UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER
PURSUANT TO RULE 13a-16 OR 15d-16
UNDER THE SECURITIES EXCHANGE ACT OF 1934

Date of report: December 7, 2021

Commission File Number: 001-39387

Renalytix plc
(Translation of registrant's name into English)

Finsgate
5-7 Cranwood Street
London EC1V 9EE
United Kingdom
(Address of principal executive office)

Indicate by check mark whether the registrant files or will file annual reports under cover of Form 20-F or Form 40-F:

☒ Form 20-F ☐ Form 40-F

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1): ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7): ☐

INFORMATION CONTAINED IN THIS REPORT ON FORM 6-K

On December 7, 2021, Renalytix plc (the "Company") published an operational update and financial results for the three months ended September 30, 2021, which are furnished as Exhibit 99.1 to this Report on Form 6-K.

The Unaudited Condensed Consolidated Balance Sheets, Statements of Operations and Comprehensive Loss, Statements of Shareholders' Equity and Cash Flows and the Notes to Unaudited Interim Condensed Consolidated Financial Statements contained in Exhibit 99.1 are hereby incorporated by reference into the Company's Registration Statement on Form S-8 (Registration No. 333-248741).

EXHIBIT INDEX

Exhibit	Description
99.1	Operational Update and Financial Results for the Three Months Ended September 30, 2021.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

RENALYTIX PLC

By: /s/ James McCullough
James McCullough
Chief Executive Officer

Date: December 7, 2021

Exhibit 99.1

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

Renalytix Reports Financial Results for First Quarter of Fiscal Year 2022

LONDON and SALT LAKE CITY, December 7, 2021 – Renalytix plc (NASDAQ: RNLX) (LSE: RENX), an artificial intelligence-enabled in vitro diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and advance value-based care, today reported financial results for the quarter ended September 30, 2021.

Recent Highlights

- KidneyIntelX market access expansion continues with:
  - Increasing sales force deployment across VA Health system
  - Increasing medical science liaison (MSL) personnel nationwide
  - Clinical testing at Wake Forest / Atrium initiated in November
  - Clinical testing with Capital District Physicians Health Plan (CDPHP) initiated in November
  - Mount Sinai physician ordering base increased, with target testing run rate of 300 patients per week
- Partnered with St. Joseph's Health, based in Syracuse, NY, part of the Trinity Health System, for KidneyIntelX deployment and to advance value-based care
- Multiple private insurance coverage determinations, including Blue Cross Blue Shield coverage in two states
- Expanded peer-reviewed publication of key analytical and clinical validation studies including presentation of therapeutic response data
- Continued advancing KidneyIntelX regulatory strategy for diabetic kidney disease
- Implemented efforts to accelerate VA Health system launch program at a national level
- Continued hiring of key commercial personnel including Southeast regional sales, market access and health systems partnership directors to support expansion with Wake Forest and additional regional healthcare providers and payers
- JP Morgan Healthcare Conference presentation confirmed for January 12, 2022

First Quarter 2022 Financial Results

During the three months ended September 30, 2021, the Company recognized $0.5 million of revenue (Q1 2021: nil). Cost of revenue for the three months ended September 30, 2021 was $0.2 million.

Operating expense for the three months ended September 30, 2021 was $12.1 million compared to $5.4 million during the prior year period.

Within operating expenses, research and development expenses were $4.0 million for the three months ended September 30, 2021, an increase of $2.3 million from $1.7 million for the three months ended September 30, 2020. The increase in R&D expense was primarily due to professional fees as the Company continued utility studies at Mount Sinai and began utility studies at Wake Forest as well as the University of Utah.

General and administrative expenses were $8.1 million for the three months ended September 30, 2021, increasing $4.0 million from $4.1 million for the three months ended September 30, 2020. The increase was primarily due to an increase in compensation and related benefits, including share-based payments, due to increased headcount, as well as an increase in consulting and professional fees as the Company continues to grow.

Net loss attributable to ordinary shareholders was $10.1 million for the three months ended September 30, 2021 compared to $7.2 million for the prior year period.

Cash and cash equivalents totaled $54.3 million as of September 30, 2021.

For further information, please contact:

Renalytix plc www.renalytix.com
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Investec Bank plc (Joint Broker) **Tel: 020 7597 4000**
Gary Clarence / Daniel Adams

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CapComm Partners **Tel: 415-389-6400** or
Peter DeNardo investors@renalytix.com

About KidneyIntelX

KidneyIntelX, is a first-of-kind decision support and implementation platform that facilitates the identification and promotes the effective management of patients at risk of early-stage diabetic kidney disease, or DKD, progression by combining diverse data inputs, including validated blood-based biomarkers, inherited genetics, and personalized patient data from electronic health record, or EHR, using a proprietary algorithm to generate a unique patient risk score. This patient risk score enables prediction of progressive decline in kidney function, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk.

