

# Renalytix Reports Financial Results for Third Quarter of Fiscal Year 2022

June 30, 2022

LONDON and SALT LAKE CITY, June 30, 2022 (GLOBE NEWSWIRE) -- Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligenceenabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported financial results for the quarter ended March 31, 2022.

# Recent Highlights (including post period events)

- Successful completion of \$30.0 million financing package (\$26.8 million gross proceeds)
- Multiple data presentations at the American Diabetes Association (ADA) 82nd Scientific Sessions® meeting
- Focused on the value of KidneyIntelX testing in patients with type 2 diabetes (T2D) and early-stage chronic kidney disease (CKD):
  - KidneyIntelX ability to assess risk of heart failure hospitalization and death in large international diabetic kidney disease patient cohort (also published in Kidney360)
  - KidneyIntelX testing in 1,112 adult diabetic kidney disease (DKD) patients at Mount Sinai Health System demonstrated utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients.
- Continued KidneyIntelX testing volume growth
- Over 3,000 KidneyIntelX risk scores generated for Mount Sinai Health System patients and over 300 at Wake Forest Baptist Health
- 33 state Medicaid programs contracted to date
- New coverage for KidneyIntelX by the largest private payer in Illinois with 8.1 million members
- KidneyIntelX coverage from the largest independent provider network in North Carolina, South Carolina and Virginia, with over 100,000 health care providers in-network

# Third Quarter 2022 Financial Results

During the three months ended March 31, 2022, the Company recognized \$0.8 million of revenue (Q3 FY21: \$0.6 million). Cost of revenue for the three months ended March 31, 2022 was \$0.7 million (Q3 FY21: \$0.2 million).

Operating expense for the three months ended March 31, 2022 was \$14.7 million compared to \$8.5 million during the prior year period.

Within operating expenses, research and development expenses were \$3.9 million for the three months ended March 31, 2022, an increase of \$0.8 million, from \$3.1 million for the three months ended March 31, 2021. The increase was driven by employee related expenses, lab supplies and professional fees associated with the utility studies at Mount Sinai, Wake Forest and University of Utah.

General and administrative expenses were \$10.8 million for the three months ended March 31, 2022, increasing by \$5.3 million from \$5.5 million for the three months ended March 31, 2021. The increase was primarily due to a \$4.3 million increase in compensation, reimbursable expenses and related benefits, including share-based payments, due to increased headcount, a \$0.7 million increase in consulting and professional fees including marketing expense, a \$0.2 million increase in computers, software and IT costs, and a \$0.1 million increase in other operating expenses.

Net loss attributable to ordinary shareholders was \$14.7 million for the three months ended March 31, 2022 compared to \$8.8 million for the prior year period.

Cash and cash equivalents totaled \$32.4 million as of March 31, 2022. This was prior to the completion of the \$26.8 million (gross) financing package, further details of which were announced on March 31, 2022, which completed post-period end on April 8, 2022.

The Company also intends to file with the Securities and Exchange Commission a shelf registration statement on Form F-3 pursuant to which the Company may offer and sell up to \$300 million of its ordinary shares, ordinary shares in the form of ADSs, debt securities and warrants, including the intention to enter into a sales agreement with a sales agent pursuant to which the Company may sell, from time to time, at its option, up to \$50 million of ADSs through the sales agent in "at the market" transactions on Nasdaq.

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:**

US/Canada Participant Toll-Free Dial-In Number: (833) 614-1551 US/Canada Participant International Dial-In Number: (914) 987-7290 United Kingdom International Dial-In Number: 0800 0288 438 United Kingdom Local Dial-In Number: 0203 1070 289 Conference ID: 1546327

#### Webcast Registration link: https://edge.media-server.com/mmc/p/y3zwhkuk

For further information, please contact:

Renalytix plc James McCullough, CEO

Stifel (Nominated Adviser, Joint Broker) Alex Price / Nicholas Moore

Investec Bank plc (Joint Broker)

Gary Clarence / Daniel Adams

Walbrook PR Limited Paul McManus / Lianne Applegarth / Alice Woodings

# CapComm Partners

Peter DeNardo

About Renalytix

Renalytix (LSE: RENX) (NASDAQ: RNLX) is the global founder and leader in the new field of bioprognosis<sup>™</sup> for kidney health. The company has engineered a new solution that enables early-stage chronic kidney disease progression risk assessment. The Company's lead product, KidneyIntelX<sup>™</sup>, 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 <u>www.kidneyintelx.com</u>). For more information, visit <u>www.renalytix.com</u>.

### **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 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 21, 2021, 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 and nine months ended March 31, 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, 2021, filed with the Securities and Exchange Commission on October 21, 2021 (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 helping lead the charge to introduce simple, more accurate prognosis and effective care management for the estimated 850 million people worldwide with chronic kidney disease. In the United States alone, chronic kidney disease affects close to an estimated 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 physicians is essential if we are to stem the growing social cost and suffering associated with kidney disease.

With our lead product, KidneyIntelX, our goal is to shift the conversation from kidney disease to kidney health through a more accurate understanding

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of early-stage risk. With the deployment of KidneyIntelX this year, Renalytix has become a global leader in the new field of bioprognosis, a biologydriven approach to risk assessment that relies on integrating information from a simple blood draw and a patient's health record to produce an accurate picture of kidney health. A doctor can use KidneyIntelX results to act on patients at high risk of kidney disease progression or failure at an early stage where active management and therapeutics have the best opportunity to impact outcomes and cost before it is too late.

