Renalytix Reports Financial Results for Third Quarter of Fiscal Year 2021

June 15, 2021

NEW YORK, June 15, 2021 (GLOBE NEWSWIRE) -- Renalytix AI plc (LSE: RENX) (NASDAQ: RNLX) (“Renalytix” or the “Company”) today reported financial results for the quarter and nine months ended March 31, 2021.

Recent Highlights

- Partnership announced with University of Utah health system to improve kidney health and reduce the risk of kidney failure for large-scale populations in the earliest stages of kidney disease. KidneyIntelX to be integrated with the university electronic health records (EHR) system, enabling access to more than 1,700 clinicians.
- 10 year, government-wide contract granted by the U.S. General Services Administration for KidneyIntelX testing services at $950 per reportable result; applies to more than 140 U.S. government departments, agencies, and affiliates including U.S. Veterans Administration (VA), Department of Defense (DoD) military branches (Army, Navy, Air Force, and Marines), and Indian Health Services (IHS)
- Data presented at World Congress of Nephrology showing KidneyIntelX accurately predicted progression of diabetic kidney disease (DKD) in a multinational cohort from the CANagliflozin CardioVAScular Assessment Study (CANVAS) with early-stage DKD (stages 1-3).
- Exclusive option to license novel biomarkers with Joslin Diabetes Center which could provide additional clinical utility for understanding early disease progression, risk of kidney failure, therapeutic response, and the mechanistic pathways of kidney disease beyond the markers that are currently captured by KidneyIntelX.
- Peer-reviewed data publication demonstrating KidneyIntelX more accurately predicted progressive kidney function decline and kidney failure in a multi-center, diverse cohort of 1,146 type 2 diabetes patients with early-stage (stages 1, 2, and 3) kidney disease versus the current standard of care.
- Partnership announced with Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement an advanced clinical care model to improve kidney health and reduce kidney disease progression and kidney failure; KidneyIntelX access to be enabled to primary care physicians, endocrinologists, nephrologists and care teams in 37 hospitals and more than 1,350 care locations across the Carolinas and Georgia.
- Expanded leadership team to support U.S. Government contract and new healthcare partnerships for broad scale KidneyIntelX deployment.
- KidneyIntelX issued coverage determination by one of New York State’s largest not-for-profit health insurance companies with over 1.5 million members.
- Agreement with Quest Diagnostics (ExamOne) to enable any patient to receive an in-home blood draw in all 50 states for KidneyIntelX risk assessment, as part of expanded access program strategy.

Third Quarter 2021 Financial Results

During the three months ended March 31, 2021 the Company recognized $0.6 million of services revenue related to work performed for Mount Sinai and $0.1 of testing revenue. Cost of revenue for the three months ended March 31, 2021 was $0.2 million.

Operating expense for the three months ended March 31, 2021 was $8.1 million compared with $2.7 million during the three months ended March 31, 2020.

Research and development expenses increased by $1.7 million from $1.4 million for the three months ended March 31, 2020 to $3.1 million for the three months ended March 31, 2021. The increase in R&D was primarily due to increased headcount, consulting, and professional fees to support the ongoing development of KidneyIntelX as well as research studies focused on long-term effects of COVID-19 on kidney health.

General and administrative expenses increased by $4.2 million from $1.3 million for the three months ended March 31, 2020 to $5.5 million for the three months ended March 31, 2021. The increase was primarily due to increased expenses related to public listing compliance, headcount and consulting and professional fees.

Net loss attributable to ordinary shareholders was $8.8 million for the three months ended March 31, 2021, compared to $0.7 million for the three months ended March 31, 2020.

Cash, cash equivalents and short-term investments were $70.1 million as of March 31, 2021, compared with $14.3 million as of June 30, 2020.

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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 U.S. 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 Renalytix

Renalytix (LSE: RENX) (NASDAQ: RNLX) 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. The Company's lead product is KidneyIntelX (visit www.kidneyintelx.com) which is designed to help make significant improvements in kidney health through early risk prognosis and optimal clinical care to reduce the incidence of advanced kidney disease and kidney failure. For more information, visit www.renalytix.com.

Forward Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended, that are based on management's beliefs and assumptions and on information currently available to management. All statements contained in this release other than statements of historical fact are forward-looking statements, including statements regarding our ability to develop, commercialize and achieve market acceptance of our current and planned products and services and indicated uses, our research and development efforts, our partnership and collaboration efforts, and other matters regarding our business strategies, use of capital, results of operations and financial position, and plans and objectives for future operations.

In some cases, you can identify forward-looking statements by the words "may," "will," "could," "would," "should," "expect," "intend," "plan," "anticipate," "believe," "estimate," "predict," "project," "potential," "continue," "ongoing" or the negative of these terms or other comparable terminology, although not all forward-looking statements contain these words. These statements involve risks, uncertainties and other factors that may cause actual results, levels of activity, performance, or achievements to be materially different from the information expressed or implied by these forward-looking statements. These risks, uncertainties and other factors are described under "Risk Factors," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and elsewhere in the documents we file with the Securities and Exchange Commission from time to time. We caution you that forward-looking statements are based on a combination of facts and factors currently known by us and our projections of the future, about which we cannot be certain. As a result, the forward-looking statements may not prove to be accurate. The forward-looking statements in this press release represent our views as of the date hereof. We undertake no obligation to update any forward-looking statements for any reason, except as required by law.

RENALYTIX AI PLC

Operational Update and Financial Results for the Three and Nine Months Ended March 31, 2021

Unless otherwise indicated, all references in this report to the terms "Renalytix," "RenalytixAI," "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 also 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, 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 positive coverage determinations from regional private insurance payors. 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 ("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 testing 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, on January 12, 2021, the U.S. Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, finalized the Medicare Coverage of Innovative Technology ("MCIT") rule. We believe that this new CMS rule could have a material positive impact on addressable market population with insurance coverage for KidneyIntelX if we obtain FDA clearance for KidneyIntelX. Following a delay to address specific questions on, among other issues, real world evidence development and medical device benefit to the Medicare population, Medicare has now stated that MCIT will be implemented on December 15, 2021, with an interim rule update report issued during the first week in July 2021.