About Renalytix

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

Forward-Looking Statements

Statements contained in this press release regarding matters that are not historical facts are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. Examples of these forward-looking statements include statements concerning: the commercial prospects of KidneyIntelX, including whether KidneyIntelX will be successfully adopted by physicians and distributed and marketed, the rate of testing with KidneyIntelX in health care systems, expectations and timing of announcement of real-world testing evidence, the potential for KidneyIntelX to be approved for additional indications, our expectations regarding regulatory and reimbursement decisions and the ability of KidneyIntelX to curtail costs of chronic and end-stage kidney disease, optimize care delivery and improve patient outcomes. Words such as "anticipates," "believes," "estimates," "expects," "intends," "plans," "seeks," and similar expressions are intended to identify forward-looking statements. We may not actually achieve the plans and objectives disclosed in the forward-looking statements, and you should not place undue reliance on our forward-looking statements. Any forward-looking statements are based on management's current views and assumptions and involve risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. These risks and uncertainties include, among others: that KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving and potential acceptance, utility and clinical practice remains uncertain; we have only recently commercially launched KidneyIntelX; and risks relating to the impact on our business of the COVID-19 pandemic or similar public health crises. These and other risks are described more fully in our filings with the Securities and Exchange Commission (SEC), including the "Risk Factors" section of our annual report on Form 20-F filed with the SEC on October 21, 2021, and other filings we make with the SEC from time to time. All information in this press release is as of the date of the release, and we undertake no obligation to publicly update any forward-looking statement, whether as a result of new information, future events, or otherwise, except as required by law.

RENALYTIX PLC

Operational Update and Financial Results for the Three Months Ended September 30, 2021

Unless otherwise indicated, all references in this report, to the terms "Renalytix," "Renalytix plc," "the company," "we," "us" and "our" refer to Renalytix plc together with its subsidiaries. We recommend that you read the discussion below together with our audited financial statements and the notes thereto, which appear in our Annual Report on Form 20-F for the year ended June 30, 2021, filed with the Securities and Exchange Commission on October 21, 2021 (our "Annual Report").

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

OPERATIONAL REVIEW

About Renalytix

At Renalytix, we are helping lead the charge to introduce simple, more accurate prognosis and effective care management for the estimated 850 million people worldwide with chronic kidney disease. In the United States alone, chronic kidney disease affects close to an estimated 40 million people and is responsible for one of the largest cost drivers in the national medical system. Early identification, prognosis and treatment beginning with primary care physicians is essential if we are to stem the growing social cost and suffering associated with kidney disease.

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

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

- A 10-year government-wide contract with the U.S. General Services Administration at $950 per test
- Hiring of sales, medical science liaison, and customer service support for national coverage
- The Centers for Medicare & Medicaid Services awarding a national price of $950 per test
- 27 state Medicaid program authorization contracts
- Partnerships announced with the Mount Sinai Health System, University of Utah, Atrium Health, Wake Forest Baptist Health, and Capital District Physicians' Health Plan (CDPHP)
- New York State Department of Health approval
- A distinct Common Procedural Terminology (CPT) Code for reimbursement granted by the American Medical Association
- 20 private payor coverage determinations
- Multi-center, peer reviewed clinical studies that found KidneyIntelX is 72% more effective than the current standard of care in identifying early-stage patients at high risk for kidney disease progression and failure

About KidneyIntelX

Our novel platform, KidneyIntelX, uses a machine-learning enabled algorithm to process predictive blood biomarkers with key features from a patient's health record to generate an early and accurate kidney health risk score. The score identifies those patients at the most risk for kidney disease progression and/or failure and further guides ongoing clinical decisions.

KidneyIntelX is initially indicated for use with adults who have diagnosed kidney disease and diabetes – diabetic kidney disease or DKD. Future KidneyIntelX products in development intend to expand the indicated uses to include broader chronic kidney disease, health equity strategies and kidney health monitoring through treatment. Diabetes is the leading cause of chronic kidney disease, representing nearly 40%, and DKD patients are the highest contributors to emergency room dialysis. Unfortunately, many DKD patients are unaware that they either have kidney disease or that their disease has been progressing, often uncontrolled, for many years and now find themselves making difficult decisions about late-stage treatments. We believe this predicament is largely avoidable and have built the KidneyIntelX care model to ultimately provide the estimated 210,000 primary care physicians in the United States with a comprehensive suite of information and guidelines driven follow-on action.

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

Operational Progress

In November 2021, Renalytix announced a partnership with St. Joseph's Health to implement an advanced clinical care model designed to improve kidney health in patients with type 2 diabetes and early-stage chronic kidney disease. The Renalytix KidneyIntelX platform will be integrated with St. Joseph's Health care management to help prevent patients with diabetes and early-stage kidney disease from unnecessarily progressing to significant disease and/or kidney failure. KidneyIntelX is designed to enable primary care and specialist physicians to easily understand risk and implement St. Joseph's Health medication management, nutrition and education intervention protocols on a timely basis. St. Joseph's Health, based in Syracuse, NY, is part of Trinity Health, one of the largest multi-institutional Catholic health care delivery systems in the U.S., serving diverse communities that include more than 30 million people across 25 states. KidneyIntelX test risk assessment will be available through St. Joseph's Hospital's electronic health record, or her, system, providing access to primary care physicians, endocrinologists, nephrologists, and care teams.

