the period in which it incurs the obligation to pay such variable amounts and will be included in variable lease costs in the leases footnote disclosure. These variable lease payments are not included in the Company's calculation of its right-of-use assets or lease liabilities.

Upon adoption of ASC 842, the Company elected the package of practical expedients and the hindsight practical expedient but did not elect the easement practical expedient which is not applicable to the Company as the Company does not have any ground leases. In accordance with the package of practical expedients, the Company has not reassessed any of their existing or expired contracts or any other agreements that were previously concluded to not contain a lease for the following practical expedient guidance: (1) whether the arrangement is or contains a lease, (2) lease classification and (3) whether previously capitalized costs continue to qualify as initial direct costs.

The Company leases certain office space and laboratory space. At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present.

The Company leased lab space in Salt Lake City, UT. Under a five-year lease, the term of which commenced in November 2019. The lease included an option for the Company to extend the lease one additional period of 60 months. The company has not exercised this option. The lessor may terminate the lease if the Company is in default as defined in the original lease agreement. The Company does not have the ability to early terminate the lease. The Company has measured its right-of-use assets and lease liabilities based on lease terms ending in October 2024.

The Company leased lab space in New York City, NY under an initial three-month lease, the term of which commenced in February 2019. The lease originally renewed automatically at the end of the initial three-month term for an additional two-month period if neither party terminated the lease. In January 2022 the Company signed an amendment extending the lease through December 31, 2022. Either party could originally terminate the lease at the end of the initial three-month term and at the end of all subsequent renewal periods, however, after the most recent Amendment, only the lessor may terminate the agreement for cause as detailed in the original agreement. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company leased lab space in St. Petersburg, FL from under an initial one-year term, the term of which commenced in January 2022. The lease originally renewed at the Company's option for a maximum of six, one month-terms at the end of the lease. In June 2022 the Company signed an amendment extending the lease through January 31, 2024. The lessor may terminate the lease if the Company is in default as defined in the original lease agreement. The Company does not have the ability to early terminate the lease. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company leased office space in New York City, NY under an initial month-to-month term, the term of which commenced in June 2018. The lease did not have termination or formal renewal options however the Company can renew their spaces if they

are still needed and are still available at the end of the term. In May 2022 the Company signed an amendment extending the lease through March 31, 2023. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company leased office space in Hancock, NH under an initial month-to-month term, the term of which commenced in November 2020. The lease renews automatically every month unless written notice to terminate the lease is provided by either party. Either party can terminate the lease with written notice (no advance notice period required). The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company identified and assessed the following significant assumptions in recognizing its right-of-use assets and corresponding lease liabilities during the adoption of ASC 842:

As the Company's leases do not provide an implicit rate, it estimated the incremental borrowing rate for each lease by considering average interest rates on commercial real estate loans during 2022 which range from 2.2%, for established borrowers with excellent credit ratings, to 18.0%, for borrowers early in the business' life cycle and with lower credit ratings. As the Company is an early-stage biotech company with minimal revenues, the Company concluded that a 10.0% IBR, the approximate midpoint between the average commercial real estate loans during 2022, is an appropriate discount rate to use for the Utah ease, which was the only lease existing as of the adoption date.

The following table shows the lease balance sheet classification of leases for the quarter ended September 30, 2022 (in thousands):

(in thousands)	<u>September 30, 2022</u>
<b>Assets</b>	
Operating lease right-of-use assets, net of accumulated amortization	\$ 239
<b>Liabilities</b>	
Current	\$ 128
Operating lease liabilities, current	
Non-current	
Operating lease liabilities, non-current	\$ 128
Total lease liabilities	<u>\$ 256</u>

The following table shows the lease costs for the quarter ended September 30, 2022 (in thousands):

Lease costs (in thousands)	Statement of operations classification	September 30, 2022
Operating lease costs	Operating expenses: research and development	\$ 32
Short term lease costs	Operating expenses: research and development	\$ 8
Short term lease costs	Operating expenses: general and administrative	\$ 38
Short term lease costs	Cost of goods sold	\$ 91
Total lease costs		<u>\$ 170</u>

Other information	September 30, 2022
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	\$ 33

Remaining lease term - operating leases (in years)	2.1
Discount rate - operating leases	10%

The future minimum payments for noncancelable leases with terms in excess of one year as of September 30, 2022 are payable as follows (in thousands):

2023	\$	125
2024	\$	157
2025	\$	46
Total	\$	<u>328</u>



## **10. Commitments and contingencies**

### ***Leases***

Lease payments under operating leases as of September 30, 2022 and information about the Company's lease arrangements are disclosed in Note 9, "Leases".