MCIT represents the culmination of a sequence of policy steps over the past decade, including finalization of the Protecting Access to Medicare Act in 2018, which have materially altered the pathway for translating innovative diagnostic technology. For emerging growth diagnostic companies such as Renalytix, MCIT can have a substantial effect in achieving comprehensive reimbursement coverage on an accelerated timeline. We believe MCIT represents one of the more significant events in the past several decades to help drive innovation in precision medicine diagnostics/prognostics.

Additionally, we have successfully completed the first stage of our statement of work with AstraZeneca Pharmaceuticals LP ("AstraZeneca") to conduct a feasibility study to determine the impact of the use of our KidneyIntelX platform to optimize utilization of various CKD agents. Further, in December 2020 we entered into a master service agreement with AstraZeneca for future services of this nature. We believe this agreement will define how we can leverage KidneyIntelX to improve the care and outcomes for patients affected by chronic diseases such as kidney disease, diabetes, and cardiovascular disease. Building on our initial success with AstraZeneca, we plan to pursue further collaborations with pharmaceutical companies and make 'Pharmaceutical Services Revenue' a core part of our 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 care management software.

Business Highlights

Reimbursement and Regulatory Pathway

With the recent finalization of the MCIT rule on January 12, 2021, and assuming its implementation takes effect on the Medicare stated schedule of December 15th, 2021, we now have a clear path to a national Medicare coverage determination for KidneyIntelX testing in the United States. In summary, MCIT provides for an opt-in national Medicare coverage determination for medical devices and diagnostics approved or cleared out of the FDA Breakthrough Device designation program. KidneyIntelX was granted breakthrough device designation in May 2019 and is currently under review by the agency as part of this process.

As Medicare beneficiaries make up the majority of individuals with kidney disease in the United States, we believe this represents a critical component in the pursuit of our national commercial strategy.

Pricing for the unique CPT code for KidneyIntelX was finalized by CMS effective January 2020 at $950 per reportable result, which will be the pricing if KidneyIntelX receives FDA clearance and a positive national Medicare coverage determination. In addition, both coverage and the established pricing for the Medicare patient population in the cleared KidneyIntelX indicated use would apply to the approximately 3,550 Medicare Advantage plans administered by private payors in the United States. Medicare Advantage programs currently cover an estimated 24 million Americans, or 36% of all Medicare beneficiaries.

We are pursuing a comprehensive Medicaid contracting program and, to date, have secured Medicaid contracts in 21 states, with additional state contracts expected throughout the course of fiscal 2021 and 2022. We are also targeting an increase in other private and public insurance and purchasing contracts during the same period.

As reported in August 2020, we submitted the final KidneyIntelX package for FDA consideration under breakthrough device designation. Due to the large influx of COVID-19 related emergency use authorization ("EUA") requests, the FDA has experienced delays in submission processing timing across the diagnostic industry. In February 2021, the FDA sent written notification to us stating that it expected the final review process would return to normal no later than April 15, 2021 and did not expect any further delays in process due to the sustained volume of EUA requests in response to the pandemic. The FDA did subsequently resume their review by that target date. While we will continue to decline forecasting specific timing for potential FDA clearance of KidneyIntelX, we have developed internal plans with an assumption that FDA will conclude its process by the end of calendar 2021.

Addressable Market and Business Strategy

One of our top priorities is to build a broad distribution network and increase physician access for KidneyIntelX over the course of 2021.

In April, the U.S. General Services Administration ("GSA") granted a ten-year governmentwide acquisition contract to Renalytix for KidneyIntelX testing. This payment contract with stated pricing of $950 per reportable result, covers KidneyIntelX testing in patient populations including the U.S. Veterans Administration (VA), Department of Defense (DoD) military branches (Army, Navy, Air Force, and Marines), and Indian Health Services (IHS). Notably, our GSA contract is structured as an Indefinite Delivery, Indefinite Quantity (IDIQ) contract providing for an unlimited quantity of services over the contract term. The GSA contract is a significant milestone for Renalytix and carries strategy planning implications for the Company in the near future. In the Veterans Administration Health System and Indian Health Service alone, we estimate the KidneyIntelX eligible testing population exceeds 500,000 individuals with diabetic kidney disease. We expect to begin commercial testing with individual VA Hospital systems in by the end of calendar 2021.

In May, Renalytix, Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine announced a partnership to implement an advanced clinical care model designed to improve kidney health and reduce kidney disease progression and kidney failure in high-risk populations. KidneyIntelX will be available through Atrium Health's electronic health record (EHR) system, providing access to primary care physicians, endocrinologists, nephrologists and care teams throughout 37 hospitals and more than 1,350 care locations across the Carolinas and Georgia. Charlotte, North Carolina-based Atrium Health serves more than 7 million people in the region, providing care under the Wake Forest Baptist Health name in the Winston-Salem, N.C. region and Atrium Health Navicent in Georgia.

We are increasingly optimistic about achieving distribution capability under our model of partnering with health care networks such as Mount Sinai, University of Utah and Atrium Health/Wake Forest. We expect to announce additional partnerships through the remainder of the calendar year. We believe these additional partnerships could materially increase patient and physician access to KidneyIntelX throughout the course of calendar 2021 in advance of broader insurance coverage.

With the GSA contract securing payment for testing, we are now moving to increase distribution, customer service, sales and marketing capacities in the United States on a region by region basis beginning with our currently announced health system partners and their contiguous VA hospital systems.

