UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended June 30, 2023

OR

c☐ **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	**Not Applicable**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
Finsgate **5-7 Cranwood Street** **London, United Kingdom**	**EC1V 9EE**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: +44 20 3139 2910

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.*

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
Emerging growth company	☒		

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

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 December 30, 2022, the aggregate market value of the Registrant's ordinary shares, nominal value £0.0025 per share, held by non-affiliates of the Registrant, based on the closing price of the American Depositary Shares on the Nasdaq Global Market on December 30, 2022, was $44,938,090 . The Registrant has no non-voting common equity.

As of September 28, 2023, there were 95,019,440 ordinary shares outstanding, which if all were held in ADS form would be represented by 47,509,720 American Depositary Shares, each representing two ordinary shares.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement related to the 2023 Annual General Meeting of the Registrant, scheduled to be filed with the Securities and Exchange Commission within 120 days after the end of the registrant's fiscal year ended June 30, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

RENALYTIX PLC
ANNUAL REPORT ON FORM 10-K
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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K for the year ended June 30, 2023 (this "Annual 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 Annual Report are based upon information available to us as of the date of this Annual 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 Annual 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 sections of this Annual Report titled “Item 1A. Risk Factors” and “Item 7. Management’s Discussion and Analysis of Financial Condition and Results of Operations” 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 Annual 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 Annual Report, the documents that we reference in this Annual Report and the documents we have filed as exhibits to this Annual 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.

PART I

Item 1. Business.

Introductory Note

In this Annual Report, we use the terms “KidneyIntelX”, “KidneyIntelX Technology”, “KidneyIntelX Technology Platform” and “KidneyIntelX.dkd.” When we refer to KidneyIntelX, we are referring to our diagnostic platform and any products developed based on this platform including our KidneyIntelX laboratory developed test currently offered as a testing service across the United States from our CLIA certified laboratories. When we refer to KidneyIntelX.dkd, we are referring to the specific testing service from our KidneyIntelX technology platform or KidneyIntelX technology that has received De Novo marketing authorization from the U.S. Food and Drug Administration (FDA) to assess risk of progressive kidney function decline in adults with diabetes and early-stage kidney disease. KidneyIntelX.dkd received FDA De Novo marketing authorization on June 29, 2023.

Overview and Recent Developments

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.

This past year has seen the achievement of milestones necessary to begin broad commercial expansion of the use of the KidneyIntelX technology in select regions of the United States with high rates of diabetes and kidney disease. Key milestones include achieving FDA De Novo marketing authorization, a significant expansion of commercial insurance coverage at the Medicare national payment rate of $950 per test, publication of real world outcomes data and real world utility data, training and deployment of a core sales force, and inclusion in the draft of the leading kidney clinical guidelines.

On June 29, 2023, the first FDA positive decision on a KidneyIntelX technology platform clinical test was achieved with De Novo marketing authorization issued to KidneyIntelX.dkd for the assessment of risk of progressive kidney function decline in adults with diabetes and early-stage kidney disease (also referred to as diabetic kidney disease ("DKD"). An estimated 14 million Americans adults currently fall within the FDA authorized indicated use population for KidneyIntelX.dkd.

Renalytix believes that with FDA marketing authorization, KidneyIntelX.dkd has achieved a number of industry firsts that may have significant implications for current clinical use and development of new applications to provide advanced prognostic tests and monitoring in widespread or highly prevalent chronic diseases such as kidney disease and diabetes. Among the core KidneyIntelX.dkd innovations that support our ability to provide safe, regulated and insurance reimbursable tests are 1) use of a non-linear or machine learning algorithm, 2) validation of an endpoint of progressive and sustained decline in estimated Glomerular Filtration Rate (eGFR), 3) use of novel disease blood biomarkers with demonstrated prognostic performance in multiple studies, and 4) incorporation of electronic health record (EHR) features, specifically laboratory measurements that are not measured in Renalytix laboratories.

We believe that collectively these innovations, which have undergone FDA regulatory review and which have now been contracted for payment by multiple major insurance companies in the United States including Medicaid, Medicare and Blue Cross Blue Shield entities, provide KidneyIntelX.dkd with the foundation to establish a broadly used standard for early prognosis to help clinicians address the threat posed by uncontrolled diabetic kidney disease. We have established coverage pricing for KidneyIntelX technology

at or above $950 per reportable result for base-line prognosis. To date we have executed over 40 commercial payor contracts at or above this price and enrolled as a provider in 35 state Medicaid programs.

Further, KidneyIntelX has been included in the draft Kidney Disease Improving Global Outcomes (KDIGO) 2023 Clinical Practice Guideline for Evaluation and Management of Chronic Kidney Disease. KDIGO guideline development follows an explicit process to translate global scientific evidence review and appraisal into practical recommendations for clinicians and patients. The final version of these kidney disease guidelines is expected to be released in the fourth calendar quarter of 2023.

Most importantly, these significant milestones in the diagnostic product lifecycle would not be achievable without establishing a comprehensive, peer reviewed portfolio of data publications covering four key areas: 1) clinical outcomes, 2) clinical utility, 3) economics, and 4) performance validations. Since Renalytix achieved its first large capital infusion from listing on the London Stock Exchange nearly five years ago, we have invested heavily in these core categories of proof in support of the KidneyIntelX technology and believe we have exceeded standards for delivering a validated data portfolio necessary to support broad-scale clinical use and insurance reimbursement. Most recently, a late-breaking clinical data release at the 83rd American Diabetes Association Scientific Sessions in July 2023 demonstrated that KidneyIntelX *in vitro* prognostic use was associated with clinical actions that in less than 12 months led to improvements in both diabetes health, as measured by hemoglobin A1C reductions, and kidney health, as measured by eGFR slope improvement in patients with diabetic kidney disease. We believe that these observed improvements in both diabetes and kidney outcomes will continue to have a positive impact on the commercial prospects of KidneyIntelX technology.

Our commercial model is now focused on expanding clinical use in a limited group of regions in the United States with high rates of adult diabetes, where we have established comprehensive insurance coverage - ideally with greater than 90% of our indicated use population with insurance coverage, and where there are hospital system partners available to enable outreach to large groups of treating primary care physician practices. Into these limited regions, we are deploying a direct-to-physician sales force. As we continue to demonstrate revenue growth and adoption, we will continue to add regions where the KidneyIntelX.dkd service provision can demonstrate specific return-on-investment targets and revenue growth.

We believe our model of deploying KidneyIntelX technology directly into the electronic medical record systems in partnership with large integrated disease network hospital systems, such as our announced partners Mount Sinai Health System in New York and Atrium Wake Forest in North Carolina, has demonstrated significant advantages in simplifying test ordering and score reporting, driving awareness and use, and unleashing the full capabilities of the clinical care pathway to help slow or stop kidney disease progression and mitigate long-term cost of care. We and our third-party hospital partners have continued to publish on the evidence of real-world benefits of this coordinated approach to enabling advanced prognosis and care management across broad primary care practices and diverse patient populations. These real-world evidence results continue to consistently validate the use of KidneyIntelX technology to combat this large unmet medical need. We also believe coordinated partnerships with hospital systems are key to leveraging the high fixed cost associated with effective sales force build and management that can potentially lead to significantly higher investment yield, ultimately increasing patient access to the benefits of innovative technology such as the FDA authorized KidneyIntelX.dkd.

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The National Kidney Foundation (the "NKF"), estimates that one-third of adults in the United States are at risk of developing kidney disease. Advanced kidney disease is generally not reversible and, once the disease progresses to kidney failure, the only available treatments are long-term dialysis or kidney transplant. In 2019, more than 809,000 patients had end-stage kidney disease ("ESKD"), with more than 566,000 requiring dialysis at least three times a week. More than 131,000 patients begin dialysis each year to treat ESKD. Once on dialysis, patients typically experience a five-year mortality rate of up to 65%, about the equivalent rate for brain cancer. Furthermore, transplants are expensive and uncertain. As of 2022, about 92,000 Americans were on the waiting list to receive a kidney transplant and six patients die in the United States while waiting for a kidney transplant every day.

Moreover, the kidney disease crisis is continuing to grow along with the increased prevalence of contributing risk factors. One of the most significant risk factors for developing CKD is diabetes. It is estimated that there are approximately 14 million adults with DKD in the United States, and DKD is the most common cause of ESKD in most developed countries. Obesity is believed to account for 80% to 85% of the risk of developing type 2 diabetes. The worldwide prevalence of obesity nearly tripled between 1975 and 2016. Further, according to a 2019 study from the Harvard T.H. Chan School of Public Health, by 2030, it is estimated that about half of the U.S. adult population will be classified as obese and about a quarter as severely obese. This significant projected increase in the prevalence of obesity is expected to continue to drive an increase in diabetes, CKD, DKD and ESKD.

Managing a CKD population of this scale and the associated healthcare spending presents a unique healthcare system challenge, requiring a solution that provides a clearer understanding of clinical risk which can inform specific guideline-driven clinical actions. The ability to predict which patients will experience progressive and sustained kidney function decline or kidney failure (requiring initiation of long-term dialysis or kidney transplant), is critical to changing patient outcomes and health economics. Other methods for risk stratification of patients with CKD lack sufficient precision in predicting progressive kidney function decline, especially at earlier

stages of the disease. This can exacerbate the occurrence of unexpected and expensive clinical events. In fact, up to 38% of patients with CKD initiate dialysis with little or no prior clinical specialist consultation, and up to 63% of patients with CKD initiate dialysis in an unplanned fashion with a central venous catheter and/or during emergency hospitalization, which we refer to as “dialysis crash.” This highlights the need for a mechanism to identify potential instances of rapidly progressing CKD before it becomes critical to the patient’s health and costly to healthcare providers.

KidneyIntelX technology addresses this challenge as a first-in-class, artificial intelligence-enabled prognostic testing platform to help guide care management for adults with DKD. KidneyIntelX.dkd provides prognostic risk stratification using three discrete risk levels (low, moderate, and high). This result provides timely information on patient risk for progressive decline in kidney function within five years, providing independent information from the current standard of care measures and can be readily deployed at the primary care level where the vast majority of patients with early-stage disease are being treated.

Early detection and intervention can result in health economic benefits in three key areas: (1) slowing progression to the next stage of DKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. According to an independent review commissioned by Boston Healthcare Associates, based on the Medicare established price of $950 per reportable test, successful incorporation of the KidneyIntelX technology could generate a positive return for health insurers in 12-24 months and deliver a cost savings of up to $1.1 billion over five years per 100,000 patients with DKD, when considering these key areas of benefit.

Our executive team has an average of 25 years’ experience in different professional disciplines including bioinformatics, digital health, data security, market access, commercial operations, medical affairs, insurance reimbursement, FDA regulation and International Organization for Standardization ("ISO"), quality management systems, population health, clinical medicine, finance and health economics. We believe the integration of such diverse experience is essential to understanding the complex dynamics of deploying a new technology into the highly regulated world of patient clinical care, and we have assembled our team specifically with this multi-disciplinary approach in mind.

We also benefit from the extensive experience of our board of directors, our clinical investigators and medical advisory board of world-leading experts in kidney disease.

Recent Clinical Publications and Presentations

Clinical outcomes, clinical utility, validations, and health economics data were published and/or presented in multiple scientific venues including the American Society of Nephrology Kidney Week 2022, the National Kidney Foundation Spring Clinical Meeting 2023, American Diabetes Association 83rd Scientific Session in June 2023, and American Association of Nurse Practitioners Annual Meeting in June 2023. Study conclusions presented included data from the Wake Forest Real World Evidence cohort, The Mount Sinai Health System Real Evidence World cohort, the Mount Sinai BioMe Biobank program, the UPenn Medicine Biobank program, the Janssen CANVAS SGLT2i clinical trial cohort, and the Veterans Affairs Department Database. Published and/or presented data included detail on the KidneyIntelX technology platform, the KidneyIntelX laboratory developed test, and the FDA De Novo authorized KidneyIntelX.dkd test. Presentations during the fiscal year included:

- American Society of Nephrology Kidney Week 2022
    - A Markov model that estimated the incremental cost-effectiveness of KidneyIntelX compared to risk stratification using eGFR and UACR, with a lifetime horizon from both a public and private payer perspective, demonstrated that population-based KidneyIntelX testing for the prognosis of progression in a DKD G1-G3b population is a cost-effective strategy for both Medicare and commercial populations in comparison to prognosis relying on eGFR and UACR alone. The analyses projected that the average Medicare and Commercial patient population would experience fewer dialysis starts and kidney transplants while experiencing an increased life span and quality-adjusted life span by using KidneyIntelX compared to the standard of care.
    - The clinical impact of the KidneyIntelX risk score was assessed in patients with T2D and early-stage CKD in the Wake Forest Health System. Initial results suggested that despite similar median eGFR and median UACR levels, African American patients tested with KidneyIntelX were three times more likely to be scored as high risk. KidneyIntelX may allow PCPs and healthcare systems to optimize the allocation of treatments and clinical resources to those at highest risk, beyond traditional clinical metrics and potentially improve equity in outcomes.
- National Kidney Foundation Spring Clinical Meeting 2023
    - In an expanded analysis of clinical utility and impact study from Wake Forest Health System, KidneyIntelX classified more Black vs non-Black patients as high risk for progression of diabetic kidney disease, and this was associated with in increased prescription of SGLT2-inhibitor drug therapy post-testing, contributing to elimination of disparity in SGLT2i usage in Blacks vs. non-Blacks.

- In a retrospective cohort study of all U.S. veterans with DKD (n>685,000) treated in the VHA between 01/2016 and 03/2022, analyses demonstrated that the majority of veterans with DKD were only first diagnosed once they had stages G3a or G3b CKD, which implies that clinical practice and lab test intervals predating VHA's Directive 1053 may not optimally identify DKD patients (nearly half of DKD should be represented by G1-G2/A2-A3 staging according to the National Health and Nutrition Examination Survey ("NHANES").

- American Diabetes Association 83rd Annual Meeting
  - In analyses from the Mount Sinai Health System, real world data on 2,317 patients that had KidneyIntelX test results with at least 12 months of post-test follow-up data demonstrated that deployment and risk stratification by KidneyIntelX was associated with escalation in actions taken to optimize cardio-metabolic-kidney health including medications and referrals. Moreover, glycemic control and eGFR slopes improved post-KidneyIntelX testing, with the largest improvements observed in those scored as high-risk.
  - In the presentation entitled "Derivation and Independent Validation of KidneyIntelX.dkd", the FDA authorized KidneyIntelX.dkd was trained in the UPenn Biobank cohort and validated in an external cohort (BioMe), with excellent performance characteristics, and was robustly prognostic after adjustment for key demographics and clinical variables (adjusted HR for high vs. low 7.7 and 3.7 for intermediate vs. low risk), with consistent performance across diverse subgroups of the intended use population. The cumulative incidence of accelerated progression of kidney function decline was approximately 2/3rds of the high-risk group (67%, 95% CI 49% - 84%), and the rates of eGFR decline in the low risk group were comparable to that of normal physiologic aging.
- American Association of Nurse Practitioners Annual Meeting
  - In a subset of patients tested with KidneyIntelX in the Mount Sinai Health System, 988 were successfully contacted by the Nurse Practitioners on the DKD Care Navigation Team at Mount Sinai and completed a post-test survey which demonstrated enhanced patient understanding about kidney disease, and revealed substantial motivation to take appropriate actions and receive further education for their kidney health, including consultations with dieticians.

Peer-reviewed publications during the year:

- The Journal of Primary Care and Community Health. Publication of real-world evidence in *Journal of Primary Care and Community Health* in which KidneyIntelX resulted in a 4.5-fold increase in new drug prescriptions (for SGLT2 inhibitors) for high-risk compared to low-risk patients; early evidence suggested that the introduction of SGLT2i contributed to an observed reduction in HbA1c levels most notably in high-risk patients, and a more than a 20% change in dose or type of antihypertensive therapeutic prescriptions in high vs. low-risk patients.
- Diabetic Nephropathy. Publication of new patient case studies in the journal *Diabetic Nephropathy* demonstrated how KidneyIntelX can optimize clinical management in early-stage kidney disease across multiple physician specialties.
- Diabetes, Obesity, and Metabolism. Acceptance and online publication of the new validation data for KidneyIntelX.dkd in the journal *Diabetes, Obesity, and Metabolism* in Sept 2023. Using data from two independent cohorts and a clinical trial population, it was demonstrated KidneyIntelX.dkd significantly enhanced risk stratification for progressive decline in kidney function, independent from known risk factors for progression.

Our strategy

Our goal is to lower healthcare costs and improve patient quality of life by transforming the paradigm for kidney disease risk assessment and clinical management through our KidneyIntelX platform technology and the now FDA authorized KidneyIntelX.dkd. Core strategy elements to achieve this goal include the following:

- ***Continue to Build Integrated Partnerships with Healthcare Systems on a Population Health Basis.*** We are focused on building partnerships with healthcare systems and the engagement and support of their clinical leadership teams, which will enable us to efficiently initiate and deploy our solution to patient populations with DKD. A key aspect of this is technical integration of the KidneyIntelX technology software platform with healthcare systems' EHR systems and clinical workflow. In September 2020, we announced the initiation of patient testing with Mount Sinai Health System. Integrated partnerships such as this is designed to allow KidneyIntelX technology to be deployed directly to patient populations and their treating clinicians in a cost-efficient and timely manner. We are engaging with multiple healthcare institutions and national payors regarding additional partnership opportunities.

- ***Further Expand Insurance Payor Coverage.*** We continue to successfully build pathways for payment for KidneyIntelX technology across a range of insurance payors in multiple states including from Blue Cross Blue Shield, Medicaid, Medicare, Medicare Advantage and other private insurance companies. We believe we are reaching critical scale of insurance payment in several key markets including in Illinois, New York, Texas, Florida and North Carolina.
- ***Continue to Pursue Permanent Medicare Coverage Through a Local Coverage Determination (LCD) and a National Coverage Determination (NCD).*** We achieved our first payments from National Government Services (NGS), a Medicare Administrative Contracto ("MAC"), in October 2022. Following FDA De Novo marketing authorization, NGS convened a Contractor Advisory Committee ("CAC") meeting as part of the LCD process. As part of the 21st Century Cures Act, Medicare Administrative Contractors are mandated to base an LCD on a review of the published clinical evidence and consensus guidelines. Part of the process is to convene a group of healthcare professionals to review the clinical literature and provide input to help inform the potential coverage decision. During the CAC meeting on August 24, 2023, the members of the panel discussed the literature and their confidence in the effectiveness and utility of the KidneyIntelX technology. While there are no guarantees, we believe KidneyIntelX has sufficient peer review literature on effectiveness to support a Local Coverage Decision from NGS, and we are pursuing additional coverage from other MACs in other jurisdictions. We are also simultaneously pursuing a National coverage determination directly from the Centers for Medicare & Medicaid Services ("CMS"). FDA and CMS have proposed a new Transitional Coverage for Emerging Technologies (TCET) program to support Medicare coverage on the national level for innovative diagnostic devices that service an urgent clinical need.
- ***Build Substantial Repository of Kidney Disease-Related Data.*** We are building a repository of kidney disease-related data for the development of progressive KidneyIntelX product versions and additional artificial intelligence-powered clinical applications. We are designing applications to examine disease patterns in large patient populations and to optimize clinical care navigation and management effectiveness. These developments are underpinned by the goals of driving patient and physician behavior changes and ultimately improving patient outcomes. Access to current and historical patient data, combined with the ability to analytically and clinically validate study results in a quality-controlled framework, provides us with a powerful product development platform. Moreover, the depth, specificity and quality of data is of paramount importance to developing solutions with demonstrated clinical utility across a range of practice specialties and patient demographics, and securing access to this data is central to our strategy of demonstrating both short- and long-term impact on patient outcomes and health economics.
- ***Expand Our Product Portfolio.*** We believe there are significant opportunities to expand our platform through incremental version releases of KidneyIntelX technology as well as through extending the KidneyIntelX platform into new applications for CKD patients beyond those with diabetes, including repeat testing to monitor changes in risk and therapeutic response and other CKD subtypes. We also intend to develop solutions for use in other large chronic disease patient populations, like CKD associated cardiovascular disease. KidneyIntelX technology has been designed within a quality controlled environment with regulatory approval process to allow us to take advantage of the dynamic nature of machine learning to improve product performance through a sequence of controlled version releases. We believe that our product development approach, which is based on a quality systems framework following FDA's Quality System Regulations and the ISO guidelines applicable to medical devices, will enable our KidneyIntelX platform to take advantage of exponential data growth and new clinical use cases, with a clearer path to achieving additional products and services.
- ***Real World Evidence Program.*** We have invested heavily over the past several years in developing a comprehensive portfolio of both real-world evidence outcomes and utility data. We have published and presented this data in various formats including in peer-reviewed publications and at major medical conferences. We believe the data released to date has largely satisfied the primary objective of demonstrating the clinical and economic impact of KidneyIntelX technology informed care management in large populations as has been evidenced by our regulatory, reimbursement and adoption achievements. We expect to continue to pursue real-world evidence generation in the future for KidneyIntelX platform products over time.
- ***Launch in Major International Markets.*** With FDA De Novo authorization for KidneyIntelX.dkd, we have seen an increase in in-bound inquiries for international licensing and distribution opportunities. Kidney disease poses an increasing threat globally and we believe there will be a number of opportunities to partner with third-party entities to carry KidneyIntelX technology internationally through license.

We believe KidneyIntelX technology produces early, actionable prognosis that can support clinical pathways to slow the progression of kidney disease and potentially prevent the occurrence of progressive kidney function decline such as kidney failure and the need for long-term dialysis or kidney transplant. We have built a comprehensive body of published evidence through clinical validation studies and patient data generation to demonstrate that accurate and early identification of high-risk patients, coupled with guidelines-driven clinical recommendations designed to maximize patient treatment and compliance, can have a measurable positive impact on patient quality of life and significantly lower healthcare costs. By involving a broad range of expert clinical opinions, testing a growing number of patient samples, consulting closely with clinical society and patient advocacy organizations, partnering with healthcare systems and payors and developing a detailed understanding of the clinical practice environment, we believe successful use of KidneyIntelX technology will help ease suffering and improve outcomes for patients living with DKD.

Our competitive strengths

The KidneyIntelX platform has the following key strengths:

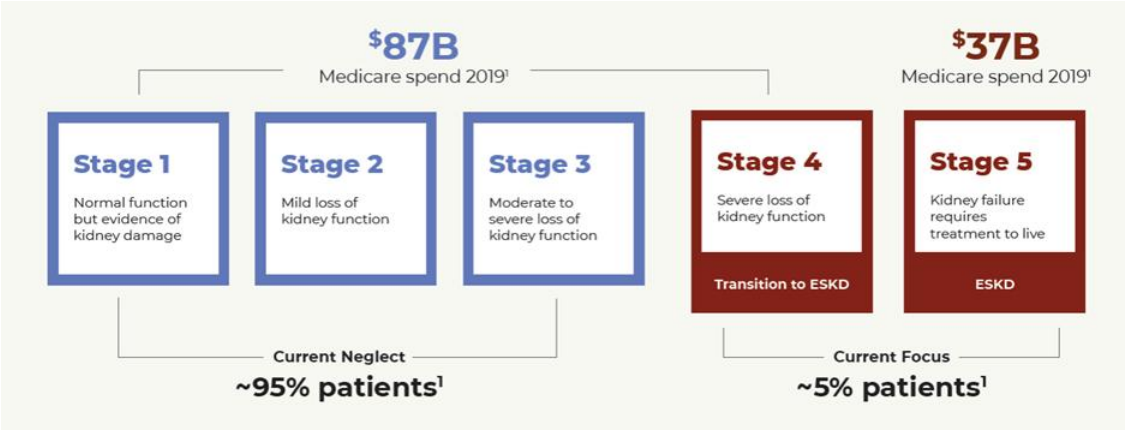
- ***Novel Bioprognostic™ Platform Incorporating Biomarkers and Health Record Features Analyzed with a Machine Learning Enabled Algorithm to Assess the Risk for Kidney Disease Progression***. KidneyIntelX technology has produced the first machine learning enabled *in vitro* prognostic device with the ability to identify patients at risk of progressive kidney function decline while in the earlier stages of DKD, when costs and outcomes can be better controlled.
- ***Large and Growing Addressable Market***. CKD affects over 850 million people worldwide, including approximately 35.5 million people in the United States. The NKF estimates that one third of adults in the United States are at risk of developing kidney disease. Type 2 diabetes is one of the most significant risk factors for developing CKD and obesity is believed to account for 80% to 85% of the risk of developing type 2 diabetes. It is estimated that there are approximately 14 million adults with DKD in the United States. Published data suggests that the DKD population will continue to grow along with the anticipated increase in the occurrence of type 2 diabetes and obesity. One study estimates that by 2060, the number of adults in the United States diagnosed with diabetes will reach 60 million. Further, according to a 2019 study from the Harvard T.H. Chan School of Public Health, by 2030, about half of the adult U.S. population will be obese and about a quarter will be severely obese.
- ***Achievements in Reimbursement and Coverage***. We have received Medicare payment, Medicare national payment rate and multiple private insurance coverage determinations to date. We believe these positive outcomes are the result of several factors: (1) our rigorous approach to a product development and the market access process, (2) significant changes in U.S. reimbursement law with the full implementation of the Protecting Access to Medicare Act, and (3) global improvements in kidney disease policy management, including the U.S. Presidential Executive Order on Advancing American Kidney Health issued in July 2019.
- ***Economic Health Benefits***. KidneyIntelX technology was designed to provide accurate, real-time, actionable results for patients and physicians while reducing costs and promoting improved health economics for patients, physicians, healthcare systems and payors. Health economic benefits are projected to be derived from three key areas: (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. By deploying our proprietary artificial intelligence-enabled algorithm in a regulated, clinically validated, *in vitro* diagnostic test, KidneyIntelX.dkd is able to help predict which patients will experience progressive kidney function decline from early stage disease (Stage 1-3b) within a five-year timeframe, equipping physicians with the information they need to understand risk in their patients. According to a study conducted by BHA, based on the Medicare price of $950 per reportable test, KidneyIntelX technology would generate a positive return for health insurers in 12-24 months and deliver a cost savings of up to $1.3 billion over five years per 100,000 patients with DKD. We believe successive and broad insurance coverage decisions have validated this health economics value proposition.
- ***Partnered Business Model at Population Health Level***. We have begun to deploy KidneyIntelX technology in the form of the KidneyIntelX laboratory developed service through partnerships with healthcare systems (including Mount Sinai Health System, and Atrium Health/Wake Forest Baptist Health) and insurance payors that provide coverage to certain healthcare systems' patients. We expect to transition these deployments and new deployments to our now FDA authorized KidneyIntelX.dkd beginning early in calendar 2024. As we have demonstrated with the KidneyIntelX laboratory developed service, we believe an EHR integrated KidneyIntelX.dkd with population health support will be able to potentially benefit significant patient populations without employing a large, traditional sales force on a provider-level basis at those health systems. In addition, integration of the KidneyIntelX.dkd software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting.
- ***Kidney Disease Data Repository***. As a result of our partnered business model at a population health level, we anticipate that we will have the opportunity to build the most comprehensive de-identified kidney disease data repository geared toward early identification of high-risk patients and optimization of care pathways. Further, our partnerships with relevant insurance payors increases the visibility and the potential cost/benefit economics of KidneyIntelX technology.

Industry background

Chronic kidney disease

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The International Society of Nephrology estimates that kidney disease affects over 850 million people worldwide. According to the Centers for Disease Control and Prevention (the "CDC") affects approximately 36 million people in the United States alone, and the National Kidney Foundation (the "NKF"), estimates that one third of adults in the United States are at risk of developing kidney disease.

CKD, also called chronic kidney disease, is the loss of kidney function over time. Advanced kidney disease is generally not reversible. There are five stages of CKD, from mild kidney damage in Stage 1 to complete kidney failure in Stage 5. The stages of kidney disease are based on how well the kidneys can filter waste and extra fluid out of the blood, as measured by an individual's estimated glomerular filtration rate ("eGFR"). The estimation of GFR is derived from a routine blood test for creatinine, a waste product in blood. When CKD reaches an advanced stage (e.g., Stage 4), dangerous levels of extra fluid, electrolytes and wastes can build up in the body. An eGFR of 60 mL/min/1.73m2 or more is considered normal function, but is classified as Stage 1 or 2 CKD if there is other evidence of kidney damage based a urinary albumin creatinine ratio ("uACR") of ≥ 30 mg/g. Albumin is a protein made by the liver that helps keep fluid in the bloodstream and albuminuria, or the presence of too much albumin in an individual's urine, is a sign that the kidneys are damaged. As a patient's disease progresses, the eGFR will decrease and uACR will typically increase. An eGFR of less than 15 mL/min/1.73m2 indicates a patient is in Stage 5, the last stage of CKD, which is kidney failure or ESKD. ESKD is fatal without long-term dialysis or a kidney transplant.



[1]United States Renal Data System. 2020 USRDS Annual Report: Epidemiology of kidney disease in the United States. National Institutes of Health, National Institute of Diabetes and Digestive and Kidney Diseases, Bethesda, MD, 2020

Commonly referred to as a “silent disease,” CKD is often asymptomatic until approximately 70% to 80% of kidney function has been lost. According to the CDC, in the United States, nine out of ten adults with CKD are not aware they have the disease. In fact, up to 38% of patients with CKD initiate dialysis with little or no prior clinical specialist consultation, and up to 63% of patients with CKD initiate dialysis in an unplanned fashion with a central venous catheter and/or during emergency hospitalization, which we refer to as “dialysis crash.” This highlights the need for an early mechanism to identify potential instances of rapidly progressing CKD before it becomes critical to the patient’s health and costly to healthcare providers.

In 2018, more than 783,000 patients had ESKD with more than 554,000 requiring dialysis at least three times a week. More than 131,000 patients begin dialysis each year to treat ESKD. The incidence and prevalence rates of ESKD are projected to increase significantly as set forth in the figure below.

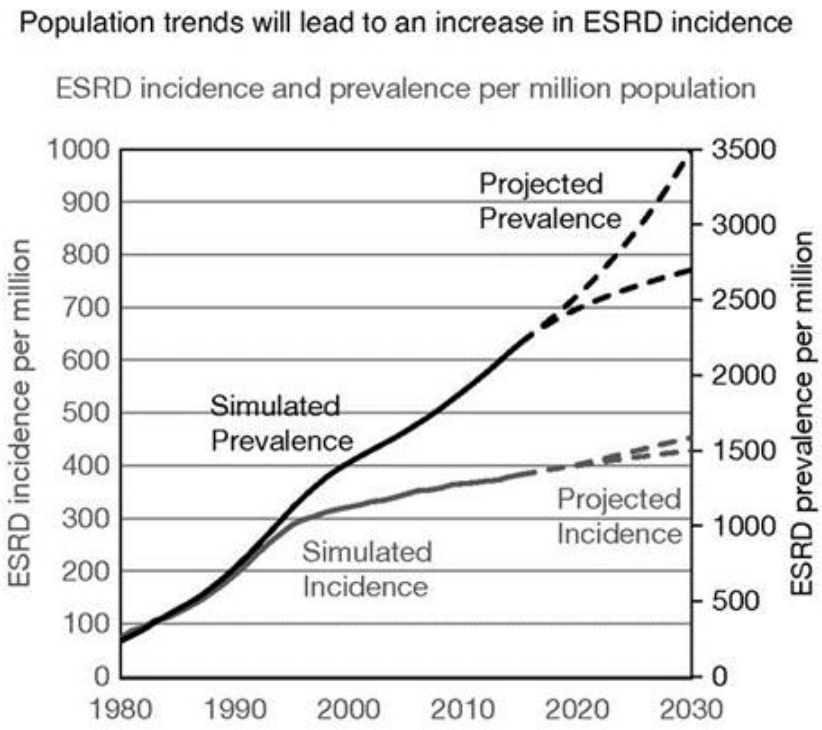


Figure. Projected Incidence and Prevalence of ESRD in the United States (McCullough, KP, et al. Journal of the American Society of Nephrology 30(1):p 127-135, 2019)

Once on dialysis, patients typically experience a five-year mortality rate of up to 70%, about the equivalent rate for brain cancer. As of July 2019, nearly 100,000 Americans were on the waiting list to receive a kidney transplant and 13 patients die in the United States while waiting for a kidney transplant every day.

Studies have shown that ancestry is a determining factor for kidney disease risk. According to the CDC, Americans of African ancestry are three times more likely to develop kidney disease than Caucasians. Since approximately 13% of the U.S. population is of African ancestry, this is a crucial population group that can benefit from advanced and ongoing risk assessment of kidney health.

Chronic kidney disease, obesity and diabetes

One of the most significant risk factors for developing CKD is type 2 diabetes, referred to as DKD. It is estimated that there are approximately 12.6 million adults with DKD in the United States. DKD is the most common cause of ESKD in most developed countries and accounts for approximately half of all patients who will experience kidney failure, or nearly 50,000 patients in the United States each year. Further, the number of individuals with diabetes is growing. According to a study published in 2018, the number of adults in the United States diagnosed with diabetes is projected to nearly triple, reaching 60 million in 2060.

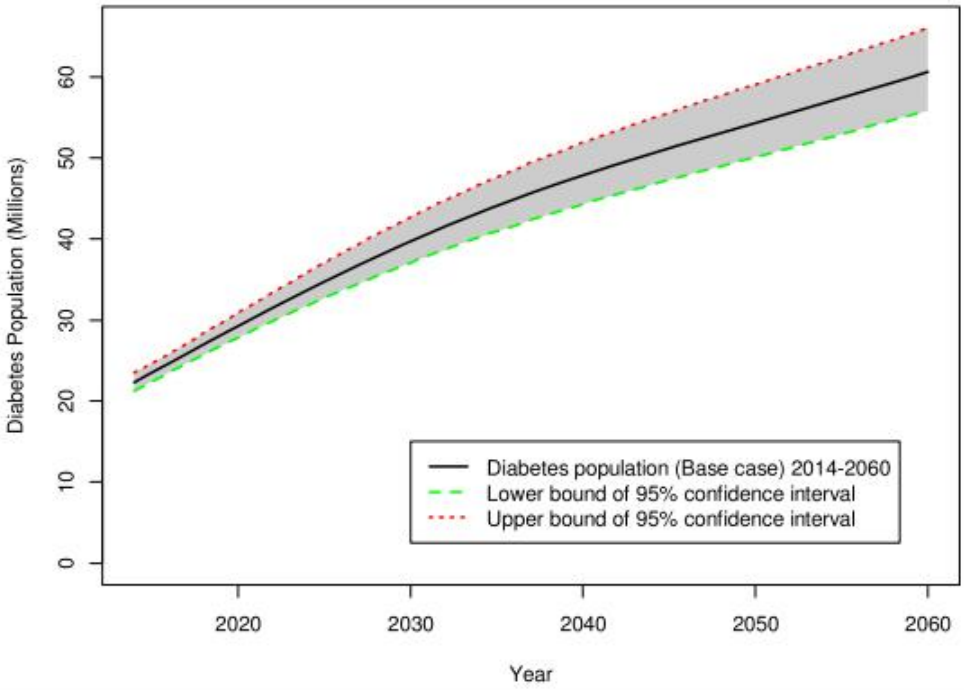


Figure. Projection of diagnosed diabetes prevalence in US adults (Lin et al. Population Health Metrics 2018 16:9)

The primary driver of type 2 diabetes is obesity, which is believed to account for 80% to 85% of the risk of developing type 2 diabetes. Recent research suggests that obese people are up to 80 times more likely to develop type 2 diabetes than those with a body mass index, or BMI of less than 22. According to the World Health Organization (the "WHO"), in 2016, more than 1.9 billion adults aged 18 years and older were overweight. Of these, over 650 million adults were obese. For adults, the WHO defines overweight as having a BMI greater than or equal to 25 and obesity as having a BMI greater than or equal to 30. The worldwide prevalence of obesity nearly tripled between 1975 and 2016. Further, according to a 2019 study from the Harvard T.H. Chan School of Public Health, by 2030, about half of the adult U.S. population will be obese and about a quarter will be severely obese, which is defined as having a BMI greater than 40 (or 100 pounds over an individual's healthy body weight). This significant projected increase in the prevalence of obesity and severe obesity is expected to continue to drive an increase in diabetes, CKD, DKD and ESKD.