We have crossed key data, reimbursement and regulatory hurdles during a relatively short time-period since we began operations in 2018 through a public listing on AIM, a market of the London Stock Exchange. We subsequently expanded our capital base by raising a further \$17 million in July 2019, \$85 million through a listing on the Nasdaq Global Market in July 2020, and \$26.8 million through an equity and convertible note financing in April 2022. The commercial roll-out of our kidney health solution, KidneyIntelX, is underscored by:

- A 10-year government-wide contract with the U.S. General Services Administration at \$950 per test
- · Hiring of sales, medical science liaison, and customer service support for national coverage
- Joint program with American Diabetes Association® to improve overall kidney health in patients with type 2 diabetes
- The Centers for Medicare & Medicaid Services awarding a national price of \$950 per test
- 33 state Medicaid program authorization contracts
- Launch of myIntelX national provider access portal for on-line ordering of KidneyIntelX
- Partnerships announced with the Mount Sinai Health System, University of Utah, Atrium Health, Wake Forest Baptist Health, Capital District Physicians' Health Plan (CDPHP), St. Joseph's Health and Singing River Health System
- · New York State Department of Health approval
- A distinct Common Procedural Terminology (CPT) Code for reimbursement granted by the American Medical Association
- 26 private payor coverage determinations
- Multi-center, peer reviewed clinical studies validating the clinical effectiveness and utility dynamics of KidneyIntelX for identifying patients at high risk for rapid kidney disease progression and/or kidney failure in the earliest stages of kidney disease

### 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, accounting for more than 40% of new cases, and DKD patients are the highest contributors to emergency room dialysis. Unfortunately, many DKD patients are unaware that they either have kidney disease or that their disease has been progressing, often uncontrolled, for many years and now find themselves making difficult decisions about late-stage treatments. We believe this predicament is largely avoidable and have built the KidneyIntelX care model to ultimately provide the estimated 210,000 primary care physicians in the United States with a comprehensive suite of information and guidelines driven follow-on action.

KidneyIntelX was designed as an expandable platform which is able to add indicated uses and a monitoring capability, all within an FDA regulated framework. Potential expansion may include extending into additional populations of chronic kidney disease patients beyond those with diabetes, including patients of African ancestry with the APOL1 high-risk genotype. We also intend to develop solutions for use in other large chronic disease patient populations, like cardiovascular disease.

# **Operational Progress**

Renalytix is pleased to report continued KidneyIntelX testing volume growth under a backdrop of increasing insurance coverage and new medical systems coming on-line. In our New York launch market, KidneyIntelX utilization has continued to accelerate through the end of March. We have now provided integrated advanced risk assessment services for over 3,000 patients with kidney disease and diabetes. In addition, over the past six months KidneyIntelX clinical testing has now been brought on-line within the Veterans Health Administration, our Albany New York physician led payor partner, Atrium Health and Wake Forest Baptist Health in the Southeast. We estimate our current serviceable patient population with insurance payment availability for KidneyIntelX testing at greater than one million patients.

Our commercial focus in calendar year 2022 remains on regions where our health system partnerships provide a base for adoption of KidneyIntelX testing. As of the end of March 2022, we have four regional sales managers and 12 account executives focused on the Veterans Health Administration. We have also added a regional manager and three sales executives focused on the New York market. This sales effort is being complemented by a medical education effort led by a team of seven medical liaisons and our partnership with the National Kidney Foundation to offer chronic kidney disease education nationally. We expect additional health providers to be brought on-line in the next few months, including recently announced St. Josephs Health in central New York State, and now expect to exceed 20 health centers running KidneyIntelX patient risk assessment in calendar 2022.

#### Reimbursement and Regulatory

Insurance payment remains the biggest factor to driving KidneyIntelX adoption and revenue growth. Over the past year, we have consistently demonstrated that we can secure payment for KidneyIntelX from a diverse set of insurance sources. To date, we have received 26 private insurance

coverage contracts, and contracted with 33 state Medicaid programs. Our \$950 reportable pricing structure has been established by National Medicare and a 10-year government contract covering, among others, payment for patient testing in the Veterans Health Administration Medical system.

Under our real-world evidence study program with Mount Sinai Health System, several metrics are pointing to greater efficiencies being achieved with KidneyIntelX physician onboarding, including the fact that time to first KidneyIntelX order from education/training has dropped to three days currently from eleven days in our fiscal second quarter.

Our partnership model with Mount Sinai Health System under our real-world evidence study program is validating the engagement of population health departments and KidneyIntelX electronic health record integration to improving primary care physician access to advanced prognosis in kidney disease. The advantages of an integrated KidneyIntelX solution in a large hospital system include 1) broad physician education and care pathway support, 2) electronic test ordering and reporting, 3) advanced data analytics and 4) patient education and support.

Our laboratory testing infrastructure and personnel include the capacity to scale efficiently as distribution opportunities expand in fiscal 2022 and 2023. We have now achieved CAP Accreditation and ISO Certification for both Salt Lake City and New York City laboratories, all important parts to expand testing services and qualify for certain reimbursement.

Continuing to build a robust peer-reviewed published data pool is a compelling driver for payer and market adoption. In January, data was published in American Journal of Nephrology demonstrating the value of KidneyIntelX for monitoring patient response to new drug therapy in 1,325 multinational clinical trial cohort patients. And in February, at the World Congress of Nephrology, we provided results demonstrating KidneyIntelX provides robust prognostic information to better predict the future rate of decline in kidney function compared with current standard diagnostics in patients with early-stage chronic kidney disease and type 2 diabetes.

#### Current trading and outlook

We reported testing revenues of \$0.8 million in our fiscal third quarter, compared to \$0.7 million in Q2 and \$0.5 million in Q1. Volumes with Mount Sinai continued to increase in Q3 and, while the first half of Q4 saw an initial reduction in these due to temporary changes in procedures and automation systems at Mount Sinai, the second half of Q4 has seen a return to Q3 levels. We anticipate that continued increasing Mount Sinai volumes, coupled with additional hospital systems coming on-line in fiscal 2023, will result in corresponding increases in testing volumes. Based on information available as of today, we anticipate Renalytix's revenue for the 2022 fiscal year ending June 30, 2022 to be approximately \$2.9 million (of which \$2.7 million is testing revenue), up from \$1.5 million in FY 2021, of which \$0.4 million was testing revenue.

In the fiscal second quarter, we made a number of one-time investments pertaining to the recruiting, equipping, training and deploying of our salesforce, and associated marketing and other expenses to enable them to be most successful in the field. We are pleased with the sales infrastructure we now have in place to pursue the large Veterans Health Administration and commercial hospital opportunities that are available to us. As we grow the business, we plan to exercise continued prudent cash discipline.