Product Development

We are continuing development work on expanding the indicated use population for KidneyIntelX risk assessment to the broader CKD population which includes the important, underserved population of kidney disease patients of African and Hispanic ancestry. These populations have been disproportionate sufferers of end stage kidney disease and we intend to provide access to advanced technology embedded in the KidneyIntelX platform to level the playing field in relation to access, knowledge and clinical care through kidney disease prognosis and treatment.

We expect to broaden the indicated use of KidneyIntelX to the larger CKD population as early as calendar 2022.

Due to the large and incremental population groups that would potentially be served by expanding indicated uses, we estimate the total addressable market for KidneyIntelX could increase to an estimated 37 million individuals in the United States.

KidneyIntelX is an *in vitro* prognostic anchored by a real-time patient blood draw and biomarker assessment. The biomarker assessment is combined with selected information from a patient's EHR, all processed by a machine-learning enabled algorithm. We believe that to achieve early and accurate disease prognosis, real-time biology accessible through a current blood or urine biomarker assessment is required.

Real-world Testing Experience

Despite COVID-19 restrictions, real-world testing experience has met or exceeded targeted quality metrics and physician and patient satisfaction measures. Approximately 120 physicians ranging from primary care to specialist nephrologists within the Mount Sinai network have been integrated with EHR-linked KidneyIntelX score ordering and reporting. We expect clinical testing deployment will be extended to over 500 physicians in the Mount Sinai Health System through the remainder of calendar 2021.

The KidneyIntelX software platform has been designed with a number of significant features to ensure efficient clinical testing implementation and, we believe, provides an outstanding platform for future feature development. KidneyIntelX cloud computing architecture couples data control and encryption protocols and has been verified to high standards. These standards ensure secure and timely access to the order information and data necessary to execute the test in accordance with all applicable regulatory requirements. Working collaboratively with an extended team of information technology professionals, we have developed a robust data pipeline that can provide access to KidneyIntelX for all clinicians across the Mount Sinai Health System and allows the creation of a rich database (using de-identified data) for ongoing product development and shared value generation through advanced data analytics. Key features of the platform such as the patient test report incorporating health system specific care pathways are uniquely developed to be translatable to other health systems and EHR platforms.

We have continued building KidneyIntelX study data with key findings presented at World Congress of Nephrology. Findings include further validation in a large international trial cohort, monitoring therapeutic response and impact in clinical decision making/therapy management.

COVID-19 Effects

COVID-19 has provided a challenge to our business, particularly during the high-intensity first deployment of KidneyIntelX in the Mount Sinai Health System. During our fiscal third quarter, both New York State and Mount Sinai continued COVID-19 surge protocols which set specific guidelines for prioritization of resources and introduced restrictions to combat infection spread.

Fortunately, with vaccinations now underway, we anticipate that these restrictions will continue to be relaxed.

We have more than doubled our employee headcount since our listing on Nasdaq in July 2020. Many key personnel have been hired using only Zoom conference, though we have recently resumed in-person interviews. Many of our employees worked remotely through the course of the first KidneyIntelX implementation and expanded deployment. While we believe our team has performed admirably and maintained a high level of productivity, the ultimate effects of possible extended virtual operation remain unknown.

We anticipate COVID-19 will have substantially less impact on our ability to scale KidneyIntelX implementation and testing in fiscal 2022 as compared with fiscal 2021.

Additional Business

The Renalytix/Mount Sinai joint venture, Kantaro Biosciences LLC ("Kantaro"), has made continued progress with its quantitative COVID-19 serologic antibody testing program. Kantaro has achieved key milestones, including: 1) FDA Emergency Use Authorization; 2) obtaining a CE Mark, which is a mandatory conformance mark that certifies the product has met EU consumer, health, and environmental requirements; 3) entering into a scaled production and distribution agreement with Bio Techne Corporation (NASDAQ: TECH); and 4) a UK/European sales and marketing agreement with EKF Diagnostics Holdings plc (LSE: EKF). As of March 31, 2021, Kantaro is generating modest revenue and our share of the equity method investment in Kantaro is reflected within the financial statement line-item Equity Losses in Affiliate. We are exploring the possibility of broadening the product technology and intellectual property portfolio of Kantaro.

Renalytix continues to hold a 6.94% equity stake in VericiDx. We believe VericiDx's unique technology and published data represent a step-change forward in kidney transplant that can drive improvements in patient quality of life, standard of treatment, cost savings and long-term viability of transplanted organs.

Current Outlook

For the nine months ending March 31, 2021, we are reporting revenue of $1.0 million and net loss attributable to ordinary shareholders of $24.9 million. Our balance sheet remains strong for planned growth activities with a cash balance of $70.1 million as of March 31, 2021.

We continue to expand our business to accommodate multiple revenue pathways from KidneyIntelX testing sales including our recently announced contract with the U.S. General Services Administration, pharma-driven development programs and other strategic partnership initiatives. However, given the early-stage nature of our commercial business and the challenges operating in a COVID-19 restricted environment, we do not expect any material revenue for the 12 months ended June 30, 2021 as we continue to focus on ensuring that all necessary regulatory and commercial building blocks are in place to enable us to scale rapidly.

For fiscal 2022, we expect a material inflection point for revenue growth to occur if KidneyIntelX receives FDA clearance and concurrent opt-in for national Medicare coverage, and an easing of COVID restrictions due to broad population vaccination uptake. We are targeting a blended gross margin across all lines of KidneyIntelX testing of greater than 70% once our commercial program scales in fiscal 2022.

We view fiscal 2022 as a year in which we plan to validate our ability to grow significant market share and revenue from KidneyIntelX testing, and pharmaceutical and other strategic partnerships. In addition, we expect our total addressable market will increase materially with the introduction of subsequent KidneyIntelX versions and potentially expanded indications.

FINANCIAL REVIEW

Financial review of the three-months ended March 31, 2021

The operating loss for the three months ended March 31, 2021 and 2020 was $8.1 million and $2.7 million, respectively, and the net loss attributable to ordinary shareholders for the three months ended March 31, 2021 and 2020 was $8.8 million and $0.7 million, respectively.

