

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended September 30, 2023

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934 FOR THE TRANSITION PERIOD FROM TO

Commission File Number 001-39387



Renalytix plc

(Exact name of Registrant as specified in its Charter)

England and Wales

(State or other jurisdiction of incorporation or organization)

Finsgate

5-7 Cranwood Street

London, United Kingdom

(Address of principal executive offices)

Not Applicable

(I.R.S. Employer Identification No.)

EC1V 9EE

(Zip Code)

+44 20 3139 2910

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
American Depositary Shares, each representing two ordinary shares, nominal value £0.0025 per share	RNLX	The Nasdaq Stock Market, LLC
Ordinary shares, nominal value £0.0025 per share	*	The Nasdaq Stock Market, LLC*

* Not for trading, but only in connection with the registration of the American Depositary Shares.

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES NO

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES NO

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
Emerging growth company	<input checked="" type="checkbox"/>		

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES NO

As of November 10, 2023, there were 97,430,156 ordinary shares, nominal value £0.0025 per share, outstanding, which if all were held in ADS form would be represented by 48,715,078 American Depositary Shares, each representing two ordinary shares.

RENALYTIX PLC
QUARTERLY REPORT ON FORM 10-Q
TABLE OF CONTENTS

	Page
PART I	
Item 1.	<u>Consolidated Financial Statements (unaudited)</u> <u>1</u>
	<u>Consolidated Balance Sheets as of September 30, 2023 (unaudited) and June 30, 2023</u> <u>1</u>
	<u>Consolidated Statements of Operations and Comprehensive Loss for the three months ended September 30, 2023 and 2022 (unaudited)</u> <u>2</u>
	<u>Consolidated Statements of Shareholders' Equity (Deficit) for the three months ended September 30, 2023 and 2022 (unaudited)</u> <u>3</u>
	<u>Consolidated Statements of Cash Flows for the three months ended September 30, 2023 and 2022 (unaudited)</u> <u>4</u>
	<u>Notes to Consolidated Financial Statements (unaudited)</u> <u>5</u>
Item 2.	<u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u> <u>21</u>
Item 3.	<u>Quantitative and Qualitative Disclosures About Market Risk</u> <u>32</u>
Item 4.	<u>Controls and Procedures</u> <u>32</u>
PART II	
Item 1.	<u>Legal Proceedings</u> <u>34</u>
Item 1A.	<u>Risk Factors</u> <u>34</u>
Item 2.	<u>Unregistered Sales of Equity Securities</u> <u>35</u>
Item 3.	<u>Defaults Upon Senior Securities</u> <u>35</u>
Item 4.	<u>Mine Safety Disclosures</u> <u>35</u>
Item 5.	<u>Other Information</u> <u>35</u>
Item 6.	<u>Exhibits</u> <u>36</u>

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q for the three months ended September 30, 2023 (this “Quarterly Report”) contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”), Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), and the Private Securities Litigation Reform Act of 1995. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “goal,” “target,” “expect,” “intend,” “plan,” “objective,” “anticipate,” “believe,” “estimate,” “predict,” “potential,” “continue” and “ongoing,” or the negative of these terms, or other comparable terminology intended to identify statements about the future. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, levels of activity, performance or achievements to be materially different from the information expressed or implied by these forward-looking statements. The forward-looking statements and opinions contained in this Quarterly Report are based upon information available to us as of the date of this Quarterly Report and, while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Forward-looking statements include statements about:

- the timing and plans for commercialization of KidneyIntelX;
- the timing and plans for regulatory filings and decisions;
- our plans to maintain regulatory approval of kidneyintelX.dkd and obtain and maintain regulatory approvals for other products from our KidneyIntelX platform;
- the potential benefits of KidneyIntelX;
- the market opportunities for KidneyIntelX and our ability to maximize those opportunities;
- our business strategies and goals;
- our ability and plans to establish and maintain partnerships and projections related to future test volume as part of those partnerships;
- our ability and plans to drive adoption of KidneyIntelX and integrate KidneyIntelX into clinical workflow;
- estimates of our sales, revenue, expenses and capital requirements and our need for and ability to obtain additional financing;
- our ability to continue as a going concern;
- third-party payor reimbursement and coverage decisions;
- the performance of our third-party suppliers and manufacturers,
- our expectations regarding our ability to obtain and maintain intellectual property protection for our diagnostic products and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding regulatory classification of KidneyIntelX, as well as the regulatory response to the marketing and promotion of KidneyIntelX;
- our expectations regarding the inclusion of KidneyIntelX in the final version of the KDIGO 2023 Clinical Practice Guideline for Evaluation and Management of Chronic Kidney Disease;
- the impact of guidelines and recommendations published by various organizations on the use of our products;
- our expectations regarding developments relating to our competitors;
- our ability to identify, recruit and retain key personnel;
- the potential for breaches of data privacy, or disruptions in our information technology systems;
- the potential direct or indirect impact of the COVID-19 pandemic and the conflict in Ukraine on the global economy and our business or operations;
- our ability to continue to satisfy the listing requirements of the NASDAQ Global Market;
- the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations and capital expenditure requirements; and
- risks detailed under the caption “Risk Factors” in this Quarterly Report and in our other reports filed with the U.S. Securities and Exchange Commission (“SEC”), from time to time hereafter.

You should refer to the section titled "Part I, Item 1A. Risk Factors" contained in the Company's Annual Report on Form 10-K for the year ended June 30, 2023 (the "Annual Report on Form 10-K") and the sections of this Quarterly Report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Risk Factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this Quarterly Report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. Forward-looking statements speak only as of the date on which such statements are made. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law, applicable regulations or the rules of the Nasdaq Stock Market LLC.

You should read this Quarterly Report, the documents that we reference in this Quarterly Report and the documents we have filed as exhibits to this Quarterly Report completely and with the understanding that our actual future results may be materially different from what we expect. We qualify all of our forward-looking statements by these cautionary statements.

RENALYTIX PLC

CONSOLIDATED BALANCE SHEETS (Unaudited)

(in thousands, except share and per share data)	September 30, 2023	June 30, 2023
Assets		
Current assets:		
Cash and cash equivalents	\$ 13,891	\$ 24,682
Accounts receivable	1,014	776
Prepaid expenses and other current assets	1,566	1,424
Total current assets	16,471	26,882
Property and equipment, net	944	1,027
Right of Use Asset	131	159
Investment in VericiDx	978	1,460
Other Assets	1,016	1,101
Total assets	\$ 19,540	\$ 30,629
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,715	\$ 1,485
Accounts payable – related party	1,653	1,451
Accrued expenses and other current liabilities	4,566	6,644
Accrued expenses – related party	2,539	1,963
Current lease liability	131	130
Convertible notes-current	4,569	4,463
Total current liabilities	15,173	16,136
Convertible notes-noncurrent	5,848	7,485
Noncurrent lease liability	10	41
Total liabilities	21,031	23,662
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 102,537,697 shares authorized; 95,019,440 and 93,781,478 shares issued and outstanding at September 30, 2023 and June 30, 2023, respectively	290	286
Additional paid-in capital	188,031	186,456
Accumulated other comprehensive loss	(1,333)	(1,450)
Accumulated deficit	(188,479)	(178,325)
Total shareholders' (deficit) equity	(1,491)	6,967
Total liabilities and shareholders' (deficit) equity	\$ 19,540	\$ 30,629

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS (Unaudited)

(in thousands, except share data)	For the Three Months Ended September 30,	
	2023	2022
Revenue	\$ 459	\$ 969
Cost of revenue	502	696
Gross (loss) profit	(43)	273
Operating expenses:		
Research and development	2,787	3,757
General and administrative	6,059	8,250
Performance of contract liability to affiliate	—	(12)
Total operating expenses	8,846	11,995
Loss from operations	(8,889)	(11,722)
Equity in net (losses) earnings of affiliate	—	(9)
Foreign currency gain, net	289	1,730
Fair value adjustment to VericiDx investment	(447)	(854)
Fair value adjustment to convertible notes	(1,207)	(1,213)
Other income, net	100	114
Net loss before income taxes	(10,154)	(11,954)
Income tax benefit	—	1
Net loss	(10,154)	(11,953)
Net loss per ordinary share—basic	\$ (0.11)	\$ (0.16)
Net loss per ordinary share—diluted	\$ (0.11)	\$ (0.16)
Weighted average ordinary shares—basic	94,767,841	74,804,712
Weighted average ordinary shares—diluted	94,767,841	74,804,712
Other comprehensive income (loss):		
Changes in the fair value of the convertible notes	75	397
Foreign exchange translation adjustment	42	(1,087)
Comprehensive loss	(10,037)	(12,643)

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY (DEFICIT) (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 (deficit)
	Shares	Amount				
Balance at July 1, 2023	93,781,478	286	186,456	(1,450)	(178,325)	6,967
Shares issued for repayment of convertible bond	1,052,422	3	1,051	—	—	1,054
Vesting of RSUs	185,540	1	—	—	—	1
Stock-based compensation expense	—	—	524	—	—	524
Currency translation adjustment	—	—	—	42	—	42
Changes in the fair value of the convertible notes at fair value through other comprehensive income	—	—	—	75	—	75
Net loss	—	—	—	—	(10,154)	(10,154)
Balance at September 30, 2023	95,019,440	\$ 290	\$ 188,031	\$ (1,333)	\$ (188,479)	\$ (1,491)

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity (deficit)
	Shares	Amount				
Balance at July 1, 2022	74,760,432	\$ 228	\$ 164,012	\$ (915)	\$ (132,718)	\$ 30,607
Shares issued under the employee share purchase program	131,412	1	115	—	—	\$ 116
Stock-based compensation expense	—	—	763	—	—	\$ 763
Currency translation adjustments	—	—	—	(1,087)	—	\$ (1,087)
Changes in the fair value of the convertible notes at fair value	—	—	—	397	—	\$ 397
Net loss	—	—	—	—	(11,953)	\$ (11,953)
Balance at September 30, 2022	74,891,844	\$ 229	\$ 164,890	\$ (1,605)	\$ (144,671)	\$ 18,843

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS (Unaudited)