### FINANCIAL REVIEW

#### Financial review of the three-month period ended March 31, 2022 and comparison to prior year period

Our operating loss for the three months ended March 31, 2022, was \$14.5 million (March 31, 2021: \$8.1 million) and the net loss attributable to ordinary shareholders for the three months ended March 31, 2022, was \$14.7 million (March 31, 2021: \$8.8 million).

#### Revenue

During the three months ended March 31, 2022, we recognized \$0.8 million of revenue related to KidneyIntelX testing. There was \$0.1 million of revenue related to KidneyIntelX testing and \$0.6 million of professional services revenue for the three months ended March 31, 2021.

### Cost of Revenue

During the three months ended March 31, 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 March 31, 2021.

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

Research and development expenses increased by \$0.8 million, from \$3.1 million for the three months ended March 31, 2021 to \$3.9 million for the three months ended March 31, 2022. The increase was driven by employee related expenses, lab supplies and professional fees associated with the utility studies at Mount Sinai, Wake Forest and University of Utah.

# General and Administrative Costs

General and administrative expenses increased by \$5.3 million, from \$5.5 million for the three months ended March 31, 2021 to \$10.8 million for the three months ended March 31, 2022. The increase was primarily due to a \$4.3 million increase in compensation, reimbursable expenses and related benefits, including share-based payments, due to increased headcount, a \$0.7 million increase in consulting and professional fees including marketing expense, a \$0.2 million increase in computers, software and IT costs, and a \$0.1 million increase in other operating expenses.

#### Performance of Contract Liability to Affiliate

In May 2020, we and the Icahn School of Medicine at Mount Sinai entered into an operating agreement to form a joint venture, Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. During the three months ended March 31, 2022, we recognized \$0.03 million of expense related to the performance of our contract liability with Kantaro compared to \$0.1 million during the three months ended March 31, 2021. This represents the allocation of costs related to performing services on behalf of Kantaro.

# Foreign Currency Loss

During the three months ended March 31, 2022, we recorded an unrealized foreign exchange gain of \$2.4 million primarily attributable to intercompany loans and cash balances denominated in currencies other than the functional currency. We recorded an unrealized foreign currency loss of \$1.1 million during the three months ended March 31, 2021.

## Fair Value Adjustments to VericiDx Investment

We account for our investment in VericiDx using the equity method of accounting and have elected to use the fair value option to value the investment. During the three months ended March 31, 2022, we recorded a loss of \$2.6 million to adjust the VericiDx investment to fair value. We recorded a gain of \$0.3 million during the three months ended March 31, 2021.

# Financial review of the nine months ended March 31, 2022 and comparison to prior year period

Our operating loss for the nine months ended March 31, 2022, was \$40.1 million (March 31, 2021: \$22.1 million) and the net loss attributable to ordinary shareholders for the nine months ended March 31, 2022, was \$40.1 million (March 31, 2021: \$24.9 million).

### Revenue

During the nine months ended March 31, 2022, we recognized \$1.9 million of revenue related to KidneyIntelX and \$0.2 million of revenue related to services performed for AstraZeneca. During the nine months ended March 31, 2021, we recognized \$0.4 million of pharmaceutical services revenue related to the statement of work with AstraZeneca, \$0.6 million of services revenue related to work performed for Mount Sinai and \$0.1 million of KidneyIntelX testing revenue.

### Cost of Revenue

During the nine months ended March 31, 2022, cost of revenue consisted of \$1.4 million primarily attributable to KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. There was \$0.4 million of cost of revenue for the nine months ended March 31, 2021.

## **Research and Development Costs**

Research and development expenses increased by \$4.7 million, from \$7.3 million for the nine months ended March 31, 2021 to \$12.0 million for the nine months ended March 31, 2022. The increased R&D expense was driven by employee related expenses and professional fees associated with the utility studies at Mount Sinai, Wake Forest and University of Utah.

# General and Administrative Costs

General and administrative expenses increased by \$12.7 million, from \$16.3 million for the nine months ended March 31, 2021 to \$29.0 million for the nine months ended March 31, 2022. The increase was primarily due to a \$8.7 million increase in compensation, reimbursable expenses and related benefits, including share-based payments, due to increased headcount, a \$2.7 million increase in consulting and professional fees including marketing expense, a \$1.0 million increase in computers, software and IT costs and a \$0.3 million increase in other operating expenses.

# Performance of Contract Liability to Affiliate

In May 2020, we and the Icahn School of Medicine at Mount Sinai entered into an operating agreement to form a joint venture, Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. During the nine months ended March 31, 2022, we recognized \$0.2 million of expense related to the performance of our contract liability with Kantaro compared to \$0.9 million during the nine months ended March 31, 2021. This represents the allocation of costs related to performing services on behalf of Kantaro.

# Foreign Currency Gain (Loss)

During the nine months ended March 31, 2022, we recorded an unrealized foreign exchange gain of \$4.6 million primarily attributable to intercompany loans and cash balances denominated in currencies other than the functional currency. We recorded an unrealized foreign currency loss of \$8.8 million during the nine months ended March 31, 2021.

# Fair Value Adjustments to VericiDx Investment

We account for our investment in VericiDx using the equity method of accounting and have elected to use the fair value option to value the investment. During the nine months ended March 31, 2022, we recorded a loss of \$4.6 million to adjust the VericiDx investment to fair value. We recorded a gain of \$5.4 million during the nine months ended March 31, 2021.

# Liquidity and Capital Resources

Since our inception, we have incurred net losses. As of March 31, 2022, we had an accumulated deficit of \$127.6 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 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 March 31, 2022, we had cash and cash equivalents of \$32.4 million. We believe that our pre-financing cash balance together with the aggregate \$26.8 million of gross proceeds raised in April 2022 will enable us to fund our current operating plan for at least the next 12 months. 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.

