RenalytixAI Reports Financial Results for First Quarter of Fiscal Year 2021

November 25, 2020

NEW YORK, Nov. 25, 2020 (GLOBE NEWSWIRE) -- Renalytix AI plc (LSE: RENX) (NASDAQ: RNLX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported financial results for the quarter ended September 30, 2020.

Recent Highlights

- Launched KidneyIntelX within the Mount Sinai Health System
- Submitted final package to FDA seeking clearance of KidneyIntelX
- Announced collaboration with AstraZeneca to develop and launch precision medicine strategies for cardiovascular, renal and metabolic diseases
- Completed spin-out of Verici Dx (previously FractalDx)
- Achieved dual listing on Nasdaq Global Market

First Quarter 2021 Financial Results
Operating expense for the three months ended September 30, 2020 was $5.4 million compared to $2.0 million during the prior year period.

Research and development expenses were 1.7 million for the three months ended September 30, 2020, increasing $0.5 million from $1.2 million for the three months ended September 30, 2019. The increase R&D expense was due to increased headcount and the associated compensation and related benefits, including share-based payments.

General and administrative expenses were $4.1 million for the three months ended September 30, 2020, increasing $3.3 million from $0.8 million for the three months ended September 30, 2019. The increase was due to an increase in insurance costs, compensation and related benefits, including share-based payments, due to increased headcount, and in fees associated with the listing on Nasdaq.

Net loss attributable to ordinary shareholders was $7.2 million for the three months ended September 30, 2020 compared to $1.5 million in the prior year period.

Cash, cash equivalents and short-term investments of $82.3 million as of September 30, 2020. This includes $76.1 million from the Company's initial public offering on the Nasdaq Global Market after commissions, fees and offering expenses.

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About Kidney Disease
Kidney disease is now recognized as a public health epidemic affecting over 850 million people globally. The Centers for Disease Control and Prevention (CDC) estimates that 15% of US adults, or 37 million people, currently have chronic kidney disease (CKD). Further, the CDC reports that 9 out of 10 adults with CKD do not know they have it and 1 out of 2 people with very low kidney function who are not on dialysis do not know they have CKD*. Kidney disease is referred to as a "silent killer" because it often has no symptoms and can go undetected until a very advanced stage. Each year kidney disease kills more people than breast and prostate cancer. Every day, 13 patients in the United States die while waiting for a kidney transplant.
* https://www.cdc.gov/kidneydisease/publications-resources/2019-national-facts.html

About RenalytixAI
RenalytixAI is a developer of artificial intelligence-enabled clinical *in vitro* diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. RenalytixAI's products are being designed to make significant improvements in kidney disease diagnosis, transplant management, clinical care, patient stratification for drug clinical trials, and drug target discovery. For more information, visit www.renalytixai.com.

Forward Looking Statements

Statements contained in this 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 ability of KidneyIntelX to lower healthcare costs, improve patient quality of life and set a long-term standard of care, trends in our market and potential benefits of government policy change, the impact of COVID-19 on our business, our expectations for product development, strategic partnerships and collaborations, reimbursement decisions, clinical studies and regulatory submissions, and our business strategies and future growth. 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 SEC, including the “Risk Factors” section of our Annual Report. All information in this 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.

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RENALYTIX AI PLC

Operational Update and Financial Results for the Three Months Ended September 30, 2020

Unless otherwise indicated, all references in this report, to the terms “Renalytix,”“ Renalytix AI,” “ Renalytix AI plc,” “the company,” “we,” “us” and “our” refer to Renalytix AI 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, 2020, filed with the Securities and Exchange Commission on October 28, 2020 (our “Annual Report”) .

The statements in this discussion regarding our expectations regarding our market opportunity 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 the section titled “Forward-Looking Statements” above.

OPERATIONAL REVIEW

Company Overview

We are an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs. KidneyIntelX, our 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 electronic health record (“EHR”) systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease (“CKD”) allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk. CKD affects approximately 37 million individuals in the United States, significantly impacting their quality of life and, according to the United States Renal Data System’s 2019 Annual Data Report, resulting in Medicare spending of over $120 billion per year. In response to this substantial kidney disease burden, a U.S. Presidential Executive Order on Advancing American Kidney Health was issued in July 2019 to support change in kidney disease care. We believe we are well-positioned to help meet this urgent medical need with KidneyIntelX, a laboratory developed test (“LDT”), initially indicated for adult patients with type 2 diabetes and existing CKD, which is referred to as diabetic kidney disease (“DKD”). KidneyIntelX has already been granted a common procedural terminology (“CPT code”), national Medicare pricing and a positive coverage determination from a regional, private physician-led health insurance payor. Further, it has been granted breakthrough device designation from the U.S. Food and Drug Administration (the “FDA”). Building on these significant reimbursement and regulatory milestones, we believe our population health-based business model, which includes partnerships with healthcare systems, such as Mount Sinai Health System, will help facilitate commercial adoption of KidneyIntelX in the United States.