### ***DaVita Inc.***

In January 2021, the Company entered into a Master Care Coordination Services Agreement with DaVita Inc. ("DaVita") whereby DaVita agreed to provide certain care coordination services to covered patients as requested by the Company ("Care Coordination Services"), with those covered patients identified by the Company's KidneyIntelX diagnostic and subject to insurance coverage ("Covered Patients"). Those covered patients may also be included in connection with various clinical research studies or quality improvement initiatives (each a "Study"). Both parties agreed to establish a joint steering committee to oversee the care coordination services and exchange and evaluate results of each Study. The Company will pay DaVita a monthly fixed fee based on the number of covered patients. The initial term of the agreement is three years with successive one-year renewals upon written mutual agreement of both parties. For the Care Coordination Services furnished by DaVita (or an affiliate of DaVita) under the terms of a statement of work, the Company shall pay DaVita (or such affiliate of DaVita) a monthly payment of (a) \$10.00 in respect of Care Coordination Services multiplied by the number of Covered Patients, plus (b) \$3.50, in respect of patient engagement services, multiplied by the number of Covered Patients. No expenses were recorded in the periods related to this agreement.

### ***Employment agreements***

The Company has entered into employment agreements with certain key executives providing for compensation and severance in certain circumstances, as set forth in the agreements.

### ***Retirement plans***

The Company maintains a defined contribution 401(k) retirement plan which covers all U.S. employees. Employees are eligible after three months of service. Under the 401(k) plan, participating employees may make contributions in an amount up to the limit set by the Internal Revenue Service on an annual basis. The Company has a safe harbor plan and makes contributions to employee accounts of 5% of compensation (as defined by the plan). The Company contributed \$0.1 million for the three months ended September 30, 2022, and \$0.05 million for the three months ended September 30, 2021.

### ***Legal proceedings***

The Company is not a party to any litigation and does not have contingency reserves established for any litigation liabilities. At each reporting date, the Company evaluates whether or not a potential loss amount or a potential range of loss is probable and reasonably estimable under the provisions of the authoritative guidance that addresses accounting for contingencies.



## **11. License and services agreements**

### ***Mount Sinai license and sponsored research agreements***

On May 30, 2018, the Company entered into an exclusive license agreement (the "ISMMS License Agreement") and, on March 7, 2019, a sponsored research agreement (the "ISMMS SRA") with Mount Sinai. Under the terms of the ISMMS License Agreement, ISMMS granted the Company (i) an exclusive, sublicensable license to use certain patent rights covering specific inventions concerning the utilization of biomarkers guided artificial intelligence techniques for detecting kidney functional decline (the "ISMMS Technology"), (ii) a non-exclusive license under unregistered licensed copyrights and licensed know-how and (iii) an exclusive option to obtain licensed technology conceived after May 30, 2018. The Company is obligated to pay Mount Sinai \$1.5 million and \$7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of \$50.0 million and \$300.0 million, respectively. The Company is also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, the Company is obligated to pay Mount Sinai between 15% and 25% of any consideration received from a sublicensee.

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred \$0.9 million under the ISMMS SRA for the three months ended September 30, 2022 and \$0.4 million in research and development expenses under the ISMMS SRA for the three months ended September 30, 2021.

### ***Mount Sinai clinical trial agreement***

In July 2021, the Company entered into a Clinical Trial Agreement (the "CTA") with ISMMS. Under the CTA, ISMMS will undertake a sponsored clinical trial entitled, "A prospective decision impact trial of KidneyIntelX in patients with Type 2 diabetes and existing chronic kidney disease". The clinical trial is to be conducted at ISMMS with Renalytix agreeing to pay ISMMS in accordance with the agreed upon budget. The clinical trial is expected to last up to four years with a total estimated budget of \$3.2 million. As of September 30, 2022, amounts due to ISMMS under the CTA totaled \$0.2 million and \$0.1 million was expensed during the quarter ended September 30, 2022.