Until such time, if ever, as we can generate substantial revenue from sales of KidneyIntelX tests, we expect to finance our cash needs through a combination of securities offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. Historically, we have not obtained traditional bank debt financing. EKF provided short-term debt financing that was repaid in November 2018 and we received a loan in an aggregate principal amount of \$255,000 pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. In April 2022, we announced that we had closed a fundraising transaction comprising (1) an \$8.8 million equity subscription at \$7.25 per ADS (\$3.625 per ordinary share) and (2) a \$21.2 million aggregate principal amount of convertible bonds with an issue price of 85 per cent of the principal amount (resulting in net cash proceeds of \$18.02 million), 5.5% coupon (payable in cash or shares at the Company's option) and a 5-year term. This transaction is further described in our Report on Form 6-K filed on April 1, 2022. See Note 13 to our financial statements found elsewhere in this report.

### **Cash Flows**

## Net cash used in operating activities

During the nine months ended March 31, 2022, net cash used in operating activities was \$31.8 million and was primarily attributable to our \$40.1 million net loss including a \$4.7 million net change in our operating assets and liabilities and \$3.7 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to a \$7.0 million increase in accrued expenses and other current liabilities, driven by a \$4.0 million current liability related to funds received from the Icahn School of Medicine at Mount Sinai ahead of the April equity investment, offset by a \$2.9 million decrease in prepaid expenses and other current assets. Noncash charges were primarily related to \$2.9 million in share-based compensation and the \$4.6 million fair value adjustment of our Verici securities, offset by a \$4.2 million unrealized foreign exchange gain.

During the nine months ended March 31, 2021, we used \$23.3 million of cash in operating activities primarily attributable to our net loss of \$25.5 million. This use of cash was partially offset by \$2.2 million in noncash items such as depreciation and amortization, share-based compensation, equity losses in Kantaro, change in fair value of our VericiDx investment and foreign exchange remeasurement losses. The net cash outflow from changes in our operating assets and liabilities remained relatively unchanged.

#### Net cash used in investing activities

During the nine months ended March 31, 2022, net cash used in investing activities was \$0.7 million, primarily attributable to \$0.6 million for purchases of lab and office equipment and \$0.1 million in software development costs.

During the nine months ended March 31, 2021, net cash used in investing activities was \$0.5 million and primarily attributable to \$1.0 million in proceeds from short-term investments. This was offset by \$0.9 million for the purchase of lab and office equipment, \$0.4 million of software development costs and an increase of \$0.2 million related to our note receivable from a related party. In addition, cash decreased by \$0.06 million due to the deconsolidation of VericiDx.

#### Net cash used in financing activities

During the nine months ended March 31, 2022, net cash provided by financing activities was \$0.3 million and was primarily attributable to \$0.1 million in proceeds from the issuance of ordinary shares under our employee stock purchase program as well as \$0.2 million in proceeds from the exercise of stock options.

During the nine months ended March 31, 2021, net cash provided by financing activities was \$76.9 million and was primarily attributable to \$79.2 million of proceeds from our IPO on the Nasdaq Global Market which was partially offset by offering costs of \$2.3 million associated with the IPO that were paid in the period.

#### Cash and Cash Equivalents

We had cash and cash equivalents of \$32.4 million as of March 31, 2022, which decreased from \$65.2 million as of June 30, 2021 due to normal operations as we continue to commercialize KidneyIntelX and grow our business. This was prior to the completion of the \$26.8 million (gross) financing package, further details of which were announced on March 31, 2022, which completed post-period end on April 8, 2022.

### 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 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 no 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 \$1.07 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 issue

## **RENALYTIX PLC**

# CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(in thousands, except share and per share data)	March 31, 2022		June 30, 2021		
Assets					
Current assets:					
Cash and cash equivalents	\$ 32,3	61 \$	65,128		
Accounts receivable	1,0	)9	594		
Prepaid expenses and other current assets	3,8	37	993		
Note receivable from Kantaro		75	75		
Receivable from affiliates		1	1		
Total current assets	37,2	33	66,791		
Property and equipment, net	2,8	50	2,490		
Investment in VericiDx	4,3	22	9,295		
Investment in Kantaro		11			
Total assets	\$ 44,4	<u> 86</u>	78,576		
Liabilities and Shareholders' Equity					
Current liabilities:					
Accounts payable	\$ 2,0	56 \$	1,403		
Accounts payable – related party	1,0	)7	361		
Accrued expenses and other current liabilities	6,6	39	4,602		
Accrued expenses – related party	5,0	31	224		
Deferred revenue		67	122		
Payable to affiliate – current	1	37	350		
Total current liabilities	15,0	37	7,062		
Other liabilities		4	53		
Total liabilities	15,0	51	7,115		

# Commitments and contingencies (Note 8)

Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 76,869,831 shares authorized; 72,308,930		
and 72,197,286 shares issued and outstanding at March 31, 2022 and June 30, 2021,		
respectively	220	220
Additional paid-in capital	153,604	150,407
Accumulated other comprehensive income	3,156	8,276
Accumulated deficit	 (127,565)	 (87,442)
Total shareholders' equity	 29,415	 71,461
Total liabilities and shareholders' equity	\$ 44,466	\$ 78,576

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

# **RENALYTIX PLC**

# CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

	Tł	ree Months Ended	Three Months Ended		Nine Months Ended		Nine Months Ended	
(in thousands, except share data)	Ма	rch 31, 2022	Ма	arch 31, 2021	Ма	arch 31, 2022	Ма	rch 31, 2021
Revenue	\$	812	\$	619	\$	2,139	\$	1,019
Cost of revenue		685		169		1,404		426
Gross profit		127		450		735		593
Operating expenses:								
Research and development		3,887		3,104		12,019		7,311
General and administrative		10,809		5,547		29,012		16,258
Performance of contract liability to affiliate		(32)		(130)		(163)		(889)
Total operating expenses		14,664		8,521		40,868		22,680
Loss from operations		(14,537)		(8,071)		(40,133)		(22,087)
Equity in net (losses) earnings of affiliate		(26)		(8)		11		(229)
Foreign currency gain (loss), net		2,447		(1,095)		4,587		(8,783)
Fair value adjustment to VericiDx investment		(2,575)		337		(4,596)		5,355
Other (expense) income, net		(4)		61		8		228
Net loss		(14,695)		(8,776)		(40,123)		(25,516)
Net loss attributable to noncontrolling interest		—		—		—		(611 )
Net loss attributable to ordinary shareholders		(14,695)		(8,776)		(40,123)		(24,905)
Other comprehensive income (loss):								
Foreign exchange translation adjustment		(2,632)		1,163		(5,120)		9,504
Comprehensive loss		(17,327)		(7,613)		(45,243)		(16,012)
Comprehensive loss attributable to noncontrolling interest								(72)
Comprehensive loss attributable to Renalytix	\$	(17,327)	\$	(7,613)	\$	(45,243)	\$	(15,940)
Net loss per ordinary share—basic and diluted	\$	(0.20)	\$	(0.12)	\$	(0.56)	\$	(0.35)
Weighted average ordinary shares—basic and diluted		72,297,309		72,035,126		72,274,979		71,294,883