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The National Kidney Foundation estimates that one-third of adults in the United States are at risk of developing kidney disease. Advanced kidney disease is generally not reversible and, once the disease progresses to kidney failure, the only available treatments are long-term dialysis and kidney transplant. In 2016, more than 726,000 patients had end-stage kidney disease (“ESKD”), with more than 500,000 requiring dialysis at least three times a week. More than 100,000 patients begin dialysis each year to treat ESKD. Once on dialysis, patients typically experience a five-year mortality rate of up to 65%, about the equivalent rate for brain cancer. As of July 2019, nearly 100,000 Americans were on the waiting list to receive a kidney transplant and 13 patients die in the United States while waiting for a kidney transplant every day. Moreover, the kidney disease crisis is continuing to grow along with the increased prevalence of contributing risk factors, such as obesity and diabetes.

Managing a CKD population of this scale and associated healthcare costs presents a unique social challenge. The ability to predict which patients will experience progressive kidney function decline, kidney failure, initiation of long-term dialysis or kidney transplant, is critical to changing patient outcomes and health economics. In our clinical validation studies in patients with DKD, we observed that the Kidney Disease: Improving Global Outcomes (KDIGO) classification system, which is the standard clinical assessment to predict risk for progression of CKD, including DKD, only identified approximately 20% of patients that experienced an adverse kidney outcome as very high-risk patients with the recommendation of referral to a nephrologist, while KidneyIntelX identified nearly half of such patients.

We believe that the utilization of KidneyIntelX across large patient populations will have a significant impact on overall healthcare costs. Health economic benefits are projected to be derived from three key areas: (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. We have partnered with Boston Healthcare

Associates, or BHA, to develop a health economic model analyzing the cost and care pathway for patients with DKD at all stages of the disease and the potential cost savings of implementing and utilizing KidneyIntelX. According to the BHA study, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in under 24 months and deliver a cost savings of up to $1.3 billion over five years per 100,000 patients with DKD.

Several federal policy and economic events, including the U.S. Presidential Executive Order on Advancing American Kidney Health issued in July 2019 and recent changes in U.S. reimbursement law, are helping disrupt the kidney disease clinical and commercial environment, highlighting the pressing need for solutions such as KidneyIntelX. We believe these favorable policy trends, which began during the Obama administration, will continue to build under a Biden administration and will support broader commercial adoption of KidneyIntelX and other derivative products contemplated in our diagnostics development planning. In addition, in August 2020, the U.S. Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, submitted for public comment a rule ("Medicare Coverage of Innovative Technology") which, if finalized, would provide an automatic National Medicare Coverage Determination for diagnostic devices that have received breakthrough device designation upon the effective date of the promotional approval by the FDA. The automatic coverage period shall continue for a period of four years, during which manufacturers of breakthrough devices may develop additional evidence regarding the applicability of their products to the Medicare population, so they might continue Medicare coverage beyond the initial four years. We believe that this new proposed CMS rule making, if adopted in its current form, could have a material positive impact on addressable market population with insurance coverage for KidneyIntelX if we obtain FDA clearance for KidneyIntelX.

Business Highlights

Launch of KidneyIntelX at Mount Sinai

In September 2020, we announced the initiation of KidneyIntelX clinical test reporting within the Mount Sinai Health System ("Mount Sinai") in New York City. In addition to patient testing and risk assessment, a central component of this operational milestone was the physician education and support program developed in close collaboration with leadership of the Mount Sinai Departments of Medicine and Population Health Science and Policy, with input from patient advocacy groups and the broader clinical community. This expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website, www.kidneyintelx.com. We believe this education and support program will be an important resource to help improve care for early stage DKD patients at Mount Sinai and support future deployments of KidneyIntelX.

Submission to FDA seeking clearance of KidneyIntelX

In August 2020, we filed a submission seeking clearance of KidneyIntelX with the FDA. This FDA filing builds on our regulatory and commercialization program, which includes our June 2020 announcement that the New York State Department of Health has issued a clinical laboratory permit for commercial clinical testing of KidneyIntelX. In May 2019, we announced that KidneyIntelX was granted breakthrough device designation by FDA, the first such designation for an artificial intelligence-enabled *in vitro* diagnostic for kidney disease publicly announced by any company. We are now seeking FDA clearance for the intended use of KidneyIntelX, in conjunction with clinical evaluation, as an aid to further assess the risk of progressive decline in kidney function within a period of up to five years in patients over the age of 21 with type 2 diabetes and existing CKD. Patients with CKD and type 2 diabetes account for approximately 25-30% of the estimated 37 million U.S. patients with CKD. Performance data we provided in our FDA 510(k) submission was based on a multi-center validation study of more than 1,100 patients that demonstrated that KidneyIntelX accurately identifies patients with type 2 diabetes in CKD stages 1, 2 and 3 who are at highest risk of progressive decline in kidney function and/or kidney failure.

COVID-19 studies

The current COVID-19 pandemic has had a devastating impact around the world. Many reports indicate that acute kidney injury occurs in approximately 20% to 40% of patients hospitalized with COVID-19, is often severe (including need for acute dialysis), and data from Mount Sinai during the initial U.S. surge indicated that 70% of patients that develop acute kidney injury in the setting of COVID-19 either die in the hospital or do not recover kidney function by discharge. We plan to investigate the use of KidneyIntelX for patients with COVID-19 in two clinical studies. The first study, entitled "Pred-MAKER" (Prediction of Major Adverse Kidney Events and Recovery) involves acutely ill patients with COVID-19 admitted to Mount Sinai. The second study, "MASKeD-COVID" (Multi-center Assessment of Survivors for Kidney Disease after COVID-19) is designed 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.