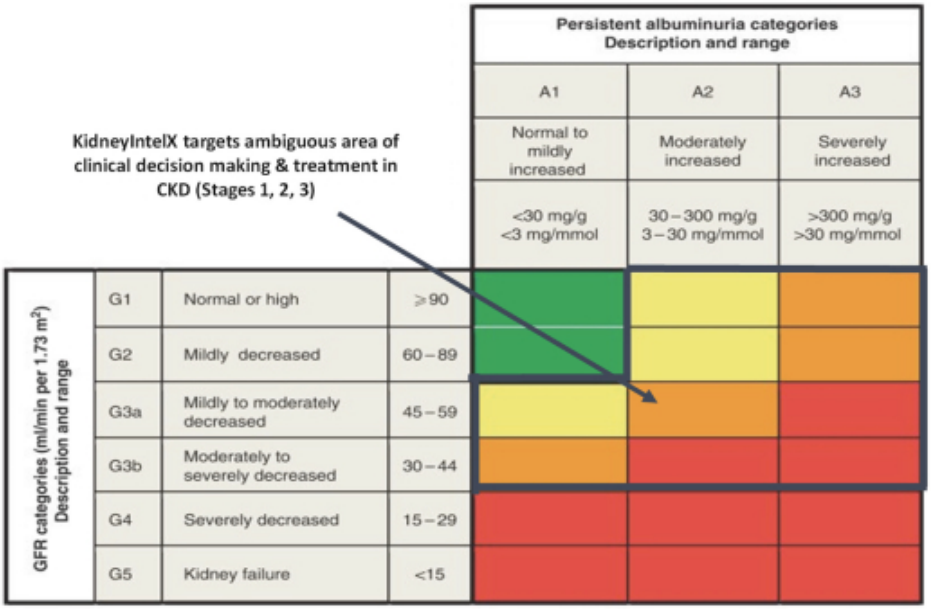
Significant healthcare system costs associated with CKD

According to the United States Renal Data System's 2019 Annual Data Report (USRDS), Medicare spends over $120 billion per year, or over 20% of its total budget, on the treatment of CKD, including approximately $36 billion for the treatment of patients with ESKD. Treatment for kidney disease consumes 6.7% of the total Medicare budget to care for less than 1% of the covered population. In the United States, hemodialysis costs approximately $90,000 per patient per year and a kidney transplant costs approximately $260,000, with annual follow-up costs averaging approximately $40,000. According to the NKF, more than two million people worldwide are treated with dialysis or kidney transplants, making CKD a global public health crisis.

Current risk classification paradigm and limitations

The KDIGO classification system is the standard clinical assessment to predict risk for progression of CKD, including DKD. The KDIGO classification system uses cut-offs of two continuous biologic variables, eGFR and uACR, to group patients into risk strata. There are six strata for eGFR and three categories of albuminuria. Patients are then categorized into four categories of risk: low risk (green), moderately increased risk (yellow), high risk (orange) and very high risk (red) as presented below.

CKD staging based on
Kidney disease improving global outcomes (KDIGO) guidelines



while we believe the KDIGO guidelines set an important baseline of classification and represent a core component for clinical management of CKD, problems arise with its real-world application. First, the KDIGO classification boundaries represent approximations, which stratify patients into easy to remember categories. As a result, however, patients at the extremes of risk strata, with widely differing risk for clinical outcomes, can be grouped into one risk category.

For example, patients with uACR 30 mg/mmol (milligram albumin per millimole creatinine) or 400 mg/mmol are both classified as A3 albuminuria. Further, a patient with an eGFR of 43 and one with an eGFR of 31 are both classified at G3b. In both cases, these patients have very different risk of disease outcomes.

Second, there are biologic differences within the KDIGO classification system that are not recognized, and there are dichotomies created that are not biologically or prognostically heterogeneous. For example, eGFR of 46 versus 44 crosses G3a to G3b and places someone in a different KDIGO risk category, as does a UACR of 29 vs. 32 mg/mmol. In other words, the KDIGO classification system imposes cutoffs of risk strata despite the fact that the underlying biologic variables are continuous. As a result, the KDIGO classification system has been shown in practice to lack sufficient precision to predict who will experience rapid and sustained progression in kidney function decline, especially in earlier stages of DKD (Stages 1 through 3).

Further, lack of ability to accurately predict which patients with CKD are at high risk of progression has led to strained clinician resources, inadequate referrals to clinical specialists and suboptimal treatment of DKD resulting in significant patient suffering and diminished quality of life. Because kidney disease is so common and the current standard of care does not adequately risk stratify patients, primary care physicians or endocrinologists typically are caring for most people with non-dialysis dependent CKD and many high-risk patients are not referred to clinical specialists in a timely manner. Indeed, more than 90% of individuals with CKD are in stages 1-3b, where awareness of the disease is only approximately 10%. One of the reasons for the inertia for most patients with stages 1-3 CKD is the high patient burden and lack of available time do not allow these physicians to fully assess the vast amount of data from the EHR to enable proper risk stratification and treatment for these patients. For example, only around half of all eligible patients with DKD are on antagonists of the renin angiotensin aldosterone system, medications which are the standard of care, and less than 10% are on sodium-glucose transport protein 2 inhibitors, (SGLT2i), newer medications that have been shown to substantially slow kidney disease progression. In addition, there is a lack of appropriate patient counseling on the progressive nature of the patient's disease, leading to lack of compliance with treatment protocol and decreased awareness of kidney disease.

Moreover, in the United States, there is a limited number of nephrologists to handle the ever-increasing number of patients with CKD. According to the CDC, there are approximately 9,000 nephrologists in the United States, or one specialist to 1,666 patients. Targeted referral of patients who have been accurately identified as having a high risk of progression over the immediate period of the next 5 years, can help to assure clinical resources are utilized efficiently and effectively. There is a critical need for easily interpretable and accurate diagnostic and predictive tools for CKD and DKD, with seamless integration into clinical workflow.

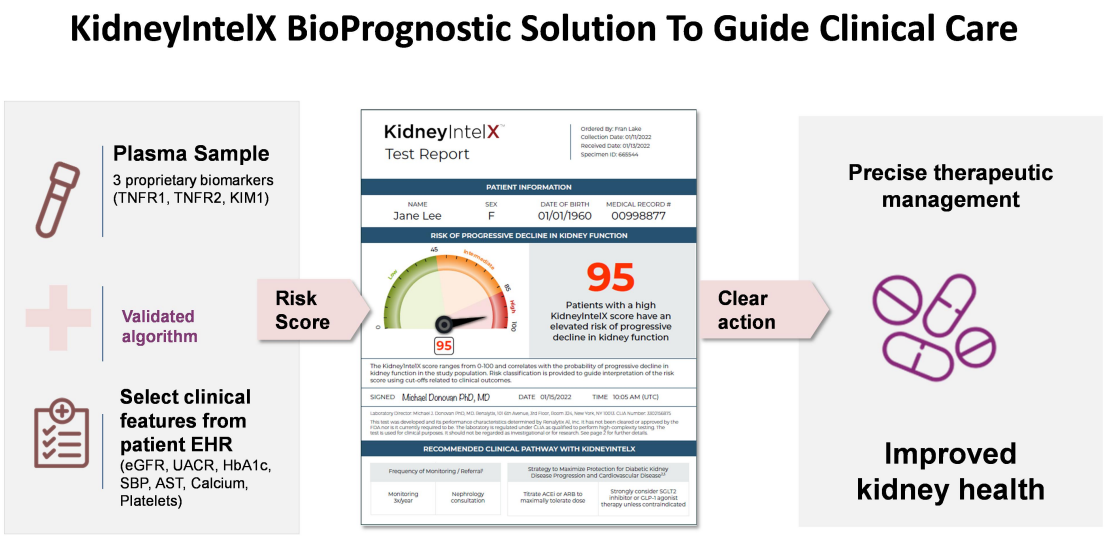
Market opportunity

Our goal is to improve quality of life and lower healthcare costs by transforming the paradigm for kidney disease risk assessment and clinical management. We believe the use of our KidneyIntelX technology and our now FDA authorized KidneyIntelX.dkd test will continue to drive improved patient outcomes and significantly lower healthcare costs. According to the CDC, in the United States alone, CKD affects approximately 36 million people with approximately 12.6 million people in our initial targeted population of DKD, stages 1-3b.

Our technology platform solution

Overview

We designed the KidneyIntelX technology platform to enable risk prediction of progressive kidney function decline in patients with CKD. The platform employs an artificial intelligence-enabled algorithm that is capable of using diverse data inputs, including validated blood-based biomarkers from a patient blood draw, inherited genetics and personalized patient data from EHR systems, to generate a unique patient risk score. The unique patient risk score is then reported to the treating clinician through an interface that provides the reportable risk level to help inform guideline-driven clinical actions.



The KidneyIntelX.dkd test is comprised of the following:

(A) A multiplex electrochemiluminescence assay for the in vitro quantitative determination of tumor necrosis factor receptors 1 and 2 (TNFR-1, TNFR-2), and kidney injury molecule 1 (KIM-1) in human plasma (whole blood K2EDTA blood collection tube). The assay is designed for use with the MESO SECTOR® S 600 instrument to quantify the three biomarkers. The assay is performed by trained laboratory personnel at Renalytix using the assay components that includes the KidneyIntelX.dkd 96-well plate, the detection antibody, calibrator, and controls along with the MesoScale Diagnostics diluents, blocker, wash buffer and read buffer.

(B) The KidneyIntelX.dkd Portal, a cloud-based system that contains the software algorithm provides a KidneyIntelX.dkd Level (High, Moderate, Low) by combining the biomarker results from the assay and patient- specific results for uACR, HbA1C, and BUN. The patient specific clinical data needed for KidneyIntelX.dkd level determination is listed in the KidneyIntelX.dkd Test Requisition Form.

(C) A KidneyIntelX.dkd Test Report containing the KidneyIntelX.dkd level and interpretation of the test result is provided to the ordering physician.

The KidneyIntelX.dkd test is an in-vitro diagnostic performed by Renalytix laboratory and is for a Prescription Use Only.

Advanced Prognostic Performance

To support FDA De Novo marketing authorization of KidneyIntelX.dkd, clinical validation studies were performed to demonstrate prognostic performance of the test in representative patient populations. Training of the machine learning algorithm was performed in the UPenn Biobank cohort and validated in an external cohort (BioMe), with excellent performance characteristics.

Kaplan-Meier curves were plotted for each of the KidneyIntelX.dkd levels to display the incidence of subjects with progressive decline in kidney function over time up to a maximum follow-up of 5 years. Progressive decline in kidney function was assessed according to estimated cumulative risk at each KidneyIntelX.dkd level as shown in the figure below, demonstrating excellent separation and stratification for progressive decline in kidney function for the 3 KidneyIntelX.dkd levels.

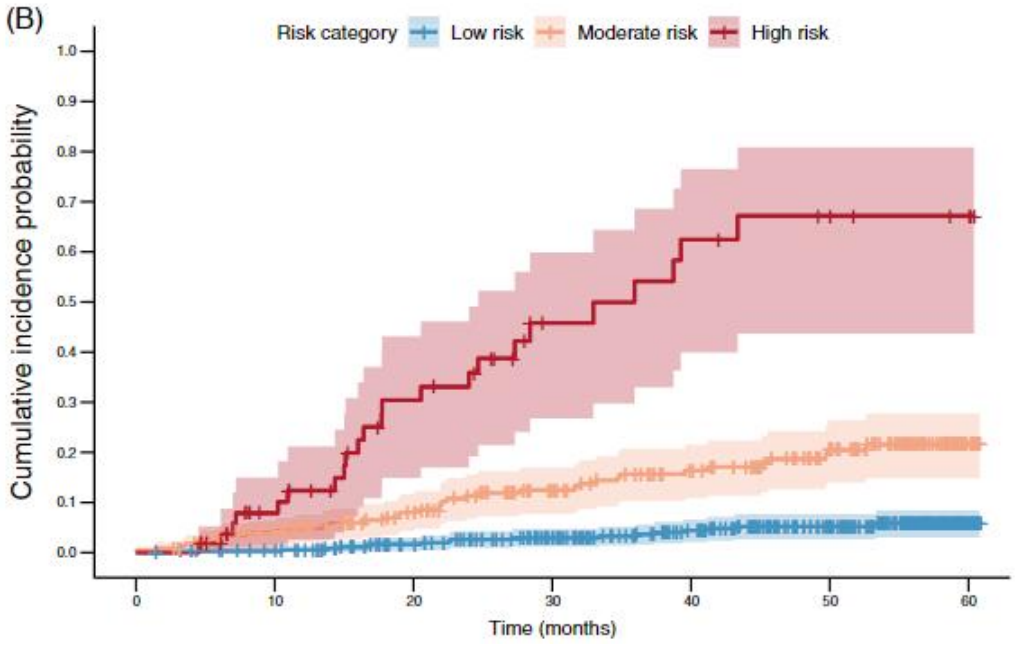


Figure. Cumulative incidence curves for progressive decline in kidney function. (Nadkarni, GN, Stapleton, S, Takale, D, et al. Derivation and independent validation of KidneyIntelX.dkd: A prognostic test for the assessment of diabetic kidney disease progression. Diabetes Obes Metab. 2023; 1-9. doi:10.1111/dom.15273)

As shown in the figure, the cumulative incidence of accelerated progression of kidney function decline was approximately 2/3rds in the high-risk group (67%, 95% CI 49% - 84%), and the rates of eGFR decline in the low risk group were comparable to that of normal physiologic aging.

Using Cox Proportional Hazard Ratios to compare risk across the levels, an18-fold increased risk for high vs. low risk levels, and 4-fold increased risk for moderate vs. low risk levels were observed. The test was shown to be robustly prognostic after adjustment for key demographics and clinical variables (adjusted HR for high vs. low 7.7 and 3.7 for intermediate vs. low risk), with consistent performance across diverse subgroups of the intended use population.

The KidneyIntelX model

At the core of our approach is an artificial intelligence-enabled algorithm capable of synthesizing a set of current and diverse data inputs, such as biomarkers, EHR data, genomics, patient-generated digital data, environmental information, clinical utility, and actuarial and clinical compliance information.

Proprietary blood-based biomarkers

Blood-based biomarkers are typically genes or proteins that indicate the existence and severity of certain conditions (such as kidney disease) and can be measured from a simple blood sample. KidneyIntelX includes inputs from three specific blood-based biomarkers that have previously been examined in several academic and clinical study settings as reported in scientific publications. These publications support consistent associations of soluble Tumor Necrosis Factor Receptor (sTNFR) 1 and 2 and plasma Kidney Injury Molecule-1 ("KIM-1"), with reliable independent predictive signals for kidney disease progression in DKD patients. We licensed the patented sTNFR1 and sTNFR2 biomarkers from the Joslin Diabetes Center of Harvard University because of this evidence of their predictive capabilities. KidneyIntelX.dkd measures these biomarkers using a proprietary, analytically validated multiplex format with reliable inter- and intra-assay results. We are exploring additional biomarkers, including both proteomic and genomic based, from blood, urine and other biological samples for subsequent KidneyIntelX technology platform service offerings that could support enhanced predictive performance and expand indicated uses.

Electronic health records data harmonization, adjudication and machine learning

The use of EHRs has been adopted broadly by hospital systems in the United States, the United Kingdom, the European Union and other developed countries. EHR data are generally collected during routine clinical encounters and contain detailed information on disease and treatment patterns. When assessed in the aggregate, EHR data can provide insights into disease progression and clinical management strategies across diverse populations. EHR factors may include items such as current or past therapeutic regimes, diagnostic results, weight, age, geographic location, physician visiting habits and physician annotations. Additional data factors can be added to the KidneyIntelX technology algorithms to address different target populations.

Through experience with our clinical study work, we have developed a proprietary data processing methods that enables us to analyze patient data collected during clinical encounters by a diverse set of physicians in different clinical environments and still ensure that the data used by the KidneyIntelX technology platform to support product development and clinical testing is consistent and falls within specific quality control metrics. We have tested this capability in our clinical validation studies involving stored specimens from over 2000 patients with DKD from the Mount Sinai Health System and University of Pennsylvania Health System biobanks.

- *EHR Data Harmonization.* EHR data from different institutions can be entered and stored in different formats. To overcome this significant limitation, we have developed proprietary algorithms to convert the diverse data (specifically laboratory values and medication names) and map to a standardized template.
- *Clinical Adjudication.* Kidney function can fluctuate over time and can vary in different clinical scenarios. In the clinical validation studies, to ensure that the kidney disease outcomes for KidneyIntelX.dkd and future service offerings were accurately classified and did not represent random non-disease variation, all kidney function changes over time and all clinical outcomes were adjudicated by examining the trajectory of kidney function over their longitudinal course of treatment to the outcome. This adjudication and knowledge base has been codified into the overall workflow for KidneyIntelX technology versioning and validation.
- *Machine Learning*. We use a proprietary machine learning-enabled algorithm to integrate the diverse inputs from biomarker data and harmonized EHR data to achieve increased predictive performance over the current metrics for prediction of kidney disease progression.

In addition, the KidneyIntelX technology risk score may, at the sole discretion of the clinical user, be tied to specific clinical guideline recommendations developed by the healthcare system, health insurance providers or practice groups. This care pathway is expected to include elements such as targets for clinician visits and referrals, blood pressure control, diabetes control and prescription of specific medications, as well as patient behavior, such as appropriate diet, exercise, weight loss, medication adherence, to provide immediate and actionable steps related to kidney health. We also plan to link reportable results to educational modules on kidney disease for patients to improve awareness and influence lifestyle practices.

Seamless integration with electronic health record systems for test ordering and reporting results

KidneyIntelX is designed to interface with EHR systems in order to securely access the information required for each ordered test, which is then combined with biomarker data to generate the risk score and test report. The test result is reported directly to the ordering physician through the EHR system.

In this way, the treating physician can have all of the relevant information pertinent to the patient's care delivered to them at the time of the clinical encounter and can trigger care pathways directly from the EHR interface, with the goal of driving a virtuous cycle in which patients and clinicians have increased visibility and awareness changes in care management and patient behavior on kidney health.

All personal health information captured by the KidneyIntelX.dkd application is at all times stored in secure Microsoft Azure-supported cloud infrastructure and is encrypted using Advanced Encryption Standard. All transfers of data and reports through firewalls of the health system are executed using secure transfer protocols in accordance with internationally accepted Transport Layer Security versions 1.2 and 1.3. Security components also include rigid authentication and authorization of all users, a continuous monitoring tool, intrusion detection system and periodic penetration testing to mitigate risks of cyber-attacks.

Our Key Agreements

Mount Sinai Health System

In May 2018, we entered into a license agreement, (the "Mount Sinai Agreement") with the Icahn School of Medicine at 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 certain 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 cost to be determined upon approval of the study protocol by the IRB.

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 on 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 Diagnostics Holding Plc ("EKF") entered into a license agreement (the "Joslin Agreement") with the Joslin Diabetes Center, Inc. ("Joslin"). In October 2018, EKF assigned to us all of its rights, title, interest and benefit in the Joslin Agreement.

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 use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD (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 certain milestone payments of up to $1.3 million in the aggregate based on specified commercial milestones as follows: $300,000 upon the achievement of total net sales of $2.0 million for any licensed products or licensed processes and $1.0 million upon the achievement of total net sales of $10.0 million for any licensed products or licensed processes. 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.

In April 2021, we entered into an exclusive option agreement (the "Joslin Option Agreement") with Joslin for patent filings on certain additional novel biomarkers in kidney disease for development and deployment in the KidneyIntelX platform. We believe that these novel biomarkers have the potential to provide additional clinical utility for understanding early disease progression and risk of kidney failure, therapeutic response, and the mechanistic pathways of kidney disease beyond the inflammatory and tubular injury markers that are currently captured by KidneyIntelX. We have entered into a multi-year program to these novel biomarkers in expanded clinical validation studies which began in the second half of 2021.

AstraZeneca

In July 2020, we entered into a statement of work (the "AZ SOW"), with AstraZeneca Pharmaceuticals LP ("AZ") in advance of entering into a more comprehensive master services agreement. Pursuant to the AZ SOW, we completed a feasibility study to determine the impact of the use of our KidneyIntelX platform to optimize utilization of various CKD agents and reported trial data our KidneyIntelX platform and care management improve uptake and adherence of certain CKD agent. AZ agreed to pay us up to $1.0 million on milestones achieved.

The SOW is now complete.

Commercialization

We plan 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. We believe that our core partnership with Mount Sinai Health System, a large integrated disease network in the New York metropolitan area, will demonstrate the value of our partnership model.

Integration of the KidneyIntelX software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting. Insurance payor participation increases the visibility and potentially the potency of the KidneyIntelX cost/benefit economics. To both health system and payors, KidneyIntelX offers a novel platform that can provide insights through the course of disease diagnosis, prognosis, clinical management and treatment.

To assist with KidneyIntelX utility and system-wide integration, we deploy a variety of critical supporting resources to providers, including direct customer service, and specialist educational programs. In addition, by deploying KidneyIntelX at a population health and clinical medicine level, we are able to reduce fixed operating costs associated with hiring and maintaining a direct sales force.

We employ an efficient team of medical educators to establish relationships with healthcare systems and relevant payors rather than expending significant resources to build a large direct sales force. In addition, we employ experts in practitioner behavior change, health economics and data management in order to help define the optimal implementation of KidneyIntelX in a specific health system.

Reimbursement and regulatory developments

We have achieved the following reimbursement and regulatory milestones critical to broad-scale commercial adoption and utilization:

- ***CPT Code 0105U Effective***. In October 2019, a distinct CPT code 0105U became effective for KidneyIntelX, which can be used to report the use of KidneyIntelX to private and public payors throughout the United States for reimbursement.
- ***Medicare National Pricing Set.*** CMS included KidneyIntelX on the Final 2020 CLFS, setting the national price for KidneyIntelX at $950 per reportable test result, effective for a three-year term as of January 1, 2020, and repriced thereafter based on the weighted-average private insurance market reimbursed rate.
- ***Utah CLIA Certificate of Registration Received.*** In January 2020, we announced that our newly established commercial laboratory operation in Salt Lake City, Utah received a CLIA Certificate of Registration. We believe our Utah facility will support our ability to scale-up test volumes, optimize processing costs and accelerate payor coverage determinations.
- ***New York State Clinical Laboratory Permit Received.*** In June 2020, we announced that our commercial laboratory in New York City received a clinical laboratory permit from the New York State Department of Health to provide

commercial testing of KidneyIntelX. With licensed CLIA commercial laboratories in Utah, Florida and New York, we can now provide KidneyIntelX testing services in all 50 states.

- ***California Clinical Laboratory Permit Received.*** In September 2020, we received a Clinical Laboratory License from the California Department of Health for our clinical laboratory in Salt Lake City, Utah.
- ***ISO Compliance.*** We successfully passed the ISO-13485:2016 inspections and retin certification to this Quality Management Systems standard at all sites that are in scope, including our clinical laboratories.
- ***FDA Grant of De Novo Marketing Authorization Received.***
- In May 2019, the FDA granted breakthrough device designation for KidneyIntelX and this process has culmulated in De Novo marketing authorization of KidneyIntelX.dkd as reported on June 29, 2023.

Coverage and reimbursement

Current environment

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a medical product is approved, sales of the medical product will depend, in part, on the extent to which third-party payors, including government health programs in the United States, such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medical products are typically made by CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for medical products exists among third-party payors. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a medical product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any medical product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, products may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor’s decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor’s determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company’s revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

These measures, and future state and federal healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding and otherwise affect the price of KidneyIntelX, whether marketed as a Laboratory Developed Test (“LDT”) or a medical device, and any other diagnostic product for which we may obtain regulatory approval or the frequency with which any such products are prescribed or used.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges, as the pricing of biological products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a

particular technology to currently available products or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Efforts to control prices and utilization of biological products will likely continue as countries attempt to manage healthcare expenditures.

Current coverage and reimbursement status

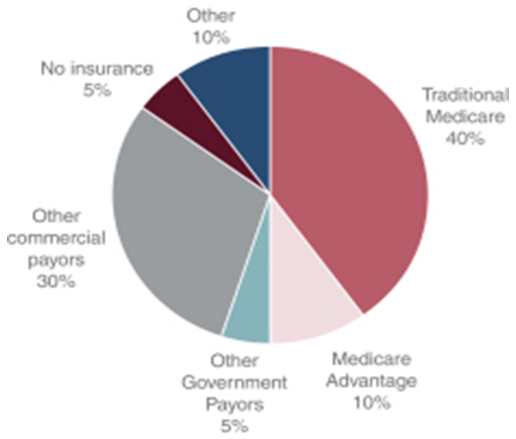
We intend to generate revenue from several sources, including government and third-party payors, and self- paying individuals.
To receive reimbursement from third-party payors, the KidneyIntelX testing services can be billed using the CPT code 0105U, as defined by the American Medical Association. This CPT code became effective throughout the United States in October 2019, meaning the code is in national payor databases in the United States in 2020. This avoids the common practice of initially billing for a novel diagnostic test under a miscellaneous code at commercial launch. Because miscellaneous codes do not describe a specific service, pricing for a unique test cannot be established. In addition, a third-party payor claim may need to be examined to determine the service that was provided, whether the service was appropriate and medically necessary and whether and at what level payment should be rendered—a process that can require a letter of medical necessity from the ordering physician and result in significant uncertainty with regard to receiving payment as well as payment delays.

Under Medicare, payment for laboratory tests generally is made under the CLFS, with payment amounts assigned to specific procedure billing codes. Having both a unique test code and an established Medicare price often accelerates reimbursement timelines and facilitates coverage determinations and success on appeal.

Our coverage and reimbursement strategy

We are actively engaged in efforts to achieve broad commercial coverage and reimbursement for KidneyIntelX and to contract with third-party payors. Achieving positive coverage determinations eliminates the need for appeals and reduces failures to collect from the patient's third-party payor. Implementing our strategy includes our managed care and medical affairs teams educating third-party payors regarding our strong health economic and clinical validation data, and in the future clinical utility and outcomes data, which we believe validates the value of our products and provides evidence for third-party payors to establish value-based reimbursement.
We believe our reimbursement strategy is aligned with our commercialization strategy. The KidneyIntelX test is a single site, *in vitro*, artificial intelligence-enabled diagnostic test, and we are both the manufacturer and the service provider for the test. In all cases, we will bill payors and patients for the test.

The overall goal of the reimbursement strategy is to execute high-quality public and private payor contracts for coverage and reimbursement of KidneyIntelX. We estimate that health insurance coverage for the eligible patient population for KidneyIntelX breaks down as follows:



At 50%, the largest payor population is traditional Medicare and Medicare Advantage insurance coverage.

In 2019, we achieved a significant milestone toward obtaining Medicare coverage, with CMS including KidneyIntelX on the Final 2020 CLFS and setting the national price for KidneyIntelX at $950 per reportable test result, effective for a three-year term as of January 1, 2020. This price will be re-evaluated at the end of this three-year period using an average of accepted payment from private health insurance plans. 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 we were granted a Medicare provider number for our Salt Lake City, Utah clinical

laboratory. As a result, we are now qualified as a provider and can bill for services provided to patients with Medicare health insurance coverage in the United States.

We are actively working to secure a coverage determination from Medicare. Our clinical laboratory in Utah is in a coverage region that follows recommendations from the MolDX Program. Coverage determinations are made under a defined process that takes up to 18 months to complete following submission. A positive coverage determination would mean that KidneyIntelX tests performed in any region that participates in the MolDX program would be covered. A positive Medicare determination could create material upside in our revenue case and could also require incremental increases in laboratory and manufacturing capacity.

While working to secure a coverage determination we will also focus on contracting with regional Medicare Advantage plans that are aligned with our test launch regions. We also plan to accelerate credentialing and coverage contracts with Medicaid programs and providers.

In April 2021, we were granted a government-wide contract by the U.S. General Services Administration for KidneyIntelX testing services at $950 per reportable result, which applies to more than 140 U.S. government departments, agencies, and affiliates including U.S. Veterans Administration, Department of Defense military branches (Army, Navy, Air Force, and Marines), and Indian Health Services. The Veterans Health Administration is America's largest integrated health care system, providing care at 1,293 health care facilities, including 171 medical centers and 1,112 outpatient sites, serving nine million enrolled veterans each year.

Non-Medicare Advantage national and regional private payor plans make up approximately 30% of the total addressable market or KidneyIntelX. A key element in selecting initial health system launch sites is to focus on areas with coverage from one or two plans at launch and an additional two to three plans within 12 months.

In addition, our focused health system partnership launch plan for KidneyIntelX is a critical component of our reimbursement strategy. We plan to collaborate with our launch partners to ensure all payor targets are prioritized and aligned. In addition, we will create a patient friendly billing program for those patients who may not have health coverage or have burdensome cost share responsibilities. This will allow those patients in need of KidneyIntelX the benefit of the test while offering a more affordable solution.

Competition

We face competition from clinical reference laboratories and diagnostics manufacturers, including large diagnostic laboratories such as Quest Diagnostics Inc. and Laboratory Corporation of America Holdings (LabCorp) and large diagnostics manufacturers such as ThermoFisher Scientific Inc., Danaher Corporation, Roche Holding AG, Abbott Laboratories, Bio-Rad Laboratories, Inc., Ortho Clinical Diagnostics NV and Siemens Healthineers AG, all of which have widespread brand recognition and market penetration and substantially greater financial, technical, research and development and selling and marketing capabilities than we do. None of these companies, however, currently offer tests that are comparable to KidneyIntelX, as existing tests, such as serum creatinine or Cystatin C, only provide information on the current status of kidney function through an estimation of eGFR.

We also face competition from data analytics companies that have developed technology-based or artificial intelligence-based approaches to healthcare applications and medical devices and that currently or in the future may develop diagnostic or prognostic products focused on kidney disease.

Principal competitive factors in our market include:

- quality and strength of clinical and analytical validation data;
- proprietary access to extensively validated biomarkers for CKD;
- partnerships with healthcare systems;
- confidence in diagnostic or prognostic performance;
- technical performance and innovation to deliver products that provide clinically actionable results;
- reputation among health systems, physicians and payors as a provider of high-value diagnostic products;
- third-party reimbursement achievements;
- regulatory achievements;
- inclusion in practice guidelines;
- economic health benefits; and
- ease of use and willingness of physicians to include products as part of their routine care for patients with kidney disease.

We believe we compete effectively based on these factors; however, we cannot assure you that we will continue to do so. Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements and devote greater resources to the development, promotion and sale of their diagnostic tests. We may not be able to compete effectively against these organizations should they choose to enter the market for kidney disease prognostics.

Manufacturing, supply and operations

KidneyIntelX is an artificial intelligence-enabled in vitro prognostic testing solution that has been developed to be commercialized as a single-site in vitro diagnostic. We operate quality management systems at our laboratories in accordance with FDA QSR 21 CFR Part 820. Medical Device Manufacturers must establish current Good Manufacturing Practices to ensure marketed devices meet applicable regulatory, quality requirements meeting the specifications. Requirements are similar to ISO 13485 – Medical Device Quality Management System Requirements, to which we are also certified. As such, we expect to achieve FDA regulatory clearance of KidneyIntelX and operate under ISO 13485 certification. We are both the Manufacturer of Record and the service provider for the testing solution.

In 2019, we established a second laboratory in Salt Lake City, Utah. This facility has been granted a CLIA Certificate of Registration and can be used for commercial testing. This laboratory has also been certified under the ISO 13485 standard. The laboratory facility in Utah is approximately 4,000 square feet and has been established to be compliant with the FDA's quality system regulation.

Our laboratory in New York City, New York is located within a JLabs facility and was established for research, development and clinical testing. In June 2020, we announced that our commercial laboratory in New York City received a clinical laboratory permit from the New York State Department of Health to provide commercial testing of KidneyIntelX. The laboratory will be utilized for initial commercial testing with KidneyIntelX.

Our Florida Lab is approximately 1,200 square feet and was established to be used for KidneyIntelX testing as well as research activities and to be compliant with the FDA's quality system regulation. The Florida lab also received a clinical laboratory permit from the New York State Department of Health and CLIA Certificate of Registration.

With licensed CLIA commercial laboratories in Utah, Florida and New York, we can now provide KidneyIntelX testing services in 49 states (Maryland pending). We are seeking separate licenses with these states.

We have established a supplier relationship with Meso Scale Diagnostics LLC based in Rockville, Maryland for the supply of reagents and materials used in measurement of our proprietary biomarkers in our laboratories. We closely monitor inventory levels and quality control parameters to ensure continuity of supply and test performance.

Intellectual property

Intellectual property is of vital importance in our field and in diagnostics generally. We seek to protect and enhance proprietary technology, inventions, and improvements that are commercially important to the development of our business by seeking, maintaining, and defending patent rights, whether developed internally, acquired or licensed from third parties. We will also seek to rely on regulatory protection afforded through data exclusivity, market exclusivity and patent term extensions where available.

Our intellectual property estate is designed to provide multiple layers of protection, including: patent rights with claims directed to platform technologies, such as key biomarkers, and patent rights covering specific products, such as KidneyIntelX. We also rely on trade secrets that may be important to the development of our business.

We believe our current patent estate, together with our efforts to develop and patent next generation technologies, provides us with substantial intellectual property protection.

We have sought patent protection in the United States and internationally for our KidneyIntelX product. However, the area of patent and other intellectual property rights in biotechnology is an evolving one with many risks and uncertainties.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future diagnostic products and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our diagnostic products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of

our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our diagnostic products, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

The term of individual patents depends upon the legal term of the patents in the countries in which they are obtained. In most countries in which we file, including the United States, the patent term is 20 years from the earliest date of filing a non-provisional patent application. In the United States, a patent’s term may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent, or may be shortened if a patent is terminally disclaimed over an earlier filed patent or delays on the part of a patentee. For more information regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

In some instances, we submit patent applications directly with the USPTO as provisional patent applications. Corresponding non-provisional patent applications must be filed not later than 12 months after the provisional application filing date. While we intend to timely file non-provisional patent applications relating to our provisional patent applications, we cannot predict whether any such patent applications will result in the issuance of patents that provide us with any competitive advantage.