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

# **RENALYTIX PLC**

# CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

	Ordinar	Ordinary shares		 Additional paid-in		Accumulated other comprehensive		Accumulated		Total areholders'
(in thousands, except share and per share data)	Shares	А	mount	 capital	inco	ome (loss)	_	deficit		equity
Balance at July 1, 2021	72,197,286	\$	220	\$ 150,407	\$	8,276	\$	(87,442)	\$	71,461
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
Exercise of stock options	68,224	—	111	—	_	111
Stock-based compensation expense	—	—	941	—	_	941
Currency translation adjustments	—	_	—	97	—	97
Net loss		 	 	 	 (15,322)	 (15,322)
Balance at December 31, 2021	72,308,930	\$ 220	\$ 152,662	\$ 5,788	\$ (112,870)	\$ 45,800
Exercise of stock options	—	_	_	—	_	—
Stock-based compensation expense	—	—	942	—	—	942
Currency translation adjustment	—	_	—	(2,632)	—	(2,632)
Net loss		 	 	 	 (14,695)	 (14,695)
Balance at March 31, 2022	72,308,930	\$ 220	\$ 153,604	\$ 3,156	\$ (127,565)	\$ 29,415

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

# RENALYTIX PLC

# CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands,	Ordinary shares					dditional other (deficit) equity paid-in comprehensive Accumulated attributable to		Noncontrolling	Total shareholders'
except share and per share data)	Shares	Amo	ount	capital	income (loss)	deficit	Renalytix	interests	equity
Balance at July 1, 2020 Sale of ordinary shares in initial public offering on Nasdaq, net of offering costs and	59,416,134	\$	179	\$ 69,650	\$ (1,200)	\$ (52,717)	\$ 15,912	\$ —	\$ 15,912
underwriting fees of \$9,007 VericiDx distribution in	12,613,500		40	76,094	—	_	76,134	—	76,134
specie Share-based compensation	_		_	1,638	(25)	_	1,613	(1,613)	_
expense Currency translation	_		_	501	_	_	501	_	501
adjustments Net loss			_		2,255	 (7,221)	2,255 (7,221 )	(67) (393)	2,188 (7,614)
Balance at September 30, 2020 VericiDx noncontrolling	72,029,634	\$	219	\$ 147,883	\$ 1,030	\$ (59,938)	\$ 89,194	\$ (2,073)	\$ 87,121
interest upon deconsolidation Share-based	_		_	_	_	_	_	2,296	2,296
compensation expense Currency translation	_		_	525	_	_	525	_	525
adjustments Net loss			_		6,086	(8,908)	6,086 (8,908 )	(5) (218)	6,081 (9,126)
Balance at December 31, 2020 Shares issued	72,029,634	\$	219	\$ 148,408	\$ 7,116	\$ (68,846)	,	<u> </u>	\$ 86,897
under the employee share purchase plan	17,652		_	111	_	_	111	_	111

Stock-based compensation expense	_	_	631	_		— 631	_	631
Currency translation adjustment	_	_	_	1,163		— 1,163	_	1,163
Net loss Balance at March					(8,7	76) (8,776	)	(8,776)
31, 2021	72,047,286	<u>\$ 219</u>	\$ 149,150	\$ 8,279	\$ (77,62	22) \$ 80,026	<u>\$                                    </u>	\$ 80,026

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

# RENALYTIX PLC

# CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

Cash flows from operating activities: Net loss Adjustments to reconcile net loss to net cash used in operating activities Gain on VericiDx deconsolidation Depreciation and amortization Share-based compensation	\$	(40,123)	\$	
Adjustments to reconcile net loss to net cash used in operating activities Gain on VericiDx deconsolidation Depreciation and amortization	\$	(40,123)	\$	
Gain on VericiDx deconsolidation Depreciation and amortization			+	(25,516
Depreciation and amortization				
•		—		(46
Share based componention		354		182
Share-based compensation		2,880		1,657
Realized gain on short-term investments		_		(18
Equity in (net earnings) losses of affiliate		(11)		229
Fair value adjustment to VericiDx investment		4,596		(5,355
Unrealized foreign exchange loss (gain) loss		(4,169)		5,546
Changes in operating assets and liabilities:				
Accounts receivable		(415)		(68
Prepaid expenses and other current assets		(2,915)		(1,951
Receivable from affiliates		_		(143
Accounts payable		673		240
Accounts payable – related party		646		_
Accrued expenses and other current liabilities		2,091		2,491
Accrued expenses – related party		4,893		287
Deferred revenue		(55)		
Payable to affiliate – current		(163)		(890
Other liabilities		(39)		53
Net cash used in operating activities		(31,757)		(23,302
Cash flows from investing activities:				
Purchases of property and equipment		(619)		(879
Software development costs		(103)		(428
Proceeds from short-term investments		_		1,000
Note receivable – related party		_		(167
Decrease in cash (VericiDx deconsolidation)		_		(62
Net cash used in investing activities		(722)		(536
Cash flows from financing activities:				
Gross proceeds from the issuance of ordinary shares, net of underwriting fees		_		79,182
Payment of offering costs		_		(2,305
Proceeds from the issuance of ordinary shares under employee share purchase plan		120		111
Proceeds from exercise of stock options		197		
Net cash provided by financing activities		317		76,988
Effect of exchange rate changes on cash		(605)		3,633
Net (decrease) increase in cash and cash equivalents		(32,767)		56,783
Cash and cash equivalents, beginning of period		65,128		13,293
Cash and cash equivalents, beginning of period	\$	32,361	\$	70,076
	φ	32,301	φ	70,070
Supplemental noncash investing and financing activities:	¢		¢	7-
Deemed distribution of VericiDx ordinary shares	\$	_	\$ ¢	75
Conversion of distribution of VericiDx note receivable into VericiDx ordinary shares	\$	_	\$ ¢	2,556
Software development costs in accounts payable and accrued expenses Purchase of property and equipment in accounts payable and accrued expenses	\$ \$	 50	\$ \$	195 31

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.