(in thousands)	For the Three Months Ended September 30,	
	2023	2022
Cash flows from operating activities:		
Net loss	\$ (10,154)	\$ (11,953)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	127	130
Stock-based compensation	523	767
Equity in (net earnings) losses of affiliate	—	9
Reduction of Kantaro liability	—	(12)
Fair value adjustment to VericiDx investment	447	854
Unrealized foreign exchange (gain) loss	—	456
Fair value adjustment to convertible debt, net interest paid	945	921
Non cash lease expense	28	—
Changes in operating assets and liabilities:		
Accounts receivable	(238)	(322)
Prepaid expenses and other current assets	(153)	312
Receivable from affiliates	—	(13)
Accounts payable	250	555
Accounts payable – related party	202	1,287
Accrued expenses and other current liabilities	(2,060)	(125)
Accrued expenses – related party	579	22
Deferred revenue	—	(7)
Net cash used in operating activities	(9,504)	(7,119)
Cash flows from investing activities:		
Net cash used in investing activities	—	—
Cash flows from financing activities:		
Payment of convertible notes principal	(1,060)	(1,060)
Payment of issuance costs	(5)	—
Proceeds from the issuance of ordinary shares under employee share purchase plan	—	116
Net cash used in financing activities	(1,065)	(944)
Effect of exchange rate changes on cash	(222)	(2,230)
Net decrease in cash and cash equivalents	(10,791)	(10,293)
Cash and cash equivalents, beginning of period	24,682	41,333
Cash and cash equivalents, end of period	\$ 13,891	\$ 31,040
Supplemental noncash investing and financing activities:		
Noncash lease liabilities arising from obtaining right-of-use assets	\$ 4	\$ —
Cash Paid for interest on convertible debt	\$ 249	\$ 292

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

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS (Unaudited)

1. Business and risks

Renalytix PLC and its wholly-owned subsidiaries, the “Company” or “Renalytix” 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 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. 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 and debt financings.

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

2. Liquidity and Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of \$188.5 million as of September 30, 2023. 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.

As a result of its losses and projected cash needs, substantial doubt exists about the Company’s ability to continue as a going concern. Substantial additional capital will be necessary to fund the Company’s operations, expand its commercial activities and develop other potential diagnostic related products. The Company is seeking 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 may not be able to meet its obligations and could be required to delay, curtail or discontinue research and development programs, product portfolio expansion or commercialization efforts, which could adversely affect its business prospects.

The Company’s ability to continue as a going concern is contingent upon successful execution of management’s intended plan over the next twelve months to improve the Company’s liquidity and profitability, which includes, without limitation:

- Seeking additional capital through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements
- Implementation of various additional operating cost reduction options that are available to the Company
- The achievement of a certain volume of assumed revenue

The consolidated financial statements do not include any adjustments that may result from the outcome of this going concern uncertainty.

3. Basis of presentation and summary of significant accounting policies

The accompanying 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”).

Principles of consolidation

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

Use of estimates

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

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

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 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. For the three months ended September 30, 2023, approximately 77% of all receivables related to KidneyIntelX testing revenue related to one customer and, approximately 23% of receivables were due from other party payors. For the three months ended September 30, 2022, one customer made up 99% of the Company’s receivables. 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 and reserved for \$0.1 million of receivables as of September 30, 2023.

Fair value of financial instruments

At September 30, 2023 and 2022, the Company's financial instruments included accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature. The convertible notes are recorded at their estimated fair value.

Fair value option

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

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of September 30, 2023 and June 30, 2023, the Company had a cash and cash equivalents of \$13.9 million and \$24.7 million, respectively.

Accounts receivable

Accounts receivable are recorded at the invoice amount and are non-interest bearing. The Company estimates expected credit losses of its accounts receivable by assessing the risk of loss and available relevant information about collectability, including historical credit losses, existing contractual payment terms, actual payment patterns of its customers, individual customer circumstances, and reasonable and supportable forecast of economic conditions expected to exist throughout the contractual life of the receivable. The Company reserved for \$0.1 million of receivables as of September 30, 2023. The Company reserved for \$0.1 million of receivables as of June 30, 2023.

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.

Investments

VericiDx plc

The Company accounts for its ownership of VericiDx securities at fair value in accordance with ASC 321, *Investments-Equity Securities*, with changes in fair value recorded in earnings as the fair value of VericiDx's ordinary shares is readily determinable via the London Stock Exchange. Based on the closing stock price of VericiDx, the fair value of the investment in VericiDx was \$1.0 million and \$1.5 million at September 30, 2023 and June 30, 2023, respectively. During the three months ended September 30, 2023 and 2022, the Company recorded a decrease in fair value of \$1.2 million and \$1.2 million, respectively, in the consolidated statements of operations and comprehensive loss. The Company owned 5.8% of the ordinary shares of VericiDx at September 30, 2023 and June 30, 2023.

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 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 quarters ended September 30, 2023 and June 30, 2023, there was no capitalization of research and development expenses related to software development to record. Technological feasibility is established upon the completion of a working model that has been validated.

Revenue recognition

Pursuant to ASC 606, *Revenue from Contracts with Customers*, 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 the present right to payment principle 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, rent, lab consumables, depreciation, amortization and sample collection costs directly related to revenue generating activities.

Research and development expenses

Research and development costs consist primarily of internal and external labor costs incurred in connection with the development of KidneyIntelX as well as expenses related to studies and clinical trials to further the clinical value, performance and utility of KidneyIntelX. 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 consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income taxes

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

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

The Company did not record a provision for income taxes for either of the three-month periods ended September 30, 2023 and 2022, as the Company has generated losses for such periods. The Company periodically evaluates the realizability of its deferred tax assets based on all available evidence, both positive and negative. The realization of deferred tax assets is dependent on the Company's ability to generate sufficient future taxable income during periods prior to the expiration of tax attributes to fully utilize these assets. The Company weighed both positive and negative evidence and determined that there is a continued need for a full valuation allowance on its deferred tax assets as of September 30, 2023. Should the Company determine that it would be able to realize its remaining deferred tax assets in the foreseeable future, an adjustment to its remaining deferred tax assets would cause a material increase to income in the period such determination is made.

Comprehensive loss

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

Net loss per ordinary share

Basic net loss per ordinary share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during each period. Diluted net loss per ordinary share includes the effect, if any, from the potential exercise or conversion of securities, such as options and convertible debt which would result in the issuance of incremental ordinary shares.

The dilutive effect of convertible securities is calculated using the if-converted method. Under the if-converted method, interest charges applicable to the convertible debt as well as nondiscretionary adjustments which include any expenses or charges that are determined based on the income (loss) for the period are added back to net income. The convertible debt is assumed to have been converted at the beginning of the period (or at time of issuance, if later). For the three months ended September 30, 2023, under the if-converted method, the add back of nondiscretionary adjustments and inclusion of potentially converted shares would be anti-dilutive.

Emerging growth company

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

Recently issued accounting pronouncements

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the previous guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The Company implemented ASU 2016-13 in the fiscal year beginning July 1, 2023 and evaluated the impact of ASU 2016-13 and it did not have a material impact on the consolidated financial statements.

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

4. Revenue

Testing services revenue

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, 2023 and 2022, the Company recognized \$0.5 million and \$1.0 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 the present right to payment principle 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, 2023, there was no pharmaceutical services revenue recognized. During the three months ended September 30, 2022, the Company recognized \$0.01 million of pharmaceutical 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 consolidated balance sheets are categorized based upon the level of judgment associated with the inputs used to measure their fair values. Fair value is defined as the exchange price that would be received for an asset or an exit price that would be paid to transfer a liability in the principal or most advantageous market for the asset or liability in an orderly transaction between market participants on the measurement date. Valuation techniques used to measure fair value must maximize the use of observable inputs and minimize the use of unobservable inputs. The authoritative guidance on fair value measurements establishes a three-tier fair value hierarchy for disclosure of fair value measurements as follows:

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

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

(in thousands)	Fair value measurement at reporting date using		
	(Level 1)	(Level 2)	(Level 3)
September 30, 2023			
Assets:			
Equity Securities	\$ 978	\$ —	\$ —
Liabilities:			
Convertible notes	\$ —	\$ —	\$ 10,417
June 30, 2023			
Assets:			
Equity Securities	\$ 1,460	\$ —	\$ —
Liabilities:			
Convertible notes	\$ —	\$ —	\$ 11,948

The Company accounts for its ownership of VericiDx securities at fair value in accordance with ASC 321, *Investments-Equity Securities*, with changes in fair value recorded in earnings as the fair value of VericiDx's ordinary shares is readily determinable via the London Stock Exchange. The Company owns 9,831,681 shares of VericiDx. Based on closing stock price of VericiDx, the fair value of the investment in VericiDx was \$1.0 million and \$1.5 million at September 30, 2023 and June 30, 2023, respectively.

As further described in Note 8, in April 2022 the Company issued convertible promissory notes (the "Notes") to an investor. The fair value option, as prescribed by ASC 815, *Derivatives and Hedging*, was elected and applied in connection with the preparation of these consolidated financial statements. The fair value of the Notes is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders.

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

(in thousands)	September 30, 2023
Balance at July 1, 2023	\$ 11,948
Change due to payment of principal and interest	(2,369)
Fair value adjustments	1,207
Change in credit risk	(75)
FX Impact	(294)
Balance at September 30, 2023	\$ 10,417

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.

6. Property and equipment, net and intangibles

Property and equipment consists of (in thousands):

(in thousands)	September 30, 2023	June 30, 2023
Lab equipment	\$ 1,142	\$ 1,142
Office equipment	124	124
Office furniture	35	35
Leasehold improvements	576	576
Total	1,877	1,877
Less accumulated depreciation	(933)	(850)
	\$ 944	\$ 1,027

Depreciation expense was \$0.1 million and \$0.1 million for the three months ended September 30, 2023 and 2022, respectively.