AstraZeneca collaboration

In August 2020, we announced a collaboration with AstraZeneca (LSE/STO/NASDAQ: AZN) to develop and launch precision medicine strategies for cardiovascular, renal, and metabolic diseases. The first stage in the collaboration is examining the uptake of, and patient adherence to, treatments for diabetes as well as common complications of CKD, including hyperkalemia and anemia. The study will provide key insights into the impact of the KidneyIntelX platform to optimize utilization of therapeutics in CKD under current standard of care protocols. Based on the insights gained from the first stage, a multi-center, randomized controlled trial will be initiated to evaluate the impact of KidneyIntelX testing and care navigation software on uptake and adherence to new potassium-binding agents in patients with CKD and hyperkalemia. We believe that this approach will accomplish the following: (1) help improve physician uptake and patient adherence to existing potassium-binding therapeutics and other approved products in CKD through early identification of previously hidden high-risk patient groups; (2) accelerate patient identification and recruitment for clinical trials; and (3) complement commercialization efforts with outcomes from KidneyIntelX results. Importantly, this collaboration extends the potential impact of KidneyIntelX to populations beyond the first indicated use, DKD, that is approved with New York State and under breakthrough review with the FDA. Hyperkalemia affects approximately 10-20% of patients with CKD or chronic heart failure. Anemia affects 15% of patients with CKD, and nearly 50% of individuals with advanced CKD.

FractalDx (Verici Dx) spin-off

In April 2020, the Company created a wholly-owned subsidiary, Verici Dx Limited ("Verici Dx"), to hold technology in-licensed from the Icahn School of Medicine at Mount Sinai in late 2018. In May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to Verici Dx in exchange for $2.0 million, which was satisfied by the issuance of convertible loan notes of Verici Dx to the Company.

We announced on July 8, 2020 that the share capital of Verici Dx had been re-designated into 59,416,134 A Shares of £0.001 each and one golden share of £0.001 (the "Golden Share") and that Renalytix would retain the Golden Share and its associated controlling voting rights. Subsequent to that

announcement, the Company entered into a declaration of trust whereby Renalytix AI plc has declared that it holds the Golden Share as nominee and on trust for certain Directors of RenalytixAI and accordingly, the Company itself has no ongoing beneficial interest in Verici Dx shares. This triggered a reconsideration event for ongoing consolidation of Verici Dx and since the Company was still the primary funding source for Verici Dx, the Company continued to hold a controlling financial interest in Verici Dx and continued to consolidate Verici Dx. Consequently, the Company recognized noncontrolling interest of $1.6 million to reflect Verici Dx's distribution of A shares and the Golden Share.

On November 3, 2020, Verici Dx completed its initial public offering (the "Verici IPO") on AIM thus triggering another reconsideration event for ongoing consolidation of Verici Dx. The Verici IPO resulted in the Company no longer having a controlling financial interest and no longer having a majority equity interest in Verici Dx.

Nasdaq dual listing

In July 2020, we completed a dual listing on the Nasdaq Global Market through the issuance of American Depository Shares under ticker symbol "RNLX," expanding our institutional investor base and raising net capital of approximately $76.1 million after commissions, fees and offering expenses. We maintain our listing on the AIM market of London Stock Exchange plc under the symbol "RENX."

Impact of COVID-19

The extent of the impact of the COVID-19 pandemic on our business, operations and regulatory and commercialization timelines will depend on certain developments, including the duration and spread of the outbreak and its impact on our partners, laboratory sites, and other third parties with whom we do business, as well as its impact on regulatory authorities and our key scientific and management personnel. For example, to the extent possible, we are conducting business as usual, with necessary or advisable modifications to employee travel and employee work locations. We will continue to actively monitor the rapidly evolving situation related to COVID-19 and may take further actions that alter our business operations, including those that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees, partners and shareholders. At this point, the extent to which the COVID-19 pandemic may impact our business, operations and regulatory and commercialization timelines remains uncertain.

FINANCIAL REVIEW

Financial review of the three-month period ended September 30, 2020

The operating loss for the three months ended September 30, 2020, was $5.4 million (September 30, 2019: $2.0 million) and the net loss attributable to ordinary shareholders for the three months ended September 30, 2020, was $7.2 million (September 30, 2019: loss of $1.5 million).

Research and Development Costs

Research and development expenses increased by $0.5 million, from $1.2 million for the three months ended September 30, 2019 to $1.7 million for the three months ended September 30, 2020. The increase R&D expense was due to increased headcount and the associated compensation and related benefits, including share-based payments.

General and Administrative Costs

General and administrative expenses increased by $3.3 million, from $0.8 million for the three months ended September 30, 2019 to $4.1 million for the three months ended September 30, 2020. The increase was due to a $1.0 million increase in insurance costs, $0.8 million increase in legal and accounting fees as a result of listing on Nasdaq, $0.6 million in compensation and related benefits, including share-based payments, due to increased headcount, $0.4 million increase in consulting and professional fees, $0.3 million increase in recruiting expense, and an increase of $0.2 million in marketing, facility and other operating expenses.

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. During the three months ended September 30, 2020, we recognized $0.5 million related to the performance of our contract liability with Kantaro. This represents the allocation of costs related to performing services on behalf of Kantaro.

Equity Losses in Affiliate

As the Company can exert significant influence over, but does not control, the investee's operations through voting rights or representation on Kantaro's board of directors, the Company accounts for the investment using the equity method of accounting. During the three months ended September 30, 2020, we recognized $0.1 million in losses which represents our proportionate share of losses in Kantaro.