We file U.S. non-provisional applications and Patent Cooperation Treaty ("PCT") applications that claim the benefit of the priority date of earlier filed provisional applications, when applicable. The PCT system allows a single application to be filed within 12 months of the original priority date of the patent application, and to designate all of the PCT member states in which national patent applications can later be pursued based on the international patent application filed under the PCT. The PCT searching authority performs a patentability search and issues a non-binding patentability opinion which can be used to evaluate the chances of success for the national applications in foreign countries prior to having to incur the filing fees. Although a PCT application does not issue as a patent, it allows the applicant to seek protection in any of the member states through national-phase applications. At the end of the period of two and a half years from the first priority date of the patent application, separate patent applications can be pursued in any of the PCT member states either by direct national filing or, in some cases by filing through a regional patent organization, such as the European Patent Organization. The PCT system delays expenses, allows a limited evaluation of the chances of success for national/regional patent applications and enables substantial savings where applications are abandoned within the first two and a half years of filing.

For all patent applications, we determine claiming strategy on a case-by-case basis. Advice of counsel and our business model and needs are always considered. We file patents containing claims for protection of all useful applications of our proprietary technologies and any products, as well as all new applications and/or uses we discover for existing technologies and products, assuming these are strategically valuable. We continuously reassess the number and type of patent applications, as well as the pending and issued patent claims to ensure that maximum coverage and value are obtained for our processes, and compositions, given existing patent office rules and regulations. Further, claims may be modified during patent prosecution to meet our intellectual property and business needs.

We recognize that the ability to obtain patent protection and the degree of such protection depends on a number of factors, including the extent of the prior art, the novelty and non-obviousness of the invention, and the ability to satisfy the enablement requirement of the patent laws. In addition, the coverage claimed in a patent application can be significantly reduced before the patent is issued, and its scope can be reinterpreted or further altered even after patent issuance. Consequently, we may not obtain or maintain adequate patent protection for any of our future diagnostic products or for our technology platform. We cannot predict whether the patent applications we are currently pursuing will issue as patents in any particular jurisdiction or whether the claims of any issued patents will provide sufficient proprietary protection from competitors. Any patents that we hold may be challenged, circumvented or invalidated by third parties.

In addition to patent protection, we also rely on trademark registration, trade secrets, know how, other proprietary information and continuing technological innovation to develop and maintain our competitive position. We seek to protect and maintain the confidentiality of proprietary information to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection. Although we take steps to protect our proprietary information and trade secrets, including through contractual means with our employees and consultants, third parties may independently develop substantially equivalent proprietary information and techniques or otherwise gain access to our trade secrets or disclose our technology. Thus, we may not be able to meaningfully protect our trade secrets. It is our policy to require our employees, consultants, outside scientific collaborators, sponsored researchers and other advisors to execute confidentiality agreements upon the commencement of employment or consulting relationships with us. These agreements provide that all confidential information concerning our business or financial affairs developed or made known to the individual during the course of the individual’s relationship with us is to be kept confidential and not disclosed to third parties except in specific circumstances. Our agreements with employees also provide that all inventions conceived by the employee in the course of employment with us or from the employee’s use of our confidential information are our exclusive property. However, such confidentiality agreements and invention assignment agreements can be breached and we may not have adequate remedies for any such breach. In addition, our trade secrets may otherwise become known or be independently discovered by competitors. To the extent that our consultants, contractors or collaborators use intellectual property owned by others in their work for

us, disputes may arise as to the rights in related or resulting trade secrets, know-how and inventions. For more information regarding the risks related to our intellectual property, see “Risk Factors—Risks Related to Our Intellectual Property.”

The patent positions of companies like ours are generally uncertain and involve complex legal, scientific and factual questions. Our commercial success will also depend in part on not infringing upon the proprietary rights of third parties. It is uncertain whether the issuance of any third-party patent would require us to alter our development or commercial strategies, or our products or processes, obtain licenses or cease certain activities. Our breach of any license agreements or our failure to obtain a license to proprietary rights required to develop or commercialize our future products may have a material adverse impact on us. If third parties prepare and file patent applications in the United States that also claim technology to which we have rights, we may have to participate in interference or derivation proceedings in the USPTO to determine priority of invention. For more information, see “Risk Factors—Risks Related to Our Intellectual Property.”

When available to expand market exclusivity, our strategy is to obtain, or license additional intellectual property related to current or contemplated development platforms, core elements of technology and/or clinical candidates.

In-licensed intellectual property

The KidneyIntelX diagnostic is covered by a published PCT application filed in December 2009 that has been in-licensed from Joslin. National phase applications from this PCT were filed in the United States and Europe. There are two issued United States patents, which will both expire in December 2029. The claims are directed to methods of determining whether a human subject has an increased risk of developing CKD or ESKD or both. There is also a pending United States divisional patent application. There is an issued European patent, which will expire in December 2029. The claims are directed to methods of determining whether a human subject has an increased risk of developing early renal function decline. The European patent is regionally validated in Belgium, Denmark, France, Germany, Ireland, Italy, Netherlands and Spain, and additionally in Hong-Kong. There is also a pending divisional EP patent application.

In addition, the KidneyIntelX diagnostic is covered by two provisional patent applications that have been in-licensed from the Mount Sinai School of Medicine. These provisional patent applications were filed in February 2020 and April 2020, respectively. If issued, these patents will expire in February 2041 and April 2041, respectively.

Government regulation and product approval

Clinical laboratory framework

Clinical Laboratory Improvement Amendments of 1988

As a clinical reference laboratory, with locations in Utah and New York, we are required to hold certain federal, state and local licenses, certifications and permits to conduct our business. CMS regulates all non-research laboratory testing performed on humans in the United States through the CLIA. In total, CLIA covers approximately 260,000 laboratory entities. The Division of Clinical Laboratory Improvement & Quality, within the Quality, Safety & Oversight Group, under the Center for Clinical Standards and Quality ("CCSQ"), has the responsibility for implementing the CLIA program. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

We maintain a CLIA Certificate of Compliance for our Utah and Florida laboratories that allows us to perform non-waived (moderate and/or high complexity) testing at those sites. In June 2020, we received CLIA certification for our New York laboratory through the New York State Department of Health.

In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate and use proprietary tests referred to as LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

Penalties for non-compliance with CLIA requirements include a range of enforcement actions, including suspension, limitation or revocation of the laboratory’s CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil monetary penalties, civil injunctive suit or criminal penalties.

State laboratory licensing

In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. A number of states have implemented

their own more stringent laboratory regulatory requirements. Such laws, among other things, establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. Five states require a separate out-of-state license before we can provide testing services for their residents: California, Maryland, New York, Pennsylvania and Rhode Island. We have received all five out-of-state licenses for our New York, Florida and Utah laboratories.

Federal oversight of laboratory developed tests

The laws and regulations governing the marketing of clinical laboratory testing and diagnostic products are evolving, extremely complex and, in many instances, there are no significant regulatory or judicial interpretations of these laws and regulations. Clinical laboratory tests are regulated under CLIA, as administered by CMS, as well as by applicable state laws. In addition, the Federal Food, Drug and Cosmetic Act ("FDCA") defines a medical device to include any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory, intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Our in vitro testing products are considered by the FDA to be subject to regulation as medical devices. Among other things, pursuant to the FDCA and its implementing regulations, the FDA regulates the research, testing, manufacturing, safety, labeling, storage, recordkeeping, pre-market clearance or approval, marketing and promotion, and sales and distribution of medical devices in the United States to ensure that medical products distributed domestically are safe and effective for their intended uses. In addition, the FDA regulates the export of medical devices manufactured in the United States to international markets.

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to *in vitro* diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory (i.e., LDTs).

Legislative and administrative proposals proposing to amend FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements to develop and introduce new tests as LDTs.

Medical device regulatory framework

Pursuant to its authority under the FDCA, the FDA has jurisdiction over medical devices, which are defined to include, among other things, in vitro diagnostic devices. The FDA regulates, among other things, the research, design, development, preclinical and clinical testing, manufacturing, safety, effectiveness, packaging, labeling, storage, recordkeeping, pre-market clearance or approval, adverse event reporting, marketing, promotion, sales, distribution and import and export of medical devices. Unless an exemption applies, each new or significantly modified medical device we seek to commercially distribute in the United States could require a premarket notification to the FDA requesting permission for commercial distribution under Section 510(k) of the FDCA, also referred to as a 510(k) clearance, approval from the FDA of a premarket approval ("PMA") application, or a de novo request for classification ("de novo request"). The 510(k) clearance, PMA and de novo processes can be resource intensive, expensive, and lengthy, and require payment of significant user fees.

Device classification

Under the FDCA, medical devices are classified into one of three classes (Class I, Class II or Class III) depending on the degree of risk associated with each medical device and the extent of control needed to provide reasonable assurances with respect to safety and effectiveness.

Class I includes devices with the lowest risk to the patient and are those for which safety and effectiveness can be reasonably assured by adherence to General Controls for Medical Devices, which require compliance with the applicable portions of the FDA's Quality System Regulation, facility registration and product listing, reporting of adverse events and malfunctions, and appropriate, truthful and non-misleading labeling and promotional materials. While some Class I devices also require premarket clearance by the FDA through the 510(k) premarket notification process described below, most Class I products are exempt from the premarket notification requirements.

Class II devices are those that are subject to the General Controls, as well as Special Controls as deemed necessary by the FDA to ensure the safety and effectiveness of the device. These Special Controls can include performance standards, patient registries and post-market surveillance. Most Class II devices are subject to premarket review and clearance by the FDA. Premarket review and clearance by the FDA for Class II devices is accomplished through the 510(k) premarket notification process.

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life- sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the

510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

Under the 510(k) clearance process, the manufacturer must submit to the FDA a premarket notification, demonstrating that the device is "substantially equivalent" to a legally marketed predicate device. A predicate device is a legally marketed device that is not subject to a PMA (i.e., a device that was legally marketed prior to May 28, 1976 (pre-amendments device) and for which a PMA is not required), a device that has been reclassified from Class III to Class II or I, or a device that was previously found substantially equivalent through the 510(k) process. To be "substantially equivalent," the proposed device must have the same intended use as the predicate device, and either have the same technological characteristics as the predicate device or have different technological characteristics and not raise different questions of safety or effectiveness than the predicate device. Clinical data is sometimes required to support substantial equivalence.

After a 510(k) premarket notification is submitted, the FDA determines whether to accept it for substantive review. If it lacks necessary information for substantive review, the FDA will refuse to accept the 510(k) premarket notification. If it is accepted for filing, the FDA begins a substantive review. By statute, the FDA is required to complete its review of a 510(k) notification within 90 days of receiving the 510(k) notification. As a practical matter, clearance often takes longer, and clearance is never assured. Although many 510(k) premarket notifications are cleared without clinical data, the FDA may require further information, including clinical data, to make a determination regarding substantial equivalence, which may significantly prolong the review process. If the FDA agrees that the device is substantially equivalent, it will grant clearance to commercially market the device.

If the FDA determines that the device is not "substantially equivalent" to a predicate device, or if the device is automatically classified into Class III, the device sponsor must then fulfill the much more rigorous premarketing requirements of the PMA approval process, or seek classification of the device through the de novo process. The de novo classification process is an alternate pathway to classify medical devices that are automatically classified into Class III but which are low to moderate risk. A manufacturer can submit a request for direct de novo review if the manufacturer is unable to identify an appropriate predicate device and the new device or new use of the device presents a moderate or low risk. De novo classification may also be available after receipt of a "not substantially equivalent" letter following submission of a 510(k) to FDA.

After a device receives 510(k) clearance or marketing authorization through the de novo classification process whereupon the device is classified into a classification regulation subject to 510(k), any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance or, depending on the modification, could require a PMA application or new de novo request. The FDA requires each manufacturer to determine whether the proposed change requires a new submission in the first instance, but the FDA can review any such decision and disagree with a manufacturer's determination. Many minor modifications are accomplished by an internal letter-to-file in which the manufacture documents its reasoning for why a change does not require premarket submission to the FDA. The letter-to-file is in lieu of submitting a new 510(k) to obtain clearance for such change. The FDA can always review these letters to file in an inspection. If the FDA disagrees with a manufacturer's determination regarding whether a new premarket submission is required for the modification of an existing 510(k)-cleared device, the FDA can require the manufacturer to cease marketing and/or recall the modified device until marketing authorization is obtained. In addition, in these circumstances, the FDA can impose significant regulatory fines or penalties for failure to submit the requisite application(s).

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

Before approving or denying a PMA, an FDA advisory committee may review the PMA at a public meeting and provide the FDA with the committee's recommendation on whether the FDA should approve the submission, approve it with specific conditions, or not approve it. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Prior to approval of a PMA, the FDA may conduct inspections of the clinical trial data and clinical trial sites, as well as inspections of the manufacturing facility and processes. Overall, the FDA review of a PMA application generally takes between one and three years, but may take significantly longer. The FDA can delay, limit or deny approval of a PMA application for many reasons, including:

- the device may not be shown safe or effective to the FDA's satisfaction;
- the data from preclinical studies and/or clinical trials may be found unreliable or insufficient to support approval;
- the manufacturing process or facilities may not meet applicable requirements; and
- changes in FDA approval policies or adoption of new regulations may require additional data.

If the FDA evaluation of a PMA is favorable, the FDA will issue either an approval letter, or an approvable letter, the latter of which usually contains a number of conditions that must be met in order to secure final approval of the PMA. When and if those conditions have been fulfilled to the satisfaction of the FDA, the agency will issue a PMA approval letter authorizing commercial marketing of the device, subject to the conditions of approval and the limitations established in the approval letter. If the FDA's evaluation of a PMA application or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. The FDA also may determine that additional tests or clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and data is submitted in an amendment to the PMA, or the PMA is withdrawn and resubmitted when the data are available. The PMA process can be expensive, uncertain and lengthy and a number of devices for which the FDA approval has been sought by other companies have never been approved by the FDA for marketing.

New PMA applications or PMA supplements are required for modification to the manufacturing process, equipment or facility, quality control procedures, sterilization, packaging, expiration date, labeling, device specifications, ingredients, materials or design of a device that has been approved through the PMA process. PMA supplements often require submission of the same type of information as an initial PMA application, except that the supplement is limited to information needed to support any changes from the device covered by the approved PMA application and may or may not require as extensive technical or clinical data or the convening of an advisory panel, depending on the nature of the proposed change.

In approving a PMA application, as a condition of approval, the FDA may also require some form of post- approval study or post-market surveillance, whereby the applicant conducts a follow-up study or follows certain patient groups for a number of years and makes periodic reports to the FDA on the clinical status of those patients when necessary to protect the public health or to provide additional or longer term safety and effectiveness data for the device. The FDA may also approve a PMA application with other post-approval conditions intended to ensure the safety and effectiveness of the device, such as, among other things, restrictions on labeling, promotion, sale, distribution and use. New PMA applications or PMA supplements may also be required for modifications to any approved diagnostic tests, including modifications to our manufacturing processes, device labeling and device design, based on the findings of post-approval studies.

De novo Classification

Medical device types that the FDA has not previously classified as Class I, II, or III are automatically classified into Class III regardless of the level of risk they pose. To market low to moderate risk medical devices that are automatically placed into Class III due to the absence of a predicate device, a manufacturer may request a de novo classification of its medical device into Class I or Class II on the basis that the device presents low or moderate risk, rather than requiring the submission and approval of a PMA application. A medical device may be eligible for de novo classification if the manufacturer first submitted a 510(k) premarket notification and received a determination from the FDA that the device was not substantially equivalent or a manufacturer may request de novo classification directly without first submitting a 510(k) premarket notification to the FDA and receiving a not substantially equivalent determination. The FDA is required to classify the device within 120 calendar days following receipt of the de novo application, although in practice, the FDA's review may take significantly longer. If the manufacturer seeks reclassification into Class II, the manufacturer must include a draft proposal for special controls that are necessary to provide a reasonable assurance of the safety and effectiveness of the medical device. In addition, the FDA may reject the de novo request for classification if it identifies a legally marketed predicate device that would be appropriate for a 510(k) or determines that the device is not low to moderate risk or that general controls would be inadequate to control the risks and special controls cannot be developed. In the event the FDA determines the data and information submitted demonstrate that general controls or general and special controls are adequate to provide reasonable assurance of safety and effectiveness, the FDA will grant the de novo request for classification. When the FDA grants a de novo request for classification, the device is granted marketing authorization and further can serve as a predicate for future devices of that type, through a 510(k) premarket notification.

The investigational device process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption, ("IDE") application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE —without affirmative submission of an IDE application to the FDA—once certain requirements are addressed and Institutional Review Board ("IRB"), approval is obtained. If the device presents a "significant risk" to human health, as

defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

Such clinical trials must be conducted in accordance with the FDA's IDE regulations that govern investigational device labeling, prohibit promotion and specify an array of recordkeeping, reporting and monitoring responsibilities of study sponsors and study investigators. Clinical trials must further comply with good clinical practice regulations for IRB approval and for informed consent and other human subject protections. Required records and reports are subject to inspection by the FDA for any clinical trials subject to FDA oversight. The results of clinical testing may be unfavorable, or, even if the intended safety and efficacy success criteria are achieved, may not be considered sufficient for the FDA to grant marketing approval or clearance of a product. The commencement or completion of any clinical trial may be delayed or halted, or be inadequate to support approval of a PMA application or clearance of a 510(k) premarket notification, for numerous reasons.

Post-market regulation

After a device is cleared or approved for marketing, numerous and pervasive regulatory requirements continue to apply. These include:

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of ‘‘off-label’’ uses of cleared or approved products;
- requirements related to promotional activities;
- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- Medical Device Reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

Device manufacturing processes are required to comply with the applicable portions of the QSR, which cover the methods and the facilities and controls for the design, manufacture, testing, production, processes, controls, quality assurance, labeling, packaging, distribution, installation and servicing of finished devices intended for human use. The QSR also requires, among other things, maintenance of a device master file, device history file, and complaint files. Manufacturers are subject to periodic scheduled or unscheduled inspections by the FDA. A failure to maintain compliance with the QSR requirements could result in the shut-down of, or restrictions on, manufacturing operations and the recall or seizure of products. The discovery of previously unknown problems with products, including unanticipated adverse events or adverse events of increasing severity or frequency, whether resulting from the use of the device within the scope of its clearance or off-label by a physician in the practice of medicine, could result in restrictions on the device, including the removal of the product from the market or voluntary or mandatory device recalls.

The FDA has broad regulatory compliance and enforcement powers. If the FDA determines that a manufacturer has failed to comply with applicable regulatory requirements, it can take a variety of compliance or enforcement actions, including the following:

- issuance of warning letters, untitled letters, fines, injunctions, consent decrees and civil penalties;

- requesting or requiring recalls, withdrawals, or administrative detention or seizure of our products;
- imposing operating restrictions or partial suspension or total shutdown of production;
- refusing or delaying requests for 510(k) marketing clearance or PMA approvals of new products or modified products;
- withdrawing 510(k) clearances or PMA approvals that have already been granted;
- refusal to grant export approvals for our products; or
- criminal prosecution.

U.S. federal and state health care laws

Federal and state physician self-referral prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to comparable state laws. Together these restrictions generally prohibit us from billing a patient or governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or a member of such physician's immediate family, has a financial relationship, such as an ownership or investment interest in or compensation arrangement with us, unless the relationship meets an applicable exception to the prohibition. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well.

Sanctions for a Stark Law violation include the following:

- denial of payment for the services provided in violation of the prohibition;
- refunds of amounts collected by an entity in violation of the Stark Law;
- a civil penalty for each bill or claim for a service arising out of the prohibited referral;
- the imposition of up to three times the amounts for each item or service wrongfully claimed;
- possible exclusion from federal healthcare programs, including Medicare and Medicaid; and
- a civil penalty for each arrangement or scheme that the parties know (or should know) has the principal purpose of circumventing the Stark Law's prohibition.

The Stark law is a strict liability statute, which means these prohibitions apply regardless of any intent by the parties to induce or reward referrals or the reasons for the financial relationship and the referral. In addition, knowing violations of the Stark Law may also serve as the basis for liability under the federal False Claims Act (the "FCA"), which can result in additional civil and criminal penalties.

Federal and state anti-kickback laws

The federal Anti-Kickback Statute (the "AKS"), makes it a felony for a person or entity, including a clinical laboratory and a medical device manufacturer, to knowingly and willfully offer, pay, solicit or receive any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in order to induce business that is reimbursable under any federal healthcare program. A violation of the AKS may result in imprisonment, significant administrative and civil penalties and monetary fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other federal healthcare programs. The government may also assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the FCA, which is discussed in greater detail below. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Although the AKS applies only to items and services reimbursable under any federal healthcare program, a number of states have passed statutes substantially similar to the AKS that apply to all payors. Penalties for violations of such state laws include imprisonment and significant monetary fines.

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of

particular products or services. Generally, courts have taken a broad interpretation of the scope of the AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

In addition to statutory exceptions to the AKS, regulations provide for a number of safe harbors. If an arrangement meets the provisions of an applicable exception or safe harbor, it is deemed not to violate the AKS. An arrangement must fully comply with each element of an applicable exception or safe harbor in order to qualify for protection.

Failure to meet the requirements of the safe harbor, however, does not render an arrangement illegal. Rather, the government may evaluate such arrangements on a case-by-case basis, taking into account all facts and circumstances. On October 9, 2019, the Office of Inspector General of HHS ("OIG"), and CMS proposed further modifications to the federal AKS safe harbor protections for certain coordinated care and value-based arrangements among clinicians, providers and others. CMS also proposed multiple new exceptions and revisions to current exceptions for value-based arrangements under the Stark Law. It is unknown at this time which, if any, of these modifications will go into effect and what effect it will have on our business.

Corporate practice of medicine; fee splitting

A number of states, including California, do not allow business corporations to employ physicians to provide professional services. This prohibition against the “corporate practice of medicine” is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. Activities in addition to those directly related to the delivery of medical care also may be considered an element of the practice of medicine in many states. We may enter into services contracts with healthcare providers organizations pursuant to which we provide them with a range of services. These contractual relationships are subject to various state laws, including those of New York, Texas and California, that prohibit fee splitting or the practice of medicine by lay entities or persons and are intended to prevent unlicensed persons from interfering with or influencing the physician’s professional judgment. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, or fee-splitting, we could be required to restructure our contractual and other arrangements with certain physicians and other healthcare professions.

Some of these requirements may apply to us even if we do not have a physical presence in the state, based solely on our agreements with providers licensed in the state. However, regulatory authorities or other parties, including our providers, may assert that we are engaged in the corporate practice of medicine or that our contractual arrangements with our provider clients constitute unlawful fee splitting. In addition, violation of these laws may result in significant civil, criminal and administrative penalties, such as sanctions imposed against us and/or the professional through licensure proceedings, and exclusion from state and federal healthcare programs.

Other federal and state healthcare laws

In addition to the requirements discussed above, several other healthcare fraud and abuse laws could have an effect on our business. For example, provisions of the Social Security Act permit Medicare and Medicaid to exclude an entity that charges the federal healthcare programs substantially in excess of its usual charges for its services. The terms “usual charge” and “substantially in excess” are subject to varying interpretations.

The FCA prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from, making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud through whistleblower or qui tam actions. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government’s involvement, then the plaintiff will receive a percentage of the recovery. In addition, the improper retention of an overpayment for 60 days or more is also a basis for a FCA action, even if the claim was originally submitted appropriately. Penalties for FCA violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government. A FCA violation may provide the basis for exclusion from the federally funded healthcare programs. In addition, some states have adopted similar fraud, whistleblower and false claims provisions. The Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. The Social Security Act also includes civil monetary penalty provisions that impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary’s selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be

liable under the civil monetary penalties statute. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries, for example, in connection with patient assistance programs, can also be held liable under the AKS and FCA. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG, emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by private third-party payors.

The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), created new federal criminal statutes that prohibit, among other actions, knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program, including private third-party payors, or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Several states in which we operate have also adopted similar fraud and abuse laws as described above. The scope of these laws and the interpretations of them vary from state to state and are enforced by state courts and regulatory authorities, each with broad discretion. Some state fraud and abuse laws apply to items or services reimbursed by any third party payor, including commercial insurers, not just those reimbursed by a federally funded healthcare program. A determination of liability under such state fraud and abuse laws could result in fines and penalties and restrictions on our ability to operate in these jurisdictions.

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH") and their respective implementing regulations, also impose certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.

The Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for payments available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members. Any failure to comply with these reporting requirements could result in significant fines and penalties. A determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition.

The Eliminating Kickbacks in Recovery Act of 2018 ("EKRA") prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. EKRA was enacted to help reduce opioid-related fraud and abuse. However, EKRA defines the term "laboratory" broadly and without reference to any connection to substance use disorder treatment. EKRA applies to all payors including commercial payors and government payors. Violations of EKRA are subject to significant fines and/or up to ten years in jail, separate and apart from existing AKS regulations and penalties. The law includes a limited number of exceptions, some of which closely align with corresponding AKS exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA.

Federal consumer protection and unfair competition laws broadly regulate marketplace activities and activities that potentially harm consumers.

Finally, there are analogous state and foreign laws and regulations, such as state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require device manufacturers to report information related to payments and other transfers

of value to physicians and other healthcare providers, marketing expenditures or product pricing; state and local laws that require the registration of medical device sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Efforts to ensure that our internal operations and business arrangements with third parties comply with applicable laws and regulations involve substantial costs. Any action brought against us for violation of these or other laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations are found to be in violation of any of the fraud and abuse laws described above or any other laws that apply to us, we may be subject to penalties, including potentially significant criminal, civil and administrative penalties, damages, fines, disgorgement, imprisonment, exclusion from participation in government healthcare programs, contractual damages, reputational harm, integrity oversight and reporting obligations, if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws, diminished profits and future earnings, and the curtailment or restructuring of our operations. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

International regulations

Many countries in which we may offer any of our testing products in the future have anti-kickback regulations prohibiting providers from offering, paying, soliciting or receiving remuneration, directly or indirectly, in order to induce business that is reimbursable under any national healthcare program. In situations involving physicians employed by state-funded institutions or national healthcare agencies, violation of a local anti-kickback law may also constitute a violation of the U.S. Foreign Corrupt Practices Act ("FCPA").

The FCPA prohibits any U.S. individual, business entity or employee of a U.S. business entity from offering or providing, directly or through a third-party, including any potential distributors we may rely on in certain markets, anything of value to a foreign government official with corrupt intent to influence an award or continuation of business or to gain an unfair advantage, whether or not such conduct violates local laws. In addition, it is illegal for a company that reports to the Securities and Exchange Commission (the "SEC") to have false or inaccurate books or records or to fail to maintain a system of internal accounting controls. We will also be required to maintain accurate information and control over sales and distributors' activities that may fall within the purview of the FCPA, its books and records provisions and its anti-bribery provisions.

The standard of intent and knowledge in the foreign anti-bribery context is minimal; intent and knowledge often may be inferred from that fact that bribery took place. The accounting provisions do not require intent.

Violations of the FCPA's anti-bribery provisions for corporations and other business entities are subject to a fine of up to $2.0 million and officers, directors, stockholders, employees, and agents are subject to a fine of up to $100,000 and imprisonment for up to five years. Other countries, including the United Kingdom and other OECD Anti-Bribery Convention members, have similar anti-corruption regulations, such as the United Kingdom Anti- Bribery Act.

When marketing our testing products outside of the United States, we may be subject to foreign regulatory requirements governing human clinical testing, prohibitions on the import of tissue necessary for us to perform our testing products or restrictions on the export of tissue imposed by countries outside of the United States or the import of tissue into the United States, and marketing approval. These requirements vary by jurisdiction, differ from those in the United States and may in some cases require us to perform additional preclinical or clinical testing. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

Privacy and security laws

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, impose, among other things, requirements relating to the privacy, security and transmission of protected health information ("PHI"), on covered entities including certain healthcare providers, health plans, and health clearinghouses and their respective "business associates," those independent contractors or agents of covered entities that perform

services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information as well as their covered subcontractors. HIPAA also regulates standardization of data content, codes and formats used in certain healthcare transactions and standardization of identifiers for health plans and providers.

HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. HIPAA also authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates that the Secretary of the Department of Health and Human Services ("HHS") conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

As a covered entity with downstream vendors and subcontractors and, in certain instances, as a business associate of other covered entities with whom we have entered into a business associate agreement, we have certain obligations under HIPAA regarding the use and disclosure of any PHI that may be provided to us. HIPAA and HITECH impose significant administrative, civil and criminal penalties against covered entities and business associates for noncompliance with privacy and security requirements.

Furthermore, we are, or may become, subject to various other data privacy and security obligations, including local and foreign laws, regulations, guidance, and industry standards related to data privacy, security, and protection. Such obligations may include, without limitation, the U.S. Federal Trade Commission Act, the U.S. Controlling the Assault of Non-Solicited Pornography And Marketing Act of 2003, the California Consumer Privacy Act of 2018 ("CCPA"), the European Union's General Data Protection Regulation 2016/679 ("EU GDPR"), the EU GDPR as it forms part of United Kingdom ("UK") law by virtue of section 3 of the European Union (Withdrawal) Act 2018 ("UK GDPR"), and the ePrivacy Directive. Several states within the United States have also enacted or proposed data privacy laws. For example, Virginia passed the Consumer Data Protection Act, and Colorado passed the Colorado Privacy Act.

The CCPA and EU GDPR are examples of the increasingly stringent and evolving regulatory frameworks related to personal data (including patient health information) processing that may increase our compliance obligations and exposure for any noncompliance. For example, the CCPA imposes obligations on covered businesses to provide specific disclosures related to a business's collecting, using, and disclosing personal data and to respond to certain requests from California residents related to their personal data (for example, requests to know of the business's personal data processing activities, to delete the individual's personal data, and to opt out of certain personal data disclosures). Also, the CCPA provides for civil penalties and a private right of action for data breaches which may include an award of statutory damages. In addition, the California Privacy Rights Act of 2020 ("CPRA"), effective January 1, 2023, expands the CCPA, and, among other things, gives California residents the ability to limit use of certain sensitive personal data, expands the types of data breaches that are subject to the CCPA's private right of action, and establishes a new California Privacy Protection Agency to implement and enforce the new law.

Furthermore, the EU GDPR imposes significant and complex compliance obligations on entities that are subject to the law. Such obligations may include limiting personal data processing to only what is necessary for specified, explicit, and legitimate purposes; requiring a legal basis for personal data processing; requiring the appointment of a data protection officer in certain circumstances; increasing transparency obligations to data subjects; requiring data protection impact assessments in certain circumstances; limiting the collection and retention of personal data; increasing rights for data subjects; formalizing a heightened and codified standard of data subject consents; requiring the implementation and maintenance of technical and organizational safeguards for personal data; and mandating notice of certain personal data breaches to the relevant supervisory authority(ies) and affected individuals.

See the section titled "Risks Related to Reimbursement and Regulation" for additional information about the laws and regulations to which we may become subject and about the risks to our business associated with such laws and regulations.

Healthcare reform

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Reconciliation Act of 2010, collectively the ACA, was enacted in the United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private insurers. For example, the ACA also contains a number of provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict. There have been executive, judicial and Congressional challenges to certain provisions of the ACA. For example, President Trump signed Executive Orders and

other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, eliminating the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.
On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. However, it is possible that the ACA will be subject to additional judicial or Congressional challenges in the future. In addition, the ACA has been subject to various health reform measures. For example, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The Inflation Reduction Act also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any additional healthcare reform measures of the Biden administration will impact the ACA.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2032 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. As part of the 2020 federal spending package, the ACA-required medical device manufacturer 2.3% sales tax has been eliminated, effective January 1, 2020.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. Further, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical and medical device pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

Corporate Information

The terms "Company", "Renalytix", "we", "us", or "our" refer to Renalytix plc and its subsidiaries. We were incorporated as a public limited company under the laws of England and Wales on March 15, 2018, with company number 11257655. Our principal executive offices in the United States are located at 1460 Broadway, New York, New York 10036, and our telephone number is +1 646 397 3970. Our registered office in the United Kingdom is located at Finsgate, 5-7 Cranwood Street, London, EC1V 9EE, United Kingdom, and the telephone number of our registered office is +44 20 3139 2910. Our agent for service of process in the United States is Renalytix AI, Inc., located at 1460 Broadway, New York, New York 10036.

Renalytix AI, Inc., a Delaware corporation, and Renalytix AI Limited, an Irish corporation, are our wholly owned subsidiaries. The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. Our website address is www.renalytix.com, and we make available free of charge on our website (https://www.renalytix.com) our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and other filings pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, and amendments to such filings, as soon as reasonably practicable after each are electronically filed with, or furnished to, the SEC. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this Annual Report is not part of this Annual Report.

Item 1A. Risk Factors.

Our business faces significant risks. You should carefully consider all of the information set forth in this annual report and in our other filings with the SEC, including the following risk factors which we face and which are faced by our industry. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. This annual report also contains forward-looking statements that involve risks and uncertainties. Our results could materially differ from those anticipated in these forward-looking statements, as a result of certain factors including the risks described below and elsewhere in this annual report and our other SEC filings. See "Special Note Regarding Forward-Looking Statements" above.

Risk Factor Summary

Our business is subject to a number of risks and uncertainties, including those risks discussed at-length in the section below titled "Risk Factors." These risks include, among others, the following:

- We have not generated material revenue, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- 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 limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional funding to commercialize and scale KidneyIntelX, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, curtail or discontinue our operations.
- If we cannot continue to execute on our strategy to partner with healthcare systems to incorporate KidneyIntelX into their treatment regime and integrate their EHR systems with our technology, our revenue prospects could be significantly reduced.
- We are highly reliant on our partnership with Mount Sinai, and our failure to maintain that relationship could negatively impact our business, reputation and strategic goals.
- We may underestimate the timing and complexity of successfully integrating KidneyIntelX into the clinical guidelines of new healthcare systems with which we partner.
- Our ability to be profitable in the future will depend on our ability to successfully commercialize KidneyIntelX, and any other products we may develop in the future, to scale nationally in the United States.
- KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving. Our artificial intelligence-enabled algorithms and other technologies depend on our ability to continue to build a substantial repository of kidney disease-related data and validate additional product designs.
- Success in early clinical study work that we have published and data that we have submitted to the FDA under breakthrough device designation does not ensure that later clinical trials will be successful, and we cannot be sure that the later trials will replicate the results of prior clinical trials and studies.
- Due to our limited resources and access to capital, our strategic decisions with respect to the development of certain diagnostic products may affect the development or timing of our business prospects.
- Our commercial success could be compromised if we do not obtain and maintain coverage and adequate reimbursement from third-party payors—Medicare, specifically—for KidneyIntelX.
- Payors from whom we may receive reimbursement are able to withdraw or decrease the amount of reimbursement provided for our products at any time in the future.
- If we are unable to compete successfully with respect to our current or future products, we may be unable to increase or sustain our revenues or achieve profitability.
- Our business could be adversely affected by the effects of health epidemics, including the current COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of validation study sites or other business operations.

- Our business could be adversely affected by the ongoing financial distress within the U.S. hospital system.
- Holders of our American Depository Shares ("ADS") have fewer rights than our shareholders and must act through the depositary to exercise their rights.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

Risks Related to Our Financial Condition and Capital Requirements

We have not generated material revenue, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.

Since inception, our operations have been primarily limited to developing clinical-grade, artificial intelligence-enabled *in vitro* diagnostics for kidney disease and investing in our technology platform. We are currently continuing to conduct clinical utility and other studies for KidneyIntelX to determine its clinical value and performance in different CKD populations and we expect to continue to conduct additional clinical studies for the foreseeable future. We have only recently begun to generate revenue from sales of KidneyIntelX and we cannot guarantee that our commercialization and partnership efforts will result in significant revenue to us in future periods. Consequently, any predictions about our future success or viability, or any evaluation of our business and prospects, may not be accurate.