(in thousands)	September 30, 2023	June 30, 2023
Software (Included in Other Assets)	\$ 1,483	\$ 1,526
Less accumulated amortization	(509)	(476)
	\$ 974	\$ 1,050

As of September 30, 2023, the expected amortization expense for the next five years and thereafter is as follows:

(in thousands)		
2024	\$	132
2025		177
2026		138
2027		121
2028		121
Thereafter		285
	\$	974

7. Accrued expenses and other current liabilities

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

	September 30, 2023	June 30, 2023
Consulting and professional fees	\$ 422	\$ 442
Research and development	1,128	1,657
Payroll and related benefits	2,308	3,866
License and Royalty Expense	698	669
Other	10	10
	\$ 4,566	\$ 6,644

8. Convertible Notes

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount of \$21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds") to Heights Capital Ireland LLC (the "Convertible Bond Investor"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million and accrue interest at an annual rate of 5.5%, payable quarterly in arrears, in cash or American Depositary Shares ("ADSs") valued at the ADS Settlement Price at the option of the Company. The principal and interest payments are due in equal quarterly installments starting in July 2022. The Bonds contain various conversion and redemption features. The initial conversion price for the Bonds of \$8.70 has been set at a 20 percent premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance, and the Bonds have a hard floor in the conversion price of \$7.25. As a result of the February 2023 private placement and pursuant to conditions of the bond agreement, the conversion price was adjusted to \$8.2508 (previously \$8.70) and the floor price was adjusted to \$6.8757 (previously \$7.25). Further, pursuant to conditions of the agreement, effective April 7, 2023, the conversion price was adjusted from \$8.2508 to \$7.7924. Between amortization dates, the Convertible Bond Investor retains the right to advance future amortization payments, provided that (a) there shall be no amortization advancements during the first 12 months, (b) no more than 2 amortization advancements may occur in any 12 month period, and (c) no more than 1 amortization advancement may occur in any 3 month period.

The Convertible Bond Investor is also permitted to defer up to two amortization payments to a subsequent amortization date. The Company retains the option to repay any deferred amortization in cash at 100 percent of the nominal amount. In July 2023, the Company made a cash amortization payment of \$1.4 million, which consisted of \$1.1 million of principal and \$0.3 million of interest. Also in July 2023, the Convertible Bond Investor exercised its right to advance an amortization payment and the Company made an accelerated repayment of \$1.06 million through the issuance of 526,211 ADSs. As of September 30, 2023, \$15.9 million of principal was outstanding.

On issuance, the Company elected to account for the Bonds at fair value in accordance with ASC 815, *Derivatives and Hedging*, with qualifying changes in fair value being recognized through the statements of operations until the Bonds are settled. Changes in fair value related to instrument-specific credit risk are recognized through comprehensive loss until the Bonds are settled. The fair value of the bonds is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders. Significant assumptions used in the fair value analysis include the volatility rate, risk-free rate, dividend yield and risky yield. The fair value of the Bonds was determined to be \$16.9 million on issuance, which is the principal amount of the Bonds. On issuance, total debt issuance costs of \$1.4 million were immediately expensed as a component of general and administrative expense in the consolidated statement of operations during the year ended June 30, 2022. As of September 30, 2023, the fair value of the Bonds was determined to be \$10.4 million. During the three months ended September 30, 2023, the Company recognized a decrease in fair value of the Notes related to the instrument-specific credit risk of \$0.1 million in the comprehensive loss and an increase in fair value related to non-instrument specific credit risk of \$1.2 million as a loss in the consolidated statement of operations. The Company recognized a decrease in fair value of the Notes related to the instrument-specific credit risk of \$0.4 million in the comprehensive loss and a decrease in fair value related to non-instrument specific credit risk of \$1.2 million as a gain in the consolidated statement of operations during the three months ended September 30, 2022.

9. Leases

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

Variable executory costs, as it relates to net leases, are excluded from the calculation of the lease liability. Variable executory costs include costs relating to utilities, repairs, maintenance, insurance, common area expenses, and taxes paid for the leased asset during its economic life.

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

The Company leased lab space in Salt Lake City, UT, under a five-year lease, the term of which commenced in November 2019. The Company has measured its right-of-use assets and lease liabilities based on lease terms ending in October 2024.

The Company leased lab space in New York City, NY under an initial three-month lease, the term of which commenced in February 2019. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company leased lab space in St. Petersburg, FL from under an initial one-year term, the term of which commenced in January 2022. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

The Company leased office space in New York City, NY under an initial month-to-month term, the term of which commenced in June 2018. The lease did not have termination or formal renewal options however the Company can renew their office space if they are still needed and are still available at the end of the term. The Company has classified this lease as a short-term lease as the Company concluded that the noncancelable terms of this lease was less than one year at the commencement and none of the Company's renewals or amendments were for additional noncancelable terms greater than one year.

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

As the Company's leases do not provide an implicit rate, it concluded that a 10.0% IBR, the approximate midpoint between the average commercial real estate loans during 2022, is an appropriate discount rate to use for the Utah lease, which was the only lease existing as of the adoption date.

The following table shows the lease balance sheet classification of leases for the three months ended September 30, 2023 (in thousands):

(in thousands)	September 30, 2023	
Assets		
Operating lease right-of-use assets, net of accumulated amortization	\$	131
Liabilities		
Current		
Operating lease liabilities, current	\$	131
Non-current		
Operating lease liabilities, non-current	\$	10
Total lease liabilities	\$	141

The following table shows the lease costs for the three months ended September 30, 2023 (in thousands):

Lease costs (in thousands)	Statement of operations classification	September 30, 2023	
Operating lease costs	Operating expenses: research and development	\$	32
Short term lease costs	Operating expenses: research and development	\$	31
Short term lease costs	Operating expenses: general and administrative	\$	26
Short term lease costs	Cost of goods sold	\$	81
Total lease costs		\$	170

Other information	September 30, 2023	
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	\$	32
Remaining lease term - operating leases (in years)		1.1
Discount rate - operating leases		10%

The future minimum payments for noncancelable leases with terms in excess of one year as of September 30, 2023 are payable as follows (in thousands):

(in thousands)		
2024	\$	139
2025		11
2026		—
Total minimum lease payments	\$	150
Less amounts representing interest	\$	(9)
Present value of lease liabilities	\$	141

10. Commitments and contingencies

Leases

Lease payments under operating leases as of September 30, 2023 and information about the Company's lease arrangements are disclosed in Note 9, "Leases".

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 paid \$0.2 million and \$0.1 million in contributions for the three months ended September 30, 2023 and 2022, respectively.

Legal proceedings

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

11. License and services agreements

Mount Sinai license and sponsored research agreements

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

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred \$0.3 million and \$0.9 million related to the ISMMS SRA for the three months ended September 30, 2023 and 2022, respectively.

Mount Sinai Clinical Trial agreement

In July 2021, the Company entered into a Clinical Trial Agreement (the "CTA") with ISMMS. Under the CTA, ISMMS will undertake a sponsored clinical trial entitled, "A prospective decision impact trial of KidneyIntelX in patients with Type 2 diabetes and existing chronic kidney disease". The clinical trial is to be conducted at ISMMS with Renalytix agreeing to pay ISMMS in accordance with the agreed upon budget. The clinical trial is expected to last up to four years with a total estimated budget of \$3.2 million. As of September 30, 2023, amounts due to ISMMS under the CTA totaled \$0.7 million, and \$0.3 million was expensed during the three months ended September 30, 2023. At September 30, 2022, amounts due to ISMMS under the CTA totaled \$0.2 million, and \$0.1 million was expensed during the three months ended September 30, 2022.

Joslin diabetes center agreement

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

Under the terms of the Joslin Agreement, the Company is obligated to pay Joslin aggregate commercial milestone payments of \$0.3 million and \$1.0 million 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 Company accrued \$0.3 million related to achievement of the first sales milestone and accrued \$0.3 million of royalties due to Joslin as of September 30, 2023 which were recorded as cost of revenue within the consolidated statement of operations. The Company accrued \$0.1 million of royalties due to Joslin for the three months ended September 30, 2022.

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.

Wake Forest/Atrium Health

In May 2021, the Company entered into a partnership 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. Through these partnerships, KidneyIntelX access will 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. Additionally, the Company entered into a five year clinical trial agreement with Wake Forest University Health Sciences to evaluate the clinical impact of KidneyIntelX on the management of patients with type 2 diabetes (T2D) and diabetic (chronic) kidney disease (stage 1-3). The total estimated cost of the clinical trial is \$6.9 million. To date the Company has incurred \$3.8 million in clinical trial costs which are recorded in the research and development line of the consolidated statement of operations. As part of the clinical trial, the Company has generated over 1,700 reportable patient results in the Atrium Wake Forest system across 78 providers. As of September 30, 2023, the Company accrued \$1.6 million related to the clinical trial agreement and expensed \$0.5 million during the three months ended September 30, 2023. As of September 30, 2022, the Company accrued \$1.1 million related to the clinical trial agreement and expensed \$0.6 million during the three months ended September 30, 2022.

12. Shareholders' equity

Ordinary shares

As of September 30, 2023, the Company had 102,537,697 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, 2023, no cash dividends have been declared or paid.

13. Share-based compensation

Equity Incentive Plan

In November 2018, Company established the Renalytix AI plc Share Option Plan (the “2018 Share Option Plan”) and a U.S. Sub-Plan and Non-Employee Sub-Plan. In July 2020, the Company's board of directors adopted and the Company's shareholders approved the 2020 Equity Incentive Plan (the “EIP”), which superseded the 2018 Share Option Plan. The equity incentive 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, 2023, there were 11,893,743 shares available for future issuance under the EIP.

The EIP 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.

With respect to the options outstanding as of September 30, 2023:

- 5,968,095 options vest equally over twelve quarters following the grant date;
- 873,362 options vest 25% on the one year anniversary of the grant date and the remaining 75% equally over twelve quarters following the one year anniversary of the grant date;
- 436,800 options vest 25% on the one year anniversary of the grant date, 50% on the two year anniversary of the grant date, and 25% on the three year anniversary;
- 190,000 options vest one third on the one year anniversary of the grant date and the remaining two thirds equally over eight quarters following the one year anniversary of the grant date;
- 40,000 options vest quarterly over two years following the grant date; and
- 10,000 options vest on the vesting commencement date.