Other Income (Expense), net

During the three months ended September 30, 2020, we recognized a realized foreign exchange gain of $0.06 million which was offset by an unrealized foreign exchange loss of $2.2 million. During the three months ended September 30, 2019, we received $0.08 million of other income in relation to a collaboration with the University Medical Center Groningen, Netherlands as well as $0.01 million of interest income as a result of interest earned on cash deposits. We recognized a realized foreign exchange gain of $0.02 million during the three months ended September 30, 2019 and had an unrealized foreign exchange gain of $0.43 million.

Cash Flows

Net cash used in operating activities

During the three months ended September 30, 2020, net cash used in operating activities was $10.4 million and was primarily attributable to our $7.6 million net loss and $3.6 million in the net change in our operating assets and liabilities that was offset by $0.8 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to $3.8 million decrease in our prepaid expenses and other current assets. Noncash

charges were primarily related to share-based compensation expense of $0.5 million.

During the three months ended September 30, 2019, net cash used in operating activities was $1.7 million and was primarily attributable to our $1.5 million net loss and $0.2 million in noncash charges.

Net cash used in investing activities

During the three months ended September 30, 2020, net cash provided by investing activities was $0.4 million and primarily attributable to $1.0 million in proceeds in short term investments offset by $0.5 million for the purchase of lab and office equipment and $0.1 million of software development costs.

During the three months ended September 30, 2019, net cash used in investing activities was $13.3 million and primarily attributable to $14.3 million in purchases of short-term investments offset by net proceeds of $1.0 million related to our short-term investments.

Net cash used in financing activities

During the three months ended September 30, 2020, net cash provided by financing activities was $76.9 million and was primarily attributable to $79.2 million of proceeds from our initial public offering on the Nasdaq Global Market which was offset by offering costs of $2.3 million associated with the IPO that were paid in the period.

During the three months ended September 30, 2019, net cash provided by financing activities was $16.4 million and was primarily attributable to $17.3 million of proceeds from our secondary public offering on the AIM which was offset by offering costs of $0.9 million associated with the public offering.

Cash, cash equivalents and short-term investments

Net cash, cash equivalents and short-term investments of $82.3 million as of September 30, 2020 increased from $13.3 million as of June 30, 2020 primarily due to the net proceeds of our initial public offering on the Nasdaq Global Market.

Post-period end

On November 3, 2020, Verici Dx completed its IPO on AIM and raised gross proceeds of £14.5 million. Verici Dx previously issued the Company $2.5 million in convertible loan notes which reflects the consideration for the FractalDx assets and the funding the Company provided Verici Dx through October 28, 2020. Prior to the Verici IPO, on November 3, 2020, the Company gave notice to convert the existing $2.5 million convertible loan notes into 9,831,681 ordinary shares of Verici Dx.

RENALYTIX AI PLC

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(in thousands, except share and per share data)	September 30, 2020	June 30, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 82,253	$ 13,293
Short-term investments	—	982
Prepaid expenses and other current assets	4,378	551
Receivable from affiliate	18	18
Total current assets	86,649	14,844
Property and equipment, net	2,644	1,655
Deferred offering costs	—	2,364
Investment in affiliate	1,821	1,937
Note receivable from affiliate	83	83
Total assets	$ 91,197	$ 20,833
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,829	$ 2,218
Accrued expenses and other current liabilities	636	683
Note payable – current	161	120
Payable to affiliate - current	1,183	271
Total current liabilities	3,809	3,292
Payable to affiliate - noncurrent	173	1,544
Note payable - noncurrent	94	135
Total liabilities	4,076	4,971
Commitments and contingencies (Note 9)		

Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 75,438,492 and 62,444,992 shares authorized at September 30, 2020 and June 30, 2020, respectively; 72,029,634 and 59,416,134 shares issued and outstanding at September 30, 2020 and June 30, 2020, respectively	219	179
Additional paid-in capital	147,883	69,650
Accumulated other comprehensive income (loss)	1,030	(1,200)
Accumulated deficit	(59,938)	(52,717)
Total shareholders' equity attributable to Renalytix AI	89,194	15,912
Noncontrolling interest	(2,073)	—
Total shareholders' equity	87,121	15,912
Total liabilities and shareholders' equity	$ 91,197	$ 20,833

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

RENALYTIX AI PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(in thousands, except share data)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019
Operating expenses:		
Research and development	$ 1,745	$ 1,180
General and administrative	4,116	837
Performance of contract liability to affiliate	(458)	—
Total operating expenses and loss from operations	(5,403)	(2,017)
Equity in losses of affiliate	(116)	—
Other (expense) income, net	(2,095)	546
Net loss	(7,614)	(1,471)
Net loss attributable to noncontrolling interest	(393)	—
Net loss attributable to ordinary shareholders	(7,221)	(1,471)
Other comprehensive income (loss):		
Foreign exchange translation adjustment	2,255	(622)
Comprehensive loss	(5,359)	(2,093)
Comprehensive loss attributable to noncontrolling interest	(67)	—
Comprehensive loss attributable to Renalytix AI	$ (5,292)	$ (2,093)
Net loss per ordinary share—basic and diluted	$ (0.10)	$ (0.03)
Weighted average ordinary shares—basic and diluted	69,835,982	58,077,004