### ***Joslin diabetes center agreement***

In October 2018, the Company purchased a worldwide exclusive license agreement (the "Joslin Agreement") with the Joslin Diabetes Center, Inc. ("Joslin") that was previously entered into with EKF Diagnostics Holding Plc ("EKF"), a related party, in July 2017. The license agreement provides the Company with the right to develop and commercialize licensed products covering a novel methodology of diagnosing and predicting kidney disease using certain biomarkers (the "Joslin Diabetes Technology").

Under the terms of the Joslin Agreement, the Company is obligated to pay Joslin aggregate commercial milestone payments of \$0.3 million and \$1.0 million in commercial milestone payments upon achieving worldwide net sales of licensed products and processes of \$2.0 million and \$10.0 million, respectively. In the three months ended September 30, 2022 the Company accrued for the \$0.3 million milestone payment as the Company achieved \$2.0 million of worldwide net sales in the calendar year. The Company is also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. The company accrued \$0.1 million of royalties due to Joslin for the quarter ended September 30, 2022. Moreover, the Company is obligated to pay Joslin 25% of any consideration received from a sublicensee.

The Joslin Agreement initially expires on July 31, 2025 and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that the Company ceases developing or commercializing licensed products or processes, if the Company fails to maintain certain required insurance policies, and if the Company fails to pay patent expenses related to the licensed patents.





## **12. Shareholders' equity**

### *Ordinary shares*

As of September 30, 2022, the Company had 79,411,245 ordinary shares authorized on a fully diluted basis. Each share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends as may be declared by the board of directors. From inception through September 30, 2022, no cash dividends have been declared or paid.

### 13. Share-based compensation

#### *Equity Incentive Plans*

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 September 30, 2022, there were 11,197,527 shares available for future issuance under the Plans.

The Plans are 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 September 30, 2022 consist of 2,984,801 options which vest equally over twelve quarters following the grant date, 994,600 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 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.

The Company recorded share-based compensation expense in the following expense categories in the condensed consolidated statements of operations for the three months ended September 30, 2022 and 2021 (in thousands):

	Three Months Ended September 30,	
	2022	2021
Research and development	\$ 67	\$ 179
General and administrative	696	795
	<u>\$ 763</u>	<u>\$ 974</u>

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying ordinary shares at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the three months ended September 30, 2022 and 2021 were determined using the methods and assumptions discussed below.

- o The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.
- o The expected volatility is based on historical volatility of the publicly-traded common stock of a peer group of companies.
- o The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- o The expected dividend yield is none because the Company has not historically paid and does not expect for the foreseeable future to pay a dividend on its ordinary shares.

For the three months ended September 30, 2022 and 2021, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	<b>Three Months Ended September 30,</b>	
	<b>2022</b>	<b>2021</b>
Expected term (in years)	6.1	6.11
Expected volatility	66.9%	66.9%
Risk-free rate	3.2%	1.02%
Dividend yield	-%	-%

There were no options granted during the three months ended September 30, 2022. The weighted average fair value of the options granted during the three months ended September 30, 2021 was \$0.71 per share.

The following table summarizes the stock option granted to employees and non-employees for the three months ended September 30, 2022:

	<b>Number of shares under option plan</b>	<b>Weighted- average exercise price per option</b>	<b>Weighted- average remaining contractual life (in years)</b>
Outstanding at June 30, 2022	4,554,901	\$ 5.34	8.1
Granted	80,000	\$ 1.71	6.1
Exercised	-	-	
Forfeited	(115,500)	\$ 12.76	8.9
Outstanding at September 30, 2022	4,519,401	\$ 5.09	8.1
Exercisable at September 30, 2022	3,549,894	\$ 4.06	6.8
Vested and expected to vest at September 30, 2022	4,519,401	\$ 5.09	8.1

As of September 30, 2022, there was \$3.8 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 2.18 years. The aggregate intrinsic value of options outstanding and options exercisable at September 30, 2022 and 2021 was \$0.0 million and \$17.4 million, respectively.