If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

The Company recorded share-based compensation expense in the following expense categories in the consolidated statements of operations for the three months ended September 30, 2023 and 2022 (in thousands):

	For the Three Months Ended September 30,	
	2023	2022
Research and development	\$ 97	\$ 67
General and administrative	\$ 424	\$ 696
Cost of revenue	\$ 3	—
	<u>\$ 524</u>	<u>\$ 763</u>

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying ordinary shares at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the three months ended September 30, 2023 and 2022 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, 2023 and 2022, 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:

	For the Three Months Ended September 30,	
	2023	2022
Expected term (in years)	6.4	6.1
Expected volatility	74.3 %	66.9 %
Risk-free rate	4.3 %	3.2 %
Dividend yield	— %	— %

The weighted average fair value of the options granted during the three months ended September 30, 2023 and 2022 was \$0.92 and \$6.60 per share, respectively.

The following table summarizes the stock option granted to employees and non-employees for the three months ended September 30, 2023:

	Number of shares under option plan	Weighted- average exercise price per option	Weighted- average remaining contractual life (in years)
Outstanding at June 30, 2023	4,968,576	\$ 4.50	6.7
Granted	2,673,296	\$ 1.26	
Exercised	—	\$ -	
Forfeited	(122,052)	\$ 6.70	
Expired	(1,563)	\$ 6.41	
Outstanding at September 30, 2023	7,518,257	\$ 3.20	7.6
Exercisable at September 30, 2023	4,092,902	\$ 4.29	6.0
Vested and expected to vest at September 30, 2023	7,518,257	\$ 3.20	7.6

As of September 30, 2023, there was \$3.86 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 2.27 years. The aggregate intrinsic value of options outstanding and options exercisable at each of September 30, 2023 and September 30, 2022 was \$0.

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 of the Company's ordinary shares. The number 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 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 remuneration committee to determine a lesser number of shares shall be added for such year.

Under the ESPP, eligible employees can purchase the Company's ordinary shares through accumulated payroll deductions at such times as are established by the board of directors or remuneration committee. Eligible employees may purchase the Company's 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 are outstanding. No shares were purchased under the ESPP during the three months ended September 30, 2023. During the three months ended September 30, 2022, 131,412 shares were purchased under the ESPP.

In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company's 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 \$0.01 million and \$0.07 million in general and administrative expense and \$0.01 million and \$0.04 million in research and development expense during the three months, ended September 30, 2023 and 2022, respectively, related to the ESPP.

Restricted Stock Units

Activity for restricted stock units for the three months ended September 30, 2023 is as follows:

	Number of Restricted Stock Units	Weighted- average Grant Date Fair Value
Non-vested balance at June 30, 2023	40,340	\$ 1.72
Granted	—	\$ -
Vested	(13,590)	\$ 1.74
Forfeited	(1,990)	\$ 1.69
Non-vested balance at September 30, 2023	<u>24,760</u>	<u>\$ 1.69</u>

The total fair value of restricted stock units vested during the three months ended September 30, 2023 was \$0.1 million. Restricted stock units vest upon the achievement of time-based service requirements.

At September 30, 2023, total unrecognized compensation expense related to non-vested restricted stock units was approximately \$0.03 million. Unrecognized compensation expense relating to restricted stock units that are deemed probable of vesting is expected to be recognized over a weighted-average period of approximately 1.02 years.

14. Related-party transactions

EKF Diagnostic Holdings

During the three months ended September 30, 2023 and 2022, the Company incurred expenses of \$0.01 million and \$0.03 million, respectively, related to employees of EKF who provided services to Renalytix.

Icahn School of Medicine at Mount Sinai

In May 2018, the Company secured its cornerstone license agreement with ISMMS for research and clinical study work and intended commercialization by the Company (see Note 11). As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's initial public offering (the "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 and private placements in April 2022 and February 2023. As of September 30, 2023 and 2022, amounts due to ISMMS totaled \$4.2 million and \$3.9 million, respectively. During the three months ended September 30, 2023 and 2022, the Company incurred expenses of \$0.7 million and \$1.4 million, respectively, related to its obligations under the ISMMS license agreement.

15. Net loss per ordinary share

Basic net loss per ordinary share is computed by dividing net loss by the weighted average number of ordinary shares outstanding during each period. Diluted net loss per ordinary share includes the effect, if any, from the potential exercise or conversion of securities, such as options which would result in the issuance of incremental ordinary shares. Potentially dilutive securities outstanding as of September 30, 2023 and September 30, 2022 have been excluded from the computation of diluted weighted average shares outstanding as they would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

The following potentially dilutive securities have been excluded from the computation of diluted weighted-average shares of ordinary shares outstanding as they would be anti-dilutive:

	Three Months Ended September 30,	
	2023	2022
Stock options to purchase ordinary shares	7,518,257	4,519,401
Restricted stock units	49,520	—
Conversion of convertible note	4,625,019	2,071,264
	<u>12,192,796</u>	<u>6,590,665</u>

16. Subsequent Events

On October 17, 2023, the Company announced the repayment of \$1.1 million of the Company's Bond through the issuance of an aggregate of 2,335,388 ordinary shares in the form of 150,000 ordinary shares and 1,092,694 ADSs. 2,335,388 ordinary shares were issued to settle the conversion of 1,092,694 ADSs, with each ADS representing two ordinary shares. As of November 14, 2023, the principal remaining under the Bond was \$14.8 million.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our unaudited consolidated financial statements and related notes thereto included in Part I, Item 1 of this Quarterly Report on Form 10-Q, our audited consolidated financial statements and related notes for the year ended June 30, 2023, included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on September 28, 2023 (the "Annual Report on Form 10-K"), as well as the information contained under Management's Discussion and Analysis of Financial Condition and Results of Operations and "Risk Factors" contained in the Annual Report on Form 10-K, and Part II, Item 1A "Risk Factors" of this Quarterly Report on Form 10-Q, and other information provided from time to time in our other filings with the SEC.

Overview

Renalytix is focused on providing doctors around the world with a safe, reliable and effective tool to identify which patients are or are not in danger of losing significant kidney function and falling into kidney failure and may require long-term dialysis or kidney transplant. Chronic kidney disease is one of the largest urgent medical needs, globally affecting an estimated 850 million people, and is responsible for an unsustainable and growing societal cost burden.

We believe an important part of the answer is preventative medicine and the ability to identify individuals with advancing chronic kidney disease early, where new drug therapies and clinical strategies have the optimal chance to stop uncontrolled disease progression.

At Renalytix, we developed kidneyintelX.dkd, the first U.S. Food and Drug Administration ("FDA"), authorized *in vitro* prognostic test that uses an artificial intelligence-enabled algorithm to aid in assessment of the risk of progressive decline in kidney function. The test is designed to predict early in the progression of kidney disease who is at risk for significant sustained decline in kidney function. Prognostic tests, such as kidneyintelX.dkd, are not intended for diagnosing any disease or for monitoring disease progression or the effect of any therapeutic product. Rather, prognostic tests are intended to be used in conjunction with other clinical and diagnostic findings and consistent with professional standards of practice, including information obtained by alternative methods, and clinical evaluation, as appropriate. When used as intended, potential interventions can be considered early, ideally before major damage is done and when treatments can be most effective. KidneyintelX.dkd is part of a family of clinical tests being developed from the KidneyIntelX technology platform developed using technology licensed from the Icahn School of Medicine at Mount Sinai in New York, the Joslin Diabetes Center in Boston and under development through U.S. and international collaborations.

We are deploying KidneyIntelX to patient populations with DKD on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients. Following the receipt of national Medicare pricing at \$950 per reportable test for KidneyIntelX in January 2020, we are actively pursuing Medicare coverage and a determination under the MolDX Program. In March 2020, we announced that our application for a Medicare PTAN was approved by Noridian Healthcare Solutions, the regional Medicare Administrative Contractor with responsibility for overseeing facilities and providers located in the western United States, and, as a result, we are now qualified as a provider and can bill for services provided to patients with Medicare and Medicaid health insurance coverage in the United States. In addition, in October 2019, Capital District Physicians' Health Plan, Inc., a physician-led health insurance payor in New York, adopted coverage determination policies that provide insurance for certain patients with DKD who are tested with KidneyIntelX. We are working with additional private insurance payors and healthcare providers to expand insurance coverage for KidneyIntelX nationwide, which we believe will be accelerated by our recent achievement of a CPT code and national Medicare pricing.

Since our inception in March 2018, we have focused primarily on organizing and staffing our company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting our intellectual property portfolio and commercial laboratory operations, pursuing regulatory approval and developing our reimbursement strategy. We have funded our operations primarily through equity financings. In November 2018, we sold 18.4 million of our ordinary shares in our initial public offering (the "IPO"), and our ordinary shares were admitted to trading on AIM, a market operated by the London Stock Exchange, resulting in gross proceeds of approximately \$29.1 million. Prior to our IPO on the London Stock Exchange, EKF provided debt financing, referred to as our related-party note payable. All borrowings with EKF were repaid in their entirety upon completion of the equity offering in November 2018.

In July 2019, we sold an additional 5.6 million of our ordinary shares in a secondary offering for approximately \$17.3 million. In July 2020, we closed our global offering and listed our American Depositary Shares ("ADS") on the Nasdaq Global Market, in which we issued and sold 12.6 million ordinary shares which converted into 6.3 million ADSs at a public offering price of \$13.50 per share. In addition, we completed a concurrent private placement in Europe and other countries outside of the United States of 30,000 ordinary shares at a price of £5.37 per ordinary share (at an exchange rate of GBP:USD 1:1.2563). We received gross proceeds of approximately \$85.1 million as a result of the offering.

Macroeconomic Considerations

During fiscal year 2023, we returned to conducting business as usual after the COVID-19 pandemic, with necessary or advisable modifications to employee travel and employee work locations. We continue to monitor the situation related to COVID-19 and may take actions that alter our business operations to the extent that may be required by federal, state or local authorities, or that we determine are in the best interests of our employees, partners and shareholders.