We have incurred losses in each year since our inception. Our net losses for the fiscal years ended June 30, 2023 and 2022 were $45.6 million and $45.3 million, respectively. We have devoted most of our financial resources to research and development, including planning and conducting clinical validation and other studies for KidneyIntelX and evaluating its potential health economic impacts.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and these net losses may fluctuate significantly. We anticipate that our expenses will increase substantially as we conduct clinical utility and other studies for KidneyIntelX and continue its commercial launch, develop and refine our artificial intelligence technology platform, seek regulatory clearances or approvals for other products 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.

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 for the fiscal years ended June 30, 2023 and 2022 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 this report a substantial doubt regarding our ability to continue as a going concern. Our financial statements 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, our shareholders may lose their entire investment in our securities. Future reports from our independent registered public accounting firm may also contain statements expressing doubt about our ability to continue as a going concern.

Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.

We are an artificial intelligence-enabled *in vitro* diagnostics company with a limited operating history. Our company was formed in March 2018. As an organization, we have limited experience in establishing and maintaining successful partnerships with healthcare systems, manufacturing KidneyIntelX at commercial scale, conducting sales and marketing activities necessary for successful commercialization and achieving major reimbursement milestones. We may encounter unforeseen expenses, difficulties, complications and delays in achieving our business objectives. Our very short history as an operating company makes any assessment of our future success or viability subject to significant uncertainty. If we do not address these risks successfully or are unable to

transition at some point to a company capable of supporting commercial activities and maintaining partnerships with healthcare systems, then our business will suffer.

We will require substantial additional funding to commercialize and scale KidneyIntelX.dkd, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, curtail or discontinue our operations.

We expect our expenses to increase in connection with our ongoing activities, particularly as we conduct commercial sales at scale. We expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We will continue to incur additional costs associated with operating as a company that is both publicly listed on Nasdaq in the United States and admitted to trading on AIM in the United Kingdom, and we expect these costs may increase in connection with our loss of foreign private issuer status.

Accordingly, we will need to obtain substantial additional funding in connection with our continuing operations. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, curtail or discontinue our research and development programs or any future commercialization efforts. We have based this estimate on assumptions that may prove to be wrong, and we could use our capital resources sooner than we currently expect, or our operating plan may change as a result of many factors unknown to us. These factors, among others, may necessitate that we seek additional capital sooner than currently planned. In addition, we may seek additional capital due to favorable market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans.

Our future capital requirements will depend on many factors, including:

- the cost, timing and outcome of our commercialization efforts for KidneyIntelX.dkd, including our efforts to build and expand our sales force;
- the cost, progress and results of our ongoing and planned clinical utility and other studies;
- the cost, timing and outcome of our efforts to enter into and, once secured, maintain partnership agreements with healthcare systems for the commercial sale of KidneyIntelX.dkd;
- the degree to which any of our healthcare system partners order KidneyIntelX.dkd;
- the cost of manufacturing clinical and commercial supply of KidneyIntelX.dkd;
- the cost, timing and outcome of regulatory review of our products, including any post-marketing studies that could be required by regulatory authorities;
- the cost, timing and outcome of identified and potential future commercialization activities, including manufacturing, marketing, sales and distribution, for KidneyIntelX;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of future revenue, 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.

Any efforts to secure additional financing may divert our management from their day-to-day activities, which may adversely affect our ability to continue development and commercialization of KidneyIntelX. In addition, we cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect our business, the holdings or the rights of our shareholders or holders of our ADSs, or the value of our ordinary shares or ADSs.

If we are unable to obtain funding on a timely basis, we may be required to significantly curtail, delay or discontinue our research and development programs relating to KidneyIntelX or any commercialization efforts, be unable to expand our operations, or be unable to otherwise capitalize on our business opportunities, as desired, which could harm our business and potentially cause us to discontinue operations.

Covenants under our Amended and Restated Bond Agreement and any future debt arrangements may result in the acceleration of outstanding indebtedness and limit the manner in which we operate.

The Amended and Restated Bond Agreement we entered into with CVI Investments, Inc. ("CVI") in April 2022 (the “Bond Agreement”) contains customary terms and covenants, as well as customary events of default, after which the bonds may be due and payable immediately, including defaults related to payment compliance, material inaccuracy of representations and warranties, covenant compliance, material adverse changes, bankruptcy and insolvency proceedings, judgments against the Company, and change of control or delisting events.

In addition, the Bond Agreement contains, and any future indebtedness we incur may contain, various negative covenants that restrict or may restrict, among other things, our ability to:

- incur additional indebtedness, guarantee indebtedness or issue disqualified stock or, in the case of such subsidiaries, preferred stock;
- declare or pay dividends on, repurchase or make distributions in respect of, their capital stock or make other restricted payments;
- make investments or acquisitions;
- create liens;
- enter into agreements restricting certain subsidiaries' ability to pay dividends or make other intercompany transfers;
- consolidate, merge, sell or otherwise dispose of all or substantially all of our assets and the assets of our restricted subsidiaries;
- enter into transactions with affiliates;
- sell, transfer or otherwise convey certain assets; and
- prepay certain types of indebtedness.

As a result, we are limited in the manner in which we conduct our business and we may be unable to engage in favorable business activities, repurchase our ordinary shares or finance future operations or capital needs.
Servicing these bonds requires a significant amount of cash, and we may not have sufficient cash flow from our business to pay our substantial debt.

Our ability to make scheduled payments of the principal of, to pay interest on or to refinance our indebtedness depends on our future performance, which is subject to economic, financial, competitive and other factors beyond our control. Our business may not generate cash flow from operations in the future sufficient to service our debt and make necessary capital expenditures. If we are unable to generate such cash flow, we may be required to adopt one or more alternatives, such as selling assets, restructuring debt or obtaining additional equity capital on terms that may be onerous or highly dilutive. If we are unable to make our quarterly instalment payments in cash, we may be forced to issue a significant number of ordinary shares which could dilute existing shareholders. Our ability to refinance our indebtedness will depend on the capital markets and our financial condition at such time. We may not be able to engage in any of these activities or engage in these activities on desirable terms, which could result in a default on our debt obligations.

Risks Related to Our Business and Strategy

If we cannot continue to execute on our strategy to partner with healthcare systems to incorporate KidneyIntelX into their treatment regime and integrate their EHR systems with our technology, our revenue prospects could be significantly reduced.

We have only recently commercially launched KidneyIntelX. Partnerships with healthcare systems are a core part of our adoption and growth strategy.

Our ability to execute on this strategy could suffer if:

- we are unable to maintain current or future partnerships or if our current or future partners do not believe KidneyIntelX is a clinically and economically beneficial diagnostic to incorporate into their treatment paradigm for patients with kidney disease;
- we are unable to build new partnerships with healthcare systems and secure partnership agreements;
- treating clinicians or our current or future partners decline to deploy KidneyIntelX in their patient populations; or

- we encounter difficulties integrating with our partners' EHR systems for test ordering and reporting.

The strength of our partnerships will depend on many factors, including effectiveness of patient and clinician compliance, the effectiveness of our efforts to educate clinicians and healthcare systems on the implementation and use of KidneyIntelX and the effectiveness of our efforts to integrate KidneyIntelX into the clinical workflow and integrate with the healthcare system's EHR systems for test ordering and reporting. The success of a partnership may also be dependent on factors that are beyond our control, such as healthcare system budgetary cuts, changes in key executive, administrative, IT and clinical personnel, changes in control or acquisitions and changes in the local regulatory environment.

If our partnership strategy is unsuccessful, we may need to change our commercialization strategy and significantly expand our direct sales force, which would involve significant time and expense and which may not be successful.

We may underestimate the timing and complexity of successfully integrating KidneyIntelX into the clinical guidelines of new healthcare systems with which we partner.

Integration of KidneyIntelX with healthcare providers' clinical workflow is a core part of our adoption and growth strategy. To assist with KidneyIntelX utility and system-wide integration, we deploy a variety of critical supporting resources to providers, including direct customer service, care navigation and specialist educator functions. Integrated partnerships are designed to allow KidneyIntelX to be deployed directly to patient populations and their treating clinicians in a cost-efficient and timely manner.

Each deployment and integration of KidneyIntelX in a new health system is complex and must be meticulously tailored to the specifics of the health system, including, among other factors:

- the behavioral dynamics of the patients and clinicians, including across specialties;
- the clinical workflow and norms of each clinical specialty;
- the way in which new solutions like KidneyIntelX are communicated, recommended or mandated within the healthcare system;
- the quality and depth of the healthcare system's EHR system;
- the health system partner's IT resources and expertise and time available to ensure a smooth and robust integration with the KidneyIntelX platform; and
- other factors such as specific institutional clinical protocols and practices.

Although we carefully study each potential partnership and expend significant time and resources to support the deployment of KidneyIntelX, we may underestimate the time, costs and complexity of integration, and our integration efforts may ultimately be unsuccessful. For example, implementation of KidneyIntelX testing with the VA medical system has been slower than planned due to the complexities in introducing a novel test and integrating its use into the VA system. If we are unable to successfully integrate KidneyIntelX into health systems, including the VA medical system, our business may be adversely affected.

Our ability to be profitable in the future will depend on our ability to successfully commercialize KidneyIntelX, and any other products we may develop in the future, to scale nationally in the United States.

Our ability to be profitable in the future will depend on our ability to commercially scale KidneyIntelX and any other products we may develop in the future in the United States, including:

- continuing to expand study data for KidneyIntelX.dkd, including data demonstrating the clinical utility over the short, intermediate and long term use of KidneyIntelX in different clinical settings;
- expanding our manufacturing of commercial supply for KidneyIntelX;
- transitioning from selling KidneyIntelX as an LDT to selling the FDA authorized KidneyIntelX.dkd;
- establishing sales, marketing and distribution capabilities to effectively market and sell KidneyIntelX in the United States, Europe and in other territories;
- achieving market acceptance by patients and the medical community of KidneyIntelX; and
- negotiating and securing coverage and adequate reimbursement from third-party payors, including Medicare, for KidneyIntelX.

If KidneyIntelX fails to demonstrate clinical utility, does not maintain regulatory approval or does not achieve market acceptance, we may never become profitable. Our net losses have had, and will continue to have, an adverse effect on our shareholders' equity and working capital. Because of the numerous risks and uncertainties associated with diagnostic product development and commercialization, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve profitability. The amount of future net losses will depend, in part, on the rate of future growth of our expenses and our ability to generate revenues.

Guidelines and recommendations published by various organizations can reduce the use of our products.

Government agencies promulgate regulations and guidelines directly applicable to us and to our products. However, professional societies, practice management groups, insurance carriers, physicians, private health/science foundations and organizations involved in various diseases from time to time may also publish guidelines or recommendations to healthcare providers, administrators and payers, and patient communities. Recommendations by government agencies or those other groups/organizations may relate to such matters as usage and reimbursement of our products by government and private payers. Recommendations or guidelines that are followed by patients, healthcare providers and payers could result in decreased use of our products, and any recommendations or guidelines that result in decreased use or reimbursement of our products could materially and adversely affect our product sales, business and operating results.

Risks Related to Development of Our Products and Technology Platform

KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving. Our artificial intelligence-enabled algorithms and other technologies depend on our ability to continue to build a substantial repository of kidney disease-related data and validate additional product designs.

KidneyIntelX is a first-in-class *in vitro* diagnostics platform that employs a proprietary artificial intelligence- enabled algorithm to combine diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from EHR systems to generate a unique patient risk score. This use of artificial intelligence-enabled algorithms that combine both biological markers of disease along with EHR systems is a novel approach to kidney disease patient risk stratification. This new category of medical device and the kidney disease clinical indication are rapidly evolving fields of specialty that include uncertainties in acceptance, utility and clinical practice. There is no guarantee that we have fully understood all the implications of introducing a novel technology such as KidneyIntelX into such a large and evolving field of medicine.

In addition, we must execute on our strategy to build a significant repository of kidney disease-related data to support the robustness and accuracy of KidneyIntelX and allow us to develop additional artificial intelligence- enabled applications. We believe that access to contemporary and historical patient data, combined with the ability to analytically and clinically validate study results in a quality-controlled framework, provides us with a robust, reproducible method for product development. Moreover, the depth, specificity and quality of data are of paramount importance to developing novel solutions such as KidneyIntelX that can demonstrate clinical utility across a range of practice specialties and patient demographics. These features are also central to our product strategy of demonstrating both short- and long-term impact on patient outcomes and health economics. If we are unable to continue to build our data repository, we may not be able to keep pace with rapidly evolving technology and improve the predictive capabilities and clinical utility of KidneyIntelX, and our business could be harmed.

KidneyIntelX.dkd is subject to ongoing regulation and could be subject to post-marketing restrictions or withdrawal from the market.

KidneyIntelX.dkd is subject to the FDA's quality system regulation ("QSR"), labeling regulations, registration and listing, the Medical Device Reporting regulation which requires that manufacturers report to the FDA if their device may have caused or contributed to a death or serious injury or malfunctioned in a way that would likely cause or contribute to a death or serious injury if it were to recur and the Reports of Corrections and Removals regulation, which requires manufacturers to report recalls and field actions to the FDA if initiated to reduce a risk to health posed by the device or to remedy a violation of the FDCA. The FDA enforces these requirements by inspection and market surveillance. If the FDA finds a violation, it can institute a wide variety of enforcement actions, ranging from an untitled or public warning letter to more severe sanctions such as fines, injunctions and civil penalties; recall or seizure of products; operating restrictions and partial suspension or total shutdown of production; refusing requests for 510(k) clearance or PMA approval of new products; withdrawing a marketing authorization already granted; and criminal prosecution.

Accordingly, we will continue to expend time, money and effort in all areas of regulatory compliance.

Modifications to our products may require new 510(k) clearances or PMAs or may require us to recall or cease marketing our products until clearances or approvals are obtained, which could harm our business, financial condition and results of operations.

In the United States, our KidneyIntelX.dkd is marketed pursuant to de novo authorization issued by the FDA. Any modifications to the device that could significantly affect its safety or effectiveness, such as changes to the intended use or technological characteristics, may require new 510(k) clearances or PMAs or require us to recall or cease marketing the modified devices until these clearances or approvals are obtained. Based on FDA published guidelines, the FDA requires device manufacturers to initially make and document a determination of whether or not a modification requires a new approval, supplemental approval or clearance; however, the FDA can review a manufacturer's decision. Any modification to an FDA-cleared device that could significantly affect its safety or efficacy or that would constitute a major change in its intended use would require a new 510(k) clearance, or if such modification put the device into Class III, possibly a PMA. We may not be able to obtain additional 510(k) clearances or PMAs for new products or for modifications to, or additional indications for, our products in a timely fashion, or at all. Delays in obtaining required future clearances or approvals would adversely affect our ability to introduce new or enhanced products in a timely manner, which in turn would harm our future growth.

Due to our limited resources and access to capital, our strategic decisions with respect to the development of certain diagnostic products may affect the development or timing of our business prospects.

Because we have limited resources and access to capital to fund our operations, we must decide which diagnostic products to pursue and the amount of resources to allocate to each. As such, we are currently primarily focused on the development of KidneyIntelX.

Our decisions concerning the allocation of research, collaboration, management and financial resources toward particular diagnostic and prognostic programs or potential new products may not lead to the development of viable commercial products and may divert resources away from more promising opportunities. We may not choose the right product or programs to develop, or may be required to collaborate with third parties to advance a particular product at terms that are less than optimal to us. If we make incorrect determinations regarding the market potential of our diagnostic products or misread trends in the diagnostics industry, our business prospects could be harmed.

Acquisitions or joint ventures we may pursue may be unsuccessful.

We may consider the acquisition of other products or businesses that either complement or expand our existing business, or may enter into joint ventures. Any future acquisitions or joint ventures we pursue may involve a number of risks, including some or all of the following:

- difficulty in identifying acceptable acquisition candidates;
- the inability to consummate acquisitions or joint ventures on favorable terms and to obtain adequate financing, which financing may not be available to us at times, in amounts or on terms acceptable to us, if at all;
- the diversion of management's attention from our core business;
- the disruption of our ongoing business;
- entry into markets in which we have limited or no experience;
- the inability to integrate our acquisitions or enter into joint ventures without substantial costs, delays or other problems;
- unexpected liabilities for which we may not be adequately indemnified;
- inability to enforce indemnification and non-compete agreements;
- the failure to successfully incorporate acquired products into our business;
- the failure of the acquired business or joint venture to perform as well as anticipated;
- the failure to realize expected synergies and cost savings;
- the loss of key employees or customers of the acquired business;
- increasing demands on our operational systems and the potential inability to implement adequate internal controls covering an acquired business or joint venture;
- possible adverse effects on our reported operating results, particularly during the first several reporting periods after the acquisition is completed; and
- impairment of goodwill relating to an acquired business, which could reduce reported income.

Risks Related to Reimbursement and Regulation

Our commercial success could be compromised if we do not obtain and maintain coverage and adequate reimbursement from third-party payors—Medicare, specifically—for KidneyIntelX.

Whether marketed as a Laboratory Developed Test (“LDT”) or a medical device, the commercial success of KidneyIntelX and any future products we may develop will depend on the extent to which our customers obtain and maintain coverage and adequate reimbursement from third-party payors, including government payors such as Medicare and Medicaid, managed care organizations and commercial payors.

There are three key components for reimbursement in the United States: (1) coding, (2) pricing and (3) coverage. “Coding” refers to distinct numeric and alphanumeric billing codes, including Current Procedural Terminology ("CPT"), codes that are used to report the provision of certain health care services, including laboratory services, to third-party payors. “Coverage” refers to decisions made by third-party payors as to whether or not to provide their members access to and pay for such health care services, and if so, what conditions, such as specific diagnoses and clinical indications, are covered.

We received a CPT code for KidneyIntelX, effective as of October 1, 2019 from the American Medical Association. We also received Medicare national pricing for KidneyIntelX set at $950 per reportable test result, effective from January 2020 through at least 2024. We are currently undergoing a Medicare coverage determination process and have begun receiving payments under an individual claims review, ("ICR"), process. Our success is highly dependent on ultimately receiving a positive local or national Medicare coverage determination. If we do not receive a positive Medicare coverage determination, we could experience negative consequences including:

- We would be forced to rely on private insurance coverage, which would greatly decrease our intended market opportunity for KidneyIntelX;
- A negative coverage determination could adversely affect our ability to enter into new partnerships with healthcare systems; and
- We may need to conduct additional clinical validation, utility and other studies as part of an appeal of a negative Medicare coverage decision, and even if we expended the substantial time and resources to conduct such studies, they may not be successful and they may not result in a positive Medicare coverage determination.

Coverage and reimbursement by a payor may depend on a number of factors, including a payor’s determination that our products are:

- not experimental or investigational;
- medically necessary;
- appropriate for the specific patient;
- cost-effective;
- supported by peer-reviewed publications; and
- included in clinical practice guidelines.

Accordingly, even though we received Medicare national pricing for KidneyIntelX set at $950 per reportable test result, we may not be reimbursed at that rate. As we enter into partnerships and contracts with healthcare systems and third-party payors, we will establish a reimbursement rate through contractual negotiations.

In the United States, the principal decisions about reimbursement for new medical products are typically made by the CMS. CMS decides whether and to what extent a new product will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. Because there is no uniform policy of coverage and reimbursement in the United States, each payor generally determines for its own enrollees or insured patients whether to cover or otherwise establish a policy to reimburse our diagnostic tests, and seeking payor approvals is a time-consuming and costly process. We cannot be certain that coverage for our current and our planned future products will be provided in the future by additional payors or that existing agreements, policy decisions or reimbursement levels will remain in place, remain adequate, or be fulfilled under existing terms and provisions.

If we cannot obtain coverage and adequate reimbursement from private and governmental payors such as Medicare and Medicaid for our current products or new products that we may develop in the future, demand for such products may decline or may not grow as we expect, which could limit our ability to generate revenue and have a material adverse effect on our financial condition, results of operations and cash flow. In order to secure coverage and reimbursement for our products that might be approved for sale, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, products may not be considered medically necessary or cost effective. Further, we may experience delays and interruptions in the receipt of payments from payors due to missing documentation and/or other issues, which could cause delay in collecting our revenue.

In addition, the coverage and reimbursement market is ever changing and we are not in control of how our competitors' coverage and pricing strategies are established. Some of our competitors have widespread brand recognition and substantially greater financial and technical resources and development, production and marketing capabilities than we do. Others may develop lower-priced, less complex tests that payors and physicians could view as functionally equivalent to our products, which could force us to lower the list price of our tests and impact our operating margins and our ability to achieve and maintain profitability. Payors may compare our products to our competitors and utilize them as precedents, which may impact our coverage and/or reimbursement. In addition, technological innovations that result in the creation of enhanced diagnostic tools that are more effective than ours may enable other clinical laboratories, hospitals, physicians or medical providers to provide specialized diagnostic tests similar to ours in a more patient-friendly, efficient or cost-effective manner than is currently possible. If we cannot compete successfully against current or future competitors, we may be unable to increase or create market acceptance and sales of our products, which could prevent us from increasing or sustaining our revenue or achieving or sustaining profitability.

In some foreign countries, the proposed pricing for a product must be approved before it may be lawfully marketed. The requirements governing pricing vary widely from country to country. For example, the European Union (the"EU"), provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. To obtain reimbursement or pricing approval, some of these countries may require the completion of clinical trials that compare the cost effectiveness of a particular product to the current standard of care. A Member State may approve a specific price for the product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for diagnostic products will allow favorable reimbursement and pricing arrangements for any of our products. Historically, products launched in the EU do not follow price structures of the United States and generally prices tend to be significantly lower.

The coverage and reimbursement market may be additionally impacted by future legislative changes. There are increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs which may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our products. Specifically, there have been several recent U.S. presidential executive orders. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and medical device pricing, reduce the cost under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

Payors from whom we may receive reimbursement are able to withdraw or decrease the amount of reimbursement provided for KidneyIntelX or our other products at any time in the future.

Our commercial success depends on our ability to maintain coverage and adequate reimbursement from those payors that decide to cover and reimburse KidneyIntelX, whether marketed as an LDT or medical device, and our other products that we commercialize. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Payors could withdraw coverage and stop providing reimbursement for our commercialized products in the future or may reimburse our products only on a case-by-case basis. Managing reimbursement on a case-by-case basis is time consuming and contributes to an increase in the number of days it takes us to collect accounts receivable and increases our risk of non-payment. Negotiating reimbursement on a case-by-case basis also typically results in the provision of reimbursement at a significant discount to the list price of our commercialized products.

Further, even if we obtain written agreements regarding coverage and reimbursement with certain payors, these agreements are not guarantees of indefinite coverage in an adequate amount. For example, these agreements are typically terminable without cause by either party and are typically renewable annually, and the applicable payor could opt against renewal upon expiration. In addition, the terms of certain of our written arrangements may require us to seek pre-approval from the payor or put in place other controls and

procedures prior to conducting a test for a customer. To the extent we fail to follow these requirements, we may fail to receive some or all of the reimbursement payments to which we are otherwise entitled. These payors must also conclude that our claim satisfies the applicable contractual criteria. In addition, our written agreements regarding reimbursement with payors may not guarantee us the receipt of reimbursement payments at what we believe to be the applicable contracted rate for each reimbursement claim that we submit to such payors. If payors withdraw coverage for KidneyIntelX or our other products, once commercialized, or reduce the reimbursement amounts for such products, our ability to generate revenue could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow.

Long payment cycles of Medicare, Medicaid and/or other third-party payors, or other payment delays, could hurt our cash flows and increase our need for working capital.

Medicare and Medicaid have complex billing and documentation requirements that we must satisfy in order to receive payment, and the programs can be expected to carefully audit and monitor our compliance with these requirements. We must also comply with numerous other laws applicable to billing and payment for healthcare services, including, for example, privacy laws. Failure to comply with these requirements may result in, among other things, non-payment, refunds, exclusion from government healthcare programs, and significant administrative, civil or criminal penalties, any of which may have a material adverse effect on our revenues and earnings. In addition, failure by third-party payors to properly process our payment claims in a timely manner could delay our receipt of payment for our products and services, which may have a material adverse effect on our cash flows.

Billing for our products is complex and requires substantial time and resources to collect payment.

Billing for clinical laboratory testing services is complex, time-consuming and expensive. With respect to our LDT products, including KidneyIntelX, while marketed as an LDT, we anticipate we, through a third party service provider, will be billing various payors, including Medicare, Medicaid, private insurance payors and patients, all of which have different billing requirements. The billing arrangements and applicable law differ, which complicates our compliance efforts. To the extent laws or contracts require us to bill patient co-payments or co-insurance, we must also comply with these requirements. We may also face increased risk in our collection efforts, including potential write-offs of accounts receivable and long collection cycles, which could adversely affect our business, results of operations and financial condition.

Several factors make the billing process complex, including:

- differences between the billing rates and reimbursement rates for our commercialized products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid;
- risk of government and commercial audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical trials, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of local coverage decisions for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

Billing code changes can result in a risk of an error being made in the claim adjudication process. Claims adjudication errors can occur with claims submission, third-party transmission or in the processing of the claim by the payor. Claim adjudication errors may result in a delay in payment processing or a reduction in payment processing or a reduction in the amount of the payment we receive. The addition of billing codes will require changes to our billing process and financial reporting systems. Failure or delays in effecting these changes in external billing and internal systems and processes could negatively affect our collection rates, revenue and cost of collecting.

Additionally, our billing activities will require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. If a payor denies a claim we may submit, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received.

Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (the "ACA"), requires providers and suppliers to report and return any overpayments received from government payors under the Medicare and Medicaid programs within 60 days of identification. Failure to identify and return such overpayments exposes the provider or supplier to liability under federal false claims laws. These billing complexities, and the related uncertainty in obtaining payment for our products, could negatively affect our revenue and cash flow, our ability to achieve profitability, and the consistency and comparability of our results of operations.

We rely on third-party billing provider software, and an in-house billing function, to transmit claims to payors, and any delay in transmitting claims could have an adverse effect on our revenue.

While we manage the overall processing of claims, we rely on third-party billing provider software to transmit the actual claims to payors based on the specific payor billing format. The potential exists for us to experience delays in claims processing when third-party providers make changes to their invoicing systems. Additionally, coding for diagnostic assays may change, and such changes may cause short-term billing errors that may take significant time to resolve. If claims are not submitted to payors on a timely basis or are erroneously submitted, or if we are required to switch to a different software provider to handle claim submissions, we may experience delays in our ability to process these claims and receipt of payments from payors, or possibly denial of claims for lack of timely submission, which would have an adverse effect on our revenue and our business.

Complying with numerous regulations pertaining to our business is an expensive and time-consuming process, and any failure to comply could result in substantial penalties or our inability to operate.

We are and will be subject to multiple different state and federal laws and regulations that require significant expense, expertise and professional support to remain within compliance. For example, we operate under CLIA, a federal law regulating clinical laboratories that perform testing on specimens derived from humans for the purpose of providing information for the diagnosis, prevention or treatment of disease. CLIA is intended to ensure the quality and reliability of clinical laboratories in the United States by mandating specific standards in the areas of personnel qualifications, administration, and participation in proficiency testing, patient test management, quality control, quality assurance and inspections. Under CLIA, we are required to hold a certificate applicable to the type of laboratory tests we perform and to comply with standards applicable to our operations, including test processes, personnel, facilities administration, equipment maintenance, recordkeeping, quality systems and proficiency testing, which are intended to ensure, among other things, that clinical laboratory testing services are accurate, reliable and timely.

We must maintain CLIA compliance and certification to be eligible to bill for clinical laboratory services provided to federal health care program beneficiaries. We have received CLIA Certificates of Compliance for our Utah, Florida and New York laboratories and CLIA Certificate of Registration for our Florida laboratory To renew our CLIA certificates, we are subject to survey and inspection every two years to assess compliance with program standards. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate and use LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

Penalties for non-compliance with CLIA requirements include a range of enforcement actions, including suspension, limitation or revocation of the laboratory’s CLIA certificate, as well as directed plan of correction, state on-site monitoring, civil monetary penalties, civil injunctive suit or criminal penalties.

In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. A number of states have implemented their own more stringent laboratory regulatory requirements. Such laws, among other things, establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control.

If we were to lose our CLIA certification, whether as a result of a revocation, suspension or limitation, we would no longer be able to offer our tests, which would limit our revenues and seriously harm our business. If we were to lose, or fail to obtain, a license in any

other state where we are required to hold a license, we would not be able to test specimens from those states, which also could limit our revenues and seriously harm our business.

We are subject to federal and state healthcare fraud and abuse laws and regulations and could face substantial penalties if we are unable to fully comply with such laws.

We are or expect to become subject to broadly applicable health care laws, including fraud and abuse, transparency, and privacy and security laws, which are regulated and enforced by both the federal government and the states in which we conduct our business. These health care laws and regulations include, for example:

- the federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibit billing a patient or governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or a member of such physician's immediate family, has a financial relationship, such as an ownership or investment interest in or compensation arrangement with us, unless the relationship meets an applicable exception to the prohibition. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements that satisfy certain requirements. A laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well. The Stark Law is a strict liability statute, meaning the prohibitions apply regardless of intent to induce or reward referrals or the motive for the financial relationship;
- the federal AKS, which prohibits, among other things, persons or entities from soliciting, receiving, offering or providing remuneration, directly or indirectly, overtly or covertly, in cash or in kind, in return for or to induce either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or services for which payment may be made under a federal health care program such as the Medicare and Medicaid programs. A violation of the AKS may result in imprisonment, significant administrative and civil penalties and monetary fines and to exclude healthcare providers and others engaged in prohibited activities from Medicare, Medicaid and other federal healthcare programs. The government may also assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim under the federal false claims act. Additionally, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- state corporate practice of medicine restrictions do not allow business corporations to employ physicians to provide professional services. This prohibition against the "corporate practice of medicine" is aimed at preventing corporations such as us from exercising control over the medical judgments or decisions of physicians. The state licensure statutes and regulations and agency and court decisions that enumerate the specific corporate practice rules vary considerably from state to state and are enforced by both the courts and regulatory authorities, each with broad discretion. Activities in addition to those directly related to the delivery of medical care also may be considered an element of the practice of medicine in many states. We may enter into services contracts with healthcare providers organizations pursuant to which we provide them with a range of services. These contractual relationships are subject to various state laws, including those of New York, Texas and California, that prohibit fee splitting or the practice of medicine by lay entities or persons and are intended to prevent unlicensed persons from interfering with or influencing the physician's professional judgment. If regulatory authorities or other parties in any jurisdiction successfully assert that we are engaged in the unauthorized corporate practice of medicine, or fee-splitting, we could be required to restructure our contractual and other arrangements with certain physicians and other healthcare professions;
- HIPAA, which established additional federal civil and criminal liability for, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud any health care benefit program or making false statements in connection with the delivery of or payment for health care benefits, items or services. Like the AKS, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH and their respective implementing regulations, which imposes certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- federal false claims and civil monetary penalties laws, including the FCA, which, prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may deem manufacturers to have "caused" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;
- the federal Physician Payments Sunshine Act requirements under the ACA, and its implementing regulations, which require certain manufacturers of drugs, devices, biologics and medical supplies to report to CMS information related to payments available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value made to or at the request of covered recipients, such as physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members;
- EKRA prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. EKRA was enacted to help reduce opioid-related fraud and abuse. However, EKRA defines the term "laboratory" broadly and without reference to any connection to substance use disorder treatment. EKRA applies to all payors including commercial payors and government payors. Violations of EKRA are subject to significant fines and/or up to ten years in jail, separate and apart from existing AKS regulations and penalties. The law includes a limited number of exceptions, some of which closely align with corresponding AKS exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims and self-referred laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, and state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or product pricing; state and local laws that require the registration of medical device sales representatives.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

Any action brought against us for violation of these laws or regulations, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. If our operations, including any of our partnerships with healthcare systems, are found to be in violation of any of these laws and regulations, we may be subject to any applicable penalty associated with the violation, including, among others, significant administrative, civil and criminal penalties, damages, fines, disgorgement, reputational harm, imprisonment, integrity oversight and reporting obligations, and exclusion from participation in government funded healthcare programs such as Medicare and Medicaid. Additionally, we could be required to refund payments received by us, and we could be required to curtail or cease our operations. Any of the foregoing consequences could seriously harm our business and our financial results.

Healthcare policy changes, including recently enacted legislation reforming the U.S. healthcare system, may have a material adverse effect on our business, financial condition and results of operations.

The ACA substantially changed the way health care is financed by both governmental and private insurers. Among other things, the ACA required each certain medical device manufacturer to pay an excise tax equal to 2.3% (the "Medical Device Excise Tax"), of the price for which such manufacturer sells its medical devices that are listed with the FDA. However, this tax was permanently

eliminated as part of the 2020 federal spending package, effective January 1, 2020. The ACA also includes provisions of importance that:

- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide 50% (increased to 70% pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Although some of these provisions may negatively impact payment rates for clinical laboratory tests, the ACA also extends coverage to over 30 million previously uninsured people. Some of the provisions of the ACA have yet to be implemented, and there have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA.

While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties effective January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and eliminating the implementation of certain ACA-mandated fees. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. However, it is possible that the ACA will be subject to additional judicial or Congressional challenges in the future. In addition, the ACA has been subject to various health reform measures. For example, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the IRA of 2022 ("IRA") into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. The Inflation Reduction Act also eliminates the "donut hole" under the Medicare Part D program beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost through a newly established manufacturer discount program. It is unclear how any additional healthcare reform measures of the Biden administration will impact the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted. PAMA was signed to law, which, among other things, significantly altered the payment methodology under the CLFS. Under the law, issued in 2016 and the reporting period beginning in 2017 and every three years thereafter (or annually in the case of advanced diagnostic laboratory tests), applicable clinical laboratories must report laboratory test payment data for each Medicare- covered clinical diagnostic laboratory test that it furnishes during the specified time period. Reporting of payment data under PAMA for clinical diagnostic laboratory tests has been delayed on numerous occasions. The reported data must include the payment rate (reflecting all discounts, rebates, coupons and other price concessions) and the volume of each test that was paid by each private payor (including health insurance issuers, group health plans, Medicare Advantage plans and Medicaid managed care organizations). Effective January 1, 2018, the Medicare payment rate for each clinical diagnostic laboratory test is equal to the weighted median amount for the test from the most recent data collection period. The payment rate applies to laboratory tests furnished by a hospital laboratory if the test is separately paid under the hospital outpatient prospective payment system. Also, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. For an existing test that is cleared or approved by the FDA and for which Medicare payment is made as of April 1, 2014, CMS is required to assign a unique billing code if one has not already been assigned by the agency. In addition to assigning the code, CMS is required to publicly report payment for the tests. Further, under PAMA, CMS is required to adopt temporary billing codes to identify new tests and new advanced diagnostic laboratory tests that have been cleared or approved by the FDA. We cannot determine at this time the full impact of PAMA on our business, financial condition and results of operations.