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. To date, the Company has generated de minimis revenue from the sales of KidneyIntelX tests. 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 \$127.6 million as of March 31, 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 \$32.4 million as of March 31, 2022 together with the aggregate \$26.8 million of gross proceeds raised in April 2022, are sufficient to fund the projected operations for at least the next twelve months from the issuance date of these financial statements. Substantial additional capital will be needed by the Company to fund its 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 prospects.

### 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 March 31, 2022 and its results of operations for the three and nine months ended March 31, 2022 and 2021 and cash flows for the nine months ended March 31, 2022 and 2021. Operating results for the three and nine months ended March 31, 2022, are not necessarily indicative of the results that may be expected for the year ending June 30, 2022. 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 and related notes as of and for the year ended June 30, 2021.

# 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 condensed 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 condensed 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 condensed 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 condensed 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, 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, fair value measurements (including those related to VericiDx), the payable to affiliates and the consolidation and deconsolidation of variable interest entities.

#### 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 condensed 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. 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 four customers for the nine months ended March 31, 2022, and two customer for the nine months ended March 31, 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 March 31, 2022 and June 30, 2021, 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.

## 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).

#### 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 March 31, 2022, the Company had a cash balance of \$32.4 million. As of June 30, 2021, the Company had a cash balance of \$65.1 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 March 31, 2022 or June 30, 2021.

#### 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.

#### 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 and nine months ended March 31, 2022, the Company recognized \$0.03 million and \$0.16 million, respectively, related to the performance of the contract liability with Kantaro. During the three and nine months ended March 31, 2021, the Company recognized \$0.13 million and \$0.89 million, respectively, 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 March 31, 2022 and June 30, 2021.

#### VericiDx Limited

As the Company can exert significant influence over, but does not control, VericiDx's operations through representation on VericiDx's board of directors, the Company accounts for this investment as an equity method investment and has elected the fair value option because VericiDx's stock price is readily observable via the London Stock Exchange. Under the fair value option, the investment in VericiDx is recorded at fair value at each reporting period with subsequent changes in fair value reported in the condensed consolidated statements of operations and comprehensive loss. Based on closing stock price of VericiDx, the fair value of the investment in VericiDx was \$4.3 million at March 31, 2022 and \$9.3 million at June 30, 2021. During the three and nine months ended March 31, 2022, the Company recorded a fair value adjustment of \$(2.6) million and \$(4.6) million, respectively, in the condensed consolidated statements of operations and comprehensive loss. During each of the three and nine months ended March 31, 2022, the Company recorded a fair value adjustment of \$(2.6) million and \$(4.6) million, respectively, in the condensed consolidated statements of operations and comprehensive loss. During each of the three and nine months ended March 31, 2021, the Company recorded a fair value adjustment of \$0.3 million and \$5.4 million in the condensed consolidated statements of operations and comprehensive loss. The Company owned 5.8% of the ordinary shares of VericiDx at March 31, 2022 and 6.9% of the ordinary shares of VericiDx at June 30, 2021.

#### 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 5). 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.

#### **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 the only other changes in shareholders' equity is from foreign currency translation.

# 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 March 31, 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.

As of March 31, 2022 and 2021, there were 4,560,901 and 3,683,858 shares, respectively, issuable upon exercise of outstanding options that were anti-dilutive and excluded from diluted loss per share for the three and nine months ended March 31, 2022 and 2021, respectively.

# 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 February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02" or "Topic 842"), in order to increase transparency and comparability among organizations by, among other provisions, recognizing lease assets and lease liabilities on the balance sheet for those leases classified as operating leases under previous U.S. GAAP. For public companies, ASU 2016-02 is effective for fiscal years beginning after December 15, 2018 (including interim periods within those periods) using a modified retrospective approach and early adoption is permitted. In transition, entities may also elect a package of practical expedients that must be applied in its entirety to all leases commencing before the adoption date, unless the lease is modified, and permits entities to not reassess (a) the existence of a lease, (b) the lease classification or (c) the determination of initial direct costs, as of the adoption date, which effectively allows entities to carryforward accounting conclusions under previous U.S. GAAP. In July 2018, the FASB issued ASU 2018-11, *Leases (Topic 842): Targeted Improvements*, which provides entities an optional transition method to apply the guidance under Topic 842 as of the adoption date, rather than as of the earliest period presented. In June 2020, the FASB issued ASU No 2020-05 that further delayed the effective date of Topic 842 to fiscal years beginning after July 1, 2022, and interim periods within those years. The Company is currently evaluating the impact of adopting this guidance to its condensed consolidated financial statements.

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 January 2020, FASB issued ASU 2020-01, Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815) ("ASU2021-01"), which, generally, provides guidance for investments in entities accounted for under the equity method of accounting. ASU 2020-01 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The Company is currently evaluating the impact of adopting this guidance to its 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 and nine months ended March 31, 2022, the Company recognized \$0.8 million and \$1.9 million, respectively, of testing services revenue. Sales tax and other similar taxes are excluded from revenues. During the three and nine

months ended March 31, 2021, the Company recognized \$0.1 million and \$0.1 million, respectively 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 and nine months ended March 31, 2022, the Company recognized \$0.0 million and \$0.2 million, respectively, of pharmaceutical services revenue where performance obligations are satisfied over time. During the, the three and nine months ended March 31, 2021 Company recognized \$0.0 million and \$0.4 million, respectively, 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 and nine months ended March 31, 2022. During the three and nine months ended March 31, 2021 the company recognized \$0.6 million and \$0.6 million, respectively, of other services revenue where performance obligations are satisfied at a point in time.