Unfavorable conditions in the economy in the United States and abroad may negatively affect the growth of our business and our results of operations. For example, macroeconomic events, including the COVID-19 pandemic, rising inflation and U.S. and U.K. interest rates and the Russia-Ukraine war, have led to economic uncertainty globally. The effect of macroeconomic conditions may not be fully reflected in our results of operations until future periods. If, however, economic uncertainty increases or the global economy worsens, our business, financial condition and results of operations may be harmed. For further discussion of the potential impacts of macroeconomic events on our business, financial condition, and operating results, see the section titled “Risk Factors.”

Our Key Agreements

Mount Sinai Health System

In May 2018, we entered into the Mount Sinai Agreement, with Mount Sinai, pursuant to which we obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how of Mount Sinai to develop and commercialize licensed products in connection with the application of artificial intelligence for the diagnosis of kidney disease. Pursuant to the terms of the Mount Sinai Agreement, we are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products, including in accordance with specified diligence milestones.

We paid Mount Sinai \$10.0 million as an up-front payment upon entering into the Mount Sinai Agreement. Under the terms of the Mount Sinai Agreement, we are 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. We are 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, we are obligated to pay Mount Sinai between 15% and 25% of any consideration received by us from a sublicensee. The two provisional patent applications covering the KidneyIntelX diagnostic in-licensed under the Mount Sinai Agreement were filed in February 2020 and April 2020, respectively. If issued, these patents will expire in February 2041 and April 2041, respectively. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a total estimated cost of \$10.7 million.

The Mount Sinai Agreement expires on the later of the tenth anniversary of the execution of the agreement and expiration of the last remaining royalty term. We may terminate the Mount Sinai Agreement at any time upon 90 days’ prior written notice. Mount Sinai may terminate the agreement for our uncured material breach, our failure to meet certain diligence milestones, our insolvency, or in the event that we challenge the validity or enforceability of any licensed patent.

Joslin Diabetes Center

In July 2017, EKF, entered into the Joslin Agreement, with Joslin. In October 2018, we purchased all of EKF’s rights, title, interest and benefit in the Joslin Agreement in exchange for the issuance of 15.4 million of our ordinary shares.

Pursuant to the Joslin Agreement and the related assignment from EKF, we obtained a worldwide, royalty- bearing, exclusive license under any patents and any related know-how of Joslin related to the patent application filed with respect to the Joslin IP to make, have made, use, offer for sale and sell licensed products covered by claims in the Joslin IP, and to perform, practice offer for sale and sell certain licensed processes related to the Joslin IP. We are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products and licensed processes, including in accordance with a development plan.

Under the terms of the Joslin Agreement, we are 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. We are also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, we are obligated to pay Joslin 25% of any consideration received by us 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 we cease developing or commercializing licensed products or processes, if we fail to maintain certain required insurance policies, and if we fail to pay patent expenses related to the licensed patents.

Recent Developments

- Financing discussions are in process with the goal to provide operating runway through at least early calendar 2026, enabled by cost reductions and sales growth from adoptions by new hospital systems and independent physicians
- Cost cutting initiative projected to reduce payroll expense by over 35% and total SG&A by over 30% year-over-year. Now with FDA authorization of kidneyintelX.dkd, real-world outcomes data published, and tracking for inclusion in final medical guidelines, personnel have been realigned to focus on sales
- KidneyIntelX EPIC-integrated commercial roll-out is progressing at Atrium Health with expected integration completion in December 2023
- Additional Illinois hospital system launch is expected in December 2023 to highlight health equity benefits of KidneyIntelX guided care pathway in diabetes.
- Long-term Medicare reimbursement process advanced with August independent Clinical Advisory Committee meeting for Local Coverage Determination (LCD), and submission of application for National Coverage Determination (NCD)
- Second Medicare contractor, First Coast Options, now paying for billed KidneyIntelX tests.
- Additional key commercial payer coverage achieved, including:
 - Contract with BlueCross and BlueShield of Texas, the largest statewide health care plan serving 7,000,000 members
 - Contract with Parkland Community Health Plan (PCHP), a Dallas-based insurance plan with over 300,000 covered lives
- Evidence from 12 months of care following KidneyIntelX prognostic testing released at American Diabetes Association demonstrated clinical actions that led to improvement in both diabetes (A1C reductions) and kidney health (eGFR slope improvement) in patients with type 2 diabetes and chronic kidney disease; detailed results paper submitted for publication
- Senior executive Howard Doran was appointed as chief business officer, leading global sales effort with full direct-to-physician sales force expected to be in field by January 2024.
- Testing volumes in fiscal first quarter:
 - Total tests of 1,297 of which 56% were billable, compared to 1,232 (57% billable) in the prior quarter and 1,252 (82% billable) in the prior-year fiscal first quarter. Certain study-related tests at Mount Sinai are no longer billable following transition from Mount Sinai as payor to traditional commercial insurance billing, as previously communicated
 - 699 tests conducted at Mount Sinai (529 were billable)
 - 396 tests conducted at Atrium Health Wake Forest (to date, all non-billable study tests);
 - Remainder mainly direct-to-physician billable commercial testing
- Clinical advisory board featuring multi-disciplinary experts was formed to advise on adoption of FDA authorized kidneyintelX.dkd within the 14 million patient addressable market in the U.S.
- Distribution agreement was executed to expand availability of kidneyintelX.dkd to an estimated four million DKD patients in the Middle East
- Intellectual property:
 - U.S. Patent Office allows patent claims for intellectual property exclusively licensed to Renalytix, specifically biomarkers sTNFR1 and sTNFR2 used in KidneyIntelX technology
 - IP relating to protein biomarker pipeline continues to expand with data presented at American Society of Nephrology Kidney Week from collaborators at Joslin showing potential for expanded indications and utility

- KidneyIntelX.dkd recommended for pricing by Centers for Medicare & Medicaid Services (CMS) at \$950 per test, matching the pricing of the pre-FDA authorized version of the prognostic; final decision to be made by the end of the calendar year
- On October 17, 2023, we announced the repayment of \$1.1 million of our Bonds (as defined below) through the issuance of an aggregate of 2,335,388 ordinary shares in the form of 150,000 ordinary shares and 1,092,694 ADSs. 2,185,388 ordinary shares were issued to settle the conversion of 1,092,694 ADSs, with each ADS representing two ordinary shares. As of November 14, 2023, the principal remaining under the Bonds was \$14.8 million.

Components of Results of Operations

Revenues

During the three months ended September 30, 2023, we continued to deploy KidneyIntelX to patient populations with DKD, on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients. If these strategic partners fail to meet their key contractual obligations or to purchase KidneyIntelX tests, that will likely have an adverse effect on us and our ability to achieve our commercial objectives, potentially including the attainment of sales volumes leading to profitability.

Cost of Revenue

During the three months ended September 30, 2023 and 2022, cost of revenue consists of costs directly attributable to the KidneyIntelX testing and services rendered, including labor, lab consumables and sample collection 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. We are currently continuing to conduct clinical utility and other studies for KidneyIntelX to determine clinical value and performance in different CKD populations. We expense research and development costs as incurred. Because we have limited resources and access to capital to fund our operations, we must decide which diagnostic product to pursue and the amount of resources to allocate to each. As such, we have been focused primarily on the development of KidneyIntelX and studies to further demonstrate the clinical utility of KidneyIntelX.

We incur both direct and indirect expenses related to our research and development programs. Direct expenses include third-party expenses related to our programs such as expenses for data science and artificial intelligence capabilities, consulting fees, lab supplies, assay development services and clinical validation costs. Indirect expenses include salaries and other personnel-related costs, including share-based compensation for personnel in research and development functions and rent.

At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate to have been made as a result of the service provided, we may record net prepaid or accrued expense relating to these costs. Upfront milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered.

The successful commercialization of KidneyIntelX is uncertain. This is due to the numerous risks and uncertainties associated with product development and commercialization, including:

- the uncertainty of the scope, progress, costs and results of clinical validation studies and other research and development activities;
- the cost of manufacturing clinical supply of KidneyIntelX;
- the efficacy and potential advantages of KidneyIntelX compared to alternative solutions, including any standard of care, and our ability to achieve market acceptance for KidneyIntelX;
- continuing to expand study data for KidneyIntelX, including data demonstrating the clinical utility over the short, intermediate and long term use of KidneyIntelX in different clinical settings;

- raising necessary additional funds to continue operations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights and defending against any intellectual property-related claims.

A change in the outcome of any of these variables could result in a significant change in the costs and timing associated with our related development.

General and Administrative Expenses

General and administrative expenses consist principally of salaries and other personnel-related costs including share-based compensation; professional fees for accounting, auditing, tax and administrative consulting services; legal fees relating to patent and corporate matters; administrative travel expenses; insurance costs; marketing expenses and other operating costs. Additionally, general and administrative expenses include the cost of maintaining our admission to AIM and Nasdaq.

Foreign Currency Gain (Loss), net

Foreign currency gain (loss), net consists of foreign currency income (losses) due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency.

Fair Value Adjustments to VericiDx Investment

In October 2020, the Company completed a spin off VericiDx, a developer of advanced clinical diagnostics for organ transplant and retained 9,831,681 ordinary shares of VericiDx. The Company accounts for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement.

Fair Value Adjustment on Convertible Notes

We elected to account for the bonds at fair value with qualifying changes in fair value recognized through the statements of operations until the notes are settled.

Other Income (Expense)

Other income primarily relates to interest income earned on our cash deposits.