In October 2021, we announced the expansion of our commercial strategy to address early-stage kidney disease in the Veterans Health Administration patient population. KidneyIntelX will be deployed to help VA primary care physicians identify DKD patients at high and low risk for rapid progression and kidney failure. The Veterans Health Administration is America's largest integrated health care system, providing care at 1,293 health care facilities, including 171 medical centers and 1,112 outpatient sites of care of varying complexity (VHA outpatient clinics), serving nine million enrolled veterans each year. The veteran population has an approximately one-third higher chronic kidney disease and DKD prevalence than the general population, which has been attributed to the significant multi-morbidity and higher mean age in this group. The prevalence of DKD in veterans is estimated to be between 4% (most conservative DKD definition) and 14%; meaning 0.5 to 1.0 million individuals. We hired Jed Fulk, VP of sales for government accounts, to develop and lead a team of regional sales managers and account executives to support KidneyIntelX™ rollout to the VA Health System.

In October 2021, we also disclosed our first Blue Cross Blue Shield coverage contract, as well as coverage with one of New York State's largest not-for-profit health insurance companies with over 1.5 million members

In September 2021, Mount Sinai Health System and Renalytix announced a scale-up of the KidneyIntelX care program to a targeted run-rate of 300 tests per week. Renalytix testing is fully covered at $950 per test under the Mount Sinai real-world evidence program and we expect an estimated 6,000 tests to be completed by the end of fiscal 2022. We expect that previously announced partnerships with Atrium Health, Wake Forest Baptist Health and University of Utah will be running live testing as early as December 2021.

Expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website – www.kidneyintelx.com. We believe our education and support program will be an important resource to help inform and improve care for early-stage diabetic kidney disease ("DKD") patients and support future hospital system deployments of KidneyIntelX in the United States and abroad.

The Company also continues to execute on a number of key operational items including (1) growing our world-class employee base and leadership team to manage U.S. national commercial expansion, (2) developing expanded products which will add to the KidneyIntelX clinical use cases and addressable market, (3) adding laboratory services capacity with our facility in Salt Lake City, Utah, and (4) generating additional utility and validation data to build-out our peer-reviewed performance data dossier.

Reimbursement and Regulatory

We have achieved full insurance coverage for U.S. government physicians ordering KidneyIntelX through our General Services Administration contract and are moving assertively to activate our VA Health System sales strategy. We estimate there is full coverage available at $950 per test to an estimated 400,000 DKD patients in the VA Health System alone.

Under our agreement with the Mount Sinai Health System, we receive payment for KidneyIntelX testing at $950 per reportable result through the first approximately 6,000 patients tested under a real-world evidence development program. In October 2021, this program was expanded system-wide and Mount Sinai is working to achieve a weekly testing run rate of 300 patients.

As we have previously reported, KidneyIntelX has achieved both a distinct Common Procedural Terminology, or CPT, reimbursement code 0105U and inclusion in the final 2020 Clinical Laboratory Fee Schedule by CMS which set a national price for KidneyIntelX at $950 per reportable test result.

As has been experienced broadly across the diagnostics industry, KidneyIntelX has had a prolonged review since our De Novo submission in August of 2020 due to FDA staffing challenges and continued prioritization of a significant number of COVID-19 related Emergency Use Authorization submissions. Across a number of applications, the FDA is not currently meeting its 150-day De Novo review goal in MDUFA IV due to “considerable increases in COVID-19 activities” and this is not unique to Renalytix. We are committed to working collaboratively and expeditiously with the FDA and continue to provide additional information, clarification and supplemental analyses related to our novel KidneyIntelX design as requested. While we will continue to decline to forecast projecting a definitive timeline for De Novo marketing authorization, we are confident that KidneyIntelX will receive FDA De Novo marketing authorization given interactive dialogue and data requirements to date and that Fiscal 2022 commercial objectives are on track.

FINANCIAL REVIEW

Financial review of the three-month period ended September 30, 2021

Our operating loss for the three months ended September 30, 2021, was $11.8 million (September 30, 2020: $5.4 million) and the net loss attributable to ordinary shareholders for the three months ended September 30, 2021, was $10.1 million (September 30, 2020: $7.2 million).

Revenue

During the three months ended September 30, 2021, we recognized $0.45 million of revenue related to testing under the Mount Sinai clinical utility study and $0.03 million of revenue related to services performed for AstraZeneca. There was no revenue for the three months ended September 30, 2020.

Cost of Revenue

During the three months ended September 30, 2021, cost of revenue consisted of $0.2 million primarily attributable to KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. There was no cost of revenue for the three months ended September 30, 2020.

Research and Development Costs

Research and development expenses increased by $2.3 million, from $1.7 million for the three months ended September 30, 2020 to $4.0 million for the three months ended September 30, 2021. The increased R&D expense was primarily due to increased professional fees as we continue utilities studies at Mount Sinai as well as began utility studies at Wake Forest and University of Utah.