Additionally, the Budget Control Act of 2011, among other things, created the Joint Select Committee on Deficit Reduction to recommend proposals in spending reductions to Congress. The Joint Select Committee did not achieve its targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers and suppliers of up to 2% per fiscal year, starting in 2013, and, due to subsequent legislative amendments to the statute, will remain in effect until 2032 unless additional congressional action is taken. The full impact on our business of the sequester law is uncertain. In addition, the Middle-Class Tax Relief and Job Creation Act of 2012 (the "MCTRJCA"), mandated an additional change in Medicare reimbursement for clinical laboratory tests. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

Some of our laboratory assay business is subject to the Medicare Physician Fee Schedule. The Medicare Access and CHIP Reauthorization Act of 2015 ended the use of the statutory formula, also referred to as the Sustainable Growth Rate, for clinician payment and established a quality payment incentive program, also referred to as the Quality Payment Program. This program provides clinicians with two ways to participate, including through the Advanced Alternative Payment Models ("APMs"), and the Merit-based Incentive Payment System ("MIPS"). In November 2019, CMS issued a final rule finalizing the changes to the Quality Payment Program. At this time, it is unclear how the introduction of the Quality Payment Program will impact overall physician reimbursement under the Medicare program. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors.

We cannot predict whether future health care initiatives will be implemented at the federal or state level, or how any future legislation or regulation may affect us. The expansion of government's role in the U.S. health care industry, and changes to the reimbursement amounts paid by Medicare and other payors for our current assays, whether marketed as an LDT or a medical device, and our planned future assays, may reduce our profits, if any, and have a materially adverse effect on our business, financial condition, results of operations and cash flows. Moreover, Congress has proposed on several occasions to impose a 20% coinsurance payment requirement on patients for clinical laboratory tests reimbursed under the Medicare Clinical Laboratory Fee Schedule, which would require us to bill patients for these amounts. In the event that Congress were to ever enact such legislation, the cost of billing and collecting for our products, once commercialized, could often exceed the amount actually received from the patient.

Our business activities may be subject to the Foreign Corrupt Practices Act and similar anti-bribery and anti- corruption laws.

Our business activities may be subject to the FCPA, and similar anti-bribery or anti-corruption laws, regulations or rules of other countries in which we operate, including, in the U.K., the Bribery Act 2010. The FCPA generally prohibits offering, promising, giving, or authorizing others to give anything of value, either directly or indirectly, to a non-U.S. government official in order to influence official action, or otherwise obtain or retain business. The FCPA also requires public companies to make and keep books and records that accurately and fairly reflect the transactions of the corporation and to devise and maintain an adequate system of internal accounting controls. Our business is heavily regulated and therefore involves significant interaction with public officials, including officials of non-U.S. governments. Recently, the SEC and Department of Justice have increased their FCPA enforcement activities with respect to biotechnology and medical device companies. There is no certainty that all of our employees, agents, contractors, or those of our affiliates, will comply with all applicable laws and regulations, particularly given the high level of complexity of these laws. Violations of these laws and regulations could result in fines, criminal sanctions against us, our officers, or our employees, the closing down of our facilities, requirements to obtain export licenses, cessation of business activities in sanctioned countries, implementation of compliance programs, and prohibitions on the conduct of our business. Any such violations could include prohibitions on our ability to offer our products in one or more countries and could materially damage our reputation, our brand, our international expansion efforts, our ability to attract and retain employees, and our business, prospects, operating results, and financial condition.

We are subject to stringent and evolving laws, regulations, rules, contractual obligations, policies and other obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could lead to regulatory investigations or actions; litigation (including class claims) and mass arbitration demands; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse business consequences.

In the ordinary course of business, we collect, receive, store, process, generate, use, transfer, disclose, make accessible, protect, secure, dispose of, transmit, and share (collectively, processing) personal data and other sensitive information, including proprietary and confidential business data, trade secrets, intellectual property, data we collect about trial participants in connection with clinical trials, and sensitive third-party data (collectively, sensitive data). Our data processing activities subject us to numerous data privacy and security obligations, such as various laws, regulations, guidance, external and internal privacy and security policies, contractual obligations, and other obligations relating to data privacy and security.

In the United States, federal, state, and local governments have enacted numerous data privacy and security laws and regulations, including data breach notification laws, state and federal health information privacy laws, personal data privacy laws, and federal and state consumer protection laws (e.g., Section 5 of the Federal Trade Commission Act), and other similar laws (e.g., wiretapping laws).

In addition, we may obtain health data from third parties (including research institutions from which we obtain clinical trial data) that is subject to privacy and security requirements under HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations. Depending on the facts and circumstances, we could be subject to civil, criminal, and administrative penalties if we knowingly obtain, use, or disclose individually identifiable protected health information in a manner that is not authorized or permitted by HIPAA. In addition, the California Consumer Privacy Act of 2018, as amended by the California Privacy Rights Act of 2020 ("CPRA"), (collectively, the CCPA), applies to personal data of consumers, business representatives, and employees, and requires businesses to provide specific disclosures in privacy notices and honor requests of California residents to exercise certain privacy rights. The CCPA provides for civil penalties of up to $7,500 per violation and allows private litigants affected by certain data breaches to recover significant statutory damages. Further, the CPRA expands the CCPA's requirements, including by adding a new right for individuals to correct their personal data and establishing a new regulatory agency to implement and enforce the law. Although the CCPA exempts some data processed in the context of clinical trials, the CCPA increases compliance costs and potential liability with respect to other personal data we maintain about California residents. Other states, such as Virginia, Colorado, Utah, and Connecticut have also passed comprehensive privacy laws, and similar laws are being considered in several other states, as well as at the federal and local levels. While these states, like the CCPA, also exempt some data processed in the context of clinical trials, these developments may further complicate compliance efforts, and increase legal risk and compliance costs for us and the third parties upon whom we rely.

Outside the United States, an increasing number of laws, regulations, and industry standards may govern data privacy and security. For example, the European Union's General Data Protection Regulation ("EU GDPR"), the United Kingdom's GDPR ("UK GDPR"), Brazil's General Data Protection Law (Lei Geral de Proteção de Dados Pessoais, or "LGPD") (Law No. 13,709/2018), and China's Personal Information Protection Law ("PIPL") impose strict requirements for processing personal data.

For example, under GDPR, companies may face temporary or definitive bans on data processing and other corrective actions; fines of up to 20 million Euros under the EU GDPR, 17.5 million pounds sterling under the UK GDPR or, in each case, 4% of annual global revenue, whichever is greater; or private litigation related to processing of personal data brought by classes of data subjects or consumer protection organizations authorized at law to represent their interests.

In addition, we may be unable to transfer personal data from Europe and other jurisdictions to the United States or other countries due to data localization requirements or limitations on cross-border data flows. Europe and other jurisdictions have enacted laws requiring data to be localized or limiting the transfer of personal data to other countries. In particular, the European Economic Area (EEA) and the United Kingdom (UK) have significantly restricted the transfer of personal data to the United States and other countries whose privacy laws it generally believes are inadequate. Other jurisdictions may adopt similarly stringent interpretations of their data localization and cross-border data transfer laws. Although there are currently various mechanisms that may be used to transfer personal data from the EEA and UK to the United States in compliance with law, such as the EEA and UK's standard contractual clauses and the UK's International Data Transfer Agreement / Addendum, these mechanisms are subject to legal challenges, and there is no assurance that we can satisfy or rely on these measures to lawfully transfer personal data to the United States. If there is no lawful manner for us to transfer personal data from the EEA, the UK, or other jurisdictions to the United States, or if the requirements for a legally-compliant transfer are too onerous, we could face significant adverse consequences, including the interruption or degradation of our operations, the need to relocate part of or all of our business or data processing activities to other jurisdictions (such as Europe) at significant expense, increased exposure to regulatory actions, substantial fines and penalties, the inability to transfer data and work with partners, vendors and other third parties, and injunctions against our processing or transferring of personal data necessary to operate our business. Additionally, companies that transfer personal data out of the EEA and UK to other jurisdictions, particularly to the United States, are subject to increased scrutiny from regulators, individual litigants, and activities groups. Some European regulators have ordered certain companies to suspend or permanently cease certain transfers of personal data out of Europe for allegedly violating the GDPR's cross-border data transfer limitations.

Our employees and personnel use generative artificial intelligence ("AI") technologies to perform their work, and the disclosure and use of personal information in generative AI technologies is subject to various privacy laws and other privacy obligations. Governments have passed and are likely to pass additional laws regulating generative AI. Our use of this technology could result in additional compliance costs, regulatory investigations and actions, and consumer lawsuits. If we are unable to use generative AI, it could make our business less efficient and result in competitive disadvantages. Several jurisdictions around the globe, including Europe and certain U.S. states, have proposed or enacted laws governing AI/ML. For example, European regulators have proposed a stringent AI regulation, and we expect other jurisdictions will adopt similar laws. Additionally, certain privacy laws extend rights to consumers (such as the right to delete certain personal data) and regulate automated decision making, which may be incompatible with our use of AI/ML. These obligations may make it harder for us to conduct our business using AI/ML, lead to regulatory fines or penalties, require us to change our business practices, retrain our AI/ML, or prevent or limit our use of AI/ML. For example, the FTC has required other companies to turn over (or disgorge) valuable insights or trainings generated through the use of AI/ML where they allege the company has violated privacy and consumer protection laws. If we cannot use AI/ML or that use is restricted, our business may be less efficient, or we may be at a competitive disadvantage.

In addition to data privacy and security laws, we are contractually subject to industry standards adopted by industry groups and may become subject to such obligations in the future. We are also bound by other contractual obligations related to data privacy and security, and our efforts to comply with such obligations may not be successful.

We publish privacy policies, marketing materials, and other statements, such as compliance with certain certifications or self-regulatory principles, regarding data privacy and security. If these policies, materials or statements are found to be deficient, lacking in transparency, deceptive, unfair, or misrepresentative of our practices, we may be subject to investigation, enforcement actions by regulators, or other adverse consequences.

Obligations related to data privacy and security are quickly changing, becoming increasingly stringent, and creating regulatory uncertainty. Additionally, these obligations may be subject to differing applications and interpretations, which may be inconsistent or conflict among jurisdictions. Preparing for and complying with these obligations requires us to devote significant resources and may necessitate changes to our services, information technologies, systems, and practices and to those of any third parties that process personal data on our behalf.

We may at times fail (or be perceived to have failed) in our efforts to comply with our data privacy and security obligations. Moreover, despite our efforts, our personnel or third parties on whom we rely may fail to comply with such obligations, which could negatively impact our business operations. If we or the third parties on which we rely fail, or are perceived to have failed, to address or comply with applicable data privacy and security obligations, we could face significant consequences, including but not limited to: government enforcement actions (e.g., investigations, fines, penalties, audits, inspections, and similar); litigation (including class-action claims) and mass arbitration demands; additional reporting requirements and/or oversight; bans on processing personal data; and orders to destroy or not use personal data. In particular, plaintiffs have become increasingly more active in bringing privacy-related claims against companies, including class claims and mass arbitration demands. Some of these claims allow for the recovery of statutory damages on a per violation basis, and, if viable, carry the potential for monumental statutory damages, depending on the volume of data and the number of violations. Any of these events could have a material adverse effect on our reputation, business, or financial condition, including but not limited to: loss of customers; inability to process personal data or to operate in certain jurisdictions; limited ability to develop or commercialize our products; expenditure of time and resources to defend any claim or inquiry; adverse publicity; or substantial changes to our business model or operations.

Our employees, principal investigators, consultants, professional service providers, manufacturers and commercial partners may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, and insider trading.

We are exposed to the risk of fraud or other misconduct by our employees, principal investigators, consultants, professional service providers, manufacturers and commercial partners. Misconduct by these parties could include intentional failures to comply with the regulations of the FDA and non-United States regulatory authorities, comply with healthcare fraud and abuse laws and regulations in the United States and abroad, report financial information or data accurately, or disclose unauthorized activities to us. In particular, sales, marketing, and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self-dealing, and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs, and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical studies, which could result in regulatory sanctions and cause serious harm to our reputation. We have implemented a code of conduct applicable to all of our employees, but it is not always possible to identify and deter employee misconduct, and our code of conduct and the other precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses, or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to comply with these laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could result in the imposition of significant fines or other sanctions, which could have a significant impact on our business. Whether or not we are successful in defending against such actions or investigations, we could incur substantial costs, including legal fees, and divert the attention of management in defending ourselves against any of these actions or investigations.

If we use hazardous materials in a manner that causes injury, we could be liable for damages.

Our activities currently require the use of hazardous chemicals and biohazardous waste, including chemical, biological agents and compounds, human blood and urine. We cannot eliminate the risk of accidental contamination or injury to employees or third parties from the use, storage, handling, or disposal of these materials. In the event of contamination or injury, we could be held liable for any resulting damages, and any liability could exceed our resources or any applicable insurance coverage we may have. Additionally, we are subject on an ongoing basis to federal, state, and local laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste services. The cost of compliance with these laws and regulations may become significant and could negatively affect our business, financial condition and results of operations.

Risks Related to Our Reliance on Third Parties

We are highly reliant on our partnership with Mount Sinai, and our failure to maintain that relationship could negatively impact our business, reputation and strategic goals.

Mount Sinai is our initial launch partner for KidneyIntelX. To the extent that this partnership fails to produce the anticipated outcomes, our business and reputation could be harmed. Under the Mount Sinai Agreement, we and Mount Sinai agreed to conduct a clinical utility study. There can be no certainty that we will complete the clinical utility study with Mount Sinai or that the Mount Sinai Agreement will not be terminated early. If our partnership with Mount Sinai is terminated and if we have not yet established, or are unable to establish, significant partnerships with other healthcare systems, our business would be adversely affected.

In October 2018, we, Mount Sinai and NPLUS1 Singer Advisory LLP ("Singer"), entered into a Relationship Agreement ("the Relationship Agreement"), to regulate the terms of the relationship between the Company and Mount Sinai and to ensure that we can operate independently of Mount Sinai, pursuant to which, among other things, Mount Sinai has the right to appoint one member to our board of directors and Mount Sinai has agreed to not take any action intended to prevent our board of directors from operating independently of Mount Sinai. The Relationship Agreement is filed with this Annual Report on Form 10-K as Exhibit 10.18 and is incorporated herein by reference, and the foregoing description of the Relationship Agreement is qualified in its entirety by reference thereto.

In September 2021, we and Mount Sinai announced scaled-up implementation of the KidneyIntelX early-stage risk assessment testing and care management program across primary care and specialty clinician networks under a real-world evidence development program for patients with DKD. There can be no guarantee that this scaled-up implementation will proceed on the timelines expected or result in the volume of tests expected.

We also license intellectual property from Mount Sinai. In May 2018, we entered into the Mount Sinai Agreement 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. If we fail to meet our obligations under the Mount Sinai Agreement or if the Mount Sinai Agreement is terminated for any reason, it could negatively impact our business and strategic goals.

Further, our collaborative research studies with Mount Sinai utilize the Mount Sinai Bio*Me* biobank. Bio*Me*, which is a biobank linked to longitudinal de-identified EHR data from consented participants, has allowed us to conduct rapid prospective validation of our platform using samples banked at “time zero” (i.e. time of sample collection), prior to the occurrence of progressive kidney function decline. If, for any reason, we are unable to continue our collaborative research studies that rely on the use of Bio*Me*, and a comparable biobank is not available or a collaborative relationship has not been established, our ability to support the continued development and validation of our KidneyIntelX platform could be harmed.

We have also entered into partnerships with health systems such as Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement KidneyIntelX testing as part of their clinical care models. If we do not continue to enter into partnerships with health systems at the rate and on the scale that we anticipate, or if these existing partnerships are terminated or do not result in the rate and quantity of KidneyIntelX testing that we anticipate, our business could be harmed.

We rely on a limited number of suppliers or, with respect to our multiplex biomarker assays, a single supplier, for the assay reagents and associated materials and may not be able to find replacements or immediately transition to alternative suppliers.

We have sourced and will continue to source components of our technology, including instruments and reagents and other laboratory materials, from third parties. The assay reagents and materials for the KidneyIntelX test are sourced from Meso Scale Diagnostics, LLC ("MSD"), and the assay is performed on the MSD instrument platform. The instruments used are not specific to KidneyIntelX; we purchase them directly from MSD as standard items along with a comprehensive service agreement. The multiplex assay plate (whereby three biomarkers—sTNFR1, sTNFR2 and KIM-1—are measured concurrently in a single well), diluents, calibrators, quality controls, detection antibodies and other assay materials were developed specifically for us under a master services agreement we entered into in 2018. In the event that this supply is interrupted, we believe the assay could be substantially reproduced through a combination of use of off-the-shelf materials provided by MSD and access to critical raw materials such as antibodies available from other manufacturers. Alternatively, the assay could be transferred to another technology platform, including those supplied by leading diagnostics manufacturers. However, either of these scenarios would require substantial development time, effort and extensive analytical and clinical validation and potentially new regulatory clearance.

If the supply of components we receive does not meet our quality control or performance standards, we may not be able to use the components, or if we use them not knowing that they are of inadequate quality, which occasionally occurs with respect to certain

reagents, our tests may not work properly or at all, or they may provide erroneous results. As a result, we may be subject to significant delays caused by interruption in production or manufacturing or to lost revenue from such interruption or from spoiled tests. In addition, any natural or other disaster, including global pandemics or diseases such as the current COVID-19 pandemic, acts of war or terrorism, shipping embargoes, labor unrest or political instability or similar events at our third-party manufacturers' facilities that cause a loss of manufacturing capacity would heighten the risks that we face.

In the event of any adverse developments with our suppliers, in particular for those products that are sole sourced, or if any of our suppliers modifies any of the components they supply to us, our ability to supply our products may be interrupted, and obtaining substitute components could be difficult or require us to re-design or re-validate our products. In addition, if we obtain FDA clearance, approval or authorization for any of our tests as an *in vitro* diagnostic, such issues with suppliers or the components that we source from suppliers could affect our commercialization efforts for such an *in vitro* diagnostic. Our failure to maintain a continued supply of components that meets our quality control requirements, or changes to or termination of our agreements or inability to renew our agreements with these parties or enter into new agreements with other suppliers, particularly in the case of sole suppliers, could result in the loss of access to important components of our tests and impact our test performance or affect our ability to perform our tests in a timely manner or at all, which could impair, delay or suspend our commercialization activities. Moreover, in the event that we transition to a new supplier from any of our sole suppliers, doing so could be time-consuming and expensive, may result in interruptions in our ability to supply our products to the market, could affect the performance of our tests or could require that we re-validate KidneyIntelX using replacement equipment and supplies, and should such a change be made following obtaining an FDA marketing authorization, may require a new submission, such as, for example, a new 510(k) and obtaining FDA clearance prior to implementation of the modified test, which could delay the performance of our tests and result in increased costs. Any of these occurrences could have a material adverse effect on our business, financial condition and results of operations.

If one or more of our laboratory facilities become damaged or inoperable, if we are required to vacate any of our laboratory facilities, or if we are delayed in obtaining or unable to obtain additional laboratory space or delayed in commencing operations in our laboratory facilities, our ability to manufacture our products, pursue our research and development efforts and fulfill our contractual obligations may be jeopardized.

We currently have laboratories in New York, Utah and Florida. These facilities are not fully redundant. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications or Internet failure or interruption, terrorism, or pandemic which may render it difficult or impossible for us to provide these services for some period of time. The inability to provide these services or to reduce the backlog of analyses that could develop if one or more of our laboratories become inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time- consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild any of our facilities or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for commercial laboratories like ours. We may be unable to negotiate commercially reasonable terms with such third parties. Adverse consequences resulting from an interruption of our overall laboratory operations could harm relationships with our customers and regulatory authorities, and our reputation, and could affect our ability to generate revenue.

We may also construct, acquire, or enter into relationships with third parties to procure additional laboratory space inside and outside the United States to support our existing and new services. If we are unable to obtain or are delayed in obtaining or establishing new laboratory space to support these commercialization and development efforts, or if our potential future ex-United States laboratory operations are harmed or are rendered inoperable, we could fail to meet certain contractual obligations and agreed upon timelines with certain of our partners or provide existing services and develop and launch new services in certain territories, which could result in harm to our business and reputation, and adversely affect our business, financial condition, and results of operations. As we continue to transition some of our services to new laboratories, we could experience disruptions in overall laboratory operations and could require adjustments to meet regulatory requirements, resulting in our inability to meet customer turnaround time expectations. Any delays in this transition could result in slower realization of laboratory efficiencies anticipated from operating an additional laboratory facility. Adverse consequences resulting from an interruption of our overall laboratory operations could harm relationships with our customers and regulators, and our reputation, and could affect our ability to generate revenue.

We carry insurance for damage to our property and laboratory and the disruption of our business, but this insurance may not cover all of the risks associated with damage to our property or laboratory or disruption to our business, may not provide coverage in amounts sufficient to cover our potential losses, may be challenged by insurers underwriting the coverage, and may not continue to be available to us on acceptable terms, if at all.

Risks Related to Our Business Operations and Industry

If we are unable to compete successfully with respect to our current or future products, we may be unable to increase or sustain our revenues or achieve profitability.

We face competition from clinical reference laboratories and diagnostics manufacturers, including large diagnostic laboratories such as Quest Diagnostics Inc. and Laboratory Corporation of America Holdings (LabCorp) and large diagnostics manufacturers such as ThermoFisher Scientific Inc., Danaher Corporation, Roche Holding AG, Abbott Laboratories, Bio-Rad Laboratories, Inc., Ortho Clinical Diagnostics NV and Siemens Healthineers AG, all of which have widespread brand recognition and market penetration and substantially greater financial, technical, research and development and selling and marketing capabilities than we do.

We also face competition from data analytics companies that have developed technology-based or artificial intelligence-based approaches to healthcare applications and medical devices and that currently or in the future may develop diagnostic or prognostic products focused on kidney disease.

Principal competitive factors in our market include:

- quality and strength of clinical and analytical validation data;
- proprietary access to extensively validated biomarkers for CKD;
- partnerships with healthcare systems;
- confidence in diagnostic or prognostic performance;
- technical performance and innovation to deliver products that provide clinically actionable results;
- reputation among health systems, physicians and payors as a provider of high-value diagnostic products;
- third-party reimbursement achievements;
- regulatory achievements;
- inclusion in practice guidelines;
- economic health benefits; and
- ease of use and willingness of physicians to include products as part of their routine care for patients with kidney disease.

While we believe we compete effectively based on these factors, our product is novel and market acceptance is untested at this time. Further, even if we are able to secure partnerships with additional healthcare systems, commercial and clinical acceptance rates are currently unknown. Many of our competitors and potential competitors have longer operating histories, larger customer bases, greater brand recognition and market penetration, substantially greater financial, technological and research and development resources and selling and marketing capabilities, and more experience dealing with third-party payors. As a result, they may be able to respond more quickly to changes in customer requirements, devote greater resources to the development, promotion and sale of their diagnostic tests. We may not be able to compete effectively against these organizations should they choose to enter the market for early stage kidney disease prognostics.

Our long-term strategy depends in part on our ability to improve KidneyIntelX, through versioning, to keep pace with rapid advances in artificial intelligence, technology, medicine and science. If we experience delays or challenges in creating and deploying new versions of KidneyIntelX, our operating results and competitive position could be harmed.

The diagnostics industry is characterized by rapid technological changes, scientific breakthroughs, frequent new product and service introductions and enhancements, and evolving industry standards, all of which could make KidneyIntelX obsolete. Further, the field of artificial intelligence is rapidly advancing and we must ensure that we keep pace with these changes in our technology and algorithms in order to ensure that KidneyIntelX delivers accurate and clinically relevant results.

Our future success will depend on our ability to keep pace with the evolving needs of our customers and the evolution of our industry on a timely and cost-effective basis and to pursue new market opportunities that develop as a result of scientific and technological advances. In recent years, there have been numerous advances in technologies relating to life sciences research and the diagnosis and treatment of kidney disease. There have also been advances in technologies used to computationally analyze very large amounts of biologic information. If we do not update KidneyIntelX through the creation and deployment of new versions to reflect advances in artificial intelligence, new scientific knowledge about new disease diagnostics and therapies or the diseases we seek to target, KidneyIntelX could become obsolete.

If we lose, or cannot garner, the support of key thought leaders, it may be difficult to establish KidneyIntelX as a standard of care for patients at risk for kidney disease, which may limit our revenue growth and ability to achieve profitability.

We have established relationships with key thought leaders at premier medical institutions and networks. If these key thought leaders determine that KidneyIntelX is not clinically effective, that alternative technologies and products are more effective, or if they elect to use internally developed products, we could encounter significant difficulty validating our technology platform, driving adoption, and establishing KidneyIntelX as a standard of care, which would limit our revenue growth and our ability to achieve profitability.

We may be unable to manage our future growth effectively, which could make it difficult to execute our business strategy.

We plan to grow our business operations initially in the United States. Any future growth could create strain on our organizational, administrative, and operational infrastructure, including laboratory operations, quality control, customer service, and sales force management. We may not be able to maintain the quality or expected turnaround times of our services or satisfy customer demand as it grows. Our ability to manage our growth properly will require us to continue to improve our operational, financial, and managerial controls, as well as our reporting systems and procedures.

For example, we believe we have capacity at our facilities in Utah, New York and Florida to manufacture and process sufficient KidneyIntelX tests to meet projected demand in the near-term. However, our strategy is based on a model that assumes we will be successful in entering into partnerships with healthcare systems and third-party payors, which could result in large increases in demand for KidneyIntelX tests as these new partnerships are forged. It will be critical that we carefully manage our ability to scale as we seek new partnerships. If we fail to do so effectively, we may not be able to meet the demand of the partners we engage, we may fail to produce and process tests in a timely manner or may be forced to forego growth opportunities because we failed to adequately scale our business. Any of these could have a material adverse effect on our business.

Adverse market and economic conditions may exacerbate certain risks associated with commercializing our products.

Future sales of our products will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, global pandemics and diseases or otherwise, these organizations may defer purchases, may be unable to satisfy their purchasing or reimbursement obligations, or may delay payment for any of our products.

Our business could be adversely affected by the effects of health pandemics or epidemics, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of validation study sites or other business operations.

Our business could be adversely affected by such pandemics or epidemics in regions where we have concentrations of validation study sites or other business operations, and could cause significant disruption in the operations of third parties upon whom we rely. Health pandemics or epidemics, including the COVID-19 pandemic, have in the past resulted, and could again in the future result, in quarantines, stay-at-home orders, remote work policies or other similar events that may disrupt businesses, delay our research and development programs and timelines, negatively impact productivity and increase risks associated with cybersecurity, the future magnitude of which will depend, in part, on the length and severity of the restrictions and other limitations.

Moreover, such pandemics or epidemics, such as the COVID-19 pandemic, could materially affect our operations, including at our U.S. headquarters in New York and at our validation study sites, as well as the business or operations of our partner, Mount Sinai, and other third parties with whom we conduct business. Such pandemics or epidemics have in the past resulted, and may in the future result, in the imposition of orders and policies that could negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which would depend, in part, on the length and severity of the restrictions and other limitations on our ability to conduct our business in the ordinary course. In addition, such orders or policies, such or the perception that such orders, shutdowns or other restrictions on the conduct of business operations could occur, related to COVID-19 or other infectious diseases could impact personnel at third-party manufacturing facilities in the United States and other countries, or the availability or cost of materials, which would disrupt our supply chain.

In addition, our validation studies and commercial launch plans or timelines have in the past, and may in the future, be affected by such pandemics or epidemics. For example, our key partner, Mount Sinai, is located in New York and is currently dedicating substantial resources to the fight against this pandemic, and our clinical utility study with Mount Sinai was currently delayed. Moreover, our ability to recruit and retain patients and site staff may be hindered, which would adversely affect our plans or timelines.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the effect of COVID-19 has subsided and continue to subside, the full extent to which the COVID-19 pandemic may continue to impact our business, results of operations, and financial condition will depend on future developments that are uncertain and cannot be accurately

predicted. We cannot assure you that these effects will remain reduced in the future, including due to potential new public health outbreaks. We could face further operational disruptions and incur additional expenses in connection with future public health outbreaks, including expenses associated with our health and safety protocols and processes, that could adversely affect our business and results of operations. To the extent future public health outbreaks adversely affect our business and financial results, they may also have the effect of heightening many of the other risks described in this "Risk Factors" section.

The loss or transition of any of our executive officers or our inability to attract and retain highly skilled scientists, clinicians, and salespeople could adversely affect our business.

Our success depends on the skills, experience, and performance of key members of our executive team. The individual and collective efforts of these individuals will be important as we continue to develop our artificial intelligence technology, develop and seek regulatory clearance for our products and prepare for commercialization. The loss or incapacity of key members of our executive team could adversely affect our operations if we experience difficulties in hiring qualified successors.

Our research and development programs and laboratory operations depend on our ability to attract and retain highly skilled scientists and technicians. We may not be able to attract or retain qualified scientists and technicians in the future due to the intense competition for qualified personnel among life science businesses. We also face competition from universities and public and private research institutions in recruiting and retaining highly qualified scientific personnel. We may have difficulties locating, recruiting, or retaining qualified sales people. Recruitment and retention difficulties can limit our ability to support our research and development and sales programs, which could in turn have an adverse effect on our business, financial condition and results of operations.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

As we mature, we expect to expand our full-time employee base and to hire more scientists and technicians. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time toward managing these growth activities. We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure, operational mistakes, loss of business opportunities, loss of employees and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional products or technologies. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenues could be reduced, and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize products and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our future growth depends, in part, on our ability to penetrate international markets, where we would be subject to additional regulatory burdens and other risks and uncertainties.

Our future profitability will depend on our ability to commercialize our products in the United States, United Kingdom, the European Union and other territories around the world. If we commercialize our products in international markets, we would be subject to additional risks and uncertainties, including:

- economic weakness, including inflation, or political instability in particular economies and markets;
- the burden of complying with complex and changing non-U.S. regulatory, tax, accounting and legal requirements, many of which vary between countries;
- different medical practices and customs in non-U.S. countries affecting acceptance in the marketplace;
- tariffs and trade barriers;
- other trade protection measures, import or export licensing requirements or other restrictive actions by U.S. or other governments;
- longer accounts receivable collection times;
- longer lead times for shipping;
- compliance with tax, employment, immigration and labor laws for employees living or traveling abroad;
- workforce uncertainty in countries where labor unrest is common;
- language barriers for technical training;

- reduced protection of intellectual property rights in some countries outside the United States, and related prevalence of generic alternatives to therapeutics;
- foreign currency exchange rate fluctuations and currency controls;
- differing reimbursement landscapes globally;
- uncertain and potentially inadequate reimbursement of our products;
- natural disasters, political and economic instability, including wars, terrorism and political unrest, outbreak of disease, boycotts, curtailment of trade and other business restrictions; and
- the interpretation of contractual provisions governed by laws outside the United States in the event of a contract dispute.

Sales of our products outside the United States could also be adversely affected by the imposition of governmental controls, political and economic instability, trade restrictions and changes in tariffs.

If we were sued for product liability or professional liability, we could face substantial liabilities that exceed our resources.

The marketing, sale, and use of our products could lead to the filing of product liability claims were someone to allege that our diagnostic tests identified inaccurate or incomplete information regarding the risk or likely severity of the patient's kidney disease, the risk of rejection of a patient's kidney transplant, or otherwise failed to perform as designed. We may also be subject to liability for errors in, a misunderstanding of, or inappropriate reliance upon the information we provide in the ordinary course of our business activities. A product liability or professional liability claim could result in substantial damages and be costly and time-consuming for us to defend.

We maintain product and professional liability insurance, but this insurance may not fully protect us from the financial impact of defending against product liability or professional liability claims. Any product liability or professional liability claim brought against us, with or without merit, could increase our insurance rates or prevent us from securing insurance coverage in the future. Additionally, any product liability lawsuit could damage our reputation or cause current partners to terminate existing agreements and potential partners to seek other partners, any of which could impact our results of operations.

If our information technology systems or data, or those of third parties upon which we rely, are or were compromised, we could experience adverse consequences resulting from such compromise, including but not limited to regulatory investigations or actions; litigation; fines and penalties; disruptions of our business operations; reputational harm; loss of revenue or profits; and other adverse consequences.

In the ordinary course of our business, we and the third parties upon which we rely process sensitive data, and, as a result, we and the third parties upon which we rely face a variety of evolving threats, including but not limited to ransomware attacks, which could cause security incidents. Cyber-attacks, malicious internet-based activity, online and offline fraud, and other similar activities threaten the confidentiality, integrity, and availability of our sensitive data and information technology systems, and those of the third parties upon which we rely. Such threats are prevalent and continue to rise, are increasingly difficult to detect, and come from a variety of sources, including traditional computer "hackers," threat actors, "hacktivists," organized criminal threat actors, personnel (such as through theft or misuse), sophisticated nation states, and nation-state-supported actors.

Some actors now engage and are expected to continue to engage in cyber-attacks, including without limitation nation-state actors for geopolitical reasons and in conjunction with military conflicts and defense activities. During times of war and other major conflicts, we and the third parties upon which we rely, may be vulnerable to a heightened risk of these attacks, including retaliatory cyber-attacks, that could materially disrupt our systems and operations, supply chain, and ability to produce, sell and distribute our services. Further, the loss of clinical trial data from completed or ongoing clinical trials could result in delays in, or cancellations of any regulatory approval or clearance efforts and significantly increase our costs to recover or reproduce the data, and subsequently commercialize the product. Additionally, theft of our intellectual property or proprietary business information could require substantial expenditures to remedy.

We and the third parties upon which we rely are subject to a variety of evolving threats, including but not limited to social-engineering attacks (including through deep fakes, which may be increasingly more difficult to identify as fake, and phishing attacks), malicious code (such as viruses and worms), malware (including as a result of advanced persistent threat intrusions), denial-of-service attacks (such as credential stuffing), credential harvesting, personnel misconduct or error, ransomware attacks, supply-chain attacks, software bugs, server malfunctions, software or hardware failures, loss of data or other information technology assets, adware, telecommunications failures, earthquakes, fires, floods, and other similar threats.

In particular, severe ransomware attacks are becoming increasingly prevalent and can lead to significant interruptions in our operations, loss of sensitive data and income, reputational harm, and diversion of funds. Extortion payments may alleviate the negative impact of a ransomware attack, but we may be unwilling or unable to make such payments due to, for example, applicable laws or regulations prohibiting such payments.

Remote work has become more common and has increased risks to our information technology systems and data, as more of our employees utilize network connections, computers, and devices outside our premises or network, including working at home, while in transit and in public locations. Additionally, future or past business transactions (such as acquisitions or integrations) could expose us to additional cybersecurity risks and vulnerabilities, as our systems could be negatively affected by vulnerabilities present in acquired or integrated entities' systems and technologies. Furthermore, we may discover security issues that were not found during due diligence of such acquired or integrated entities, and it may be difficult to integrate companies into our information technology environment and security program.

In addition, our reliance on third-party service providers could introduce new cybersecurity risks and vulnerabilities, including supply-chain attacks, and other threats to our business operations. We rely on third-party service providers and technologies to operate critical business systems to process sensitive data in a variety of contexts, including, without limitation, cloud-based infrastructure, data center facilities, encryption and authentication technology, employee email, content delivery to customers, and other functions. We also rely on third-party service providers to provide other products, services, parts, or otherwise to operate our business. Our ability to monitor these third parties' information security practices is limited, and these third parties may not have adequate information security measures in place. If our third-party service providers experience a security incident or other interruption, we could experience adverse consequences. While we may be entitled to damages if our third-party service providers fail to satisfy their privacy or security-related obligations to us, any award may be insufficient to cover our damages, or we may be unable to recover such award. In addition, supply-chain attacks have increased in frequency and severity, and we cannot guarantee that third parties' infrastructure in our supply chain or our third-party partners' supply chains have not been compromised.