#### 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 21 months.

The following table summarizes the changes in deferred revenue:

	March	June 30, 2021		
Balance, beginning of period	\$	122	\$	—
Deferral of revenue		67		250
Revenue recognized		(122)		(128)
Balance, end of period	\$	67	\$	122

#### 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:

	Fair value measurement at reporting date using								
(in thousands)	(Level 1)			(Level 2)	(Level 3)	el 3)			
March 31, 2022									
Assets:									
Equity investment in VericiDx	\$	4,322	\$	—	\$		—		
June 30, 2021									
Assets:									
Equity investment in VericiDx	\$	9,295	\$	_	\$		—		

#### 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. Based on sales forecasts, the Company concluded that its equity method investment in Kantaro was impaired due to a shift in focus from COVID antibody testing to promoting vaccination in the United States and European

Union. As a result of this shift, demand for COVID antibody testing decreased. The forecasts indicate there is a prolonged period of time that Kantaro's fair value is below the carrying value of the investment and the discounted and undiscounted cash flows are also below the carrying value of the investment. For these reasons, the Company concluded the decline in value is other-than-temporary. As such, during the year ended June 30, 2021, the Company determined the fair value using a discounted cash flow model and concluded that the fair value of the equity method investment in Kantaro was zero.

# 6. Property and equipment

Property and equipment consists of (in thousands):

	March	June 30, 2021		
Lab equipment	\$	1,144	\$	592
Software		1,574		1,534
Office equipment		121		84
Office furniture		35		35
Leasehold improvements		576		576
Construction in progress		79		_
Total		3,529		2,821
Less accumulated depreciation and amortization		(679)		(331)
	\$	2,850	\$	2,490

Depreciation expense was \$0.1 million and \$0.2 million for the three and nine months ended March 31, 2022, respectively. Depreciation expense was \$0.05 million and \$0.1 million for the three and nine months ended March 31, 2021, respectively.

As of March 31, 2022 and June 30, 2021, there was \$1.1 million and \$1.3 million, respectively, of unamortized capitalized software development costs. Amortization expense related to capitalized software development costs was \$0.03 million and \$0.1 million for the three and nine months ended March 31, 2022, respectively. Amortization expense related to capitalized software development costs was \$0.03 million and \$0.05 million for the three and nine months ended March 31, 2022, respectively.

As of March 31, 2022, the expected amortization expense for software for the next five years and thereafter is as follows:

2022 (remaining three months)	\$ 33
2023	130
2024	130
2025	130
2026	130
Thereafter	 567
	\$ 1,120

# 7. Accrued expenses and other current liabilities

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

	March 31, 2022			June 30, 2021		
Consulting and professional fees	\$	328	\$	954		
Research and development		875		—		
Payroll and related benefits		4,701		3,493		
Deferred offering		504		—		
Other		281		155		
	\$	6,689	\$	4,602		

## 8. Commitments and contingencies

#### Leases

The Company entered into operating lease agreements for office space and laboratory testing facilities with terms ranging from month-to-month to five years. During the three and nine months ended March 31, 2022, the Company recognized rent expense of \$0.1 million and \$0.3 million, respectively. During the three and nine months ended March 31, 2021, the Company recognized rent expense of \$0.1 million and \$0.3 million, respectively, related to all leases.

The future minimum payments for noncancelable leases with terms in excess of one year for each fiscal year are as follows (in thousands):

2022 (remaining three months)	\$ 33
2023	134
2024	138
2025	46
2026	—
Thereafter	 
Total	\$ 351

### 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 plus (b) \$3.50, in respect of patient engagement services, multiplied by the number of Covered Patients.

#### 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 and \$0.3 million for the three and nine months ended March 31, 2022, respectively, and the Company contributed \$0.05 million and \$0.1 million for the three and nine months ended March 31, 2021, respectively.

### 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.

#### 9. 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. Furthermore, the Company agreed to carry out and fund a clinical utility study for KidneyIntelX at an estimated cost of \$0.7 million.

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred no expenses under the ISMMS SRA for the three months ended March 31, 2022 and \$0.4 million in research and development expenses under the ISMMS SRA for the nine months ended March 31, 2022. The Company incurred \$0.03 million and \$0.3 million in research and development expenses under the ISMMS SRA for the three and nine months ended March 31, 2021, respectively.

#### Mount Sinai COVID-19 sponsored research agreement

In August 2020, and as amended in December 2020, the Company entered into a Multi-center Assessment of Survivors for Kidney Disease after COVID-19 Study (the "MASKeD-COVID Study") with ISMMS. This study involves multiple major academic institutions, including Mount Sinai, University of Michigan, Johns Hopkins, Yale University and Rutgers University. The goal of this study is to understand the long-term kidney epidemiology of CKD in survivors of COVID-19 and validate KidneyIntelX for prediction of long-term kidney outcomes post-COVID hospitalization that will inform further prevention, treatment and clinical care.

Under the terms of the MASKeD-COVID Study, the Company is obligated to pay for all direct and indirect costs incurred under the sponsored research agreement in an amount totaling \$1.8 million. As of March 31, 2022, amounts due to ISMMS under the MASKeD-COVID Study totaled \$1.0 million. No expenses were recorded during the three months ended March 31, 2022 and \$0.6 million was expensed during the nine months ended March 31, 2022. The Company did not incur any expenses related to this program during the three and nine months ended March 31, 2021.

## 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. 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 as of March 31, 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.

# 10. Shareholders' equity

# Ordinary shares

As of March 31, 2022, the Company had 76,869,831 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 March 31, 2022, no cash dividends have been declared or paid.