Revenue

During the three months ended March 31, 2021, we recognized $0.6 million of services revenue related to the work performed for Mount Sinai and $0.1 million of testing revenue related to the Mount Sinai Clinical Utility study. There was no revenue for the three months ended March 31, 2020.

Cost of revenue

During the three months ended March 31, 2021, cost of revenue consisted of $0.2 million directly attributable to the services provided as well as KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. There was no cost of revenue for the three months ended March 31, 2020.

Research and Development Costs

Research and development expenses increased by $1.7 million, from $1.4 million for the three months ended March 31, 2020 to $3.1 million for the three months ended March 31, 2021. The increase in R&D was primarily due to increased headcount and the associated compensation and benefits, including share-based payments, as we continue to develop our technology, prepare for expanded clinical operations with Mount Sinai and other health systems, and initiate product development studies focused on examining the long-term effects of COVID-19 on kidney health.

General and Administrative Costs

General and administrative expenses increased by $4.2 million, from $1.3 million for the three months ended March 31, 2020 to $5.5 million for the

three months ended March 31, 2021. The increase was due to a $1.5 million increase in compensation and related benefits, including share-based payments, a $1.1 million increase in insurance costs, a $0.7 million increase in legal and accounting fees due to Securities and Exchange Commission ("SEC") filings and U.S. public listing compliance, due to increased headcount, a $0.5 million increase in consulting and professional fees, $0.1 million increase in recruiting expense and $0.3 million in other expenses.

Performance of contract liability to affiliate

In May 2020, we entered into an operating agreement ("Kantaro Operating Agreement") with the Icahn School of Medicine at Mount Sinai ("Mount Sinai") to form a joint venture, Kantaro Biosciences LLC, 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, 2021, we recognized $0.1 million of expenses related to the performance of our contract liability with Kantaro. This represents the allocation of costs related to performing services on behalf of Kantaro.

Foreign Currency Loss

During the three months ended March 31, 2021, we recognized foreign currency losses of $1.1 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the three months ended March 31, 2020, we recognized foreign currency gains of $1.6 million.

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, 2021, we recorded a gain of $0.3 million to adjust the VericiDx investment to fair value. There was no fair value adjustment for the three months ended March 31, 2020 as we did not have an investment in VericiDx at that time.

Other Income, net

During the three months ended March 31, 2021, we recognized other income of $0.06 million which was primarily due to interest income. During the three months ended March 31, 2020, we recognized interest income of $0.05 million.

Financial review of the nine-months ended March 31, 2021

The operating loss for the nine months ended March 31, 2021 and 2020 was $22.1 million and $7.4 million, respectively, and the net loss attributable to ordinary shareholders for the nine months ended March 31, 2021 and 2020 was $24.9 million and $6.9 million, respectively.

Revenue

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 testing revenue related to the Mount Sinai Clinical Utility study. There was no revenue for the nine months ended March 31, 2020.

Cost of revenue

During the nine months ended March 31, 2021, cost of revenue consisted of $0.4 million directly attributable to services rendered to AstraZeneca and Mount Sinai as well as KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities including labor costs directly related to revenue generating activities. There was no cost of revenue for the nine months ended March 31, 2020.

Research and Development Costs

Research and development expenses increased by $3.7 million, from $3.7 million for the nine months ended March 31, 2020 to $7.3 million for the nine months ended March 31, 2021. The increase was primarily due to increased headcount and the associated compensation and benefits, including share-based payments, as we continue to develop our technology, prepare for expanded clinical operations with Mount Sinai and other health systems as well as product development studies focused on examining the long-term effects of COVID-19 on kidney health.

General and Administrative Costs

General and administrative expenses increased by $12.5 million, from $3.8 million for the nine months ended March 31, 2020 to $16.3 million for the nine months ended March 31, 2021. The increase was due to a $4.3 million increase in compensation and related benefits, including share-based payments, due to increased headcount, a $3.3 million increase in insurance costs, a $2.4 million increase in legal and accounting fees due to SEC filings and U.S. public listing compliance, a $1.3 million increase in consulting and professional fees, a $0.7 million increase in recruiting expense, and an increase of $0.5 million in marketing, facility and other operating expenses.

Performance of contract liability to affiliate

During the nine months ended March 31, 2021, we recognized $0.9 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.

Foreign Currency Loss

During the nine months ended March 31, 2021, we recognized foreign currency losses of $8.8 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the nine months ended March 31, 2020, we recognized foreign currency gains of $0.02 million.

Fair Value Adjustments to VericiDx Investment

During the nine months ended March 31, 2021, we recorded a gain of $5.4 million to adjust the VericiDx investment to fair value. There was no fair value adjustment for the nine months ended March 31, 2020 as we did not have an investment in VericiDx at that time.

Other Income, net

During the nine months ended March 31, 2021, we recognized $0.18 million of interest income and a gain of $0.05 million on the deconsolidation of VericiDx. During the nine months ended March 31, 2020, we received $0.1 million of other income in relation to the sale of excess supplies and $0.1 million of interest income as a result of interest earned on cash deposits and $0.3 million of realized gains on foreign currency transactions.

Cash Flows

Net cash used in operating activities

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.

During the nine months ended March 31, 2020, we used $7.1 million of cash in operating activities primarily attributable to our $6.9 million net loss. This use of cash was partially offset by $0.4 million of noncash items such as depreciation and amortization, share-based compensation, and foreign exchange remeasurement losses. The net cash outflow of $0.7 million from changes in our operating assets and liabilities was primarily attributable to an increase in our prepaid expenses of $0.3 million and $0.3 million of accrued expenses.

Net cash used in investing activities

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.

During the nine months ended March 31, 2020, net cash used in investing activities was $7.6 million and primarily attributable to $21.3 million in purchases of short-term investments partially offset by net proceeds of $14.4 million related to our short-term investments. In addition, we purchased $0.6 million of lab and office equipment.