#### ***Employee Share Purchase Plan***

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

Under the ESPP, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the board of directors or remuneration committee. Eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of the Company's common stock on the first day of the offering period or on the purchase date. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not purchase more than \$25,000 worth of the Company's common stock for each calendar year in which such rights are outstanding. During the three months ended September 30, 2022, 131,412 shares were purchased under the ESPP.

In accordance with the guidance in ASC 718-50 - *Compensation - Stock Compensation*, the ability to purchase shares of the Company's common stock at 85% of the lower of the price on the first day of the offering period or the last day of the offering

period (i.e. the purchase date) represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, share-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period. The Company recognized share-based compensation expense of \$0.02 million three months ended September 30, 2022, and \$0.02 million during the three months ended September 30, 2021, related to the ESPP.



## **14. Related-party transactions**

### ***EKF Diagnostic Holdings***

During the three months ended September 30, 2022, the Company incurred expenses of \$0.03 million, related to employees of EKF who provided services to Renalytix and this amount is included in general and administrative expenses in the condensed consolidated statements of operations. During the three months ended September 30, 2021, the Company incurred expenses of \$0.1 million, respectively, related to employees of EKF who provided services to Renalytix and this amount is included in general and administrative expenses in the condensed consolidated statements of operations.

### ***Icahn School of Medicine at Mount Sinai***

In May 2018, the Company secured its cornerstone license agreement with the Icahn School of Medicine at Mount Sinai ("ISMMS") for research and clinical study work and intended commercialization by the Company (see Note 11). As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's IPO on AIM in November 2018, the subsequent sale of ordinary shares in July 2019 and the Company's IPO on Nasdaq in July 2020. As of September 30, 2022, amounts due to ISMMS totaled \$3.9 million and are included within accrued expenses and other current liabilities and accounts payable on the balance sheet. During the three months ended September 30, 2022, the Company incurred expenses of \$1.4 million which are included in research and development expenses in the condensed consolidated statement of operations. During the three months ended September 30, 2021, the Company incurred expenses of \$1.3 million which are included in research and development expenses in the condensed consolidated statement of operations.

### ***Kantaro Biosciences LLC***

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, 2021, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services to be provided under the Advisory Agreement was \$2.0 million and the fair value of the Class A units received from Kantaro was \$2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions which include discount rates and future cash flows, among others. As a result of the prior year impairment charge discussed in Note 3, the carrying value of the Kantaro investment was written down to zero.

A contributing factor to the impairment consideration for Kantaro was lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees. Based on these circumstances, the Company adjusted the liability to perform services to Kantaro under the Advisory Agreement during the year ended June 30, 2021. As of September 30, 2022, the total liability associated with the services was \$0.04 million, of which the total amount is classified as a current liability within the Payables to affiliate - current line on the balance sheet.

For the three months ended September 30, 2022, the Company recognized \$0.03 million, in the statement of operations related to services performed under the Advisory Agreement. For the three months ended September 30, 2022, \$0.02 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 three months ended September 30, 2021, the Company recognized \$0.1 million in the condensed consolidated statements of operations related to services performed under the Advisory Agreement. For the three months ended September 30, 2021, \$0.03 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.03 million were

included within general and administrative expense, respectively.

In addition to the equity granted at formation, in May 2020 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 \$0.08 million and an additional \$0.17 million thereafter. Each loan bears interest at a per year 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 based on each investor's proportionate ownership). The Company loaned Kantaro \$0.25 million and initially recorded a note receivable. The Company elected to recognize the equity investment losses based on the ownership level of each specific investment and will continue to record equity method losses until the amount of the loan receivable is reduced to zero. The loan had a carrying value of approximately \$0.04 million at September 30, 2022 and \$0.05 million at June 30, 2022.

## 15. Net loss per ordinary 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 September 30, 2022 and 2021 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 common stock outstanding, as they would be anti-dilutive:

	Three Months Ended September 30,	
	2022	2021
Stock options to purchase common stock	4,519,401	4,155,125
Conversion of convertible note	2,071,264	-
	<u>6,590,665</u>	<u>4,155,125</u>

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