General and Administrative Costs

General and administrative expenses increased by $4.0 million, from $4.1 million for the three months ended September 30, 2020 to $8.1 million for the three months ended September 30, 2021. The increase was primarily due to a $2.3 million increase in compensation and related benefits, including share-based payments, due to increased headcount, a $0.5 million increase in consulting and professional fees, a $0.4 million increase in marketing expense, a $0.4 million increase in computers, software and IT costs, a $0.2 million increase in insurance expense, and a $0.2 million increase in other operating expenses.

Performance of Contract Liability to Affiliate

In May 2020, we and the Icahn School of Medicine at Mount Sinai entered into an operating agreement to form a joint venture, Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. During the three months ended September 30, 2021, we recognized $0.1 million related to the performance of our contract liability with Kantaro compared to $0.5 million during the three months ended September 30, 2020. This represents the allocation of costs related to performing services on behalf of Kantaro.

Foreign Currency Gain (Loss)

During the three months ended September 30, 2021, we recorded an unrealized foreign exchange gain of $2.3 million primarily attributable to intercompany loans and cash balances denominated in currencies other than the functional currency. We recognized a realized foreign exchange gain of $0.1 million during the three months ended September 30, 2020 and had an unrealized foreign exchange loss of $2.2 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 September 30, 2021, we recorded a loss of $0.6 million to adjust the VericiDx investment to fair value. There was no fair value adjustment for the three months ended September 31, 2020.

Cash Flows

Net cash used in operating activities

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

During the three months ended September 30, 2020, net cash used in operating activities was $10.4 million and was primarily attributable to our $7.6 million net loss and $3.6 million in the net change in our operating assets and liabilities that was offset by $0.8 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to a $3.8 million decrease in our prepaid expenses and other current assets. Noncash charges were primarily related to share-based compensation expense of $0.5 million.

Net cash used in investing activities

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

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

Net cash used in financing activities

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

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

Cash and Cash Equivalents

We had cash and, cash equivalents of $54.3 million as of September 30, 2021, decreased from $65.2 million as of June 30, 2021 due to normal operations as we continue to commercialize KidneyIntelX and grow our business.

RENALYTIX PLC

CONDENSED CONSOLIDATED BALANCE SHEETS (UNAUDITED)

(in thousands, except share and per share data)	September 30, 2021	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 54,326	$ 65,128
Accounts receivable	352	594
Prepaid expenses and other current assets	1,378	993
Note receivable from Kantaro—current	75	75
Receivable from affiliates	29	1
Total current assets	56,160	66,791
Property and equipment, net	2,632	2,490
Investment in VericiDx	8,473	9,295
Total assets	$ 67,265	$ 78,576
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 788	$ 1,403
Accounts payable – related party	871	361
Accrued expenses and other current liabilities	4,594	4,602
Accrued expenses – related party	607	224
Deferred revenue	90	122
Payable to affiliate—current	289	350
Total current liabilities	7,239	7,062
Other liabilities	53	53
Total liabilities	7,292	7,115
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 76,395,831 and 76,463,244 shares authorized at September 30, 2021 and June 30, 2021, respectively; 72,240,706 and 72,197,286 shares issued and outstanding at September 30, 2021 and June 30, 2021, respectively	220	220
Additional paid-in capital	151,610	150,407
Accumulated other comprehensive income (loss)	5,691	8,276
Accumulated deficit	(97,548)	(87,442)
Total shareholders' equity	59,973	71,461
Total liabilities and shareholders' equity	$ 67,265	$ 78,576

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

RENALYTIX PLC

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (UNAUDITED)

(in thousands, except share data)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020
Revenue	$ 482	$ —
Cost of revenue	227	—
Gross profit	255	—
Operating expenses:		
Research and development	3,998	1,745
General and administrative	8,132	4,116
Performance of contract liability to affiliate	(61)	(458)
Total operating expenses	12,069	5,403
Loss from operations	(11,814)	(5,403)
Equity in losses of affiliate	—	(116)
Foreign currency gain (loss)	2,303	(2,147)
Fair value adjustment to VericiDx investment	(607)	—
Other income, net	12	52
Net loss	(10,106)	(7,614)
Net loss attributable to noncontrolling interest	—	(393)
Net loss attributable to ordinary shareholders	(10,106)	(7,221)
Other comprehensive income (loss):		
Foreign exchange translation adjustment	(2,585)	2,255
Comprehensive loss	(12,691)	(5,359)
Comprehensive loss attributable to noncontrolling interest	—	(67)
Comprehensive loss attributable to Renalytix	$ (12,691)	$ (5,292)
Net loss per ordinary share—basic and diluted	$ (0.14)	$ (0.10)
Weighted average ordinary shares—basic and diluted	72,230,803	69,835,982

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

RENALYTIX PLC

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity attributable to Renalytix	Noncontrolling interests	Total shareholders' equity
	Shares	Amount						
Balance at July 1, 2021	72,197,286	$ 220	$ 150,407	$ 8,276	$ (87,442)	$ 71,461	$ —	$ 71,461
Shares issued under the employee share purchase plan	10,920	—	120	—	—	120	—	120
Exercise of stock options	32,500	—	86	—	—	86	—	86
Share-based compensation expense	—	—	997	—	—	997	—	997
Currency translation adjustments	—	—	—	(2,585)	—	(2,585)	—	(2,585)
Net loss	—	—	—	—	(10,106)	(10,106)	—	(10,106)
Balance at September 30, 2021	72,240,706	$ 220	$ 151,610	$ 5,691	$ (97,548)	$ 59,973	$ —	$ 59,973