Net cash used in financing activities

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.

During the nine months ended March 31, 2020, 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 partially 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 increased to $70.1 million as of March 31, 2021 from $14.3 million as of June 30, 2020 primarily due to the net proceeds of our IPO on the Nasdaq Global Market, partially offset by utilization of cash in ordinary operating activities.

RENALYTIX AI PLC

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(in thousands, except share and per share data)	**March 31, 2021**	**June 30, 2020**
Assets		
Current assets:		
Cash and cash equivalents	$ 70,076	$ 13,293
Short-term investments	—	982
Accounts receivable	68	—
Prepaid expenses and other current assets	2,282	551
Note receivable from Kantaro - current	250	—
Receivable from VericiDx	161	18
Total current assets	72,837	14,844
Property and equipment, net	2,594	1,655
Investment in VericiDx	8,209	—
Investment in Kantaro	1,708	1,937
Note receivable from Kantaro - noncurrent	—	83
Deferred offering costs	—	2,364
Total assets	$ 85,348	$ 20,833
Liabilities and Shareholders' Equity		

Current liabilities:		
Accounts payable	$ 1,066	$ 2,218
Accrued expenses and other current liabilities	2,736	683
Accrued expenses – related party	287	—
Note payable – current	226	120
Payable to Kantaro - current	925	271
Total current liabilities	5,240	3,292
Payable to Kantaro - noncurrent	—	1,544
Note payable - noncurrent	29	135
Other liabilities	53	—
Total liabilities	5,322	4,971
Commitments and contingencies (Note 9)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 75,731,144 and 62,444,992 shares authorized at March 31, 2021 and June 30, 2020, respectively; 72,047,286 and 59,416,134 shares issued and outstanding at March 31, 2021 and June 30, 2020, respectively	219	179
Additional paid-in capital	149,150	69,650
Accumulated other comprehensive income (loss)	8,279	(1,200)
Accumulated deficit	(77,622)	(52,717)
Total shareholders' equity	80,026	15,912
Total liabilities and shareholders' equity	$ 85,348	$ 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 March 31, 2021	Three Months Ended March 31, 2020	Nine Months Ended March 31, 2021	Nine Months Ended March 31, 2020
Revenue	$ 619	$ —	$ 1,019	$ —
Cost of revenue	169	—	426	—
Gross profit	450	—	593	—
Operating expenses:				
Research and development	3,104	1,361	7,311	3,659
General and administrative	5,547	1,320	16,258	3,770
Performance of contract liability to affiliate	(130)	—	(889)	—
Total operating expenses	8,521	2,681	22,680	(7,429)
Loss from operations	(8,071)	(2,681)	(22,087)	(7,429)
Equity in losses of affiliate	(8)	—	(229)	—
Foreign currency gain (loss)	(1,095)	1,903	(8,783)	340
Fair value adjustment to VericiDx investment	337	—	5,355	—
Other income, net	61	47	228	222
Net loss	(8,776)	(731)	(25,516)	(6,867)
Net loss attributable to noncontrolling interest	—	—	(611)	—
Net loss attributable to ordinary shareholders	(8,776)	(731)	(24,905)	(6,867)
Other comprehensive income (loss):				
Foreign exchange translation adjustment	1,163	(2,021)	9,504	(343)
Comprehensive loss	(7,613)	(2,752)	(16,012)	(7,210)
Comprehensive loss attributable to noncontrolling interest	—	—	(72)	—
Comprehensive loss attributable to Renalytix AI	$ (7,613)	$ (2,752)	$ (15,940)	$ (7,210)
Net loss per ordinary share—basic and diluted	$ (0.12)	$ (0.01)	$ (0.35)	$ (0.12)
Weighted average ordinary shares—basic and diluted	72,035,126	59,416,134	71,294,883	58,968,134

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 RenalytixAI	Noncontrolling interests	Total shareholders' equity
	Shares	Amount						
Balance at July 1, 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 costs and underwriting fees of $9,007	12,613,500	40	76,094	—	—	76,134	—	76,134
VericiDx 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	$ 147,833	$ 1,030	$ (59,938)	$ 89,194	$ (2,073)	$ 87,121
VericiDx distribution in specie	—	—	—	—	—	—	2,296	2,296
Share-based compensation expense	—	—	525	—	—	525	—	525
Currency translation adjustments	—	—	—	6,086	—	6,086	(5)	6,081
Net loss	—	—	—	—	(8,908)	(8,908)	(218)	(9,126)
Balance at December 31, 2020	72,029,634	$ 219	$ 148,408	$ 7,116	$ (68,846)	$ 86,897	$ —	$ 86,897
Shares issued under the employee share purchase plan	17,652	—	111	—	—	111	—	111
Share-based compensation expense	—	—	631	—	—	631	—	631
Currency translation adjustments	—	—	—	1,163	—	1,163	—	1,163
Net loss	—	—	—	—	(8,776)	(8,776)	—	(8,776)
						—	—	—
Balance at March 31, 2021	72,047,286	$ 219	$ 149,150	$ 8,279	$ (77,622)	$ 80,026	$ —	$ 80,026

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' equity attributable to RenalytixAI	Noncontrolling interests	Total shareholders' equity
	Shares	Amount						
Balance at July 1, 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
Share-based compensation expense	—	—	296	—	—	296	—	296
Currency translation adjustments	—	—	—	2,300	—	2,300	—	2,300
Net loss	—	—	—	—	(4,665)	(4,665)	—	(4,665)
Balance at December 31, 2019	59,416,134	$ 179	$ 69,034	$ 856	$ (49,009)	$ 21,060	$ —	$ 21,060
Share-based compensation expense	—	—	306	—	—	306	—	306
Other	—	—	9	—	—	9	—	9
Currency translation adjustments	—	—	—	(2,021)	—	(2,021)	—	(2,021)
Net loss	—	—	—	—	(731)	(731)	—	(731)
Balance at March 31, 2020	59,416,134	$ 179	$ 69,349	$ (1,165)	$ (49,740)	$ 18,623	$ —	$ 18,623