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

RENALYTIX AI PLC

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' (deficit) equity attributable to Renalytix AI	Noncontrolling interests	Total shareholders' (deficit) equity
	Shares	Amount						
Balance at June 30, 2020	59,416,134	$ 179	$ 69,650	$ (1,200)	$ (52,717)	15,912	—	$ 15,912
Sale of ordinary shares in initial public offering on Nasdaq, net of offering	12,613,500	40	76,094	—	—	76,134	—	76,134

costs and underwriting fees of $9,007								
Verici distribution in specie			1,638	(25)	—	1,613	(1,613)	—
Share-based compensation expense	—	—	501	—	—	501	—	501
Currency translation adjustments	—	—	—	2,255	—	2,255	(67)	2,188
Net loss	—	—	—	—	(7,221)	(7,221)	(393)	(7,614)
Balance at September 30, 2020	72,029,634	$ 219	$ 147,883	$ 1,030	$ (59,938)	89,194	(2,073)	$ 87,121

(in thousands, except share and per share data)	Ordinary shares Shares	Amount	Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' (deficit) equity attributable to Renalytix AI	Noncontrolling interests	Total shareholders' (deficit) equity
Balance at June 30, 2019	53,816,134	$ 162	$ 52,084	$ (822)	$ (42,873)	8,551	—	$ 8,551
Sale of ordinary shares in secondary offering, net of offering costs of $842	5,600,000	17	16,407	—	—	16,424	—	16,424
Share-based compensation expense	—	—	247	—	—	247	—	247
Currency translation adjustments	—	—	—	(622)	—	(622)	—	(622)
Net loss	—	—	—	—	(1,471)	(1,471)	—	(1,471)
Balance at September 30, 2019	59,416,134	$ 179	$ 68,738	$ (1,444)	$ (44,344)	23,129	—	$ 23,129

RENALYTIX AI PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)	Three Months Ended September 30, 2020	Three Months Ended September 30, 2019
Cash flows from operating activities:		
Net loss	$ (7,614)	$ (1,471)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation	27	9
Share-based compensation	501	247
Realized gain on short-term investments	(18)	(6)
Equity losses in affiliate	116	—
Unrealized foreign exchange loss (gain)	178	(415)
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	(3,845)	80
Accounts payable	810	83
Accrued expenses and other current liabilities	(111)	(207)
Payable to affiliate	(459)	—
Net cash used in operating activities	(10,415)	(1,680)
Cash flows from investing activities:		
Purchases of property and equipment	(441)	(31)
Software development costs	(122)	—
Purchase of short-term investments	—	(14,290)
Proceeds from short-term investments	1,000	1,000
Net cash provided by (used in) investing activities	437	(13,321)
Cash flows from financing activities:		
Gross proceeds from the issuance of ordinary shares, net of underwriting fees	79,182	—
Gross proceeds from the issuance of ordinary shares	—	17,276
Payment of offering costs	(2,304)	(851)
Net cash provided by financing activities	76,878	16,425

Effect of exchange rate changes on cash	2,060	(233)
Net increase in cash and cash equivalents	68,960	1,191
Cash and cash equivalents, beginning of period	13,293	8,201
Cash and cash equivalents, end of period	$ 82,253	$ 9,392
Supplemental noncash financing activities:		
Financing costs in accounts payable and accrued expenses	$ 1	$ —
Software development costs in accounts payable and accrued expenses	$ 311	$ 427
Purchase of property and equipment in accounts payable and accrued expenses	$ 177	$ —

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

RENALYTIX AI PLC

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Business and risks

Renalytix AI plc and its wholly-owned subsidiary, Renalytix AI, Inc., (collectively, Renalytix AI, 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.

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 not generated any revenue from the sales of KidneyIntelX tests. The Company has funded its operations primarily through equity financings.

In April 2020, the Company created a wholly-owned subsidiary, Verici Dx Limited ("Verici Dx"), to hold technology in-licensed from the Icahn School of Medicine at Mount Sinai (ISMMS or Mount Sinai) in late 2018. In May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to Verici Dx in exchange for $2.0 million, which was satisfied by the issuance of convertible loan notes of Verici Dx to the Company. The reduction of capital necessary to implement this transaction was approved by the Company's shareholders at a general meeting held on May 15, 2020 and confirmed by the High Court in England and Wales on June 9, 2020. The Company's board of directors declared the distribution of shares of Verici Dx to the then shareholders of the Company, to effect the FractalDx spin-off, on July 7, 2020, and the distribution occurred on July 10, 2020.

The Company announced on July 8, 2020 that the share capital of Verici Dx had been re-designated into 59,416,134 A Shares of £0.001 each and one golden share of £0.001 (the "Golden Share") and that Renalytix would retain the Golden Share and its associated controlling voting rights. Subsequent to that announcement, the Company entered into a declaration of trust whereby Renalytix AI plc has declared that it holds the Golden Share as nominee and on trust for certain Directors of Renalytix AI and accordingly, the Company itself has no ongoing beneficial interest in Verici Dx shares. This triggered a reconsideration event for ongoing consolidation of Verici Dx and since the Company was still the primary funding source for Verici Dx, the Company continued to hold a controlling financial interest in Verici Dx and continued to consolidate Verici Dx. Consequently, the Company recognized noncontrolling interest of $1.6 million to reflect Verici Dx's distribution of A shares and the Golden Share.