Consolidated Results of Operations

(in thousands, except share data)	Three Months Ended		Change 2023 vs. 2022	
	September 30, 2023	September 30, 2022	Change	%
Revenue	\$ 459	\$ 969	\$ (510)	-53 %
Cost of revenue	502	696	(194)	-28 %
Gross (loss) profit	(43)	273	(316)	-116 %
Operating expenses:				
Research and development	2,787	3,757	(970)	-26 %
General and administrative	6,059	8,250	(2,191)	-27 %
Performance of contract liability to affiliate	—	(12)	12	-100 %
Total operating expenses	8,846	11,995	(3,149)	-26 %
Loss from operations	(8,889)	(11,722)	2,833	-24 %
Equity in net (losses) earnings of affiliate	—	(9)	9	-100 %
Foreign currency gain, net	289	1,730	(1,441)	-83 %
Fair value adjustment to VericiDx investment	(447)	(854)	407	-48 %
Fair value adjustment to convertible notes	(1,207)	(1,213)	6	0 %
Other income, net	100	114	(14)	-12 %
Net loss before income taxes	(10,154)	(11,954)	1,800	-15 %
Income tax benefit	—	1	(1)	-100 %
Net loss	(10,154)	(11,953)	1,799	-15 %
Net loss per ordinary share—basic	\$ (0.11)	\$ (0.16)	\$ 0.05	-33 %
Net loss per ordinary share—diluted	\$ (0.11)	\$ (0.16)	\$ 0.05	-33 %
Weighted average ordinary shares—basic	94,767,841	74,804,712	19,963,129	27 %
Weighted average ordinary shares—diluted	94,767,841	74,804,712	19,963,129	27 %
Other comprehensive income (loss):				
Changes in the fair value of the convertible notes	75	397	(322)	-81 %
Foreign exchange translation adjustment	42	(1,087)	1,129	-104 %
Comprehensive loss	(10,037)	(12,643)	2,606	-21 %

Comparison of three months ended September 30, 2023 and 2022

Revenue

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Revenue	\$ 459	\$ 969	\$ (510)	-53%

During the three months ended September 30, 2023, we recognized \$0.5 million of revenue related to sales of KidneyIntelX. During the three months ended September 30, 2022, we recognized \$1.0 million revenue related to sales of KidneyIntelX and \$0.01 million of revenue of pharmaceutical services revenue related to services performed for AstraZeneca. The \$0.5 million decrease in revenue was primarily driven by a decrease in KidneyIntelX billable testing volumes due to the transition to a commercial billing structure under our arrangement with Mount Sinai.

Cost of Revenue

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Cost of revenue	\$ 502	\$ 696	\$ (194)	-28%

During the three months ended September 30, 2023, we recognized cost of revenue of \$0.5 million primarily attributable to KidneyIntelX testing, including labor, lab consumables and sample collection costs related to revenue generating activities. We recognized \$0.7 million of cost of revenue for the three months ended September 30, 2022. The \$0.2 million decrease in cost of revenue was primarily driven by a decrease in KidneyIntelX billable testing volumes.

Research and Development Expenses

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Research and development expenses	\$ 2,787	\$ 3,757	\$ (970)	-26%

Research and development expenses decreased by \$1.0 million from \$3.8 million for the three months ended September 30, 2022 to \$2.8 million for the three months ended September 30, 2023. The decrease was attributable to a \$0.7 million decrease in compensation and related benefits and a \$0.7 million decrease related to external R&D projects and studies with Mount Sinai, Wake Forest and Joslin, offset by a \$0.3 million increase related to consulting and professional fees and \$0.1 million increase in other miscellaneous expenses.

General and Administrative Expenses

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
General and administrative expenses	\$ 6,059	\$ 8,250	\$ (2,191)	-27%

General and administrative expenses decreased \$2.2 million from \$8.3 million for the three months ended September 30, 2022 to \$6.1 million for the three months ended September 30, 2023. The decrease was driven by even further cost cutting measures, which resulted in a \$1.0 million decrease in compensation and related benefits, including share-based payments, due to decreased headcount, \$0.4 million decrease in consulting and professional fees, \$0.3 million decrease in insurance costs, \$0.2 million decrease in marketing, and \$0.3 million decrease in other operating expenses. We have implemented a plan to further reduce payroll expense and total general and administrative expenses while preserving our sales capacity.

Foreign Currency Gain (Loss)

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Foreign currency gain, net	\$ 289	\$ 1,730	\$ (1,441)	-83%

During the three months ended September 30, 2023, we recognized a foreign currency gain of \$0.3 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the three months ended September 30, 2022, we recognized a foreign currency gain of \$1.7 million primarily attributable to cash balances denominated in currencies other than our functional currency, GB Pounds.

Fair Value Adjustments to VericiDx Investment

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Fair value adjustment to VericiDx investment	\$ (447)	\$ (854)	\$ 407	-48%

We account for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During the three months ended September 30, 2023, we recorded a loss of \$0.4 million to adjust the VericiDx investment to fair value. During the three months ended September 30, 2022, we recorded a loss of \$0.9 million to adjust the VericiDx investment to fair value.

Fair Value Adjustment on Convertible Notes

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Fair value adjustment to convertible notes	\$ (1,207)	\$ (1,213)	\$ 6	0%

We elected to account for the Bonds (as defined below) at fair value with qualifying changes in fair value recognized through the statements of operations until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in Other Comprehensive Income (Loss). For the three months ended September 30, 2023, we recorded a loss of \$1.2 million to adjust the bonds to fair value. For the three months ended September 30, 2022, we recorded a loss of \$1.2 million to adjust the bonds to fair value. The change in fair value of the bond was driven by a decrease in term to maturity, increase in risk free rate and change in stock price.

Other Income (Expense)

(in thousands)	Three Months Ended		Change 2023 vs.2022	
	September 30, 2023	September 30, 2022	Change	%
Other income, net	\$ 100	\$ 114	\$ (14)	-12%

During the three months ended September 30, 2023, we realized \$0.1 million of income related to interest income earned on our cash deposits. During the three months ended September 30, 2022, we realized \$0.1 million of other income for additional services performed outside the scope of the operating agreement.

Liquidity and Capital Resources

Since our inception, we have incurred net losses. We incurred net losses of \$10.2 million and \$12.0 million for the three months ended September 30, 2023 and 2022, respectively. As of September 30, 2023, we had an accumulated deficit of \$188.5 million.

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

- the cost, progress and results of our ongoing and planned validation studies and health economic studies;
- the cost of manufacturing clinical and commercial supply of KidneyIntelX;
- the cost, timing and outcome of regulatory review of current and future products from the KidneyIntelX platform, including any post-marketing studies that could be required by regulatory authorities;
- the cost, timing and outcome of commercialization activities, including manufacturing, marketing, sales and distribution, for KidneyIntelX;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of revenue received from commercial sales of KidneyIntelX;

- the sales price and availability of adequate third-party coverage and reimbursement for KidneyIntelX;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, although we currently have no other commitments or agreements to complete any such transactions.

To date, we have primarily financed our operations through equity and debt financings. As of September 30, 2023, we had cash and cash equivalents of \$13.9 million. We have incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of \$188.5 million as of September 30, 2023. We anticipate incurring additional losses until such time, if ever, that we can generate significant sales of KidneyIntelX or any future products currently in development. As a result of our losses and our projected cash needs, substantial doubt exists about our ability to continue as a going concern within 12 months after the date that the financial statements are issued.

Substantial additional capital will be necessary to fund our operations, expand our commercial activities and develop other potential diagnostic related products. We plan to finance our cash needs through a combination of revenue from sales, securities offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders.

Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or diagnostic products or grant licenses on terms that may not be favorable to us. Additional capital may not be available when needed, on reasonable terms, or at all, and our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and disruptions to and volatility in the credit and financial markets in the United States and worldwide. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may not be able to meet our obligations and we may be required to delay, curtail or discontinue our product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Going Concern

We have limited sources of revenue to provide incoming cash flows to sustain our future operations. As outlined above, our ability to pursue our planned business activities is dependent upon our successful efforts to raise additional capital and the effectiveness of our cost-cutting and other capital preservation measures. Without additional financing, we expect our cash and cash equivalents as of September 30, 2023, combined with additional cost reduction options available, will be sufficient to fund our operating expenses and capital expenditure requirements for an additional five to seven months from the date of this report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect or may fail in our efforts to enact additional cost reduction options. Furthermore, our operating plan may change, and we may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization.

These factors raise substantial doubt regarding our ability to continue as a going concern. Our condensed consolidated financial statements have been prepared on a going concern basis, which implies that we will continue to realize our assets and discharge our liabilities in the normal course of business. Our financial statements do not include any adjustments to the recoverability and classification of recorded asset amounts and classification of liabilities that might be necessary should we be unable to continue as a going concern.

Cash Flows

The following table shows a summary of our cash flows from operations for the periods indicated (in thousands):

(in thousands, except share and per share amounts)	Three Months Ended September 30,		Change 2023 vs. 2022	
	2023	2022	Change	%
Net cash used in operating activities	\$ (9,504)	\$ (7,119)	(2,385)	34 %
Net cash used in investing activities	—	—	—	—
Net cash used in financial activities	(1,065)	(944)	(121)	13 %
Effect of exchange rate changes on cash	(222)	(2,230)	2,008	-90 %

Net cash used in operating activities

During the three months ended September 30, 2023, net cash used in operating activities was \$9.5 million and was primarily attributable to our \$10.1 million net loss as well as \$2.5 million of noncash charges and \$1.9 million net change in our operating assets and liabilities. Noncash charges were primarily related to \$1.0 million in share-based compensation expense, \$0.9 million fair value adjustment related to the bonds, \$0.4 million fair value adjustment on our VericiDx investment, \$0.1 million of depreciation and amortization expense. The change in our operating assets and liabilities was primarily attributable to \$1.0 million decrease in accrued expenses and other current liabilities, \$0.9 million decrease in accounts receivables, prepaids and other current assets.

During the three months ended September 30, 2022, net cash used in operating activities was \$7.1 million and was primarily attributable to our \$12.0 million net loss including a \$1.7 million net change in our operating assets and liabilities and \$3.2 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to a \$1.7 million increase in accounts payable and accrued expenses and other current liabilities. Noncash charges were primarily related to \$0.8 million in share-based compensation, \$0.9 million fair value adjustment of our VericiDx securities, \$0.9 million fair value adjustment of our convertible debt, \$0.5 million unrealized foreign exchange loss and \$0.2 million of depreciation and amortization.

Net cash provided by and used in investing activities

During the three months ended September 30, 2023, no cash was used in investing activities.

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

Net cash used in financing activities

During the three months ended September 30, 2023, net cash used in financing activities was \$1.1 million and was primarily attributable to \$1.0 million in cash used to pay down the principal of the Bonds.