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

RENALYTIX AI PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)	**Nine Months Ended March 31, 2021**	**Nine Months Ended March 31, 2020**
Cash flows from operating activities:		
Net loss	$ (25,516)	$ (6,867)
Adjustments to reconcile net loss to net cash used in operating activities		
Gain on deconsolidation of VericiDx	(46)	—
Depreciation and amortization	182	40
Share-based compensation	1,657	849
Realized gain on short-term investments	(18)	(98)
Equity losses in affiliate	229	—
Fair value adjustment to VericiDx investment	(5,355)	—
Unrealized foreign exchange loss (gain)	5,546	(321)
Changes in operating assets and liabilities:		—
Accounts receivable	(68)	—
Prepaid expenses and other current assets	(1,951)	(343)
Related party receivable	(143)	—
Accounts payable	240	(52)
Accrued expenses and other current liabilities	2,491	(343)
Accrued expenses – related party	287	—
Payable to affiliate	(890)	—
Other liabilities	53	—

Net cash used in operating activities		(23,302)		(7,135)
Cash flows from investing activities:				
Note receivable – related party		(167)		—
Purchases of property and equipment		(879)		(599)
Software development costs		(428)		(92)
Purchase of short-term investments		—		(21,260)
Proceeds from short-term investments		1,000		14,400
Decrease in cash (VericiDx deconsolidation)		(62)		—
Net cash used in investing activities		(536)		(7,551)
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		(2,305)		(892)
Proceeds from the issuance of ordinary shares under employee share purchase plan		111		—
Net cash provided by financing activities		76,988		16,384
Effect of exchange rate changes on cash		3,633		(25)
Net increase in cash and cash equivalents		56,783		1,673
Cash and cash equivalents, beginning of period		13,293		8,201
Cash and cash equivalents, end of period	$	70,076	$	9,874
Supplemental noncash investing and financing activities:				
Software development costs in accounts payable and accrued expenses	$	195	$	150
Offering costs within accrued expenses	$	—	$	408
Purchase of property and equipment in accounts payable and accrued expenses	$	31	$	—
Deemed distribution of VericiDx ordinary shares	$	75	$	—
Conversion of VericiDx note receivable into VericiDx ordinary shares	$	2,556	$	—

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

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

Since inception in March 2018, the Company has focused primarily on organizing and staffing the Company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting its intellectual property portfolio and commercial laboratory operations, pursuing regulatory clearance and developing a reimbursement strategy. To date, the Company has generated de minimis revenue from the sales of KidneyIntelX tests. The Company has funded its operations primarily through equity 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 $77.6 million as of March 31, 2021. 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 $70.1 million as of March 31, 2021, 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 March 31, 2021 and its results of operations for the three and nine months ended March 31, 2021 and 2020, and cash flows for the nine months ended March 31, 2021 and 2020. Operating results for the three and nine months ended March 31, 2021 are not necessarily indicative of the results that may be expected for the year ending June 30, 2021. The unaudited interim condensed consolidated financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended June 30, 2020.

The Company reclassified certain prior year comparative figures in the condensed consolidated statements of operations and comprehensive loss to conform to the current year's presentation. This change in presentation did not have an impact on the Company's financial condition or operating results.

Principles of consolidation

The unaudited interim condensed consolidated financial statements include the accounts of Renalytix AI 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.

Deconsolidation

Upon the occurrence of certain events and on a regular basis, the Company evaluates whether it no longer has a controlling interest in its subsidiaries, including consolidated variable interest entities. If the Company determines it no longer has a controlling interest, the subsidiary is deconsolidated. The Company records a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in the former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

The Company assesses whether a deconsolidation is required to be presented as discontinued operations in its consolidated financial statements on the deconsolidation date. This assessment is based on whether or not the deconsolidation represents a strategic shift that has or will have a major effect on the Company's operations or financial results. If the Company determines that a deconsolidation requires presentation as a discontinued operation on the deconsolidation date, or at any point during the one-year period following such date, it will present the former subsidiary as a discontinued operation in current and comparative period financial statements.

Verici Dx Limited

In April 2020, the Company created a wholly-owned subsidiary, Verici Dx Limited ("VericiDx"), 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 VericiDx in exchange for $2.0 million, which was satisfied by the issuance of convertible loan notes of VericiDx 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 VericiDx 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 VericiDx 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 had declared that it held the Golden Share as nominee and on trust for certain Directors of Renalytix AI and accordingly, the Company itself had no ongoing beneficial interest in VericiDx shares. This triggered a reconsideration event for ongoing consolidation of VericiDx and since the Company was still the primary funding source for VericiDx, the Company continued to hold a controlling financial interest in VericiDx and continued to consolidate VericiDx. Consequently, the Company recognized noncontrolling interest of $1.6 million to reflect VericiDx's distribution of A Shares and the Golden Share.

As the Company had been the primary funding source for VericiDx since its distribution to the Company's stockholders, the operations and financial

position of VericiDx were included in the condensed consolidated financial statements of the Company. Participation of the stockholders in the net assets and losses of VericiDx were 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 VericiDx as Renalytix AI had no direct equity ownership in VericiDx from the date of the distribution through October 28, 2020. Changes in the underlying net book value of VericiDx due to equity issuances are reflected as equity transactions in the Company’s condensed consolidated statements of stockholders’ equity.