As discussed in Note 14, on October 28, 2020, the Company gave notice to convert the outstanding $2.5 million convertible loan notes, which reflects the consideration for the FractalDx assets and the funding the Company provided Verici Dx through October 28, 2020, into 9,831,681 ordinary shares of Verici Dx. On November 3, 2020, Verici Dx completed an initial public offering ("Verici IPO") on AIM thus triggering another reconsideration event for ongoing consolidation of Verici Dx. The Verici IPO resulted in the Company no longer having a controlling financial interest and no longer having a majority equity interest in Verici Dx.

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. Going Concern

On November 6, 2018, the Company sold 18.4 million ordinary shares in its initial public offering, or IPO, at $1.57 per share resulting in net proceeds of approximately $27.4 million and its ordinary shares were admitted to trading on the AIM.

In July 2019, the Company sold 5.6 million of its ordinary shares to several new and existing investors in exchange for $16.4 million of net cash proceeds.

In July 2020, the Company closed an IPO on Nasdaq Global Market in which the Company issued and sold 12.6 million ordinary shares, which converted into 6.3 million American depository shares, at a public offering price of $13.50 per share. In addition, the Company completed a concurrent private placement in Europe and other countries outside of the United States of 30,000 ordinary shares at a price of £5.37 per ordinary share (at an exchange rate of GBP:USD 1:1.2563). The Company received net proceeds of approximately $76.1 million as a result of the offering.

The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of $59.9 million as of September 30, 2020. 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 $82.3 million as of September 30, 2020, 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 prospect.

3. Basis of presentation and summary of significant accounting policies

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

In the opinion of management, the accompanying unaudited interim condensed consolidated financial statements include all normal and recurring adjustments (which consist primarily of accruals and estimates that impact the financial statements) considered necessary to present fairly the Company's financial position as of September 30, 2020 and its results of operations and cash flows for the three months ended September 30, 2020 and 2019. Operating results for the three months ended September 30, 2020 are not necessarily indicative of the results that may be expected for the year ending June 30, 2021. The unaudited interim financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended June 30, 2020.

Principles of consolidation

The unaudited interim condensed consolidated financial statements include the accounts of Renalytix AI plc, its wholly-owned subsidiary, Renalytix AI, Inc., and Verici Dx Limited in which the Company holds a controlling financial interest as of the financial statement date. As the Company has been the primary funding source for Verici Dx since its distribution to the Company's stockholders, the operations and financial position of Verici Dx are included in the condensed consolidated financial statements of the Company. Participation of the stockholders in the net assets and losses of Verici Dx are reflected in the line items "Noncontrolling interests" in the Company's condensed consolidated balance sheets and "Net loss attributable to the noncontrolling interests" in the Company's condensed consolidated statements of operations and comprehensive loss. Noncontrolling interests adjusts the Company's condensed consolidated results of operations and comprehensive loss to exclude all of the losses of Verici Dx as Renalytix AI has no direct equity ownership in Verici Dx. Changes in the underlying net book value of Verici Dx due to equity issuances are reflected as equity transaction in the Company's condensed consolidated statements of stockholders' equity. All inter-company balances and transactions have been eliminated in consolidation.

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, the value of consideration for the acquired in-process research and development and in recording the prepaid/accrual, and associated expense, for research and development activities performed for the Company by third parties.

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 AI plc and Verici Dx Limited is GB Pounds. The functional currency of Renalytix AI, Inc. and Verici Dx Inc. is the U.S. dollar. Assets and liabilities of Renalytix AI plc and Verici Dx Limited are translated at the rate of exchange at year-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported within other (expenses) income in the condensed consolidated statements of operations and comprehensive loss. For the three months ended September 30, 2020 transaction losses were $2.2 million. For the three months ended September 30, 2019 transaction gains were $0.4 million.

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. 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. At September 30, 2020 and June 30, 2020, all of the Company's cash was held at two accredited financial institutions.

Fair value of financial instruments

At September 30, 2020 and June 30, 2020, the Company's financial instruments included prepaid expenses and other current assets, accounts payable and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of September 30, 2020, the Company had a cash balance of $82.3 million. As of June 30, 2020, the Company had a cash balance of $12.8 million and cash equivalents consisting of $0.5 million held in a money market account.

Short-term investments

Short-term investments consist of debt securities with a maturity date greater than three months when acquired. The Company classifies its short-term investments at the time of purchase as available-for-sale securities. Available-for-sale securities are carried at fair value. Unrealized gains or losses on available-for-sale securities are reported in accumulated other comprehensive income (loss), a component of the shareholders' equity, until realized. Short-term investments at June 30, 2020 consisted of U.S. Treasury Bills with a fair value of $1.0 million. Unrealized gains (losses) at June 30, 2020 were de minimis as their maturity date was 91 days from original purchase. The Company had no short-term investments at September 30, 2020.

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.

Deferred offering costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process common equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the condensed consolidated statements of operations and comprehensive loss. As of June 30, 2020, the Company had deferred offering costs of $2.4 million related to the IPO on the Nasdaq Global Market which was completed in July 2020. Upon completion of the IPO, the deferred offering costs were reclassified into additional paid-in capital.

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 are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. During the three months ended September 30, 2020, the Company recognized $0.5 million related to the performance of the contract liability with Kantaro. This represents the allocation of costs for performing services on behalf of Kantaro.

Equity method investment

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 the 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.