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

RENALYTIX PLC

CONDENSED CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (UNAUDITED)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity attributable to Renalytix	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
Verici distribution in specie	—	—	1,638	(25)	—	1,613	(1,613)	—
Share-based compensation expense	—	—	501	—	—	501	—	501
Currency translation adjustments	—	—	—	2,255	—	2,255	(67)	2,188
Net loss	—	—	—	—	(7,221)	(7,221)	(393)	(7,614)
Balance at September 30, 2020	72,029,634	$ 219	$147,883	$ 1,030	$ (59,938)	$ 89,194	$ (2,073)	$ 87,121

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

RENALYTIX PLC

CONDENSED CONSOLIDATED STATEMENTS OF CASH FLOWS (UNAUDITED)

(in thousands)	Three Months Ended September 30, 2021	Three Months Ended September 30, 2020
Cash flows from operating activities:		
Net loss	$ (10,106)	$ (7,614)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	119	27
Share-based compensation	997	501
Realized gain on short-term investments	—	(18)
Equity losses in affiliate	—	116
Fair value adjustment to VericiDx investment	607	—
Unrealized foreign exchange loss (gain)	(2,058)	178
Changes in operating assets and liabilities:		
Accounts receivable	242	—
Prepaid expenses and other current assets	(431)	(3,845)
Related party receivable	(28)	—
Accounts payable	(646)	810
Accounts payable – related party	510	—
Accrued expenses and other current liabilities	14	(111)
Accrued expenses – related party	383	—
Deferred revenue	(32)	—
Payable to affiliate	(61)	(459)
Net cash used in operating activities	(10,490)	(10,415)
Cash flows from investing activities:		
Purchases of property and equipment	(224)	(441)
Software development costs	(33)	(122)
Proceeds from short-term investments	—	1,000
Net cash used in investing activities	(257)	437
Cash flows from financing activities:		
Gross proceeds from the issuance of ordinary shares, net of underwriting fees	—	79,182
Payment of offering costs	—	(2,304)
Proceeds from the issuance of ordinary shares under employee share purchase plan	120	—
Proceeds from exercise of stock options	86	—
Net cash provided by financing activities	206	76,878
Effect of exchange rate changes on cash	(261)	2,060
Net increase in cash and cash equivalents	(10,802)	68,960
Cash and cash equivalents, beginning of period	65,128	13,293
Cash and cash equivalents, end of period	$ 54,326	$ 82,253
Supplemental noncash investing and financing activities:		
Financing costs in accounts payable and accrued expenses	$ —	$ 1
Software development costs in accounts payable and accrued expenses	$ 19	$ 311
Purchase of property and equipment in accounts payable and accrued expenses	$ 15	$ 177

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

RENALYTIX PLC

NOTES TO UNAUDITED INTERIM CONDENSED CONSOLIDATED FINANCIAL STATEMENTS

1. Business and risks

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

Since inception in March 2018, the Company has focused primarily on organizing and staffing the Company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting its intellectual property portfolio and commercial laboratory operations, pursuing regulatory clearance and developing a reimbursement strategy. 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 $97.5 million as of September 30, 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 $54.3 million as of September 30, 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 September 30, 2021 and its results of operations for the three

months ended September 31, 2021 and 2020, respectively, and cash flows for the three months ended September 30, 2021 and 2020. Operating results for the three months ended September 30, 2021 are not necessarily indicative of the results that may be expected for the year ending June 30, 2022. The unaudited interim condensed consolidated financial statements, presented herein, do not contain the required disclosures under U.S. GAAP for annual financial statements. The accompanying unaudited interim condensed consolidated financial statements should be read in conjunction with the annual audited consolidated financial statements and related notes as of and for the year ended June 30, 2021.

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

Use of estimates

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

Estimates and assumptions are periodically reviewed, and the effects of revisions are reflected in the condensed consolidated financial statements in the period they are determined to be necessary. Significant areas that require management's estimate include the assumptions used in determining the fair value of share-based awards, recording the prepaid/accrual and associated expense for research and development activities performed for the Company by third parties, determining useful lives of property and equipment and capitalized software, the assessment of noncontrolling interest and equity method investments, fair value measurements (including those related to VericiDx), 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 consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The functional currency of Renalytix plc and Renalytix AI Limited is GB Pounds. The functional currency of Renalytix AI, Inc. is the U.S. dollar. Assets and liabilities of Renalytix plc and Renalytix AI Limited are translated at the rate of exchange at period-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported in the consolidated statements of operations and comprehensive loss.

Concentrations of credit risk and major customers

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

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

Fair value of financial instruments

At September 30, 2021 and June 30, 2021, the Company's financial instruments included accounts receivable, prepaid expenses and other current assets, accounts payable and accrued expenses and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature.