### 11. 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 March 31, 2022, there were 2,642,062 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 March 31, 2022 vest equally over twelve quarters following the grant date, with the exception of 80,724 options which vested immediately when granted, 1,077,100 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary and 500,000 which vest 1/12th on the commencement date and equally over twelve quarters following the one year anniversary and 500,000 which vest 1/12th on the commencement date and equally over twelve quarters following the one year anniversary. If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

The Company recorded share-based compensation expense in the following expense categories in the condensed consolidated statements of operations for the three and nine months ended March 31, 2022 and 2021 (in thousands):

	Three Mo	Three Months Ended March 31,			Nine Months Ended March 31,			
	2022			2021		2022		2021
Research and development	\$	78	\$	237	\$	378	\$	631
General and administrative		845		374		2,432		973
	\$	923	\$	611	\$	2,810	\$	1,604

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 nine months ended March 31, 2022 and 2021 were determined using the methods and assumptions discussed below.

- 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.
- The expected volatility is based on historical volatility of the publicly-traded common stock of a peer group of companies.
- 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.
- 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 nine months ended March 31, 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:

	Nine Months Ended	Nine Months Ended March 31,		
	2022	2021		
Expected term (in years)	6.0	5.8		
Expected volatility	65.77 %	67.10%		
Risk-free rate	1.43 %	0.50 %		
Dividend yield	—%	—%		

The weighted average fair value of the options granted during the nine months ended March 31, 2022 and 2021 was \$6.02 and \$4.51 per share,

#### respectively.

The following table summarizes the stock option granted to employees and non-employees for the nine months ended March 31, 2022:

	Number of shares under option plan	Weighted- average exercise price per option		Weighted- average remaining contractual life (in years)	
Outstanding at June 30, 2021	4,265,958	\$	4.73	8.2	
Granted	515,000	\$	10.06		
Exercised	(100,724)	\$	1.89		
Forfeited	(119,333)	\$	6.67		
Outstanding at March 31, 2022	4,560,901	\$	4.99	8.7	
Exercisable at March 31, 2022	3,213,850	\$	3.44	8.1	
Vested at March 31, 2022	4,560,901	\$	4.99	8.7	

As of March 31, 2022, there was \$8.1 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 1.91 years. The aggregate intrinsic value of options outstanding and options exercisable at March 31, 2022 was \$4.4 million and \$4.4 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 is outstanding. During the nine months ended March 31, 2022, 10,920 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 \$0.2 million and \$0.07 million during the three and nine months ended March 31, 2022, respectively, and \$0.02 million and \$0.05 million during the three and nine months ended March 31, 2021, respectively, related to the ESPP.

#### 12. Related-party transactions

# **EKF Diagnostic Holdings**

During the three and nine months ended March 31, 2022, the Company incurred expenses of \$0.1 million and \$0.2 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. During the three and nine months ended March 31, 2021, the Company incurred expenses of \$0.1 million and \$0.1 million, respectively, related to employees of EKF who provided services to Renalytix and this amount is included in general and administrative expenses of \$0.1 million and \$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 9). 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 March 31, 2022, amounts due to ISMMS totaled \$2.1 million and are included within accrued expenses and other current liabilities and accounts payable on the balance sheet. During the three and nine months ended March 31, 2022, the Company incurred expenses of \$0.2 million and \$2.9 million, respectively, which are included in research and development expenses in the condensed consolidated statement of operations. During the three and nine months ended March 31, 2021, the Company incurred expenses of \$0.2 million are included in research and development expenses in the condensed consolidated statement of operations. During the three and nine months ended March 31, 2021, the Company incurred expenses of \$0.2 million are included in research and development expenses in the condensed consolidated statement of operations.

On March 31, 2022, the Company announced a financing package which included a \$4.0 million dollar equity investment by ISMMS. At the time of the deal announcement and prior to completion of the financing transaction, the Company received \$4.0 million in funds from ISMMS which were recorded as a \$4.0 million current liability due to ISMMS, which is to be satisfied upon successful completion of the financing transaction and issuance of equity in April 2022, as noted in Note 13.

### 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 5, 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 March 31, 2022, the total liability associated with the services was \$0.2 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 and nine months ended March 31, 2022, the Company recognized \$0.1 million and \$0.1 million, respectively, in the statement of operations related to services performed under the Advisory Agreement. For the three and nine months ended March 31, 2022, \$0.01 million and \$0.1 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.02 million and \$0.06 million were included in general and administrative expense, respectively. For the three and nine months ended March 31, 2021, the Company recognized \$0.1 million and \$0.9 million, respectively, in the condensed consolidated statements of operations related to services performed under the Advisory Agreement. For the three and nine months ended March 31, 2021, the Company recognized \$0.1 million and \$0.9 million, respectively, in the condensed consolidated statements of operations related to services performed under the Advisory Agreement. For the three and nine months ended March 31, 2021, \$0.04 million and \$0.4 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and \$0.04 million and \$0.2 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 \$0.075 million at both March 31, 2022 and June 30, 2021.

### VericiDx

During the three and nine months ended March 31, 2022, the Company paid the salary of an executive of VericiDx and VericiDx has agreed to reimburse the Company for those amounts. As of March 31, 2022, amounts due from VericiDx were recorded within the related party receivable line of the balance sheet and totaled less than one thousand dollars. As of March 31, 2021, amounts due from VericiDx totaled \$0.2 million.

# 13. Subsequent events

The Company has evaluated subsequent events from the condensed consolidated balance sheet date through the date at which the condensed consolidated financial statements were available to be issued, and determined there are no other items requiring disclosure beyond those disclosed below.

In April 2022, the Company announced the successful completion of (i) an \$8.8 million equity subscription (the "Equity Fundraise") and (ii) a subscription for convertible bonds with an aggregate principal amount of \$21.2 million, raising aggregate gross proceeds of \$26.8 million for the Company.

The convertible bonds were issued at 85% of the principal amount (resulting in net cash proceeds of \$18.02 million, 5.5% coupon (payable in cash or shares at the Company's option) and a 5 year term. The Equity Fundraise consisted of subscriptions for 2,221,794 Ordinary Shares ("New Ordinary Shares") and 103,447 American Depositary Shares ("ADSs") (the "New ADS"), at a price of \$7.25 per ADS (the "Reference ADS Price") or \$3.625 per Ordinary Share, equivalent to approximately 276 pence per Ordinary Share.