Impairment of long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. The Company has not recognized any impairment of long-lived assets during the three months ended September 30, 2020 and 2019.

Software development costs

The Company follows the provisions of ASC 985, Software, which requires software development costs for software to 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. Technological feasibility is established upon the completion of a working model that has been validated.

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 chronic kidney disease 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 September 30, 2020 and 2019 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 September 30, 2020, and 2019, there were 3,408,858 and 2,833,858 shares issuable upon exercise of outstanding options that were anti-dilutive and excluded from diluted loss per share for the three months ended September 30, 2020 and 2019, 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)*, 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 July 1, 2022, and interim periods within those years. The Company is currently evaluating the impact of adopting this guidance to its 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)*, 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. Fair value

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 Company has classified cash equivalents and short-term investments at June 30, 2020, which were comprised of amounts held in a money market account and invested in U.S. Treasury Bills, respectively, and measured at fair value on a recurring basis, as Level 1.

5. Prepaid expenses and other current assets

Prepaid expenses and other current assets consisted of (in thousands):

	September 30, 2020	June 30, 2020
Insurance	$ 3,652	$ 40
Other	726	511
	$ 4,378	$ 551

6. Property and equipment

Property and equipment consists of (in thousands):

	September 30, 2020	June 30, 2020
Lab equipment	$ 890	$ 862
Software	1,254	744
Office equipment	57	31
Office furniture	10	10
Construction in process	568	113
Total	2,779	1,760
Less accumulated depreciation	(135)	(105)
	$ 2,644	$ 1,655

Depreciation expense was $30,000 and $9,000 for the three months ended September 30, 2020 and 2019, respectively.

As of September 30, 2020, and June 30, 2020, there was $1.0 and $0.6 million of capitalized software development costs, respectively. Amortization expense related to capitalized software development costs was immaterial for the three months ended September 30, 2020. There was no amortization expense related to capitalized software development costs for the three months ended September 30, 2019.

7. Accrued expenses and other current liabilities

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

	September 30, 2020	June 30, 2020
Consulting and professional fees	$ 545	$ 567
Research and development	—	80
Payroll and related benefits	52	24
Other	39	12
	$ 636	$ 683

8. Debt

Paycheck Protection Program

On April 29, 2020, the Company entered into an original loan agreement with Fortis Private Bank as the lender (“Lender”) for a loan in an aggregate principal amount of $255,000 (the “Loan”) pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. The Loan matures in two years and bears interest at a rate of 1% per year, with all payments deferred through the six-month anniversary of the date of the Loan. Principal and interest are payable monthly commencing on October 29, 2020 and may be prepaid by the Company at any time prior to maturity without penalty. The Company may apply for forgiveness of amounts due under the Loan, with the amount of potential loan forgiveness to be calculated in accordance with the requirements of the PPP based on payroll costs, any mortgage interest payments, any covered rent payments and any covered utilities payments during the 8-24 week period after the origination date of the Loan. The Company utilized the proceeds of the Loan for payroll and other qualifying expenses, but there can be no assurances that any portion of the Loan will be forgiven.

At September 30, 2020, the outstanding principal balance of the Loan is $255,000, of which $120,000 is payable in fiscal year 2021 and $135,000 is payable in fiscal year 2022. The fair value of the Loan as of September 30, 2020 is $245,000, which is determined based on a discounted cash flow model using an estimated market rate of interest of 4.75%, which is classified as a Level 3 fair value measurement.

9. Commitments and contingencies

Leases

In June 2018, the Company entered into an office lease and, in February 2019, the Company entered into a lease for laboratory testing facilities and offices. Each lease is located in New York City and are month-to-month leasing arrangements. Additionally, in February 2019, the Company entered into a lease for an apartment used by executives for traveling requirements. The apartment was located in New York and expired in October 2019. On October 31, 2019, the Company entered into a lease agreement that established a commercial laboratory operation in Salt Lake City, Utah. The lease has a term of five years and is the first long-term lease entered into by the Company. Rent expense for all leases was $0.2 million and $0.1 million for the three months ended September 30, 2020 and 2019, respectively.

The future minimum payments are as follows (in thousands):

2021	$	184
2022		83
2023		83
2024		83
2025		28
	$	461

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).

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.

10. License 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, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred approximately $0.1 million in research and development expenses under the ISMMS SRA for the three months ended September 30, 2019. The Company did not incur any expenses related to the ISMMS SRA for the three months ended September 30, 2020.

Mount Sinai license agreement for FractalDx

On December 21, 2018, the Company entered into an exclusive license agreement (the ISMMS FractalDx License Agreement) with ISMMS. Under the terms of the ISMMS FractalDx License Agreement, ISMMS granted the Company (i) an exclusive license, with sub-license rights, 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 $0.3 million upon receipt of certain regulatory clearance and approval, $0.3 million upon receipt of U.S. CMS reimbursement code or PAMA reimbursement approval. In addition, the Company is obligated to pay Mount Sinai $1.0 million and $4.0 million in commercial milestone payments upon achieving worldwide net sales of FractalDx of $50.0 million and $250.0 million, respectively. The Company is also obligated to pay Mount Sinai a 6% to 8% royalty on net sales of FractalDx, subject to customary reductions. Moreover, the Company is obligated to pay Mount Sinai between 15% and 70% of any consideration received from a sublicensee.