Fair value option

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

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of September 30, 2021, the Company had a cash balance of $54.3 million. As of June 30, 2021, the Company had a cash balance of $65.1 million.

Accounts receivable

Accounts receivable are recorded at the invoice amount and are non-interest bearing. The Company considers receivables past due based on the contractual payment terms. The Company reserves specific receivables if collectability is no longer reasonably assured. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations, historical payment patterns, and individual customer circumstances. No reserves have been recorded as of September 30, 2021 or June 30, 2021.

Property and equipment

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

Performance of contract liability to affiliate

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement ("Kantaro Operating Agreement") to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. During the three months ended September 30, 2021 and 2020, the Company recognized $0.1 million and $0.5 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. During the year ended June 30, 2021, the company concluded that the fair value of its equity method investment in Kantaro was zero and recorded a $1.9 million impairment charge. The Company owned 25% of the membership equity units in Kantaro at September 30, 2021 and June 30, 2021.

VericiDx Limited

As the Company can exert significant influence over, but does not control, VericiDx's operations through representation on VericiDx's board of directors, the Company accounts for this investment as an equity method investment and has elected the fair value option because VericiDx's stock price is readily observable via the London Stock Exchange. Under the fair value option, the investment in VericiDx is recorded at fair value at each reporting period with subsequent changes in fair value reported in the condensed consolidated statements of operations and comprehensive loss. Based on closing stock price of VericiDx, the fair value of the investment in VericiDx was $8.5 million at September 30, 2021 and $9.3 million at June 30, 2021. During the three months ended September 30, 2021, the Company recorded a fair value adjustment of $0.6 million in the condensed consolidated statements of operations and comprehensive loss. The Company owned 6.9% of the ordinary shares of VericiDx at September 30, 2021 and 6.9% at June 30, 2021.

Impairment assessment

The Company evaluates its investments that are in unrealized loss positions, if any, and equity method investments for other-than-temporary impairment on a quarterly basis (see Note 5). Such evaluation involves a variety of considerations, including assessments of the risks and uncertainties associated with general economic conditions and distinct conditions affecting specific issuers or investees. Factors considered by the Company include (i) the length of time and the extent to which an investment's fair value has been below its cost; (ii) the financial condition, credit worthiness, and near-term prospects of the issuer; (iii) the length of time to maturity; (iv) future economic conditions and market forecasts; (v) the Company's intent and ability to retain its investment for a period of time sufficient to allow for recovery of market value; (vi) an assessment of whether it is more likely than not that the Company will be required to sell its investment before recovery of market value; and (vii) whether events or changes in circumstances indicate that the investment's carrying amount might not be recoverable.

Software development costs

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

Revenue recognition

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

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. Certain contracts have options for the customer to acquire additional services. The Company evaluates these options to determine if a material right exists. If, after that evaluation, it determines a material right

does exist, it assigns value to the material right based upon the renewal option approach. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer occurs at a point in time. Sales tax and other similar taxes are excluded from revenues.

Cost of revenue

Cost of revenue consists of costs directly attributable to the services rendered, including labor costs 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 September 30, 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 September 30, 2021 and 2020, there were 4,155,125 and 3,408,858 shares, respectively, issuable upon exercise of outstanding options that were anti-dilutive and excluded from diluted loss per share for the three months ended September 30, 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 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 months ended September 30, 2021, the Company recognized $0.4 million of testing services revenue. Sales tax and other similar taxes are excluded from revenues. The Company did not recognize any testing services revenue during the three months ended September 30, 2020.

Pharmaceutical services revenue

Pharmaceutical services revenue is generated from the provision of analytical services to customers. Contracts with customers generally include an initial upfront payment and additional payments upon achieving performance milestones. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer which may occur at a point in time or over time depending on the individual contract terms. Sales tax and other similar taxes are excluded from revenues. During the three months ended September 30, 2021, the Company recognized $32,000 of pharmaceutical services revenue where performance obligations are satisfied at a point in time. There was no pharmaceutical services revenue recognized during the three months ended September 30, 2020.

Professional services revenue

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

The Company did not recognize any professional services revenue during the three months ended September 30, 2021 or 2020.

Deferred revenue

Deferred revenue represents the allocated transaction price to the material right which will be recognized as revenue when the renewal options are exercised which is expected to occur over the next 24 months.

The following table summarizes the changes in deferred revenue (in thousands):

	September 30, 2021	June 30, 2021
Balance, beginning of period	$ 122	$ —
Deferral of revenue	—	250
Revenue recognized	(32)	(128)
Balance, end of period	$ 90	$ 122

5. Fair value measurements and the fair value option

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

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

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

	Fair value measurement at reporting date using		
(in thousands)	(Level 1)	(Level 2)	(Level 3)
September 30, 2021:			
Assets:			
Equity investment in VericiDx	$ 8,473	$ —	$ —
June 30, 2021:			
Assets:			
Equity investment in VericiDx	$ 9,295	$ —	$ —

Non-financial assets and liabilities

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

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

6. Property and equipment

Property and equipment consists of (in thousands):

	September 30, 2021	June 30, 2021
Lab equipment	$ 825	$ 592
Software	1,554	1,534
Office equipment	90	84
Office furniture	35	35
Leasehold improvements	576	576
Total	3,080	2,821
Less accumulated depreciation and amortization	(448)	(331)
	$ 2,632	$ 2,490

Depreciation expense was $0.1 million and $30,000 for the three months ended September 30, 2021 and 2020, respectively.