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

Recent Accounting Pronouncements

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

JOBS Act Transition Period

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an “emerging growth company” can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. An emerging growth company can delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards and, as a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We have evaluated the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we have chosen to rely on certain of these exemptions, including without limitation exemptions to the requirements for (1) providing an auditor’s attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor’s report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) June 30, 2026, (b) the last day of the fiscal year (1) in which we have total annual gross revenues of at least \$1.235 billion or (2) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our ordinary shares and ADSs that are held by non-affiliates exceeds \$700.0 million as of the prior December 31, or (c) the date on which we have issued more than \$1.0 billion in non-convertible debt during the prior three-year period.

Critical Accounting Estimates

Our management's discussion and analysis of our financial condition and results of operations are based on our financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and share-based compensation. We base our estimates on historical experience, known trends and events, and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in Note 3 to our financial statements included elsewhere in this report, we believe the following accounting policies are the most critical to the judgments and estimates used in the preparation of our financial statements.

Research and Development Expenses

Research and development expenses consist primarily of costs incurred in connection with the development of KidneyIntelX. We expense research and development costs as incurred.

At the end of the reporting period, we compare payments made to third-party service providers to the estimated progress toward completion of the research or development objectives. Such estimates are subject to change as additional information becomes available. Depending on the timing of payments to the service providers and the progress that we estimate has been made as a result of the service provided, we may record a prepaid expense or accrued liability relating to these costs. Upfront milestone payments made to third parties who perform research and development services on our behalf are expensed as services are rendered. Contingent development or regulatory milestone payments are recognized upon the related resolution of such contingencies.

We make estimates of our accrued expenses as of each balance sheet date in our financial statements based on facts and circumstances known at that time. If the actual timing of the performance of services or the level of effort varies from the estimate, we will adjust the accrual accordingly. Nonrefundable advance payments for goods and services, including fees for process development or manufacturing and distribution of clinical supplies that will be used in future research and development activities, are deferred and recognized as expense in the period that the related goods are consumed or services are performed.

Share-based Compensation

We measure equity classified share-based awards granted to employees and nonemployees based on the estimated fair value on the date of grant and recognize compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. We account for forfeitures as they occur. For share-based awards with service-based vesting conditions, we recognize 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 our expected dividend yield. We were a privately-held organization prior to November 2018 and have been a publicly-traded company for a limited period of time and therefore lack company-specific historical and implied volatility information for our shares. Therefore, we estimate our expected share price volatility based on the historical volatility of publicly-traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price. The expected term of our 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 we have never paid cash dividends on ordinary shares and do not expect to pay any cash dividends in the foreseeable future.

We classify share-based compensation expense in our 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.

Convertible Notes

In April 2022, we issued amortizing senior convertible bonds with a principal amount of \$21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds") to Heights Capital Ireland LLC (the "Convertible Bond Investor"). The Bonds were issued at 85% par value with total net proceeds of \$18.0 million and accrue interest at an annual rate of 5.5%, payable quarterly in arrears, in cash or ADSs valued at the ADS Settlement Price at the option of the Company. The principal and interest payments are due in equal quarterly installments starting in July 2022. The Bonds contain various conversion and redemption features. The initial

conversion price for the Convertible Bonds of \$8.70 has been set at a 20 percent premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance, the Bonds have a hard floor in the conversion price of \$7.25. As a result of the February 2023 private placement and pursuant to conditions of the bond agreement, the conversion price was adjusted to \$8.2508 (previously \$8.70) and the floor price was adjusted to \$6.8757 (previously \$7.25). Further, pursuant to conditions of the agreement, effective April 7, 2023, the conversion price was adjusted from \$8.2508 to \$7.7924. Between amortization dates, Heights Convertible Bond Investor retains the right to advance future amortization payments, provided that (a) there shall be no amortization advancements during the first 12 months, (b) no more than 2 amortization advancements may occur in any 12 month period, and (c) no more than 1 amortization advancement may occur in any 3 month period.

The Convertible Bond Investor is also permitted to defer up to two amortization payments to a subsequent amortization date. The Company retains the option to repay any deferred amortization in cash at 100 percent of the nominal amount. In July 2022, we made a cash amortization payment of \$1.4 million, which consisted of \$1.1 million of principal and \$0.3 million of interest. In October 2022, the Convertible Bond Investor deferred the October amortization payment to maturity of the bond and we made an interest payment of \$0.3 million. In January 2023, we made a cash amortization payment of \$1.4 million, which consisted of \$1.1 million of principal and \$0.3 million of interest. In April 2023, we made a cash amortization payment of \$1.4 million, which consisted of \$1.1 million of principal and \$0.3 million of interest. In October 2023, we made a repayment of \$1.06 million through the issuance of 150,000 Ordinary Shares and 1,092,694 American Depositary Shares. As of September 30, 2023, \$15.9 million of principal was outstanding.

We elected the fair value option to account for the Bonds as we believe the fair value option provides users of the financial statements with greater ability to estimate the outcome of future events as facts and circumstances change, particularly with respect to changes in the fair value of the ordinary shares underlying the conversion option. The fair value of the Bonds is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders. For each reporting period, changes in the fair value of the Bonds are recognized through other income (expense) with the portion of the change that results from a change in the instrument-specific credit risk recorded separately in Other Comprehensive Income for each reporting period.

Item 3. Quantitative and Qualitative Disclosures About Market Risk.

We are a smaller reporting company and not required to provide this information.

Item 4. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

We maintain “disclosure controls and procedures,” as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act, that are designed to ensure that information required to be disclosed in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the rules and forms of the Securities and Exchange Commission. Disclosure controls and procedures include, without limitation, controls and procedures designed to ensure that information required to be disclosed in our reports filed or submitted under the Exchange Act is accumulated and communicated to management, including our chief executive officer (*principal executive officer*) and chief financial officer (*principal financial officer*), as appropriate, to allow timely decisions regarding required disclosure.

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of September 30, 2023, have concluded that, as of such date, our disclosure controls and procedures were effective as described further below.

It should be noted that any system of controls is based in part upon certain assumptions designed to obtain reasonable (and not absolute) assurance as to its effectiveness, and there can be no assurance that any design will succeed in achieving its stated goals.

Management does not expect that our internal control over financial reporting will prevent or detect all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control systems are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in a cost-effective control system, no evaluation of internal control over financial reporting can provide absolute assurance that misstatements due to error or fraud will not occur or that all control issues and instances of fraud, if any, have been or will be detected.

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) that occurred during the fiscal quarter ended September 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

PART II

Item 1. Legal Proceedings.

From time to time, we may become involved in legal proceedings arising in the ordinary course of our business. We are not currently subject to any material legal proceedings.

Item 1A. Risk Factors.

In addition to the other information set forth in this Quarterly Report, you should carefully consider the risk factors and other cautionary statements described under the heading “Item 1A. Risk Factors” included in our 2023 Annual Report on Form 10-K and the risk factors and other cautionary statements contained in our other SEC filings, which could materially affect our business, financial condition or future results. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition or future results.

Our future capital needs are uncertain, and our independent registered public accounting firm has expressed in its report on our audited financial statements for the fiscal year ended June 30, 2023 a substantial doubt about our ability to continue as a going concern. Our ability to continue as a going concern is dependent on our ability to raise additional capital and our operations could be curtailed if we are unable to obtain the required additional funding when needed. We may not be able to do so when necessary, and/or the terms of any financings may not be advantageous to us.

Our financial statements included in this report have been prepared assuming we will continue to operate as a going concern. However, due to our recurring losses from operations, and working capital deficiency, there is substantial doubt about our ability to continue as a going concern. Because we expect to continue to experience negative cash flow, our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from offerings of our equity securities or debt, transactions involving product development, licensing or collaboration, or other forms of financing. Management intends to continue its efforts to contain costs and to raise additional capital until we can generate sufficient cash from commercial sales to support operations, if ever. If we are unable to obtain sufficient financing, we may be required to delay, scale back or discontinue one or more product development programs, curtail our commercialization activities and significantly reduce expenses or we may not be able to continue as a going concern. As a result, our independent registered public accounting firm has expressed in its auditors’ report on the financial statements included in our Annual Report on Form 10-K a substantial doubt regarding our ability to continue as a going concern. Our financial statements in our Annual Report on Form 10-K and in this report do not include any adjustments that might result from the outcome of the uncertainty regarding our ability to continue as a going concern. If we cannot continue as a going concern, we may have to liquidate our assets and may receive less than the value at which those assets are carried on our financial statements, and our shareholders may lose their entire investment in our securities. Further, the perception that we may be unable to continue as a going concern may impede our ability to pursue strategic opportunities or operate our business due to concerns regarding our ability to discharge our contractual obligations. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern.

Without additional financing, we expect our cash and cash equivalents as of September 30, 2023, combined with additional cost reduction options available, will be sufficient to fund our operating expenses and capital expenditure requirements for an additional five to seven months from the date of this report. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect or may fail in our efforts to enact additional cost reduction options. Furthermore, our operating plan may change, and we may need additional funds sooner than planned in order to meet operational needs and capital requirements for product development and commercialization.

Item 2. Unregistered Sales of Equity Securities, Use of Proceeds, and Issuer Purchase of Equity Securities

Recent Sales of Unregistered Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures.

Not applicable.

Item 5. Other Information.

None

Item 6. Exhibits, Financial Statement Schedules.

Exhibit No.	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association	F-1	333- 239414	3.1	June 24, 2020
4.1	Reference is made to Exhibit 3.1				
4.2	Form of Deposit Agreement	F-1/A	333- 239414	4.1	July 13, 2020
4.3	Form of American Depositary Receipt (included in Exhibit 4.2)	F-1/A	333- 239414	4.1	July 13, 2020
4.4	Description of Securities	20-F	001- 39387	4.3	October 28, 2020
10.1†	Amended and Restated Bond Agreement between registrant and CVI Investments, dated as of April 5, 2022	20-F	001- 39387	10.11	October 31, 2022
10.2+*	Employment Agreement, dated as of August 22, 2023, by and among Howard Doran, Renalytix AI, Inc. and Renalytix plc				
31.1*	Certification of Chief Executive Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14a				
31.2*	Certification of Chief Financial Officer pursuant to Securities Exchange Act of 1934 Rule 13a-14(a) or 15d-14a				
32.1**	Certification by the Principal Executive Officer and Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
101.INS*	Inline XBRL Instance Document				
101.SCH*	Inline XBRL Taxonomy Extension Schema Document				
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase				
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document				
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document				
104*	Cover Page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)				

* Filed herewith.