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. The Company is also subject to an annual license maintenance fee of $25,000 in calendar year 2020 and 2021, $50,000 in calendar year 2022 and 2023, $0.1 million in calendar years 2024 through 2027, and $0.2 million for calendar year 2028 and beyond.

As discussed in Note 1, in May 2020 the Company transferred the in-licensed FractalDx technology and associated assets to Verici Dx.

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. 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.

AstraZeneca statement of work

In July 2020, we entered into a statement of work (the "AZ SOW") with AstraZeneca Pharmaceuticals LP ("AZ") in advance of entering into a more comprehensive master services agreement. Pursuant to the AZ SOW, the Company will conduct a feasibility study to determine the impact of the use of the KidneyIntelX platform to optimize utilization of various CKD agents and a randomized trial of the KidneyIntelX platform and the Company's care management software versus routine clinical care to improve uptake and adherence of certain CKD agent. Additionally, AZ has agreed to pay the Company up to $1.0 million if certain milestones are achieved. The agreement will terminate upon completion of the activities under the AZ SOW.

11. Shareholders' equity

Ordinary shares

As of September 30, 2020, the Company had 75,438,492 ordinary shares authorized on a fully diluted basis. Each share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends as may be declared by the board of directors. From inception through September 30, 2020, no cash dividends have been declared or paid.

12. Share-based compensation

Equity Incentive Plan

In November 2018, Company established the Renalytix AI plc Share Option Plan (the Plan) and a U.S. Sub-Plan and Non-Employee Sub-Plan. The Plan provides for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of September 30, 2020, there were 3,794,105 shares available for future issuance under the Plan.

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

The options granted as of September 30, 2020 vest equally over twelve quarters following the grant date, with the exception of 80,724 options which vested immediately when granted and 145,000 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary. If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

The Company recorded share-based compensation expense in the following expense categories in the condensed consolidated statements of operations for the three months ended September 30, 2020 and 2019 (in thousands):

	Three Months Ended September 30,	
	2020	**2019**
Research and development	$ 195	$ 134
General and administrative	296	113
	$ 491	$ 247

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying ordinary shares at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the three months ended September 30, 2020 and 2019 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 three months ended September 30, 2020 and 2019, 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:

	Three Months Ended September 30,	
	2020	**2019**
Expected term (in years)	5.7	5.7
Expected volatility	67.3%	63.6%
Risk-free rate	0.3%	1.9%
Dividend yield	— %	— %

The weighted average fair value of the options granted during the three months ended September 30, 2020 and 2019 was $4.31 and $2.05 per share, respectively.

The following table summarizes the stock option granted to employees and nonemployees for the three months ended September 30, 2020:

	Number of shares under option plan	Weighted-average exercise price per option	Weighted-average remaining contractual life (in years)
Outstanding at June 30, 2020	3,028,858	$ 1.95	8.6
Granted	380,000	$ 7.46	
Outstanding at September 30, 2020	3,408,858	$ 2.56	8.5
Exercisable at September 30, 2020	1,649,525	$ 1.94	8.3
Vested and expected to vest at September 30, 2020	3,408,858	$ 2.56	8.5

As of September 30, 2020, there was $3.3 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 1.56 years. The aggregate intrinsic value of options outstanding and options exercisable at September 30, 2020 was $7.0 million and $4.0 million, respectively.

Employee Stock 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 renumeration 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 renumeration 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.

Effective August 28, 2020, employees who elected to participate in the ESPP commenced payroll withholdings that accumulate through February 27, 2021. 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 $10,000 during the three months ended September 30, 2020 related to the ESPP.

13. Related-party transactions

EKF Diagnostic Holdings

During the three months ended September 30, 2020 and 2019, the Company paid fees to employees of EKF who provided services to Renalytix.

Icahn School of Medicine at Mount Sinai

In May 2018, the Company secured its cornerstone license agreement with ISMMS for research and clinical study work and intended commercialization by the Company (see Note 10). 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.

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, 2020, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services 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 of September 30, 2020, the total liability associated with the services was $1.4 million, of which $1.2 million is classified as a current liability and $0.2 million is classified as a non-current liability. For the three months ended September 30, 2020, the Company recognized $0.5 million in the statement of operations related to services performed under the Advisory Agreement. For the three months ended September 30, 2020, $0.2 million and $0.1 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and general and administrative expense, respectively.

In addition to the equity granted at formation, the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $0.3 million and an additional $0.5 million thereafter. The Company committed to lend an initial amount of $83,333 and an additional $166,667 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 $83,333 and had a note receivable for this amount at September 30, 2020. In addition, the Company recognized losses of $0.1 million on their investment in Kantaro during the three months ended September 30, 2020.

14. Subsequent events

The Company has evaluated subsequent events from the 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.

Verici Dx

On November 3, 2020, Verici Dx completed an initial public offering on AIM and raised gross proceeds of £14.5 million ("Verici IPO") triggering a reconsideration event for ongoing consolidation of Verici Dx. The IPO of Verici Dx resulted in the Company no longer having a controlling financial interest and no longer having a majority equity interest. Verici Dx previously issued the Company $2.5 million in convertible loan notes which reflects the consideration for the FractalDx assets and the funding the Company provided Verici Dx through October 28, 2020. Prior to the Verici IPO, on October 28, 2020, the Company gave notice to convert the existing $2.5 million convertible loan notes into 9,831,681 ordinary shares of Verici Dx.