Any of the previously identified or similar threats could cause a security incident or other interruption that could result in unauthorized, unlawful, or accidental acquisition, modification, destruction, loss, alteration, encryption, disclosure of, or access to our sensitive data or our information technology systems, or those of the third parties upon whom we rely. A security incident or other interruption could disrupt our ability (and that of third parties upon whom we rely) to provide our services.

We may expend significant resources or modify our business activities to try to protect against security incidents. Additionally, certain data privacy and security obligations may require us to implement and maintain specific security measures or industry-standard or reasonable security measures to protect our information technology systems and sensitive data.

While we have implemented security measures designed to protect against security incidents, there can be no assurance that these measures will be effective. We take steps to detect and remediate vulnerabilities, but we may not be able to detect and remediate all vulnerabilities because the threats and techniques used to exploit the vulnerability change frequently and are often sophisticated in nature. Therefore, such vulnerabilities could be exploited but may not be detected until after a security incident has occurred. These vulnerabilities pose material risks to our business. Further, we may experience delays in developing and deploying remedial measures designed to address any such identified vulnerabilities.

Applicable data privacy and security obligations may require us to notify relevant stakeholders of security incidents. Such disclosures are costly, and the disclosure or the failure to comply with such requirements could lead to adverse consequences.

If we (or a third party upon whom we rely) experience a security incident or are perceived to have experienced a security incident, we may experience adverse consequences, such as government enforcement actions (for example, investigations, fines, penalties, audits, and inspections); additional reporting requirements and/or oversight; restrictions on processing sensitive data (including personal data); litigation (including class claims); indemnification obligations; negative publicity; reputational harm; monetary fund diversions; interruptions in our operations (including availability of data); financial loss; and other similar harms. Security incidents and attendant consequences may cause customers to stop using our services, deter new customers from using our services, and negatively impact our ability to grow and operate our business. Likewise, we rely on third parties to conduct clinical trials, and similar incidents relating to their information technology systems or data could also have a material adverse effect on our business.

Our contracts may not contain limitations of liability, and even where they do, there can be no assurance that limitations of liability in our contracts are sufficient to protect us from liabilities, damages, or claims related to our data privacy and security obligations. We cannot be sure that our insurance coverage will be adequate or sufficient to protect us from or to mitigate liabilities arising out of our privacy and security practices, that such coverage will continue to be available on commercially reasonable terms or at all, or that such coverage will pay future claims.

In addition to experiencing a security incident, third parties may gather, collect, or infer sensitive information about us from public sources, data brokers, or other means that reveals competitively sensitive details about our organization and could be used to undermine our competitive advantage or market position.

Furthermore, any sensitive information (including confidential, competitive, proprietary, or personal data) that we input into a third-party generative AI/ML platform could be leaked or disclosed to others, including if sensitive information is used to train the third parties' AI/ML model. Additionally, where an AI/ML model ingests personal data and makes connections using such data, those technologies may reveal other personal or sensitive information generated by the model. Moreover, AI/ML models may create flawed, incomplete, or inaccurate outputs, some of which may appear correct. This may happen if the inputs that the model relied on were inaccurate, incomplete or flawed (including if a bad actor "poisons" the AI/ML with bad inputs or logic), or if the logic of the AI/ML is flawed (a so-called "hallucination"). We may use AI/ML outputs to make certain decisions. Due to these potential inaccuracies or flaws, the model could be biased and could lead us to make decisions that could bias certain individuals (or classes of individuals), and adversely impact their rights, employment, and ability to obtain certain pricing, products, services, or benefits, including exposure to reputational and competitive harm, customer loss, and legal liability.

Changes in U.S. tax law could adversely affect our business and could differ materially from the financial statements provided herein.

The rules dealing with U.S. federal, state and local income taxation are constantly under review by the Internal Revenue Service, the U.S. Treasury Department and other governmental bodies. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our ADSs or ordinary shares. In recent years, many such changes have been made and changes are likely to continue to occur in the future. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implication of potential changes in tax laws on an investment in our ADSs or ordinary shares.

Our ability to use our U.S. net operating loss carryforwards and certain other U.S. tax attributes may be limited.

As of June 30, 2023, we had U.S. federal net operating loss carryforwards of approximately $98.6 million and U.S. state and local net operating loss carryforwards of approximately $177.3 million due to prior period losses. Under the Tax Cuts and Jobs Act of 2017 as modified by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, (collectively, the "Tax Acts"), U.S. federal net operating losses incurred in taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited to 80% of our taxable income in taxable years beginning after December 31, 2020. It is uncertain if and to what extent various states will conform to the Tax Acts. In addition, under Sections 382 and 383 of the U.S. Internal Revenue Code of 1986, as amended, (the "Code"), if a corporation undergoes an "ownership change" (generally defined as a greater than 50 percentage-point cumulative change (by value) in the equity ownership of certain shareholders over a rolling three-year period), the corporation's ability to use its pre-change net operating losses and other pre-change tax attributes to offset its post-change taxable income or taxes may be limited. We have not completed an analysis to determine whether any such limitations have been already triggered. We may also experience ownership changes as a result of shifts in our share ownership, some of which are outside our control. Therefore, as a result of ownership changes with respect to our ordinary shares, our ability to use our current net operating losses and other pre-change tax attributes to offset post-change taxable income or taxes could be subject to limitation. We will be unable to use our net operating losses if we do not attain profitability sufficient to offset our available net operating losses prior to their expiration.

We may be unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefit from favorable U.K. tax legislation.

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception. As of June 30, 2023, we had cumulative carryforward tax losses of approximately $26.6 million in the UK. Subject to any relevant utilization criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half the ordinary shares of the company and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits.

As a company that carries out extensive research and development ("R&D") activities, we seek to benefit from the U.K. R&D tax relief programs, being the Small and Medium-sized Enterprises R&D tax relief program (the "SME Program"), and, for certain specific categories of expenditure, the Research and Development Expenditure Credit program (the "RDEC Program"). The SME Program may be particularly beneficial to us, as under such program the trading losses that arise from our qualifying R&D activities can be surrendered for a cash rebate of up to 33.35% of qualifying R&D expenditure incurred prior to April 1, 2023, and up to 18.6% of qualifying expenditure incurred thereafter (unless we qualify as an "R&D-intensive SME" for an accounting period (broadly, a loss making SME whose qualifying R&D expenditure for an accounting period represents 40% or more of its total expenditure for that

accounting period), in which case the cash rebate that may be claimed will be 26.97% of qualifying expenditure). Further, amendments to the U.K. R&D tax credit regime have been proposed that may (unless limited exceptions apply) introduce restrictions on the tax relief that can be claimed for expenditure incurred on sub-contracted R&D activities or externally provided workers, where such sub-contracted activities are not carried out in the U.K. or such workers are not subject to U.K. payroll taxes. These amendments are expected to take effect from April 1, 2024. In addition, the U.K. Government is currently considering a proposal to merge the SME Program and the RDEC Program into a single scheme with effect from April 2024; if such proposal is implemented in the manner provided in recently-published draft legislation, and we do not qualify as an R&D-intensive SME, we will either cease to be able to claim cash rebates in respect of our R&D activities, or only be able to receive such cash rebates at a significantly lower rate than at present. These and other potential future changes to the U.K. R&D tax relief programs may mean we no longer qualify or have a material impact on the extent to which we can make claims or benefit from them.

We may benefit in the future from the United Kingdom's "patent box" regime, which allows certain profits attributable to revenues from patented products (and other qualifying income) to be taxed at an effective rate of 10% by giving an additional tax deduction. We are the exclusive licensee or owner of one patent and several patent applications which, if issued, would cover our product candidates, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be eligible for this deduction. When taken in combination with the enhanced relief available on our R&D expenditures, we expect a long-term rate of corporation tax lower than the statutory rate to apply to us. If, however, there are unexpected adverse changes to the U.K. R&D tax relief programs or the "patent box" regime, or for any reason we are unable to qualify for such advantageous tax legislation, or we are unable to use net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments then our business, results of operations and financial condition may be adversely affected. This may impact our ongoing requirement for investment and the time frames within which additional investment is required.

Future changes to tax laws could materially adversely affect our company and reduce net returns to our shareholders.

The tax treatment of the company is, and our ADSs and ordinary shares are, subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organization for Economic Co-Operation and Development's, (the "OECD"), Base Erosion and Profit Shifting ("BEPS"), Project, the European Commission's state aid investigations and other initiatives. Such changes may include (but are not limited to) the taxation of operating income, investment income, dividends received or (in the specific context of withholding tax) dividends paid, or the stamp duty or stamp duty reserve tax treatment of our ADSs or ordinary shares. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

Tax authorities may disagree with our positions and conclusions regarding certain tax positions, or may apply existing rules in an unforeseen manner, resulting in unanticipated costs, taxes or non-realization of expected benefits.

A tax authority may disagree with tax positions that we have taken, which could result in increased tax liabilities. For example, His Majesty's Revenue & Customs, ("HMRC"), the U.S. Internal Revenue Service or another tax authority could challenge our allocation of income by tax jurisdiction and the amounts paid between our affiliated companies pursuant to our intercompany arrangements and transfer pricing policies, including amounts paid with respect to our intellectual property development. Similarly, a tax authority could assert that we are subject to tax in a jurisdiction where we believe we have not established a taxable connection, often referred to as a ‘‘permanent establishment’’ under international tax treaties, and such an assertion, if successful, could increase our expected tax liability in one or more jurisdictions.

A tax authority could also disagree with our analysis of the tax treatment of the FractalDx spin-off, for ourselves and/or for our shareholders. A tax authority may take the position that material tax liabilities, interest and penalties are payable by us, in which case we expect that we might contest such assessment. Contesting such an assessment may be lengthy and costly and if we were unsuccessful in disputing the assessment, the implications could increase our anticipated effective tax rate, where applicable, or result in other liabilities.

Risks Related to Our Intellectual Property

If we are unable to obtain and maintain sufficient patent protection for our products, or if the scope of the patent protection is not sufficiently broad, our competitors could develop and commercialize products similar or identical to ours, and our ability to commercialize our products successfully may be adversely affected.

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary products. If we do not adequately protect our intellectual property, competitors may be able to erode or

negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel products that are important to our business. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

Our ability to obtain patent protection for our products is uncertain due to a number of factors, including:

- we may not have been the first to make the inventions covered by pending patent applications or issued patents;
- we may not have been the first to file patent applications for our products or the compositions we developed or for their uses;
- others may independently develop identical, similar or alternative products or compositions and uses thereof;
- our disclosures in patent applications may not be sufficient to meet the statutory requirements for patentability;
- any or all of our pending patent applications may not result in issued patents;
- we may not seek or obtain patent protection in countries that may eventually provide us a significant business opportunity;
- any patents issued to us may not provide a basis for commercially viable products, may not provide any competitive advantages, or may be successfully challenged by third parties;
- our compositions and methods may not be patentable;
- others may design around our patent claims to produce competitive products which fall outside of the scope of our patents; or
- others may identify prior art or other bases which could invalidate our patents.

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until patent issues from such applications. Because the issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, (the "USPTO"), or become involved in post-grant review procedures, oppositions, derivations, reexaminations, *inter partes* review or interference proceedings, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse determination in any such challenges may result in loss of exclusivity or in patent claims being narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to stop others from using or commercializing similar or identical technology and products, or limit the duration of the patent protection of our technology and products. In addition, given the amount of time required for the development, testing and regulatory review of new products, patents protecting such products might expire before or shortly after such products are commercialized.

Obtaining and maintaining a patent portfolio entails significant expense and resources. Part of the expense includes periodic maintenance fees, renewal fees, annuity fees, various other governmental fees on patents and/or applications due in several stages over the lifetime of patents and/or applications, as well as the cost associated with complying with numerous procedural provisions during the patent application process. We may not choose to pursue or maintain protection for particular inventions. In addition, there are situations in which failure to make certain payments or noncompliance with certain requirements in the patent process can result in abandonment or lapse of a patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we choose to forgo patent protection or allow a patent application or patent to lapse purposefully or inadvertently, our competitive position could suffer.

Even if our patent applications issue as patents, they may not issue in a form that will provide us with any meaningful protection, prevent competitors from competing with us or otherwise provide us with any competitive advantage. Our competitors may be able to circumvent our patents by developing similar or alternative technologies or products in a non-infringing manner. Our competitors may also seek approval to market their own products similar to or otherwise competitive with our products. In these circumstances, we may need to defend or assert our patents, or both, including by filing lawsuits alleging patent infringement. In any of these types of proceedings, a court or other agency with jurisdiction may find our patents invalid or unenforceable, or that our competitors are competing in a non-infringing manner. Thus, even if we have valid and enforceable patents, these patents still may not provide protection against competing products or processes sufficient to achieve our business objectives.

Legal actions to enforce our patent rights can be expensive and may involve the diversion of significant management time. In addition, these legal actions could be unsuccessful and could also result in the invalidation of our patents or a finding that they are unenforceable. We may or may not choose to pursue litigation or other actions against those that have infringed or are currently

infringing our patent rights, or used them without authorization, due to the associated expense and time commitment of monitoring these activities. If we fail to protect or to enforce our intellectual property rights successfully, our competitive position could suffer, which could harm our results of operations.

Even if we have or obtain patents covering our products or compositions, we may still be prevented from making, using, selling, offering for sale, or importing our products or technologies because of the patent rights of others. Others may have filed, and in the future may file, patent applications covering compositions or products that are similar or identical to ours. These filings could materially affect our ability to develop or sell our products. Because patent applications can take many years to issue and are not published for a period of time after filing, there may be currently pending applications unknown to us that may later result in issued patents that our products or compositions may infringe. These patent applications may have priority over patent applications filed by us.

We may become involved in lawsuits to protect or enforce our patents or other intellectual property, which could be expensive, time consuming and unsuccessful and issued patents covering our products could be found invalid or unenforceable if challenged in court.

If we initiate legal proceedings against a third party to enforce a patent covering one of our products or technologies, the defendant could counterclaim that the patent covering one of our products or technologies is invalid or unenforceable. In patent litigation in the United States, defendant counterclaims alleging invalidity and unenforceability of an asserted patent or patents are commonplace. Grounds for a validity challenge include alleged failures to meet any of several statutory requirements, including lack of novelty, obviousness, written description or non-enablement. Grounds for unenforceability assertions include allegations that someone connected with prosecution of the patent withheld relevant information from the USPTO, or made a misleading statement, during prosecution. Third parties may also raise similar claims before administrative bodies in the United States or abroad, even outside the context of litigation. Such mechanisms include re-examination, post- grant review and/or *inter partes* review and equivalent proceedings in foreign jurisdictions, such as, opposition proceedings. Such proceedings could result in revocation or amendment of our patents in such a way that they no longer cover our products or competitive products. Similarly, we may initiate proceedings before the Patent Trial and Appeal Board (the "PTAB") of the USPTO, such as post grant review ("PGR"), derivation, or *inter partes* review, against patents granted to third parties.

Even if we establish infringement, the court may decide not to grant an injunction against further infringing activity and instead award only monetary damages, which may or may not be an adequate remedy. Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation in the United States, there is a risk that some of our confidential information could be compromised by disclosure during litigation. There could also be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a material adverse effect on the price of our ADSs or ordinary shares. Moreover, there can be no assurance that we will have sufficient financial or other resources to file and pursue such infringement claims in the federal courts, which typically last for years before they are concluded. Even if we ultimately prevail in such claims, the monetary cost of such litigation and the diversion of the attention of our management and scientific personnel could outweigh any benefit we receive as a result of the proceedings.

Diagnostic patents and patent applications involve highly complex legal and factual questions, which, if determined adversely to us, could negatively impact our patent position.

The patent positions of diagnostic companies can be highly uncertain and involve complex legal and factual questions. The interpretation and breadth of claims allowed in some patents covering our diagnostic products may be uncertain and difficult to determine, and are often affected materially by the facts and circumstances that pertain to the patented compositions and the related patent claims. The standards of the USPTO are evolving and could change in the future. Consequently, we cannot predict the issuance and scope of patents with certainty. Patents, if issued, may be challenged, invalidated or circumvented. U.S. patents and patent applications may also be subject to derivation or interference proceedings, and U.S. patents may be subject to reexamination proceedings, post-grant review and/or *inter partes* review in the USPTO. Foreign patents may be subject also to opposition or comparable proceedings in the corresponding foreign patent office, which could result in either loss of the patent or denial of the patent application or loss or reduction in the scope of one or more of the claims of the patent or patent application. In addition, such interference, reexamination, post-grant review, *inter partes* review and opposition proceedings may be costly. Accordingly, rights under any issued patents may not provide us with sufficient protection against competitive products or processes.

In addition, changes in or different interpretations of patent laws in the United States and foreign countries may permit others to use our discoveries or to develop and commercialize our technology and products without providing any compensation to us, or may limit the number of patents or claims we can obtain. The laws of some countries do not protect intellectual property rights to the same extent as U.S. laws and those countries may lack adequate rules and procedures for defending our intellectual property rights.

If we fail to obtain and maintain patent protection and trade secret protection for our products, we could lose our competitive advantage and competition we face would increase, reducing any potential revenues and adversely affecting our ability to attain or maintain profitability.

If we are sued for infringing intellectual property rights of third parties, such litigation could be costly and time consuming and could prevent or delay us from developing or commercializing our products.

Our commercial success depends, in part, on our ability to develop, manufacture, market and sell our products and use our technologies without infringing the intellectual property and other proprietary rights of third parties. If any third-party patents or patent applications are found to cover our products or their methods of use, we may not be free to manufacture or market our products as planned without obtaining a license, which may not be available on commercially reasonable terms, or at all.

There is a substantial amount of intellectual property litigation in the biotechnology and pharmaceutical diagnostic industries, and we may become party to, or threatened with, litigation or other adversarial proceedings regarding intellectual property rights with respect to our products, including interference proceedings before the USPTO. Third parties may assert infringement claims against us based on existing or future intellectual property rights. The outcome of intellectual property litigation is subject to uncertainties that cannot be adequately quantified in advance. The biotechnology and pharmaceutical diagnostic industries have produced a significant number of patents, and it may not always be clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we were sued for patent infringement, we would need to demonstrate that our products or methods either do not infringe the patent claims of the relevant patent or that the patent claims are invalid or unenforceable, and we may not be able to do this. Proving invalidity is difficult. For example, in the United States, proving invalidity requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents. Even if we are successful in these proceedings, we may incur substantial costs and the time and attention of our management and scientific personnel could be diverted in pursuing these proceedings, which could significantly harm our business and operating results. In addition, we may not have sufficient resources to bring these actions to a successful conclusion.

If we are found to infringe a third party's intellectual property rights, we could be forced, including by court order, to cease developing, manufacturing or commercializing the infringing product. Alternatively, we may be required to obtain a license from such third party in order to use the infringing technology and continue developing, manufacturing or marketing the infringing product. However, we may not be able to obtain any required license on commercially reasonable terms or at all. Even if we were able to obtain a license, it could be non-exclusive, thereby giving our competitors access to the same technologies licensed to us. In addition, we could, in certain circumstances, be found liable for monetary damages, including treble damages and attorneys' fees if we are found to have willfully infringed a patent. A finding of infringement could prevent us from commercializing our products or force us to cease some of our business operations, which could materially harm our business. Claims may also be made that we have misappropriated the confidential information or trade secrets of third parties could have a similar negative impact on our business.

Developments in patent law in the United States and in other jurisdictions could have a negative impact on our business.

From time to time, the U.S. Supreme Court, other federal courts, the U.S. Congress, the USPTO or similar foreign authorities may change the standards of patentability and any such changes could have a negative impact on our business. In addition, the Leahy-Smith America Invents Act (the "America Invents Act"), which was signed into law in 2011, includes a number of significant changes to U.S. patent law. These changes include a transition from a "first-to-invent" system to a "first-to-file" system, changes to the way issued patents are challenged, and changes to the way patent applications are disputed during the examination process. In certain areas, these changes may favor larger and more established companies that have greater resources to devote to patent application filing and prosecution. The USPTO has developed new regulations and procedures to govern the full implementation of the America Invents Act, and many of the substantive changes to patent law associated with the America Invents Act, and, in particular, the first-to-file provisions, became effective on March 16, 2013. Substantive changes to patent law associated with the America Invents Act, or any subsequent U.S. legislation regarding patents, may affect our ability to obtain patents, and if obtained, to enforce or defend them.

Furthermore, recent U.S. Supreme Court rulings have narrowed the scope of patent protection available in certain circumstances for diagnostic method claims and "gene patents" (see, two landmark Supreme Court cases, *Mayo Collaborative v. Prometheus Laboratories* ("Prometheus"), and *Association for Molecular Pathology v. Myriad Genetics* ("Myriad")).

In view of the Supreme Court decisions in Prometheus, Myriad, and *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, as well as other federal appellate cases, we cannot guarantee that our efforts to seek patent protection for our tools and biomarkers will be successful.

If we are unable to protect the confidentiality of our trade secrets, our business and competitive position would be harmed.

In addition to patent protection, because we operate in the highly technical field of molecular diagnostics, we rely in part on trade secret protection in order to protect our proprietary technology and processes. However, trade secrets are difficult to protect. We have entered into confidentiality and intellectual property assignment agreements with our employees, consultants, outside scientific collaborators, sponsored researchers, and other advisors. These agreements generally require that the other party keep confidential and not disclose to third parties all confidential information developed by the party or made known to the party by us during the course of the party's relationship with us. These agreements also generally provide that inventions conceived by the party in the course of rendering services to us will be our exclusively licensed property. However, these agreements may not be honored and may not effectively license intellectual property rights to us.

In addition to contractual measures, we try to protect the confidential nature of our proprietary information using physical and technological security measures. Such measures may not, for example, in the case of misappropriation of a trade secret by an employee or third party with authorized access, provide adequate protection for our proprietary information. Our security measures may not prevent an employee or consultant from misappropriating our trade secrets and providing them to a competitor, and recourse we take against such misconduct may not provide an adequate remedy to protect our interests fully. Enforcing a claim that a party illegally disclosed or misappropriated a trade secret can be difficult, expensive, and time-consuming, and the outcome is unpredictable. In addition, courts outside the United States may be less willing to protect trade secrets. Trade secrets may be independently developed by others in a manner that could prevent legal recourse by us. If any of our confidential or proprietary information, such as our trade secrets, were to be disclosed or misappropriated, or if any such information was independently developed by a competitor, our competitive position could be harmed.

We will not seek to protect our intellectual property rights in all jurisdictions throughout the world and we may not be able to adequately enforce our intellectual property rights even in the jurisdictions where we seek protection.

Filing, prosecuting and defending patents on our products in all countries and jurisdictions throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States and Europe could be less extensive than those in the United States and Europe, assuming that patent rights are obtained in the United States. Competitors may use our technologies in jurisdictions where we do not pursue and obtain patent protection to develop their own products and further, may export otherwise infringing products to territories where we have patent protection, but enforcement is not as strong as that in the United States and Europe. These products may compete with our products and our patents or other intellectual property rights may not be effective or sufficient to prevent them from competing. Even if we pursue and obtain issued patents in particular jurisdictions, our patent claims or other intellectual property rights may not be effective or sufficient to prevent third parties from so competing.

In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as the federal and state laws in the United States. Many companies have encountered significant problems in protecting and defending intellectual property rights in certain foreign jurisdictions. The legal systems of some countries, particularly in developing countries, do not favor the enforcement of patents and other intellectual property protection, especially those relating to biotechnology or biopharmaceutical diagnostics. This could make it difficult for us to stop the infringement of our patents, if obtained, or the misappropriation of our other intellectual property rights. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties for certain products. In addition, many countries limit the enforceability of patents against third parties, including government agencies or government contractors. In these countries, patents may provide limited or no benefit. Patent protection must ultimately be sought on a country-by-country basis, which is an expensive and time-consuming process with uncertain outcomes. Accordingly, we may choose not to seek patent protection in certain countries, and we will not have the benefit of patent protection in such countries.

Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly, could put our patent applications at risk of not issuing and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. In addition, changes in the law and legal decisions by courts in the United States and foreign countries may affect our ability to obtain adequate protection for our technology and the enforcement of intellectual property. Accordingly, our efforts to enforce our intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

Third parties may assert ownership or commercial rights to inventions we develop.

Third parties may in the future make claims challenging the inventorship or ownership of our intellectual property. We have written agreements with collaborators that provide for the ownership of intellectual property arising from our collaborations. These agreements provide that we must negotiate certain commercial rights with collaborators with respect to joint inventions or inventions made by our collaborators that arise from the results of the collaboration. In some instances, there may not be adequate written

provisions to address clearly the resolution of intellectual property rights that may arise from collaboration. If we cannot successfully negotiate sufficient ownership and commercial rights to the inventions that result from our use of a third-party collaborator's materials where required, or if disputes otherwise arise with respect to the intellectual property developed with the use of a collaborator's samples, we may be limited in our ability to capitalize on the market potential of these inventions. In addition, we may face claims by third parties that our agreements with employees, contractors, or consultants obligating them to assign intellectual property to us are ineffective, or in conflict with prior or competing contractual obligations of assignment, which could result in ownership disputes regarding intellectual property we have developed or will develop and interfere with our ability to capture the commercial value of such inventions. Litigation may be necessary to resolve an ownership dispute, and if we are not successful, we may be precluded from using certain intellectual property, or may lose our exclusive rights in that intellectual property. Either outcome could have an adverse impact on our business.

Third parties may assert that our employees or consultants have wrongfully used or disclosed confidential information or misappropriated trade secrets.

We employ individuals who were previously employed at universities or other biotechnology or diagnostics companies, including our competitors or potential competitors. Although we try to ensure that our employees and consultants do not use the proprietary information or know-how of others in their work for us, and no such claims against us are currently pending, we may be subject to claims that we or our employees, consultants or independent contractors have used or disclosed intellectual property, including trade secrets or other proprietary information, of a former employer or other third parties. Litigation may be necessary to defend against these claims. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights or personnel. Even if we are successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

A dispute concerning the infringement or misappropriation of our proprietary rights or the proprietary rights of others could be time-consuming and costly, and an unfavorable outcome could harm our business.

There is significant litigation in the biopharmaceutical and diagnostics industry regarding patent and other intellectual property rights. While we are not currently subject to any pending intellectual property litigation, and are not aware of any such threatened litigation, we may be exposed to future litigation by third parties based on claims that our products, technologies or activities infringe the intellectual property rights of others. If our development activities are found to infringe any such patents, we may have to pay significant damages or seek licenses to such patents. A patentee could prevent us from using the patented diagnostic. We may need to resort to litigation to enforce a patent issued to us, to protect our trade secrets, or to determine the scope and validity of third-party proprietary rights. From time to time, we may hire scientific personnel or consultants formerly employed by other companies involved in one or more areas similar to the activities conducted by us. Either we or these individuals may be subject to allegations of trade secret misappropriation or other similar claims as a result of prior affiliations. If we become involved in litigation, it could consume a substantial portion of our managerial and financial resources, regardless of whether we win or lose. We may not be able to afford the costs of litigation. Any adverse ruling or perception of an adverse ruling in defending ourselves against these claims could have a negative impact on our cash position. Any legal action against us or our collaborators could lead to:

- payment of damages, potentially treble damages, if we are found to have willfully infringed a party's patent rights;
- injunctive or other equitable relief that may effectively block our ability to further develop, commercialize, and sell products; or
- us having to enter into license arrangements that may not be available on commercially acceptable terms, if at all.

Any of these outcomes could hurt our cash position and financial condition and our ability to develop and commercialize our products.

If our trademarks and trade names are not adequately protected, we may not be able to build name recognition in our markets of interest.

Our registered or unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we will need to build name recognition by potential partners or customers in our markets of interest. Over the long term, if we are unable to establish name recognition based on our trademarks and trade names, we may not be able to compete effectively.

Risks Related to Ownership of Our ADSs and Ordinary Shares and Our Status as a U.S. Listed Company

The trading price of our ADSs and our ordinary shares may be volatile, and you could lose all or part of your investment.

The trading price of our ADSs and our ordinary shares has fluctuated, and is likely to continue to fluctuate, substantially in response to various factors, some of which are beyond our control, including limited trading volume. The stock market in general, and the market for diagnostics companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of these companies. As a result of this volatility, investors may not be able to sell their ADSs or ordinary shares at or above the price paid for the ADSs or ordinary shares, respectively. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report, these factors include:

- the volume and timing of sales of KidneyIntelX;
- an inability to obtain additional financing and our ability to continue as a going concern;
- the commencement or results of our planned and future clinical utility and other studies;
- positive or negative results from, or delays in, testing and utility studies by us, collaborators or competitors;
- the loss of any of our key scientific or management personnel;
- regulatory or legal developments in the United States, the United Kingdom, the European Union and other countries;
- the success of competitive products or technologies;
- adverse actions taken by regulatory agencies with respect to our products or delays in the regulatory process;
- changes or developments in laws or regulations applicable to our products and commercialization strategy;
- changes to our relationships with health system partners, manufacturers or suppliers;
- announcements concerning our competitors or the diagnostics industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the results of our efforts to discover, develop, acquire or in-license additional intellectual property or technologies;
- the trading volume of our ADSs on Nasdaq and the trading volume of our ordinary shares on AIM;
- sales of our ADSs or ordinary shares by us, our executive officers and directors or our large shareholders or the anticipation that such sales may occur in the future;
- general economic, political, and market conditions and overall fluctuations in the financial markets in the United States, the United Kingdom, the European Union and other countries;
- stock market price and volume fluctuations of comparable companies and, in particular, those that operate in the diagnostics industry sector;
- investors' general perception of us and our business; and
- other events and factors, many of which are beyond our control.

These and other market and industry factors may cause the market price and demand for our ADSs and ordinary shares to fluctuate substantially, regardless of our actual operating performance, which may limit or prevent investors from selling their ADSs or ordinary shares at or above the price paid for the ADSs or ordinary shares, respectively, and may otherwise negatively affect the liquidity of our ADSs and our ordinary shares.

Some companies that have experienced volatility in the trading price of their shares have been the subject of securities class action litigation. Any lawsuit to which we are a party, with or without merit, may result in an unfavorable judgment. We also may decide to settle lawsuits on unfavorable terms.

Any such negative outcome could result in payments of substantial damages or fines, damage to our reputation or adverse changes to our business practices. Defending against litigation is costly and time-consuming, and could divert our management's attention and our resources. Furthermore, during the course of litigation, there could be negative public announcements of the results of hearings, motions or other interim proceedings or developments, which could have a negative effect on the market price of our ADSs and our ordinary shares.

The sale of a substantial number of our total outstanding ADSs or ordinary shares could cause the market price of our ADSs and ordinary shares to drop significantly, even if our business is doing well.

Sales of a substantial number of our ordinary shares or ADSs in the public market could occur at any time. If our shareholders sell, or the market perceives that our shareholders intend to sell, substantial amounts of our ordinary shares or ADSs in the public market, the market price of our ADSs and ordinary shares could decline significantly.

We had 93,781,478 ordinary shares outstanding as of June 30, 2023. Sales of a substantial number of such ADSs or ordinary shares or the perception that such sales may occur could cause the market price of our ADSs and/or ordinary shares to fall or make it more difficult for purchasers of ADSs to sell their ADSs at a time and price that they deem appropriate.

In addition, we have filed a registration statement on Form S-8 (File No. 333-248741) registering the issuance of an aggregate of 12,378,858 ordinary shares subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement, or any registration statements on Form S-8 that we file in the future, will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act.

Additionally, we have filed: (i) a registration statement on Form F-3 (File No. 333-265280) registering the resale of an aggregate of 11,075,220 ordinary shares and 1,052,197 ADSs pursuant to our obligations under a registration rights agreement with Icahn School of Medicine at Mount Sinai and registration rights of holders of shares purchased in our private placement in April 2022; and (ii) a registration statement on Form F-3 (File No. 333-271579) registering the resale of an aggregate of 3,379,237 ordinary shares and 7,511,525 ADSs pursuant to our obligations under a registration rights agreement with Icahn School of Medicine at Mount Sinai, a registration rights agreement with The Hamilton E. James 2003 Children's Trust and registration rights of holders of shares purchased in our private placement in February 2023. If these ordinary shares and ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs and ordinary shares could decline.

The dual listing of ordinary shares and ADSs is costly to maintain and may adversely affect the liquidity and value of our ordinary shares and ADSs.

Our ordinary shares trade on AIM and our ADSs trade on the Nasdaq Global Market. We plan for the foreseeable future to maintain a dual listing, which will continue to generate additional costs, including increased legal, accounting, investor relations and other expenses, in addition to the costs associated with the additional reporting requirements described elsewhere in this annual report. We cannot predict the effect of this dual listing on the value of our ADSs and our ordinary shares. However, the dual listing of ADSs and ordinary shares may dilute the liquidity of these securities in one or both markets and may adversely affect the development of an active trading market for our ADSs. The price of our ADSs could also be adversely affected by trading in ordinary shares on AIM.

We are an "emerging growth company," and the reduced disclosure requirements applicable to emerging growth companies may make our ADSs and ordinary shares less attractive to investors.

We are an "emerging growth company" as defined in the SEC's rules and regulations and 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. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act ("Section 404");
- not being required to comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board, ("PCAOB"), regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- reduced disclosure obligations regarding executive compensation; and
- an exemption from the requirement to seek nonbinding advisory votes on executive compensation or golden parachute arrangements.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this annual report. In particular, we have not included all of the executive compensation information that would be required

if we were not an emerging growth company. We cannot predict whether investors will find our ADSs less attractive if we rely on certain or all of these exemptions. If some investors find our ADSs less attractive as a result, there may be a less active trading market for our ADSs and our ADS price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company may take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to 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.

Even after we no longer qualify as an emerging growth company, we may still qualify as a "smaller reporting company" if the market value of our ordinary shares and ADSs held by non-affiliates is below $250 million (or $700 million if our annual revenue is less than $100 million) as of December 31 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and, when required, our proxy statements.

We will continue to incur significant increased costs as a result of operating as a company that is both publicly listed on Nasdaq in the United States and admitted to trading on AIM in the United Kingdom, and our executive officers and other personnel will continue to be required to devote substantial time to new compliance initiatives and corporate governance practices.

As a company publicly listed in the United States, and particularly after we no longer qualify as an emerging growth company, we have begun to, and will continue to, incur significant legal, accounting and other expenses that we did not incur previously. The Sarbanes-Oxley Act of 2002, the Dodd-Frank Wall Street Reform and Consumer Protection Act, the listing requirements of the Nasdaq Global Market and other applicable securities rules and regulations impose various requirements on non-U.S. reporting public companies, including the establishment and maintenance of effective disclosure and financial controls and corporate governance practices. Our executive officers and other personnel must devote a substantial amount of time to these compliance initiatives. Moreover, these rules and regulations increase our legal and financial compliance costs and make some activities more time-consuming and costly. For example, we expect that these rules and regulations may make it more difficult and more expensive for us to obtain director and officer liability insurance, which in turn could make it more difficult for us to attract and retain qualified senior management personnel or members for our board of directors.

In addition, these rules and regulations are often subject to varying interpretations, in many cases due to their lack of specificity, and, as a result, their application in practice may evolve over time as new guidance is provided by regulatory and governing bodies. This could result in continuing uncertainty regarding compliance matters and higher costs necessitated by ongoing revisions to disclosure and governance practices.