** Furnished herewith and not deemed to be “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and shall not be deemed to be incorporated by reference into any filing under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended.

+ Indicates a management contract or any compensatory plan, contract or arrangement.

† Certain portions of this exhibit will be omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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

November 14, 2023

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

RENALYTIX PLC

November 14, 2023

By: /s/ O. James Sterling
Name: O. James Sterling
Title: Chief Financial Officer (*Principal Financial Officer*)



Howard Doran

August 22, 2023

Dear Howard:

Renalytix AI, Inc. ("Renalytix" or the "Company") is pleased to offer you the position of Chief Business Officer, reporting to James McCullough, Chief Executive Officer, with a dotted line to Tom Mclain, President. We feel strongly that your intellect, energy and experience are an ideal fit with our Company culture and objectives, and that you would make a tremendous addition to our core team.

As the Chief Business Officer, you will be responsible for building upon, shaping, and executing the sales strategy for Renalytix Kidney bioprognosis™ solutions. This is a hands-on position which will require both extensive in-field presence as well as regular interaction with senior leadership. You will be responsible for providing exceptional leadership in alignment with the Renalytix Cultural Values (Accountability, Communication, Teamwork, Strategic Thinking & Initiative, Urgency).

- Develop monthly, quarterly, and annual sales forecasts for all products by territory and physician demographics to drive revenue achievement.
- Develop key testing and revenue targets working closely with the President.
- Ensure current sales and structure is effectively positioned to achieve revenue goals.
- Develop and track key sales metrics for all growth initiatives. Monitor and report sales achievements for the executive management team.
- Provide leadership through effective communication of vision and active coaching and development, while taking appropriate action to hold teams accountable to objectives.
- Review and design compensation structure and variable compensation plans in conjunction with the President and CFO.
- Build an effective structure, processes and culture of collaboration and hands-on accountability within Renalytix sales organization.
- Collaborate with Marketing, Market Access, Project Management, and Medical Affairs to refine/update functional plans, ensuring KidneyIntelX is positioned appropriately in the marketplace and growing at an accelerated pace.
- Continue to develop and drive the use of the Salesforce platform by the Commercial Sales team.
- Regular in-field presence to evaluate commercial experience and sales performance of the team.
- Recruit, develop and retain top performers and high potential talent with a focus in the Primary Care market.
- Keep informed and educated on competitive offerings, new products, services, and other general information in the diabetic kidney disease and laboratory services/diagnostics space.
- Demonstrate exceptional leadership by developing, motivating, leading, and growing a high performing commercial sales team.
- Prioritize multiple objectives in a rapidly changing environment while delivering quality outcomes
- Promote and reinforce effective communication with medical advisors and key opinion leaders.
- Develop and manage departmental budgets.

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- Represent Renalytix at conferences, national meetings, and conventions, as necessary.

You shall devote your best efforts, skill and such time, attention and energy as may be necessary to fully and effectively perform your duties and responsibilities. Additionally, you shall not engage in any activities which directly or indirectly are in competition with the performance of your duties and responsibilities and/or the business of the Company. Further, you shall faithfully carry out any and all instructions given to you by your supervisors and shall observe all of the Company's policies, procedures, rules and regulations as may be implemented from time to time.

It is anticipated that your start date will be on September 1, 2023, based on successful completion of a background screen and reference check. Your primary work location will be your home office; however, you will be expected to travel up to 75%, to our customer locations and clinical laboratories/offices when required.

The position will include a base salary of \$300,000 per year. You will also be eligible for an annual bonus with a target of 60% of your base salary, subject to individual and Company performance. Details of the Bonus Plan including management approved targets will be shared with you by the end of September, 2023. Your offer includes an attractive package of benefits including insurance coverage, time-off, and long-term savings vehicles. Please see the appendix on the last page of this letter for a summary list of benefits.

Your offer also includes a grant of options for 300,000 common shares, currently traded on the London (AIM) market under ticker RENX. Options vest quarterly over three years with a 1-year cliff. The grant date of the options will be the Board approval date, which will occur at the board meeting following the latter of a) your start date, or b) if the company is in a close period on your start date, when the company is back in an open trading period. Close periods generally occur in the 30 days prior to release of quarterly financials, and/or when there is material information not yet publicly announced. Exercise price of the options shall equal the RENX closing price on the trading day before the grant.

If you choose to accept this job offer, please sign a copy of this letter where indicated below and return it to me by August 24, 2023. Nothing stated in this letter or in any prior discussions regarding the terms of your employment will serve as an employment contract or a guarantee of continued employment.

For legal purposes, we must emphasize that this letter is not a contract of employment; it merely lists the salary and other benefits that you will be eligible for as well as the general terms and conditions of employment under which you will be employed if you accept our offer of employment. Your employment with the Company is at-will. Just as you retain the right to resign, without notice or cause, the Company has the same right with respect to termination. Your employment is for no definite term, regardless of any other oral or written statement by any officer or representative, with the exception of an express written employment contract signed by the CEO.

Except as permitted in writing signed by the Company's CEO, during the term of your employment, or at any time thereafter, you shall not divulge, furnish or make accessible to anyone or use in any way (other than in the ordinary course of business of the Company) any confidential or secret knowledge or information of the Company which you acquire or become acquainted with during the term of your employment, whether developed by you or others, concerning any confidential information of the Company's operations and activities. The foregoing obligations of confidentiality shall not apply to any confidential information which is now published, or which subsequently becomes known to the general public other than as in direct result of the breach of this agreement by you or which is required to be disclosed by you by order of any court or governmental agency or pursuant to any statute or governmental regulation.

In the event you should choose to resign at some point, we ask that you provide two weeks' notice. In the event you fail to provide the requested two weeks' notice, you may forfeit any accrued but unused vacation, and other paid time off benefits.

The Immigration Reform and Control Act requires employers to verify the employment eligibility and identity of new employees. You will need to submit documentation confirming your employment eligibility so that an I-9 can be completed. We will not be able to employ you if you do not present appropriate documentation.

In making this offer, you acknowledge, and the Company understands that you are not under any obligation to any former employer or any person, firm or corporation which would prevent, limit, or impair in any way the performance of your duties as the Company's employee and the Company receiving the exclusive benefit of your services. You acknowledge that you have not taken any property from your former employer, including but not limited to, any confidential information or trade secret information, and that you will leave all of your former employer's property at your previous employment. You are being offered this employment because of your skills and your experience and not because you may have had access to any confidential information. In the event this agreement is violated, we reserve the right to terminate your employment.

Per Company policy, our offer is contingent upon the favorable results of your background check and your signing the Company's "Non-Disclosure, Confidentiality, Non-Solicitation and Non-Compete Agreement," "Employee Proprietary Information and Inventions Assignment Agreement," as well as a "Jury Trial and Class Action Waiver." You may not begin work until these agreements are signed and returned to the Company.

Per Company policy, all employees are required to be fully vaccinated against COVID-19 infection. You may not begin work until proof of full vaccination is presented by signing the Company's "Employee COVID-19 Vaccine Certification Form". If you are not fully vaccinated on account of a disability or a sincerely held religious belief, please contact Human Resources at HR@Renalytix.com.

When your acknowledgement to this letter is received, appropriate links to set up your employee benefits and payroll will be sent along with an employee handbook for your review.

We very much look forward to having you join the team during this exciting time in Renalytix's development.

Sincerely,

/s/ O. James Sterling
.....
O. James Sterling
Chief Financial Officer

About Renalytix

Renalytix plc (LON:RENX) (Nasdaq:RNLX) is a developer of artificial intelligence (AI) enabled clinical diagnostic solutions for kidney disease, one of the most common and costly chronic medical conditions globally. Renalytix solutions are designed to make significant improvements in kidney disease risk assessment, clinical care and patient stratification for drug clinical trials. Our technology platform draws from distinct sources of patient data, including large electronic health records, predictive blood-based biomarkers and other genomic information for analysis by learning computer algorithms. We intend to build a deep, unique pool of kidney disease-related data for different AI-enabled applications designed to improve predictive capability and clinical utility over time. In 2020, Renalytix launched KidneyIntelX™, an AI-enabled, clinical-laboratory based solution intended to support physician decision making by improving identification, prediction, and risk stratification of patients with progressive kidney disease. Renalytix AI, Inc. is a wholly-owned subsidiary of Renalytix plc.

I hereby accept the Chief Business Officer position as described herein.

Howard Doran Jr.

Full legal name

/s/ Howard Doran Jr.

Signature

CERTIFICATIONS

I, James McCullough, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Renalytix plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ James McCullough
(Principal Executive Officer)

CERTIFICATIONS

I, O. James Sterling, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Renalytix plc;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 14, 2023

/s/ O. James Sterling
Chief Financial Officer
(Principal Financial Officer)

CERTIFICATION

Pursuant to the requirement set forth in Rule 13a-14(b) of the Securities Exchange Act of 1934, as amended, (the “Exchange Act”) and Section 1350 of Chapter 63 of Title 18 of the United States Code (18 U.S.C. §1350), James McCullough, Chief Executive Officer of Renalytix plc (the “Company”), and O. James Sterling, Chief Financial Officer of the Company, each hereby certify that, to the best of his or her knowledge:

1. The Company’s Quarterly Report on Form 10-Q for the period ended September 30, 2023, to which this Certification is attached as Exhibit 32.1 (the “Report”), fully complies with the requirements of Section 13(a) or Section 15(d) of the Exchange Act; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Dated: November 14, 2023

IN WITNESS WHEREOF, the undersigned have set their hands hereto as of the 14th day of November, 2023.

/s/ James McCullough
James McCullough
Principal Executive Officer

/s/ O. James Sterling
O. James Sterling
Principal Financial Officer

“This certification accompanies the Form 10-Q to which it relates, is not deemed filed with the Securities and Exchange Commission and is not to be incorporated by reference into any filing of Renalytix plc under the Securities Act of 1933, as amended, or the Securities Exchange Act of 1934, as amended (whether made before or after the date of the Form 10-Q), irrespective of any general incorporation language contained in such filing.”