As of September 30, 2021 and June 30, 2021, there was $1.2 million and $1.3 million, respectively, of unamortized capitalized software development costs. Amortization expense related to capitalized software development costs was $40,000 for the three months ended September 30, 2021 and immaterial for the three months ended September 30, 2020. Amortization is expensed within cost of revenue in the condensed consolidated statement of operations.

As of September 30, 2021, the expected amortization expense for software for the next five years and thereafter is as follows:

2022 (remaining nine months)	$ 96
2023	128
2024	128
2025	128
2026	128
Thereafter	544
	$ 1,152

7. Accrued expenses and other current liabilities

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

	September 30, 2021	June 30, 2021
Consulting and professional fees	$ 485	$ 954
Research and development	321	—
Payroll and related benefits	3,592	3,493
Other	196	155
	$ 4,594	$ 4,602

8. Commitments and contingencies

Leases

The Company entered into operating lease agreements for office space and laboratory testing facilities with terms ranging from month-to-month to five years. The Company recognized rent expense of $0.1 million and $0.2 million during the three months ended September 30, 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):

2022 (remaining nine months)	$ 62
2023	83
2024	83
2025	28
	$ 256

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). The company contributed $73,000 to employee accounts for the three months ended September 30, 2021 and $25,000 for the three months ended September 30, 2020.

Legal proceedings

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

9. License and services agreements

Mount Sinai license and sponsored research agreements

On May 30, 2018, the Company entered into an exclusive license agreement (the "ISMMS License Agreement") and, on March 7, 2019, a sponsored research agreement (the "ISMMS SRA") with Mount Sinai. Under the terms of the ISMMS License Agreement, ISMMS granted the Company (i) an exclusive, sublicensable license to use certain patent rights covering specific inventions concerning the utilization of biomarkers guided artificial intelligence techniques for detecting kidney functional decline (the "ISMMS Technology"), (ii) a non-exclusive license under unregistered licensed copyrights and licensed know-how and (iii) an exclusive option to obtain licensed technology conceived after May 30, 2018. The Company is obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. The Company is also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, the Company is obligated to pay Mount Sinai between 15% and 25% of any consideration received from a sublicensee. Furthermore, the Company agreed to carry out and fund a clinical utility study for KidneyIntelX at an estimated cost of $0.7 million 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 $0.4 million in research and development expenses under the ISMMS SRA for the three months ended September 30, 2021. The Company did not incur any expenses related to the ISMMS SRA for the three months ended September 30, 2020.

Mount Sinai COVID-19 sponsored research agreement

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

Under the terms of the MASKeD-COVID Study, the Company is obligated to pay for all direct and indirect costs incurred under the sponsored research agreement in an amount totaling $1.8 million. As of September 30, 2021, amounts due to ISMMS under the MASKeD-COVID Study totaled $0.9 million, and $0.5 million was expensed during the three months ended September 30, 2021. The Company did not incur any expenses related to this program during the three months ended September 30, 2020.

Joslin diabetes center license 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.

Joslin sponsored research agreement

In September 2021, the Company finalized a sponsored research agreement (the "Joslin SRA") with Joslin for patent filings on certain additional novel biomarkers in kidney disease for development and deployment in the KidneyIntelX platform. The novel biomarkers have the potential to provide additional clinical utility for understanding early disease progression and risk of kidney failure, therapeutic response, and the mechanistic pathways of kidney disease beyond the inflammatory and tubular injury markers that are currently captured by KidneyIntelX. The agreement provides for performance of research and development activities up to a total amount of $1.7 million related to completion of the study.

The Company did not incur any expenses related to the Joslin SRA during the three months ended September 30, 2021.

Other collaborative research and development agreements

The Company entered into collaborative research and development agreements with several parties, including Wake Forest University Health Sciences and University of Utah, among other parties, for mutually agreed upon programs such as clinical trials, sponsored projects, and sponsored research agreements to improve outcomes for kidney disease patients and reduce long-term costs for the treatment of kidney disease. The research under these agreements will span several years and the Company has total funding commitments of $12.3 million. Research and development expenses were $0.3 million under these agreements for the three months ended September 30, 2021, and the remaining funding commitments at September 30, 2021 totaled $12.0 million.

10. Shareholders' equity

Ordinary shares

As of September 30, 2021, the Company had 76,395,831 ordinary shares authorized on a fully diluted basis. Each share entitles the holder to one vote on all matters submitted to a vote of the Company's shareholders. Ordinary shareholders are entitled to receive dividends as may be declared by the board of directors. From inception through September 30, 2021, no cash dividends have been declared or paid.