To prepare for eventual compliance with Section 404, once we no longer qualify as an emerging growth company, we will be engaged in a process to document and evaluate our internal control over financial reporting, which is both costly and challenging. In this regard, we will need to continue to dedicate internal resources, potentially engage outside consultants, adopt a detailed work plan to assess and document the adequacy of internal control over financial reporting, continue steps to improve control processes as appropriate, validate through testing that controls are functioning as documented, and implement a continuous reporting and improvement process for internal control over financial reporting. Despite our efforts, there is a risk that we will not be able to conclude, within the prescribed timeframe or at all, that our internal control over financial reporting is effective as required by Section 404. If we identify one or more material weaknesses, or fail to fully remediate any of our past material weaknesses, it could result in an adverse reaction in the financial markets due to a loss of confidence in the reliability of our financial statements.

Further, being a U.S. listed company and an English public company with ordinary shares admitted to trading on AIM impacts the disclosure of information and requires compliance with two sets of applicable rules. From time to time, this may result in uncertainty regarding compliance matters and result in higher costs necessitated by legal analysis of dual legal regimes, ongoing revisions to disclosure and adherence to heightened governance practices. As a result of the enhanced disclosure requirements of the U.S. securities laws, business and financial information that we report is broadly disseminated and highly visible to investors, which we believe may increase the likelihood of threatened or actual litigation, including by competitors and other third parties, which could, even if unsuccessful, divert financial resources and the attention of our management from our operations.

Securities traded on AIM may carry a higher risk than securities traded on other exchanges, which may impact the value of your investment.

Our ordinary shares are currently traded on AIM. Investment in equities traded on AIM is sometimes perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the main market of the London Stock Exchange, New York Stock Exchange or Nasdaq. This is because AIM is less heavily regulated, imposes less stringent

corporate governance and ongoing reporting requirements than those other exchanges. In addition, AIM requires only half-yearly, rather than quarterly, financial reporting. You should be aware that the value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the market price of our ordinary shares, the ADSs, or the ordinary shares underlying the ADSs, may not reflect the underlying value of our company.

Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may increase the risk of holding ADSs and ordinary shares.

The share price of our ordinary shares is quoted on AIM in pounds sterling, while our ADSs trade on the Nasdaq Global Market in U.S. dollars. Fluctuations in the exchange rate between the U.S. dollar and the pound sterling may result in differences between the value of our ADSs and the value of our ordinary shares, which may result in heavy trading by investors seeking to exploit such differences. In addition, as a result of fluctuations in the exchange rate between the U.S. dollar and the pound sterling, the U.S. dollar equivalent of the proceeds that a holder of the ADSs would receive upon the sale in the United Kingdom of any ordinary shares withdrawn from the depositary, and the U.S. dollar equivalent of any cash dividends paid in pounds sterling on ordinary shares represented by the ADSs, could also decline.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, the price and trading volume of our ADSs and ordinary shares could decline.

The trading market for our ADSs and ordinary shares is influenced in part by the research and reports that equity research analysts publish about us and our business. If no or few equity research analysts cover our company, the trading price for our ADSs and ordinary shares would be negatively impacted. We do not have any control over the analysts or the content and opinions included in their reports. The price of our ADSs and ordinary shares could decline if one or more equity research analysts downgrade our ADSs or ordinary shares or issue other unfavorable commentary or research about us. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our ADSs and ordinary shares could decrease, which in turn could cause the trading price or trading volume of our ADSs and ordinary shares to decline.

We have broad discretion in the use of proceeds from our global offering and private placements and may invest or spend the proceeds in ways with which you do not agree and in ways that may not increase the value of your investment.

Our management has broad discretion in the application of our cash including the net proceeds from the global offering we completed in July 2020 and the private placements of securities we completed in April 2022 and February 2023, and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our ADSs or ordinary shares. The failure by our management to apply these funds effectively could result in financial losses that could have a negative impact on our business, cause the price of our ADSs or ordinary shares to decline and delay the development and commercialization of our products. Pending their use, we may invest our cash, in a manner that does not produce income or that loses value.

Raising additional capital may cause dilution to holders of our ADSs or ordinary shares or may restrict our operations.

We expect that significant additional capital may be needed in the future to continue our planned operations, including conducting verification studies, commercialization efforts, expanded research and development activities and costs associated with operating a public company. Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through any or a combination of securities offerings, debt financings, collaborations, agreements, strategic alliances and marketing, distribution or licensing arrangements with third parties. If we raise capital through securities offerings, such sales may also result in material dilution to our existing shareholders, and new investors could gain rights, preferences and privileges senior to the holders of our ADSs or ordinary shares.

To the extent that we raise additional capital through the sale of equity or convertible debt securities, your ownership interest will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect your rights as a holder of ADSs or ordinary shares. Debt financing and preferred equity financing, if available, could result in fixed payment obligations, and we may be required to accept terms that restrict our ability to incur additional indebtedness, force us to maintain specified liquidity or other ratios or restrict our ability to pay dividends or make acquisitions.

Raising additional capital through any of these or other means could adversely affect our business and the holdings or rights of our security holders, and may cause the market price of our ADSs or ordinary shares to decline.

Holders of our ADSs have fewer rights than our shareholders and must act through the depositary to exercise their rights.

Holders of our ADSs do not have the same rights as shareholders who hold our ordinary shares directly and may only exercise their voting rights with respect to the underlying ordinary shares in accordance with the provisions of the deposit agreement. Holders of the ADSs will appoint the depositary or its nominee as their representative to exercise the voting rights attaching to the ordinary shares represented by the ADSs. When a general meeting is convened, if you hold ADSs, you may not receive sufficient notice of a shareholders' meeting to permit you to withdraw the ordinary shares underlying your ADSs to allow you to vote with respect to any specific matter. We will make all commercially reasonable efforts to cause the depositary to extend voting rights to holders of ADSs in a timely manner, but we cannot assure purchasers of ADSs that they will receive voting materials in time to instruct the depositary to vote, and it is possible that they, or persons who hold their ADSs through brokers, dealers or other third parties, will not have the opportunity to exercise a right to vote. Furthermore, the depositary will not be liable for any failure to carry out any instructions to vote, for the manner in which any vote is cast or for the effect of any such vote. As a result, purchasers of ADSs may not be able to exercise their right to vote and they may lack recourse if their ADSs are not voted as they request. In addition, in their capacity as ADS holders, they will not be able to call a shareholders' meeting.

The depositary for our ADSs is entitled to charge holders fees for various services, including annual service fees.

The depositary for our ADSs is entitled to charge holders fees for various services including for the issuance of ADSs upon deposit of ordinary shares, cancellation of ADSs, distributions of cash dividends or other cash distributions, distributions of ADSs pursuant to share dividends or other free share distributions, distributions of securities other than ADSs and annual service fees. In the case of ADSs issued by the depositary into The Depository Trust Company ("DTC"), the fees will be charged by the DTC participant to the account of the applicable beneficial owner in accordance with the procedures and practices of the DTC participant as in effect at the time. The depositary for our ADSs will not generally be responsible for any United Kingdom stamp duty or stamp duty reserve tax arising upon the issuance or transfer of ADSs.

Purchasers of ADSs may be subject to limitations on the transfer of ADSs and the withdrawal of the underlying ordinary shares.

ADSs are transferable on the books of the depositary. However, the depositary may close its books at any time or from time to time when the depositary determines such action is necessary or advisable pursuant to the deposit agreement. The depositary may refuse to deliver, transfer or register transfers of ADSs generally when our books or the books of the depositary are closed, or at any time if we or the depositary thinks it is necessary or advisable to do so because of any requirement of law, government or governmental body, or under any provision of the deposit agreement, or for any other reason, subject to certain rights to cancel ADSs and withdraw the underlying ordinary shares. Temporary delays in the cancellation of ADSs and withdrawal of the underlying ordinary shares may arise because the depositary has closed its transfer books or we have closed our transfer books, the transfer of ordinary shares is blocked to permit voting at a shareholders' meeting, or because we are paying a dividend on our ordinary shares or similar corporate actions.

In addition, purchasers of ADSs may not be able to cancel their ADSs and withdraw the underlying ordinary shares when they owe money for fees, taxes and similar charges and when it is necessary to prohibit withdrawals in order to comply with any laws or governmental regulations that apply to the ADSs or to the withdrawal of our ordinary shares or other deposited securities.

ADS holders may not be entitled to a jury trial with respect to claims arising under the deposit agreement, which could result in less favorable results to the plaintiff(s) in any such action.

The deposit agreement governing our ADSs provides that owners and holders of ADSs irrevocably waive the right to a trial by jury in any legal proceeding arising out of or relating to the deposit agreement or the ADSs, including claims under U.S. federal securities laws, against us or the depositary to the fullest extent permitted by applicable law. If this jury trial waiver provision is prohibited by applicable law, an action could nevertheless proceed under the terms of the deposit agreement with a jury trial. Although we are not aware of a specific federal decision that addresses the enforceability of a jury trial waiver in the context of U.S. federal securities laws, it is our understanding that jury trial waivers are generally enforceable. Moreover, insofar as the deposit agreement is governed by the laws of the State of New York, New York laws similarly recognize the validity of jury trial waivers in appropriate circumstances. In determining whether to enforce a jury trial waiver provision, New York courts and federal courts will consider whether the visibility of the jury trial waiver provision within the agreement is sufficiently prominent such that a party has knowingly waived any right to trial by jury. We believe that this is the case with respect to the deposit agreement and the ADSs.

In addition, New York courts will not enforce a jury trial waiver provision in order to bar a viable setoff or counterclaim of fraud or one which is based upon a creditor's negligence in failing to liquidate collateral upon a guarantor's demand, or in the case of an intentional tort claim (as opposed to a contract dispute). No condition, stipulation or provision of the deposit agreement or ADSs serves as a waiver by any holder or beneficial owner of ADSs or by us or the depositary of compliance with any provision of U.S. federal securities laws and the rules and regulations promulgated thereunder.

If any owner or holder of our ADSs brings a claim against us or the depositary in connection with matters arising under the deposit agreement or the ADSs, including claims under U.S. federal securities laws, such owner or holder may not be entitled to a jury trial with respect to such claims, which may have the effect of limiting and discouraging lawsuits against us or the depositary. If a lawsuit is brought against us or the depositary under the deposit agreement, it may be heard only by a judge or justice of the applicable trial court, which would be conducted according to different civil procedures and may result in different results than a trial by jury would have had, including results that could be less favorable to the plaintiff(s) in any such action, depending on, among other things, the nature of the claims, the judge or justice hearing such claims, and the venue of the hearing.

Concentration of ownership of our ordinary shares (including ordinary shares represented by ADSs) among our executive officers, directors and principal shareholders may prevent new investors from influencing significant corporate decisions and matters submitted to shareholders for approval.

Our executive officers, directors and current beneficial owners of 5% or more of our ordinary shares and their respective affiliates, in the aggregate, beneficially owned approximately 58.1% of our outstanding ordinary shares, based on the number of ordinary shares outstanding as of June 30, 2023. As a result, depending on the level of attendance at our general meetings of shareholders, these persons, acting together, would be able to significantly influence all matters requiring approval by our shareholders, including the election, re-election and removal of directors, any merger, scheme of arrangement, or sale of all or substantially all of our assets, or other significant corporate transactions, and amendments to our articles of association. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our ADSs and ordinary shares by:

- delaying, deferring, or preventing a change in control;
- entrenching our management and/or the board of directors;
- impeding a merger, scheme of arrangement, takeover, or other business combination involving us; or
- discouraging a potential acquirer from making a takeover offer or otherwise attempting to obtain control of us.

In addition, some of these persons or entities may have interests different than yours. For example, because some of these shareholders may have purchased their shares at prices substantially below the price at which you purchased your shares and may have held their shares for a longer period, they may be more interested in selling our company to an acquirer than other investors, or they may want us to pursue strategies that deviate from the interests of other shareholders.

Because we do not anticipate paying any cash dividends on ordinary shares (including ordinary shares represented by ADSs) in the foreseeable future, capital appreciation, if any, will be your sole source of gains and you may never receive a return on your investment.

You should not rely on an investment in our ADSs or ordinary shares to provide dividend income. Under current English law, a company's accumulated realized profits must exceed its accumulated realized losses (on a non-consolidated basis) before dividends can be paid. Therefore, we must have distributable profits before issuing a dividend. We have never declared or paid a dividend on our ordinary shares in the past, and we currently intend to retain our future earnings, if any, to fund the development and growth of our business. As a result, capital appreciation, if any, on our ADSs or ordinary shares will be your sole source of gains for the foreseeable future.

Purchasers of ADSs may not receive distributions on our ordinary shares represented by the ADSs or any value for them if it is illegal or impractical to make them available to holders of ADSs.

Although we do not have any present plans to declare or pay any dividends, in the event we declare and pay any dividend, the depositary for the ADSs has agreed to pay to ADS holders the cash dividends or other distributions it or the custodian receives on our ordinary shares or other deposited securities after deducting its fees and expenses. Purchasers of ADSs will receive these distributions in proportion to the number of our ordinary shares their ADSs represent. However, in accordance with the limitations set forth in the deposit agreement, it may be unlawful or impractical to make a distribution available to holders of ADSs. We have no obligation to register under U.S. securities laws any offering of ADSs, ordinary shares or other securities received through such distributions. We also have no obligation to take any other action to permit distribution on the ADSs, ordinary shares, rights or anything else to holders of the ADSs. This means that purchasers of ADSs may not receive the distributions we make on our ordinary shares or any value from them if it is unlawful or impractical to make them available to them. These restrictions may have an adverse effect on the value of your ADSs.

Your right to participate in any future rights offerings may be limited, which may cause dilution to your holdings.

Under English law, shareholders usually have preemptive rights to subscribe on a pro rata basis in the issuance of new shares for cash. The exercise of preemptive rights by certain shareholders not resident in the United Kingdom may be restricted by applicable law or practice in the United Kingdom and overseas jurisdictions. We may from time to time distribute rights to our shareholders, including rights to acquire our securities. However, we cannot make rights available to shareholders in the United States unless we register the rights and the securities to which the rights relate under the Securities Act or an exemption from the registration requirements is available. Also, under the deposit agreement, the depositary bank will not make rights available to ADS holders unless either both the rights and any related securities are registered under the Securities Act, or the distribution of them to ADS holders is exempted from registration under the Securities Act. We are under no obligation to file a registration statement with respect to any such rights or securities or to endeavor to cause such a registration statement to be declared effective. Moreover, we may not be able to establish an exemption from registration under the Securities Act. If the depositary does not distribute the rights, it may, under the deposit agreement, either sell them, if possible, or allow them to lapse. Accordingly, ADS holders may be unable to participate in our rights offerings and may experience dilution in their holdings. We are also permitted under English law to disapply preemptive rights (subject to the approval of our shareholders by special resolution or the inclusion in our articles of association of a power to disapply such rights) and thereby exclude certain shareholders, such as overseas shareholders, from participating in a rights offering (usually to avoid a breach of local securities laws).

If we are a passive foreign investment company, now or in the future, there could be adverse U.S. federal income tax consequences to U.S. Holders.

Under the Code, we will be a passive foreign investment company, ("PFIC"), for any taxable year in which (1) 75% or more of our gross income consists of passive income or (2) 50% or more of the average quarterly value of our assets consists of assets that produce, or are held for the production of, passive income. For purposes of these tests, passive income generally includes dividends, interest, gains from the sale or exchange of investment property and certain rents and royalties. In addition, for purposes of the above calculations, a non-U.S. corporation that directly or indirectly owns at least 25% by value of the shares of another non-U.S. corporation is treated as if it held its proportionate share of the assets and received directly its proportionate share of the income of such other non-U.S. corporation. If we are a PFIC for any taxable year during which a U.S. Holder holds our ADSs, the U.S. Holder may be subject to adverse tax consequences regardless of whether we continue to qualify as a PFIC, including ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations.

We have not yet completed a final analysis to determine whether we were a PFIC for our taxable year ended June 30, 2023, but we currently believe based on the information available that we were a PFIC for our taxable year ended June 30, 2023. U.S. Holders should consult with their tax advisors regarding the implications of owning stock in a PFIC. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering. We cannot provide any assurances regarding our PFIC status. Because of the uncertainties involved in establishing our PFIC status, our U.S. tax counsel expresses no opinion regarding our PFIC status.

If we are a PFIC, U.S. holders of our ADSs would be subject to adverse U.S. federal income tax consequences, such as ineligibility for any preferred tax rates on capital gains or on actual or deemed dividends, interest charges on certain taxes treated as deferred, and additional reporting requirements under U.S. federal income tax laws and regulations.

Each U.S. Holder is strongly urged to consult its tax advisor regarding these issues.

A “U.S. Holder” is a holder of our common stock who, for U.S. federal income tax purposes: is an individual who is a citizen or resident of the United States; a corporation, or other entity taxable as a corporation, created or organized in or under the laws of the United States, any state therein or the District of Columbia; an estate the income of which is subject to U.S. federal income taxation regardless of its source; or a trust (a) that is subject to the primary supervision of a court within the United States and the control of one or more United States persons as described in Section 7701(a)(30) of the Code, or (b) that has a valid election in effect under applicable Treasury regulations to be treated as a United States person.

If a United States person is treated as owning at least 10% of our ordinary shares, such United States person may be subject to adverse U.S. federal income tax consequences.

For U.S. federal income tax purposes, if a United States person is treated as owning (directly, indirectly or constructively) 10% or more of our stock by vote or value, such United States person will be treated as a "United States shareholder" with respect to each "controlled foreign corporation" in our group (if any). Because our group includes at least one U.S. subsidiary, any non-U.S. subsidiaries we were to form or acquire in the future will be treated as controlled foreign corporations.

A United States shareholder of a controlled foreign corporation will be required to annually report and include in its U.S. federal taxable income its pro rata share (if any) of "subpart F income," "global intangible low-taxed income" and investments in U.S. property by the controlled foreign corporation, regardless of whether such corporation makes any distributions of such income. Special rules, however, apply to United States persons that are partnerships or other pass-through entities for U.S. federal income tax purposes. Certain deductions and credits for foreign income taxes paid or accrued by the controlled foreign corporation may be claimed by a corporate United States shareholder, but may not be claimed by an individual United States shareholder.

We cannot provide any assurance that we will furnish to any United States shareholder the information required to comply with the reporting and tax-paying obligations discussed applicable to a United States shareholder in respect of controlled foreign corporations. Failure to comply with such reporting obligations may subject a holder of our ordinary shares that is a United States shareholder to significant monetary penalties and may prevent the statute of limitations with respect to its U.S. federal income tax return for the year for which reporting was due from starting. Holders of our ordinary shares that are United States persons should consult their tax advisors regarding the potential application of these rules to their investment in our ordinary shares.

Risks Related to Investing in a U.K. Company

The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

We are incorporated under English law. The rights of holders of ordinary shares and, therefore, certain of the rights of holders of our ADSs, are governed by English law, including the provisions of the U.K. Companies Act 2006 (the "Companies Act"), and by our articles of association. These rights differ in certain respects from the rights of shareholders in typical U.S. corporations.

Protections found in provisions under the U.K. City Code on Takeovers and Mergers may delay or discourage a takeover attempt, including attempts that may be beneficial to holders of our ADSs and ordinary shares.

The U.K. City Code on Takeovers and Mergers (the "Takeover Code") applies, among other things, to an offer for a public company whose registered office is in the United Kingdom and whose securities are admitted to trading on a multilateral trading facility in the United Kingdom, which includes AIM. We are therefore currently subject to the Takeover Code.

The Takeover Code provides a framework within which takeovers of certain companies organized in the United Kingdom are regulated and conducted. The following is a brief summary of some of the most important rules of the Takeover Code:

- In connection with a potential offer, if following an approach by or on behalf of a potential bidder, the company is "the subject of rumor or speculation" or there is an "untoward movement" in the company's share price, there is a requirement for the potential bidder to make a public announcement about a potential offer for the company, or for the company to make a public announcement about its review of a potential offer.
- When a person or group of persons acting in concert (a) acquires, whether by a series of transactions over a period of time or not, interests in shares carrying 30% or more of the voting rights of a company (which percentage is treated by the Takeover Code as the level at which effective control is obtained) or (b) increases the aggregate percentage interest they have when they are already interested in not less than 30% and not more than 50%, they must make a cash offer to all other shareholders at the highest price paid by them or any person acting in concert with them in the 12 months before the offer was announced.
- When interests in shares carrying 10% or more of the voting rights of a class have been acquired by an offeror (i.e., a bidder) in the offer period (i.e., before the shares subject to the offer have been acquired) or within the previous 12 months, the offer must be in cash or be accompanied by a cash alternative for all shareholders of that class at the highest price paid by the offeror or any person acting in concert with them in that period. Further, if an offeror or any person acting in concert with them acquires any interest in shares during the offer period, the offer for the shares must be in cash or accompanied by a cash alternative at a price at least equal to the price paid for such shares during the offer period.
- If after an announcement is made, the offeror or any person acting in concert with them acquires an interest in shares in an offeree company (i.e., a target) at a price higher than the value of the offer, the offer must be increased accordingly.

- The board of directors of the offeree company must appoint a competent independent adviser whose advice on the financial terms of the offer must be made known to all the shareholders, together with the opinion of the board of directors of the offeree company.
- Favorable deals for selected shareholders are not permitted, except in certain circumstances where independent shareholder approval is given and the arrangements are regarded as fair and reasonable in the opinion of the financial adviser to the offeree.
- All shareholders must be given the same information.
- Those issuing documents in connection with a takeover must include statements taking responsibility for the contents thereof.
- Profit forecasts, quantified financial benefits statements and asset valuations must be made to specified standards and must be reported on by professional advisers.
- Misleading, inaccurate or unsubstantiated statements made in documents or to the media must be publicly corrected immediately.
- Actions during the course of an offer by the offeree company, which might frustrate the offer are generally prohibited unless shareholders approve these plans. Frustrating actions would include, for example, lengthening the notice period for directors under their service contract or agreeing to sell off material parts of the target group.
- Stringent requirements are laid down for the disclosure of dealings in relevant securities during an offer, including the prompt disclosure of positions and dealing in relevant securities by the parties to an offer and any person who is interested (directly or indirectly) in 1% or more of any class of relevant securities.
- Employees of both the offeror and the offeree company and the trustees of the offeree company's pension scheme must be informed about an offer. In addition, the offeree company's employee representatives and pension scheme trustees have the right to have a separate opinion on the effects of the offer on employment appended to the offeree board of directors' circular or published on a website.

As an English public company, certain capital structure decisions will require shareholder approval, which may limit our flexibility to manage our capital structure.

English law provides that a board of directors may only allot shares (or grant rights to subscribe for, or to convert any security into, shares) with the prior authorization of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, such authorization stating the aggregate nominal amount of shares that it covers and being valid for a maximum period of five years, each as specified in the articles of association or relevant shareholder resolution. In either case, this authorization would need to be renewed by our shareholders upon expiration (i.e., at least every five years). Typically, English public companies renew the authorization of their directors to allot shares on an annual basis at their annual general meeting. We have obtained authority from our shareholders to allot additional shares up to an aggregate nominal amount of 77,369.72 from June 8, 2023 (being the date of our general meeting) until the conclusion of our next annual general meeting or the close of business on September 8, 2024, whichever is earlier, which authorization will need to be renewed or replaced upon expiration (other than in the case of a preemptive offering).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the articles of association, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the disapplication is contained in the articles of association, or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution, but not longer than the duration of the authority to allot shares to which the disapplication relates. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). Typically, English public companies renew the disapplication of preemptive rights on an annual basis at their annual general meeting. We have obtained authority from our shareholders to disapply preemptive rights in respect of shares allotted under the authorization described in the paragraph above up to an aggregate nominal amount of £46,890.74 from June 8, 2023 (being the date of our general meeting) until the conclusion of our next annual general meeting, or the close of business on September 8, 2024, whichever is earlier, which disapplication will need to be renewed or replaced upon expiration.

English law also generally prohibits a public company from repurchasing its own shares without the prior approval of shareholders by ordinary resolution, being a resolution passed by a simple majority of votes cast, and other formalities. Such approval may be for a maximum period of up to five years.

Claims of U.S. civil liabilities may not be enforceable against us.

We are incorporated under English law. A substantial amount of our assets are located outside the United States. In addition, some of our executive officers and directors reside outside the United States. As a result, it may not be possible for investors to effect service of process within the United States upon such persons or to enforce judgments obtained in U.S. courts against them or us, including judgments predicated upon the civil liability provisions of the U.S. federal securities laws.

The United States and the United Kingdom do not currently have a treaty providing for the reciprocal recognition and enforcement of judgments (other than arbitration awards) in civil and commercial matters. Consequently, a final judgment for payment given by a court in the United States, whether or not predicated solely upon U.S. securities laws, would not automatically be recognized or enforceable in England and Wales. In addition, uncertainty exists as to whether the English and Welsh courts would entertain original actions brought in England and Wales against us or our directors or executive officers predicated upon the securities laws of the United States or any state in the United States. Any final and conclusive monetary judgment for a definite sum obtained against us in U.S. courts would be treated by the courts of England and Wales as a cause of action in itself and sued upon as a debt so that no retrial of the issues would be necessary, provided that certain requirements are met consistent with English law and public policy. Whether these requirements are met in respect of a judgment based upon the civil liability provisions of the U.S. securities laws is an issue for the English court making such decision. If an English court gives judgment for the sum payable under a U.S. judgment, the English judgment will be enforceable by methods generally available for this purpose.

As a result, U.S. investors may not be able to enforce against us or our executive officers, board of directors or certain experts named herein who are residents of the United Kingdom or countries other than the United States any judgments obtained in U.S. courts in civil and commercial matters, including judgments under the U.S. federal securities laws.

Our articles of association provide that the U.S. federal district courts are the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act.

Our articles of association provide that, unless we consent in writing to the selection of an alternative forum in the United States of America, the U.S. federal district courts are the exclusive forum for resolving any complaint asserting a cause of action arising under the Securities Act. There is uncertainty as to whether a court would enforce such provision, and the enforceability of similar choice of forum provisions in other companies' constitutive documents has been challenged in legal proceedings. If a court were to find the choice of forum provision contained in our articles of association to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions, which could adversely affect our results of operations and financial condition.

This choice of forum provision may limit a shareholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers or other employees, which may discourage such lawsuits.

The withdrawal of the United Kingdom from the EU may result in our having to obtain relevant regulatory clearances for our products for the United Kingdom and the rest of Europe separately.

We are not actively pursuing regulatory clearance and commercialization of our products outside of the United States at this time. Prior to the withdrawal of the United Kingdom from the EU, the United Kingdom benefited from, and we expected to be able to benefit from, the harmonization of certain regulatory requirements within the EU. Such regulatory requirements are no longer harmonized between the EU and Great Britain. As a result, any future efforts to market our products in both Great Britain and the EU may require us to complete separate regulatory processes, which may increase the time and cost associated with gaining relevant regulatory approvals in such markets depending on the arrangements in place between the United Kingdom and the EU at the relevant time.

Exchange rate fluctuations may adversely affect our results of operations and financial condition.

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, may adversely affect us. Since the Brexit referendum in 2016, there has been a significant increase in the volatility of the exchange rate between the pound sterling and the U.S. dollar and an overall weakening of the pound sterling. Our business and the price of our ADSs may be affected by fluctuations in foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the currencies of other countries, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Item 1B. Unresolved Staff Comments.
Not applicable.

Item 1C. Cybersecurity
Not applicable.

Item 2. Properties.

We lease laboratory and office space in New York City, New York on short-term leases that automatically renew. The laboratory is use for KidneyIntelX testing and the office is used for corporate. Combined, our laboratory and office space in New York are approximately 1,000 square feet. In addition, we lease laboratory space in Salt Lake City, Utah (the "Utah Lab") and laboratory space in St. Petersburg, Florida (the "Florida Lab"). The Utah Lab is approximately 4,000 square feet and established for KidneyIntelX testing as well and research activities, and this lease expires in October 2024. The Florida Lab is approximately 1,200 square feet and was established to be used for KidneyIntelX testing as well as research activities and to be compliant with the FDA's quality system regulation, and this lease expires in January 2024.

Item 3. 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 4. Mine Safety Disclosures.
Not applicable.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our ADSs have been listed on the Nasdaq Global Market under the symbol "RNLX" since July 17, 2020. Our ordinary shares have been listed on AIM, a market operated by the London Stock Exchange, under the symbol, "RENX," since November 6, 2018.

Holders of Common Equity

As of September 28, 2023, there were approximately 200 holders of record of our ordinary shares and 4,900 holders of record of our ADSs. Because our ADSs are held by depositaries, brokers and other nominees, the number of beneficial holders of our shares is substantially larger than the number of stockholders of record.

Dividend Distribution Policy

Since our incorporation, we have not declared or paid any dividends on our issued share capital. We intend to retain any earnings for use in our business and do not currently intend to pay dividends on our ordinary shares. The declaration and payment of any future dividends will be at the discretion of our board of directors and will depend upon our results of operations, cash requirements, financial condition, contractual restrictions, any future debt agreements or applicable laws and other factors that our board of directors may deem relevant.

Under the laws of England and Wales, among other things, we may only pay dividends if we have sufficient distributable reserves (on a non-consolidated basis), which are our accumulated realized profits that have not been previously distributed or capitalized less our accumulated realized losses, so far as such losses have not been previously written off in a reduction or reorganization of capital.

On May 15, 2020, our shareholders approved at a general meeting the reduction of our share capital by the cancellation of our share premium account in its entirety in order to create realized profits, which was confirmed by the High Court in England and Wales on June 9, 2020. This was necessary to increase our distributable reserves to allow us to implement the distribution in specie for the FractalDx spin-off, which distribution was declared by our board of directors on July 7, 2020 and distributed on July 10, 2020.

Recent Sales of Unregistered Securities

On February 7, 2023, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with certain existing shareholders, "qualified institutional buyers" as defined in Rule 144A(a) under the Securities Act and qualified investors in the United Kingdom, pursuant to which the Company agreed to issue and sell in a private placement (the "Private Placement") an aggregate of 7,511,525 ADS and 3,699,910 ordinary shares, at a price of $2.17 per ADS and £0.90 per ordinary share for gross cash proceeds of $20.3 million. The Company received net proceeds of $20.0 million. The Company intends to use the net proceeds of the private placement for clinical product development, general and administrative expenses and working capital. Based in part upon the representations of the investors in the Purchase Agreement, the offering and sale of the securities was made in reliance on the exemption afforded by Section 4(a)(2) under the Securities Act and Regulation S under the Securities Act inasmuch as certain investors are not a "U.S. person" (as defined in Rule 902 under the Securities Act) and the requirements of Rule 903 under the Securities Act are otherwise met, and corresponding provisions of state securities or "blue sky" laws. The sale of the securities did not involve a public offering and was made without general solicitation or general advertising.

Use of Proceeds

The net proceeds from our global offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering declared effective on July 16, 2020 and filed with the SEC on July 17, 2020.

None of the net proceeds of the global offering were paid directly or indirectly to any director, officer, general partner of ours or to their associates, persons owning ten percent or more of any class of our equity securities, or to any of our affiliates.

Item 6. [Reserved]

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following management's discussion and analysis of financial condition and results of operations describes the principal factors affecting our results of operations, liquidity, capital resources and contractual cash obligations. This discussion should be read in conjunction with "Item 1A. Risk Factors", the accompanying audited consolidated financial statements and related notes thereto, as well as other cautionary statements and risks described elsewhere in this Annual Report on Form 10-K. For the discussion of the financial condition and results of operations for the year ended June 30, 2022 compared to the year ended June 30, 2021, please refer to "Item 5. Operating and Financial Review and Prospectus—Financial operations overview", "—Consolidated results of operations" and "—Liquidity and capital resources" included in the Company's Annual Report on Form 20-F for the year ended June 30, 2022, which was filed with the SEC, on October 31, 2022.

Overview

We are an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs. KidneyIntelX, our first-in-class diagnostic platform, employs a proprietary artificial intelligence-enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from EHR systems to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk. CKD affects approximately 37 million individuals in the United States, significantly impacting their quality of life and, according to the United States Renal Data System's 2019 Annual Data Report, resulting in Medicare spending of over $120 billion per year. In response to this substantial kidney disease burden, a U.S. Presidential Executive Order on Advancing American Kidney Health was issued in July 2019 to support change in kidney disease care. We believe we are well-positioned to help meet this urgent medical need with KidneyIntelX, an LDT initially indicated for adult patients with DKD. KidneyIntelX has already been granted a CPT code, national Medicare pricing and a positive coverage determination from a regional, private physician-led health insurance payor. Further, it has been granted breakthrough device designation from the FDA. Building on these reimbursement and regulatory milestones, we believe our population health-based business model, which includes partnerships with healthcare systems, such as Mount Sinai Health System, will help facilitate commercial adoption of KidneyIntelX in the United States.

We plan 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. 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. To date, we have not generated any revenue from the sales of KidneyIntelX tests. 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 ADSs 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.

Components of Results of Operations

Revenues

During the fiscal year ended June 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.

Additionally, during the fiscal year ended June 30, 2023, we recognized services revenue upon completion of two services contracts, including our project with AstraZeneca. We plan to continue to pursue further collaborations with pharmaceutical companies with the goal of improving guideline-based standard-of-care for optimal utilization of existing and novel therapeutics using the KidneyIntelX testing platform and care management software.

Cost of Revenue

During the fiscal years ended June 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.

Equity Losses in Affiliate

Equity losses in affiliate represents the recognition of our proportionate share of loss from operations of Kantaro Biosciences LLC.

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 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 income realized on the dissolution of Kantaro, and interest income earned on our cash deposits.

Consolidated Results of Operations

(in thousands, except share data)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Revenue	$ 3,403	$ 2,970	$ 433	15 %
Cost of revenue	2,683	2,096	587	28 %
Gross profit	720	874	(154)	-18 %
Operating expenses:				
Research and development	14,298	14,648	(350)	-2 %
General and administrative	28,662	39,524	(10,862)	-27 %
Performance of contract liability to affiliate	(19)	(115)	96	-83 %
Total operating expenses	42,941	54,057	(11,116)	-21 %
Loss from operations	(42,221)	(53,183)	10,962	-21 %
Equity in net (losses) earnings of affiliate	(9)	9	(18)	-200 %
Foreign currency gain (loss), net	358	9,694	(9,336)	-96 %
Fair value adjustment to VericiDx investment	(1,282)	(5,900)	4,618	-78 %
Fair value adjustment to convertible notes	(3,107)	3,998	(7,105)	-178 %
Other income, net	656	131	525	401 %
Net loss before income taxes	(45,605)	(45,251)	(354)	1 %
Income tax expense	(2)	(25)	23	-90 %
Net loss	(45,607)	(45,276)	(331)	1 %
Net loss per ordinary share—basic	$ (0.55)	$ (0.62)	$ 0.07	-11 %
Net loss per ordinary share—diluted	$ (0.55)	$ (0.67)	$ 0.11	-17 %
Weighted average ordinary shares—basic	82,210,050	72,861,448	9,348,602	13 %
Weighted average ordinary shares—diluted	82,210,050	73,837,496	8,372,554	11 %
Other comprehensive income (loss):				
Changes in the fair value of the convertible notes	(337)	536	(873)	-163 %
Foreign exchange translation adjustment	(198)	(9,727)	9,529	-98 %
Comprehensive loss	(46,142)	(54,467)	8,325	-15 %

Comparison of years ended June 30, 2023 and 2022

Revenue

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Revenue	$ 3,403	$ 2,970	$ 433	15%

During the year ended June 30, 2023, we recognized $3.1 million of revenue related to sales of KidneyIntelX and $0.3 million of revenue related to services performed for AstraZeneca and University Medical Center Gronigen. During the year ended June 30, 2022, we recognized $2.7 million revenue related to sales of KidneyIntelX and $0.2 million of revenue of pharmaceutical services revenue related to services performed for AstraZeneca. The $0.4 million increase in revenue was primarily driven by an increase in KidneyIntelX testing volumes.