On November 3, 2020, VericiDx completed an initial public offering on AIM and raised gross proceeds of £14.5 million (“VericiDx IPO”) triggering a reconsideration event for ongoing consolidation of VericiDx. The VericiDx IPO resulted in the Company no longer having a controlling financial interest in VericiDx as the Company was no longer VericiDx’s primary funding source. VericiDx previously issued the Company an aggregate of $2.5 million in convertible loan notes which reflected the $2.0 million consideration for the FractalDx assets and $0.5 million of additional funding the Company provided VericiDx through October 28, 2020. Prior to the VericiDx IPO, on October 28, 2020, the Company gave notice to convert the aggregate outstanding $2.5 million convertible loan notes into 9,831,681 ordinary shares of VericiDx. As a result of the VericiDx IPO, the Company deconsolidated VericiDx from the condensed consolidated financial statements of the Company as of that date and recognized a gain of $46,000 within other income, net in the condensed consolidated statements of operations and comprehensive loss for the nine months ended March 31, 2021.

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 the investment as an equity method investment and has also elected the fair value option. In connection with the deconsolidation of VericiDx, the Company evaluated whether the results of VericiDx should be presented as discontinued operations for the period ended March 31, 2021. The Company concluded that the deconsolidation of VericiDx, as a result of the VericiDx IPO, is not a development that significantly impacts the Company’s overall operations and financial results. Research and development expenses incurred related to this program accounted for a minor portion of the Company’s overall annual research and development expenses and the Company remains focused on developing the KidneyIntelX platform. Therefore, the Company has not presented the results related to VericiDx as discontinued operations in its condensed consolidated statements of operations and comprehensive loss for the period ended March 31, 2021.

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), 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 AI 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 AI plc and Renalytix AI Limited are translated at the rate of exchange at period-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported within foreign currency gain (loss) in the condensed consolidated statements of operations and comprehensive loss. For the three and nine months ended March 31, 2021, transaction losses were $1.1 million and $8.8 million, respectively. For the three and nine months ended March 31, 2020, transaction gains were $1.9 million and $0.3 million, respectively.

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 two customers for the three and nine month periods 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, 2021 and June 30, 2020, 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, 2021, the Company had a cash balance of $70.1 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 March 31, 2021.

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, 2021 or June 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 and nine months ended March 31, 2021, the Company recognized $0.1 million and $0.9 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, 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 $8.2 million at March 31, 2021. During each of the three and nine months ended March 31, 2021, the Company recorded a fair value adjustment of $0.3 million and $5.3 million, respectively, in the condensed consolidated statements of operations and comprehensive loss. The Company owned 6.94% of the ordinary shares of VericiDx at March 31, 2021.

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 did not recognize any impairment of long-lived assets during the nine months ended March 31, 2021 and 2020.

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 of ten years. For the nine months ended March 31, 2020, the Company expensed $0.6 million of research and development expenses related to capitalized software. There was no research and development expense related to capitalized software during the three months ended March 31, 2020. There was no research and development expense related to capitalized software for the three and nine months March 31, 2021. Technological feasibility is established upon the completion of a working model that has been validated.

Revenue recognition

The Company adopted ASC 606 – *Revenue from Contracts with Customers* (“ASC 606”) on July 1, 2018. The adoption of ASC 606 did not have a material impact on the condensed consolidated financial statements.

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. 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 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, 2021 and 2020 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, 2021 and 2020, there were 3,683,858 and 3,028,858 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, 2021 and 2020, 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 December 2019, the FASB issued ASU 2019-12, *Income Taxes (Topic 740) - Simplifying the Accounting for Income Taxes*. ASU 2019-12 simplifies the accounting for income taxes by removing exceptions within the general principles of Topic 740 regarding the calculation of deferred tax liabilities, the incremental approach for intraperiod tax allocation, and calculating income taxes in an interim period. In addition, the ASU adds clarifications to the accounting for franchise tax (or similar tax), which is partially based on income, evaluating tax basis of goodwill recognized from a business combination and reflecting the effect of any enacted changes in tax laws or rates in the annual effective tax rate computation in the interim period that includes the enactment date. The ASU is effective for fiscal year beginning after December 15, 2020, and will be applied either retrospectively or prospectively based upon the applicable amendments. Early adoption is permitted. The Company has elected to adopt this ASU as of January 1, 2020 on a prospective basis. The adoption of ASU 2019-12 did not have a material impact on the current 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. 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, 2021, the Company recognized $0.1 million and $0.1 million respectively, of testing services revenue. Sales tax and other similar taxes are excluded from revenues.

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 nine months ended March 31, 2021, the Company recognized $0.4 million of pharmaceutical services revenue where performance obligations are satisfied at a point in time. The Company did not recognize any pharmaceutical services revenue during the three months ended March 31, 2021.

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. 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.

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)**
March 31, 2021:			
Assets:			
Equity investment in VericiDx	$ 8,209	$ —	$ —
June 30, 2020:			
Assets:			
Cash equivalents (Money Market Fund)	$ 500	$ —	$ —
U.S. Treasury Bills	982	—	—
Total	$ 1,482	$ —	$ —

6. Property and equipment

Property and equipment consists of (in thousands):

	March 31, 2021	June 30, 2020
Lab equipment	$ 591	$ 862
Software	1,534	744
Office equipment	81	31
Office furniture	35	10
Leasehold improvements	576	—
Construction in process	—	113
Total	2,817	1,760
Less accumulated depreciation and amortization	(223)	(105)
	$ 2,594	$ 1,655

Depreciation expense was $0.05 million and $0.1 million for the three and nine months ended March 31, 2021, respectively. Depreciation expense was $9,000 and $40,000 for the three and nine months ended March 31, 2020, respectively.

As of March 31, 2021 and June 30, 2020, there was $1.3 million and $0.6 million, respectively, of unamortized capitalized software development costs. Amortization expense related to capitalized software development costs was $30,000 and $53,000 for the three and nine months ended March 31, 2021, respectively, and expensed within cost of revenue in the condensed consolidated statement of operations. There was no amortization expense related to capitalized software development costs for the three and nine months ended March 31, 2020.