11. Share-based compensation

Equity Incentive Plan

In November 2018, Company established the Renalytix plc Share Option Plan (the "Plan") and a U.S. Sub-Plan and Non-Employee Sub-Plan. The Plan provides for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of September 30, 2021, there were 3,047,838 shares available for future issuance under the Plan.

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

The options granted as of September 30, 2021 vest equally over twelve quarters following the grant date, with the exception of 80,724 options which vested immediately when granted, 602,100 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary and 500,000 which vest 1/12th on the one year anniversary and equally over twelve quarters following the one year anniversary. If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

The Company recorded share-based compensation expense in the following expense categories in the condensed consolidated statements of operations for the three months ended September 30, 2021 and 2020 (in thousands):

	Three Months Ended September 30,	
	2021	2020
Research and development	$ 179	$ 195
General and administrative	795	296
	$ 974	$ 491

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

	Three Months Ended September 30,	
	2021	2020
Expected term (in years)	6.11	5.7
Expected volatility	66.9%	67.3%
Risk-free rate	1.02%	0.3%
Dividend yield	— %	— %

The weighted average fair value of the options granted during the three months ended September 30, 2021 and 2020 was $8.14 and $4.31 per share, respectively.

The following table summarizes the stock option granted to employees and non-employees for the three months ended September 30, 2021:

	Number of shares under option plan	Weighted-average exercise price per option	Weighted-average remaining contractual life (in years)
Outstanding at June 30, 2021	4,265,958	4.73	8.2
Granted	40,000	13.47	
Exercised	(32,500)	2.56	
Forfeited	(118,333)	6.67	
Outstanding at September 30, 2021	4,155,125	4.51	8.0
Exercisable at September 30, 2021	2,304,788	2.21	7.4
Vested and expected to vest at September 30, 2021	4,155,125	4.51	8.0

As of September 30, 2021, there was $7.8 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 1.96 years. The aggregate intrinsic value of options outstanding and options exercisable at September 30, 2021 was $17.4 million and $25.1 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 common stock. The number of shares of the Company's common stock that may be issued pursuant to rights granted under the ESPP shall automatically increase on January 1st of each year, commencing on January 1, 2021 and continuing for ten years, in an amount equal to the lesser of one percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, and 2,000,000 ordinary shares, subject to the discretion of the board of directors or renumeration committee to determine a lesser number of shares shall be added for such year.

Under the ESPP, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the board of directors or renumeration committee. Eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of the Company's common stock on the first day of the offering period or on the purchase date. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not purchase more than $25,000 worth of the Company's common stock for each calendar year in which such rights is outstanding. During the three months ended September 30, 2021, 10,920 shares were purchased under the ESPP.

In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company's common stock at 85% of the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, share-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period. The Company recognized share-based compensation expense of $23,000 and $10,000 during the three months ended September 30, 2021 and 2020, respectively, related to the ESPP.

12. Related-party transactions

EKF Diagnostic Holdings

During the three months ended September 30, 2021 and 2020, the Company incurred expenses of $0.1 million and $0.1 million, respectively, related to employees of EKF who provided services to Renalytix and is 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 9). As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's IPO on AIM in November 2018, the subsequent sale of ordinary shares in July 2019 and the Company's IPO on Nasdaq in July 2020. As of September 30, 2021, amounts due to ISMMS totaled $1.5 million. During the three months ended September 30, 2021 and 2020 the Company incurred expenses of $1.3 million and $0.1 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 December 31, 2021, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services to be provided under the Advisory Agreement was $2.0 million and the fair value of the Class A units received from Kantaro was $2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions which include discount rates and future cash flows, among others. As a result of the impairment charge in the year ended June 30, 2021 as discussed in Note 5, the carrying value of the Kantaro investment was written down to zero.

A contributing factor to the impairment consideration for Kantaro was lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees. Based on these circumstances, the Company adjusted the liability to perform services to Kantaro under the Advisory Agreement during the year ended June 30, 2021. As of September 30, 2021, the total liability associated with the services was $0.3 million, of which the total amount is classified as a current liability.

For the three months ended September 30, 2021 and 2020, the Company recognized $0.1 million and $0.5 million, respectively, in the statement of operations related to services performed under the Advisory Agreement. For the three months ended September 30, 2021, $33,000 and $28,000 of costs incurred related to the performance of the Advisory Agreement services were included within research and development and general and administrative expense, respectively. For the three months ended September 30, 2020, $0.2 million and $0.1 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and general and administrative expense, respectively.

In addition to the equity granted at formation, the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $0.3 million and an additional $0.5 million thereafter. The Company committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per year rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to the Company based on each investor’s proportionate ownership). The Company loaned Kantaro $250,000 and initially recorded a note receivable. The Company elected to recognize the equity investment losses based on the ownership level of each specific investment and will continue to record equity method losses until the amount of the loan receivable is reduced to zero. The loan had a carrying value of $75,000 at September 30, 2021 and June 30, 2021.

VericiDx

During the three months ended September 30, 2021, the Company paid the salary of an executive of VericiDx and VericiDx has agreed to reimburse the Company for those amounts. As of September 30, 2021, amounts due from VericiDx totaled $29,000.