As of March 31, 2021, the expected amortization expense for the next five years and thereafter is as follows:

2021 (remaining three months)	$ 31
2022	123
2023	124

2024	124
2025	124
Thereafter	730
	$ 1,256

7. Accrued expenses and other current liabilities

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

	March 31, 2021	June 30, 2020
Consulting and professional fees	$ 491	$ 567
Research and development	—	80
Payroll and related benefits	2,136	24
Other	109	12
	$ 2,736	$ 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. In June 2020, the Paycheck Protection Program Flexibility Act was enacted which, among other things, extended the deferral period for loan payments to either (1) the date that SBA remits the borrower's loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, ten months after the end of the borrower's loan forgiveness covered period. The Loan matures in two years and bears interest at a rate of 1% per year, with all payments deferred through August 15, 2021. Principal and interest are payable monthly commencing on August 15, 2021 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.

At March 31, 2021, the outstanding principal balance of the Loan was $255,000, of which $255,000 is payable in fiscal 2022. The fair value of the Loan as of March 31, 2021 was $246,000, which was 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. On April 28, 2021, the Company received notification that the full amount of the PPP Loan and accrued interest was forgiven.

9. 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. The Company recognized rent expense of $0.1 million and $0.1 million during the three months ended March 31, 2021 and 2020, respectively, and $0.3 million and $0.4 million during the nine months ended March 31, 2021 and 2020, 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):

2021 (remaining three months)	$ 21
2022	83
2023	83
2024	83
2025	28
	$ 298

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, with those covered patients identified by the Company's KidneyIntelX diagnostic and subject to insurance coverage. 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.

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 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 upon approval of the study protocol by the Institutional Review Board.

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 $30,000 and $6,000 in research and development expenses under the ISMMS SRA for the three months ended March 31, 2021 and 2020, respectively. The Company incurred $0.3 million and $0.2 million related to the ISMMS SRA for the nine months ended March 31, 2021 and 2020, respectively.

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 3, in May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to VericiDx.

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.

11. Shareholders' equity

Ordinary shares

As of March 31, 2021, the Company had 75,731,144 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, 2021, 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 March 31, 2021, there were 3,519,105 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 March 31, 2021 vest equally over twelve quarters following the grant date, with the exception of 80,724 options which vested immediately when granted and 370,000 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 and nine months ended March 31, 2021 and 2020 (in thousands):

	Three Months Ended March 31,		Nine Months Ended March 31,	
	2021	2020	2021	2020
Research and development	$ 237	$ 145	$ 631	$ 419
General and administrative	374	161	973	430
	$ 611	$ 306	$ 1,604	$ 849

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, 2021 and 2020 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, 2021 and 2020, 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 March 31,	
	2021	2020
Expected term (in years)	5.8	5.7
Expected volatility	67.1%	63.7%
Risk-free rate	0.5%	1.7%
Dividend yield	— %	— %

The weighted average fair value of the options granted during the nine months ended March 31, 2021 and 2020 was $4.51 and $2.09 per share, respectively.

The following table summarizes the stock option granted to employees and non-employees for the nine months ended March 31, 2021:

	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	655,000	$	7.83	
Outstanding at March 31, 2021	3,683,858	$	2.97	8.1
Exercisable at March 31, 2021	2,221,298	$	2.13	7.8
Vested and expected to vest at March 31, 2021	3,683,858	$	2.97	8.1

As of March 31, 2021, there was $3.8 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 1.71 years. The aggregate intrinsic value of options outstanding and options exercisable at March 31, 2021 was $36.9 million and $24.1 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 ordinary shares. The number of shares of the Company's ordinary shares 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 ordinary shares 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 ordinary shares 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 ordinary shares at 85% of the lower of the fair market value of the Company's ordinary shares 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 ordinary shares for each calendar year in which such rights is outstanding. During the nine months ended March 31, 2021, 17,652 ordinary shares were purchased under the ESPP.

In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase the Company's ordinary shares 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 $20,000 and $53,000 during the three and nine months ended March 31, 2021, respectively, related to the ESPP.

13. Related-party transactions

EKF Diagnostic Holdings

During the three and nine months ended March 31, 2021, the Company incurred expenses of $51,000 and $0.1 million, respectively, related to employees of EKF who provided services to Renalytix which are included in general and administrative expenses in the condensed consolidated statement of operations. During the three and nine months ended March 31, 2020, the Company incurred expenses of $51,000 and $0.1 million, respectively, related to employees of EKF who provided services to Renalytix which are included in general and administrative expenses in the condensed consolidated statement of operations.

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. As of March 31, 2021, amounts due to ISMMS totaled $0.3 million. During the three and nine months ended March 31, 2021, the Company incurred expenses of $0.2 million and $0.5 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, 2020, the Company incurred expenses of $0.2 million and $0.3 million, respectively, which are included in research and development expenses in the condensed consolidated statement of operations.

Kantaro Biosciences LLC

In connection with the formation of Kantaro, the Company entered into a five-year Advisory Services Agreement ("Advisory Agreement") pursuant to which the Company has agreed to provide certain advisory services to Kantaro. Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250

Class A Units to the Company as the sole consideration for the services to be rendered by the Company under the Advisory Agreement. A portion of the Company's units are subject to forfeiture if, prior to March 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 of March 31, 2021, the total liability associated with the services was $0.9 million, of which the total amount is classified as a current liability. For the three and nine months ended months ended March 31, 2021, the Company recognized $0.1 million and $0.9 million, respectively, in the statement of operations related to services performed under the Advisory Agreement. For the three and nine months ended March 31, 2021, $43,000 and $0.4 million, respectively, of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $41,000 and $0.2 million, respectively, were included within 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 $250,000 and had a note receivable for this amount at March 31, 2021. In addition, the Company recognized losses of $0.2 million on their investment in Kantaro during the nine months ended March 31, 2021.

VericiDx

During the three and nine months ended March 31, 2021, 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, 2021, amounts due from VericiDx totaled $0.2 million.