Cost of Revenue

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Cost of revenue	$ 2,683	$ 2,096	$ 587	28%

During the year ended June 30, 2023, we recognized cost of revenue of $2.7 million primarily attributable to KidneyIntelX testing, including labor, lab consumables and sample collection costs related to revenue generating activities. We recognized $2.1 million of cost of revenue for the year ended June 30, 2022. The $0.6 million increase in cost of revenue was primarily driven by an increase in KidneyIntelX testing volumes.

Research and Development Expenses

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Research and development expenses	$ 14,298	$ 14,648	$ (350)	-2%

Research and development expenses decreased by $0.4 million from $14.6 million for the year ended June 30, 2022 to $14.3 million for year ended June 30, 2023. The decrease was attributable to a $2.1 million decrease related to consulting and professional fees, $0.3 million decrease in lab supplies purchases, offset by a $1.6 million increase related to external R&D projects and studies with Mount Sinai, Wake Forest and Joslin Diabetes and $0.4 million increase in other miscellaneous expenses.

General and Administrative Expenses

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
General and administrative expenses	$ 28,662	$ 39,524	$ (10,862)	-27%

General and administrative expenses decreased $10.9 million from $39.5 million for the year ended June 30, 2022 to $28.7 million for the year ended June 30, 2023. The decrease was driven by our previously announced cost cutting measures and was due to a $4.8 million decrease in consulting and professional fees, $2.8 million decrease in compensation and related benefits, including share-based payments, due to decreased headcount, $2.0 million decrease in insurance costs, $0.7 million decrease in marketing and public relations, $0.4 million decrease in IT costs, and $0.2 million decrease in other operating expenses.

Foreign Currency Gain (Loss)

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Foreign currency gain (loss), net	$ 358	$ 9,694	$ (9,336)	-96%

During the year ended June 30, 2023, we recognized a foreign currency gain of $0.4 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the year ended June 30, 2022, we recognized a foreign currency gain of $9.7 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency and remeasurement of intercompany payables/receivables. The decrease in foreign currency gain from the prior year was primarily driven by settlement of foreign currency denominated intercompany payables/receivables during the year ended June 30 2023 which reduced the foreign currency gain driven by remeasurement of the intercompany balances.

Fair Value Adjustments to VericiDx Investment

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Fair value adjustment to VericiDx investment	$ (1,282)	$ (5,900)	$ 4,618	-78%

We account for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During the year ended June 30, 2023, we recorded a loss of $1.3 million to adjust the VericiDx investment to fair value. During the year ended June 30, 2022, we recorded a loss of $5.9 million to adjust the VericiDx investment to fair value.

Fair Value Adjustment on Convertible Notes

(in thousands)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Fair value adjustment to convertible notes	$ (3,107)	$ 3,998	$ (7,105)	-178%

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. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. For the year ended June 30, 2023, we recorded a loss of $3.1 million to adjust the bonds to fair value. For the year ended June 30, 2022, we recorded a gain of $4.0 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)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022	Change 2023 vs.2022 Change	Change 2023 vs.2022 %
Other income, net	$ 656	$ 131	$ 525	401%

During the year ended June 30, 2023, we realized $0.2 million of income related to the dissolution of Kantaro, $0.3 million of income for refunds from Citibank, and $0.1 million interest income earned on our cash deposits. During the year ended June 30, 2022, we realized $0.1 million of income on the reduction of the Kantaro liability for future services to be performed for the joint venture as well as $0.01 million interest income earned on our cash deposits.

Liquidity and Capital Resources

Since our inception, we have incurred net losses. We incurred net losses of $45.6 million and $45.3 million for the years ended June 30, 2023 and 2022, respectively. As of June 30, 2023, we had an accumulated deficit of $178.3 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 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 KidneyIntelX, including any post-marketing studies that could be required by regulatory authorities;
- the cost, timing and outcome of identified and potential future commercialization activities, including manufacturing, marketing, sales and distribution, for KidneyIntelX;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of future revenue 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 June 30, 2023, we had cash of $24.7 million. The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of $178.3 million as of June 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 our losses and our projected cash needs, substantial doubt exists about the Company's 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 the Company's operations, expand its commercial activities and develop other potential diagnostic related products. The Company plans to finance our cash needs through a combination of securities offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements with third parties. For example, in February 2023, we entered into securities purchase agreements with certain investors to issue and sell an aggregate of 18,722,960 ordinary shares (including in the form of ADSs) for a purchase price of £0.90 per ordinary share ($2.17 per ADS) and an aggregate purchase price of $20.3 million. 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 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.

Cash Flows

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

	Year ended June 30,		Change 2023 vs.2022	
(in thousands, except share and per share amounts)	**2023**	**2022**	**Change**	**%**
Net cash used in operating activities	$ (34,085)	$ (45,924)	11,839	-26%
Net cash used in investing activities	-	(662)	662	-100%
Net cash provided by financial activities	16,386	25,630	(9,244)	-36%
Effect of exchange rate changes on cash	1,048	(2,839)	3,887	-137%

Net cash used in operating activities

During the year ended June 30, 2023, net cash used in operating activities was $34.1 million and was primarily attributable to our $45.6 million net loss as well as $5.8 million of noncash charges and $5.7 million net change in our operating assets and liabilities. Noncash charges were primarily related to $2.9 million in share-based compensation expense, $2.0 million fair value adjustment related to the bonds, $1.3 million fair value adjustment on our VericiDx investment, $0.5 million of depreciation and amortization expense and $0.1 million of non cash lease expense, offset by $1.0 million in foreign exchange gains. The change in our operating assets and liabilities was primarily attributable to $4.2 million increase in accrued expenses and other current liabilities, $1.5 million increase in accounts receivables, prepaids and other current assets.

During the year ended June 30, 2022, net cash used in operating activities was $45.9 million and was primarily attributable to our $45.3 million net loss as well as $0.2 million net change in our operating assets and liabilities and $0.5 million of noncash charges. The change in our operating assets and liabilities was primarily attributable to $1.8 million increase in accounts receivables, prepaids and other current assets, offset by a $1.6 million increase in accrued expenses and other current liabilities. Noncash charges were primarily related to $7.3 million in foreign exchange gains, $3.9 million fair value adjustment related to the bonds, which were offset by $4.6 million in share-based compensation expense, $5.6 million unrealized loss on the company's shares of VericiDx and a $0.5 million increase in depreciation and amortization.

Net cash provided by and used in investing activities

During the year ended June 30, 2023, no cash was used in investing activities.

During the year ended June 30, 2022, net cash used in investing activities was $0.7 million and primarily attributable to $0.6 million for the purchase of lab and office equipment and $0.1 million of software development costs.

Net cash provided by financing activities

During the year ended June 30, 2023, net cash provided by financing activities was $16.4 million and was primarily attributable to $20.3 million of proceeds from the issuance of ordinary shares, offset by $1.0 million in offering costs. Additionally, we received $0.3 million in proceeds from the issuance of ordinary shares under our employee share purchase program. Net cash provided by financing activities was offset by $3.2 million for the repayment of convertible notes during the year.

During the year ended June 30, 2022, net cash provided by financing activities was $25.6 million and was primarily attributable to $18.0 million of proceeds from the issuance of a convertible note, offset by $1.4 million in debt issuance costs and $8.8 million gross proceeds from our equity offering which was partially offset by offering costs of $0.2 million associated with the equity offering that were paid in the period. Additionally, the Company received $0.2 million in proceeds from the exercise of stock options and $0.2 million in proceeds from the issuance of ordinary shares under employee share purchases.

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) the last day of the fiscal year (1) following the fifth anniversary of the completion of our U.S. IPO, (2) in which we have total annual gross revenues of at least $1.235 billion or (3) in which we are deemed to be a “large accelerated filer” under the rules of the SEC, which means the market value of our ordinary shares and ADSs that are held by non-affiliates exceeds $700.0 million as of the prior December 31, or (b) the date on which we have 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

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 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. For each reporting period, changes in the fair value of the notes 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 OCI for each reporting period.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk.

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

Item 8. Financial Statements and Supplementary Data.

The financial statements and supplementary financial information required by this Item 8 are included in our Consolidated Financial Statements and the Notes to Consolidated Financial Statements and are set forth in the pages indicated in Part IV, Item 15(a)(1) and 15(a)(2) of this Report and are incorporated herein by reference.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure.
None.

Item 9A. 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 June 30, 2023, have concluded that, as of such date, our disclosure controls and procedures were effective as described further below.

Management's Annual Report on Internal Control Over Financial Reporting

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of June 30, 2023 based on the framework in "Internal Control—Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, management has concluded that, as June 30, 2023, the Company's internal control over financial reporting was effective to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Remediation of Previously Disclosed Material Weakness

In connection with the preparation of our consolidated financial statements for the year ended June 30, 2022, we concluded that there were material weaknesses in the design of our internal control over financial reporting impacting accounting for stock-based based compensation. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to the lack of formal processes and procedures and our lack of maintaining a sufficient complement of personnel commensurate with our accounting and reporting requirements.

During the year ended June 30, 2023, we executed our remediation plan by implementing an external stock plan management system and engaging a third-party service provider to administer and manage our employee stock-based compensation plan. The third-party service provider has a proven track record of stock plan management to help companies seamlessly integrate data, manage their stock plan and ensure accurate financial reporting. We have also implemented controls to review the service organization control report as well as review information within the service provider's system to ensure that the stock option data is appropriately recorded in our financial statements. These efforts ensure that our financial records are managed appropriately but also help ensure that the appropriate level of review is performed. We have concluded that the applicable remediated controls are designed, implemented and operating effectively.

As a result of these remediation activities we concluded the previously reported material weakness have been remediated as of June 30, 2023.

Attestation Report of the Registered Public Accounting Firm

This annual report does not include an attestation report of the company's registered public accounting firm. For so long as we qualify as an "emerging growth company" as defined under the JOBS Act, our independent registered accounting firm is not required to issue an attestation report on our internal control over financial reporting.

Changes in Internal Control Over Financial Reporting

Besides the remediation of the previously disclosed material weakness is the design of our internal control over financial reporting impacting accounting for stock-based based compensation, there have been no change in our internal control over financial reporting during the fiscal year ended June 30, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

The information required to be disclosed by this item is incorporated herein by reference to the Company's definitive Proxy Statement for its 2023 Annual General Meeting, which we expect to file with the SEC within 120 days after the end of our fiscal year ended June 30, 2023.

We have adopted a Code of Conduct applicable to our and our subsidiaries' employees, independent contractors, executive officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A copy of the Code of Conduct is posted on our website, which is located at www.renalytix.com, under "Governance." We intend to disclose on our website any amendments to, or waivers from, the code of conduct that are required to be disclosed pursuant to the disclosure requirements of Item 5.05 of Form 8-K within four business days following the date of the amendment or waiver.

Item 11. Executive Compensation.

The information required to be disclosed by this item is incorporated herein by reference to the Company's definitive Proxy Statement for its 2023 Annual General Meeting, which we expect to file with the SEC within 120 days after the end of our fiscal year ended June 30, 2023.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required to be disclosed by this item is incorporated herein by reference to the Company's definitive Proxy Statement for its 2023 Annual General Meeting, which we expect to file with the SEC within 120 days after the end of our fiscal year ended June 30, 2023.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required to be disclosed by this item is incorporated herein by reference to the Company's definitive Proxy Statement for its 2023 Annual General Meeting, which we expect to file with the SEC within 120 days after the end of our fiscal year ended June 30, 2023.

Item 14. Principal Accounting Fees and Services.

The information required to be disclosed by this item is incorporated herein by reference to the Company's definitive Proxy Statement for its 2023 Annual General Meeting, which we expect to file with the SEC within 120 days after the end of our fiscal year ended June 30, 2023.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

(a) List the following documents filed as a part of the report:

(1) All financial statements;

The report of our independent registered public accounting firm and Consolidated Financial Statements listed in the Index to Consolidated Financial Statements herein are filed as part of this Annual Report on Form 10-K.

(2) Financial Statement Schedules

There are no financial statement schedules filed as part of this this Annual Report on Form 10-K, since the required information is included in the financial statements, including the notes thereto, included in "Item 8. Financial Statements and Supplementary Data" or the circumstances requiring inclusion of such schedules are not present.

(2) Exhibits

We have filed, or incorporated by reference into this Annual Report on Form 10-K, the exhibits set forth on the accompanying Exhibit Index immediately preceding the Index to Consolidated Financial Statements.

Exhibit No.	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association	F-1	333-239414	3.1	6/24/2020
4.1	Reference is made to Exhibit 3.1.				
4.2	Form of Deposit Agreement	F-1/A	333-239414	4.1	7/13/2020
4.3	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-239414	4.1	7/13/2020
4.4	Description of Securities	20-F	001-39387	4.3	10/28/2020
10.1+	Renalytix plc Share Option Plan for Employees with Non-Employee Sub-Plan and U.S. Sub-Plan	F-1	333-239414	10.1	6/24/2020
10.2†#	Exclusive License and Collaboration Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of May 30, 2018, as amended to date	F-1	333-239414	10.2	6/24/2020
10.3†#	License Agreement, by and between the registrant and Joslin Diabetes Center, Inc., as assigned to the registrant on October 23, 2018, as amended to date	F-1	333-239414	10.3	6/24/2020
10.4+	2020 Equity Incentive Plan with Non-Employee Sub-Plan and forms of grant notices and agreements thereunder	F-1	333-239414	10.6	6/24/2020
10.5+	2020 Employee Share Purchase Plan	F-1	333-239414	10.7	6/24/2020
10.6+*	Employment Agreement, dated as of October 22, 2018, by and among James McCullough, Renalytix AI, Inc. and Renalytix plc				
10.7+*	Employment Agreement, dated as of October 12, 2018, by and among O. James Sterling, Renalytix AI, Inc. and Renalytix plc				
10.8+*	Employment Agreement, dated June 1, 2019, by and among Thomas McLain, Renalytix AI, Inc. and Renalytix plc				
10.9+*	Employment Agreement, dated as of November 2, 2018, by and among Fergus Fleming, Renalytix AI, Inc. and Renalytix plc				
10.10+*	Employment Agreement, dated December 12, 2020, by and among Michael Donovan, Renalytix AI, Inc. and Renalytix plc				

Exhibit No.	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
10.11+	Form of Amended Deed of Indemnity between registrant and each of its directors	F-1	333-239414	10.8	6/24/2020
10.12+	Form of Deed of Indemnity between registrant and each of its executive officers	F-1	333-239414	10.9	6/24/2020
10.13	Registration Rights Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of June 24, 2020	F-1	333-239414	10.1	6/24/2020
10.14	Registration Rights Agreement, by and between The Hamilton E. James 2003 Childrens Trust, Jefferson River Capital LLC and Renalytix plc, dated as of February 7, 2023	6-K	001-39387	99.4	2/8/2023
10.15	Amended and Restated Bond Agreement between registrant and CVI Investments, dated as of April 5, 2022	20-F	001-39387	10.11	10/31/2022
10.16*	Relationship Agreement, by and among Renalytix plc, the Icahn School of Medicine at Mount Sinai and NPLUS1 Singer Advisory LLP, dated as of October 30, 2018				
21.1*	Subsidiaries of the registrant				
23.1*	Consent of Ernst & Young LLP, independent registered public accounting firm (PCAOB ID No. 42)				
24.1*	Power of Attorney (included on signature page)				
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.
+ 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.
# Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

Item 16. Form 10-K Summary

Not applicable.

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

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

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints James McCullough and O. James Sterling, each acting alone, his or her true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person and in his or her name, place and stead, in any and all capacities, to sign any and all amendments to this report, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-facts and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or his substitutes or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
/s/ James McCullough James McCullough	Chief Executive Officer and Chairman of the Board (*Principal Executive Officer*)	September 28, 2023
/s/ O. James Sterling O. James Sterling	Chief Financial Officer (*Principal Financial Officer and Principal Accounting Officer*)	September 28, 2023
/s/ Fergus Fleming Fergus Fleming	Chief Technical Officer and Director	September 28, 2023
/s/ Catherine Coste Catherine Coste	Director	September 28, 2023
/s/ Daniel J. Levangie Daniel J. Levangie	Director	September 28, 2023
/s/ Erik Lium Erik Lium, Ph.D.	Director	September 28, 2023
/s/ Christopher Mills Christopher Mills	Director	September 28, 2023
/s/ Chirag R. Parikh Chirag R. Parikh	Director	September 28, 2023
/s/ Timothy Scannell Timothy Scannell	Director	September 28, 2023

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Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Renalytix plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Renalytix plc (the Company) as of June 30, 2023 and 2022, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the two years in the period ended June 30, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2023, in conformity with U.S. generally accepted accounting principles.

The Company's Ability to Continue as a Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has suffered recurring losses and negative cash flows from operations, expects to incur additional losses and require substantial additional capital to fund its operations, and has stated that substantial doubt exists about the Company's ability to continue as a going concern. Management's evaluation of the events and conditions and management's plans regarding these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Ernst & Young LLP
We have served as the Company's auditor since 2021.
Iselin, New Jersey
September 28, 2023

RENALYTIX PLC

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	June 30, 2023	June 30, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 24,682	$ 41,333
Accounts receivable	776	901
Prepaid expenses and other current assets	1,424	2,445
Note receivable from Kantaro	—	75
Total current assets	26,882	44,754
Property and equipment, net	1,027	1,369
Right of Use Asset	159	—
Investment in VericiDx	1,460	2,744
Investment in Kantaro	—	9
Other Assets	1,101	1,189
Total assets	$ 30,629	$ 50,065
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,485	$ 1,376
Accounts payable – related party	1,451	1,083
Accrued expenses and other current liabilities	6,644	3,060
Accrued expenses – related party	1,963	1,496
Deferred revenue	—	46
Current lease liability	130	—
Convertible notes-current	4,463	4,660
Payable to affiliate – current	—	55
Total current liabilities	16,136	11,776
Convertible notes-noncurrent	7,485	7,682
Noncurrent lease liability	41	—
Total liabilities	23,662	19,458
Commitments and contingencies (Note 10)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 98,750,054 shares authorized; 93,781,478 and 74,760,432 shares issued and outstanding at June 30, 2023 and June 30, 2022, respectively	286	228
Additional paid-in capital	186,456	164,012
Accumulated other comprehensive income	(1,450)	(915)
Accumulated deficit	(178,325)	(132,718)
Total shareholders' equity	6,967	30,607
Total liabilities and shareholders' equity	$ 30,629	$ 50,065

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share data)	Twelve Months Ended June 30, 2023	Twelve Months Ended June 30, 2022
Revenue	$ 3,403	$ 2,970
Cost of revenue	2,683	2,096
Gross profit	720	874
Operating expenses:		
Research and development	14,298	14,648
General and administrative	28,662	39,524
Performance of contract liability to affiliate	(19)	(115)
Total operating expenses	42,941	54,057
Loss from operations	(42,221)	(53,183)
Equity in net (losses) earnings of affiliate	(9)	9
Foreign currency gain (loss), net	358	9,694
Fair value adjustment to VericiDx investment	(1,282)	(5,900)
Fair value adjustment to convertible notes	(3,107)	3,998
Other income, net	656	131
Net loss before income taxes	(45,605)	(45,251)
Income tax expense	(2)	(25)
Net loss	(45,607)	(45,276)
Net loss per ordinary share—basic	$ (0.55)	$ (0.62)
Net loss per ordinary share—diluted	$ (0.55)	$ (0.67)
Weighted average ordinary shares—basic	82,210,050	72,861,448
Weighted average ordinary shares—diluted	82,210,050	73,837,496
Other comprehensive income (loss):		
Changes in the fair value of the convertible notes	(337)	536
Foreign exchange translation adjustment	(198)	(9,727)
Comprehensive loss	(46,142)	(54,467)

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity
	Shares	Amount				
Balance at June 30, 2021	72,197,286	220	150,407	8,276	(87,442)	71,461
Shares issued under the Securities Purchase Agreement	2,428,688	8	8,578	—	—	8,586
Shares issued under the employee share purchase plan	33,734	—	209	—	—	209
Exercise of stock options	100,724	—	197	—	—	197
Stock-based compensation expense	—	—	4,621	—	—	4,621
Changes in the fair value of the convertible notes	—	—	—	536	—	536
Currency translation adjustments	—	—	—	(9,727)	—	(9,727)
Net loss	—	—	—	—	(45,276)	(45,276)
Balance at June 30, 2022	74,760,432	$ 228	$ 164,012	$ (915)	$ (132,718)	$ 30,607
Shares issued under the Securities Purchase Agreement	18,722,960	57	19,248	—	—	19,305
Shares issued under the employee share purchase plan	298,086	1	260	—	—	261
Stock-based compensation expense	—	—	2,936	—	—	2,936
Changes in the fair value of the convertible notes	—	—	—	(337)	—	(337)
Currency translation adjustments	—	—	—	(198)	—	(198)
Net loss	—	—	—		(45,607)	(45,607)
Balance at June 30, 2023	93,781,478	$ 286	$ 186,456	$ (1,450)	$ (178,325)	$ 6,967

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

RENALYTIX PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended June 30, 2023	Year Ended June 30, 2022
Cash flows from operating activities:		
Net loss	$ (45,607)	$ (45,276)
Adjustments to reconcile net loss to net cash used in operating activities		
Depreciation and amortization	508	489
Stock-based compensation	2,932	4,621
Equity in (net earnings) losses of affiliate	9	(9)
Reduction of Kantaro liability	(55)	(119)
Fair value adjustment to VericiDx investment	1,282	5,900
Unrealized foreign exchange (gain) loss	(1,008)	(7,340)
Fair value adjustment to convertible debt, net interest paid	1,999	(3,998)
Non cash lease expense	106	—
Changes in operating assets and liabilities:		
Accounts receivable	125	(307)
Prepaid expenses and other current assets	1,299	(1,487)
Receivable from affiliates	75	1
Accounts payable	80	1,418
Accounts payable – related party	368	722
Accrued expenses and other current liabilities	3,397	(1,505)
Accrued expenses – related party	451	1,271
Deferred revenue	(46)	(76)
Payable to affiliate – current	—	(176)
Other liabilities	—	(53)
Net cash used in operating activities	(34,085)	(45,924)
Cash flows from investing activities:		
Purchases of property and equipment	—	(557)
Software development costs	—	(105)
Net cash used in investing activities	—	(662)
Cash flows from financing activities:		
Payment of convertible notes principal	(3,180)	—
Proceeds from convertible notes	—	18,020
Payment of debt issuance costs	—	(1,382)
Gross proceeds from the issuance of ordinary shares	20,296	8,804
Payment of offering costs	(991)	(218)
Proceeds from the issuance of ordinary shares under employee share purchase plan	261	209
Proceeds from exercise of stock options	—	197
Net cash provided by financing activities	16,386	25,630
Effect of exchange rate changes on cash	1,048	(2,839)
Net (decrease) increase in cash and cash equivalents	(16,651)	(23,795)
Cash and cash equivalents, beginning of period	41,333	65,128
Cash and cash equivalents, end of period	$ 24,682	$ 41,333
Supplemental noncash investing and financing activities:		
Noncash lease liabilities arising from obtaining right-of-use assets	$ 265	$ —

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

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 $178.3 million as of June 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 our losses and our 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 plans to seek additional funding through public or private equity offerings, debt financings, other collaborations, strategic alliances and licensing arrangements. The Company may not be able to obtain financing on acceptable terms, or at all, and the Company may not be able to enter into strategic alliances or other arrangements on favorable terms, or at all. The terms of any financing may adversely affect the holdings or the rights of the Company’s shareholders. If the Company is unable to obtain funding, the Company could be required to delay, curtail or discontinue research and development programs, product portfolio expansion or future commercialization efforts, which could adversely affect its business prospect.

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 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 income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported in the consolidated statements of operations and comprehensive loss.

Concentrations of credit risk and major customers

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

The Company's accounts receivable are derived from revenue earned from customers located in the U.S. For the year ended June 30, 2023, approximately 70% of all receivables related to KidneyIntelX testing revenue related to one customer, approximately 19% of receivables were due from other party payors and approximately 11% of receivables outstanding related to pharmaceutical services performed for one customer. For the year ended June 30, 2022, the Company's accounts receivable were derived from two customers which provided approximately 99% of the Company's revenue, of which one customer made up 91% of the Company's revenue. 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 for the year ended June 30, 2023.

Fair value of financial instruments

At June 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 June 30, 2023 and 2022, the Company had a cash balance of $24.7 million and $41.3 million, respectively.

Accounts receivable

Accounts receivable are recorded at the invoice amount and are non-interest bearing. The Company considers receivables past due based on the contractual payment terms. The Company reserves specific receivables if collectability is no longer reasonably assured. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations, historical payment patterns, and individual customer circumstances. The Company reserved for $0.1 million of receivables as of June 30, 2023. No reserves were recorded as of June 30, 2022.

Property and equipment

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

Performance of contract liability to affiliate

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement ("Kantaro Operating Agreement") to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. Kantaro has a fiscal year ending December 31st. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the Kantaro business. As part of the termination agreement, the members agreed that Renalytix has no further liability to perform services on behalf of Kantaro. During the years ended June 30, 2023 and 2022, the Company recognized $0.01 million and $0.1 million, respectively, related to the performance of the contract liability with Kantaro. This represents the allocation of costs for performing services on behalf of Kantaro.

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 closing stock price of VericiDx, the fair value of the investment in VericiDx was $1.5 million and $2.7 million at June 30, 2023 and 2022, respectively. During the year ended June 30, 2023 and 2022, the Company recorded a decrease in fair value of $1.3 million and $5.9 million, respectively, in the consolidated statements of operations and comprehensive loss. The Company owned 5.8% of the ordinary shares of VericiDx at June 30, 2023 and 2022.

Equity Method Investments

Kantaro Biosciences LLC

The Company accounts for equity investments where it owns a non-controlling interest, but has the ability to exercise significant influence, under the equity method of accounting. Under the equity method of accounting, the original cost of the investment is adjusted for the Company’s share of equity in the earnings of the equity investee and reduced by dividends and distributions of capital received, unless the fair value option is elected, in which case the investment balance is marked to fair value each reporting period and the impact of changes in fair value of the equity investment are reported in earnings.

As the Company can exert significant influence over, but does not control, Kantaro’s operations through voting rights or representation on Kantaro’s board of directors, the Company accounts for this investment using the equity method of accounting. The Company records its share in Kantaro’s earnings and losses in the consolidated statement of operations. The Company assesses its investment for other-than-temporary impairment when events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable and recognize an impairment loss to adjust the investment to its then-current fair value. On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the business and unanimously signed a termination agreement. As part of the termination agreement, the members agreed to wind up Kantaro's business and dissolve it promptly after the effective date of the termination agreement. As of June 30, 2023, Kantaro's business was completely dissolved and the Company no longer held an equity interest in Kantaro. The Company owned 25% of the membership equity units in Kantaro at June 30, 2022.

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 year ended June 30, 2023, there was no capitalization of research and development expenses related to software development to record. For the year ended June 30, 2022, the Company capitalized $0.1 million of research and development expenses related to software development. 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.

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

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2023. The Company plans to implement ASU 2016-13 in the fiscal year beginning July 1, 2023 and evaluated the impact of ASU 2016-13 and it is not expected to 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 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 years ended June 30, 2023 and 2022, the Company recognized $3.1 million and $2.7 million, respectively, of testing services revenue. Sales tax and other similar taxes are excluded from revenues.

During the year ended June 30, 2023, the Company performed testing and provided approved KidneyIntelX risk scores for approximately 100 samples or $0.1 million of potential revenue where collectability was determined to not be reasonably assured. The Company will continue to assess each contract to determine whether the collectability criterion is met and recognize revenue when collectability is reasonable assured.

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 years ended June 30, 2023 and 2022, the Company recognized $0.3 million and $0.2 million, respectively, of pharmaceutical services revenue where performance obligations are satisfied at a point in time.

Professional services revenue

Professional services revenue consists of services related to the creation of a branded care navigation portal/pathway for use with KidneyIntelX. Revenue is recognized when control of the promised services is transferred to customers and the performance obligation is fulfilled in an amount that reflects the consideration that the Company expects to be entitled to in exchange for those services. There was no professional services revenue recognized in the fiscal years ended June 30, 2023 and 2022.

Deferred revenue

Deferred revenue represents the allocated transaction price to the material right which will be recognized as revenue when the renewal options are exercised which is expected to occur over the next 6 months.

The following table summarizes the changes in deferred revenue:

(in thousands)	June 30, 2023	June 30, 2022
Balance, beginning of period	$ 46	$ 122
Deferral of revenue	—	67
Revenue recognized	(46)	(143)
Balance, end of period	$ —	$ 46

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:

	Fair value measurement at reporting date using		
(in thousands)	(Level 1)	(Level 2)	(Level 3)
June 30, 2023			
Assets:			
Equity Securities	$ 1,460	$ —	$ —
Liabilities:			
Convertible notes	$ —	$ —	$ 11,948
June 30, 2022			
Assets:			
Equity Securities	$ 2,744	$ —	$ —
Liabilities:			
Convertible notes	$ —	$ —	$ 12,342

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 $1.5 million and $2.7 million at June 30, 2023 and 2022, respectively.

As further described in Note 8, in April 2022 the Company issued convertible promissory notes (the "Notes") to various investors. 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)	June 30, 2023
Balance at the beginning of the year	$ 12,342
Change due to payment of principal and interest	(4,287)
Fair value adjustments	3,107
Change in credit risk	(337)
FX Impact	1,123
Balance at June 30, 2023	$ 11,948

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)	June 30, 2023	June 30, 2022
Lab equipment	$ 1,142	$ 1,143
Office equipment	124	124
Office furniture	35	35
Leasehold improvements	576	576
Total	1,877	1,878
Less accumulated depreciation	(850)	(509)
	$ 1,027	$ 1,369

Depreciation expense was $0.3 million and $0.3 million for the years ended June 30, 2023 and 2022, respectively.

(in thousands)	June 30, 2023	June 30, 2022
Software	$ 1,526	$ 1,476
Total	1,526	1,476
Less accumulated amortization	(476)	(287)
	$ 1,050	$ 1,189

As of June 30, 2023 and 2022 there was $1.1 million and $1.2 million, respectively, of unamortized costs of software development and purchased software. Amortization expense related to capitalized software development costs was $0.2 million and $0.2 million for the years ended June 30, 2023 and 2022, respectively, and was expensed within cost of revenue in the consolidated statements of operations.

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

(in thousands)	
2024	$ 181
2025	181
2026	142
2027	125
2028	125
Thereafter	296
	$ 1,050

7. Accrued expenses and other current liabilities

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

	June 30, 2023	June 30, 2022
Consulting and professional fees	$ 442	$ 551
Research and development	1,657	909
Payroll and related benefits	3,866	1,437
License and Royalty Expense	669	151
Other	10	12
	$ 6,644	$ 3,060

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"). 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, 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 2022, 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. In October 2022, the investor deferred the October amortization payment to maturity of the bond and the Company made an interest payment of $0.3 million. In January 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. In April 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. As of June 30, 2023, $18.0 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 June 30, 2023, the fair value of the Bonds was determined to be $11.9 million. During the twelve months ended June 30, 2023, the Company recognized a decrease in fair value of the Notes related to the instrument-specific credit risk of $0.3 million in the comprehensive loss and an increase in fair value related to non-instrument specific credit risk of $3.1 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 $0.5 million in the comprehensive loss and a decrease in fair value related to non-instrument specific credit risk of $4.0 million as a gain in the consolidated statement of operations during the year ended June 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 quarter ended June 30, 2023 (in thousands):

(in thousands)	June 30, 2023
Assets	
Operating lease right-of-use assets, net of accumulated amortization	$ 159
Liabilities	
Current	$ 130
Operating lease liabilities, current	
Non-current	
Operating lease liabilities, non-current	$ 41
Total lease liabilities	$ 171

The following table shows the lease costs for the year ended June 30, 2023 (in thousands):

Lease costs (in thousands)	Statement of operations classification		June 30, 2023
Operating lease costs	Operating expenses: research and development	$	129
Short term lease costs	Operating expenses: research and development	$	59
Short term lease costs	Operating expenses: general and administrative	$	132
Short term lease costs	Cost of goods sold	$	368
Total lease costs		$	688

Other information		June 30, 2023
Cash paid for amounts included in the measurement of lease liabilities (in thousands)	$	129
Remaining lease term - operating leases (in years)		1.4
Discount rate - operating leases		10%

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

(in thousands)	
2024	$ 138
2025	46
2026	—
Total minimum lease payments	$ 184
Less amounts representing interest	$ (13)
Present value of lease liabilities	$ 171

The Company recognized rent expense of $0.7 million and $0.7 million during the years ended June 30, 2023 and 2022, respectively, related to all leases. Rent expense is included within cost of revenue, research and development and general and administrative expenses in the consolidated statement of operations.

10. Commitments and contingencies

Leases

Lease payments under operating leases as of June 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 $0.4 million and $0.4 million in contributions for the year ended June 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 $2.6 million and $1.4 million related to the ISMMS SRA for the years ended June 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 is 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 June 30, 2023, amounts due to ISMMS under the CTA totaled $0.8 million and $0.5 million was expensed during the year ended June 30, 2023. As of June 30, 2022, amounts due to ISMMS under the CTA totaled $0.4 million and $0.6 million was expensed during the year ended June 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 June 30, 2023 which were recorded as cost of revenue within the statement of operations. Royalties recorded for the year ended June 30, 2022 were immaterial.

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 $3.3 million in expenses and provided over 1,700 reportable patient results in the Atrium Wake Forest system across 78 providers. As of June 30, 2023, the Company accrued for $1.1 million of expense related to the clinical trial agreement and amounts due to Wake Forest/Atrium Health under the clinical trial agreement totaled $3.3 million and $2.1 million was expensed during the year ended June 30, 2023. As of June 30, 2022, the Company accrued for $0.6 million of expense related to the clinical trial agreement and amounts due to Wake Forest/Atrium Health under the clinical trial agreement $1.2 million and $1.2 million was expensed during the year ended June 30, 2022.

12. Shareholders’ equity

Ordinary shares

As of June 30, 2023, the Company had 98,750,054 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 June 30, 2023, no cash dividends have been declared or paid.

PIPE Funding

On February 9, 2023, the Company entered into security purchase agreements to sell an aggregate of 3,699,910 Ordinary Shares at a price of £0.90 per Ordinary Share and 7,511,525 American Depositary Shares ("ADSs"), at a price of $2.17 per ADS. The private placement generated gross cash proceeds of $20.3 million, the net proceeds of which will be used for sales and marketing, clinical product development, and corporate support and financing costs.

In prior fiscal year, on March 31, 2022, the Company entered into subscription agreements to sell an aggregate of 2,428,688 ordinary shares, including in the form of ADSs (the "PIPE Shares"), for a purchase price of $3.626 per ordinary share and an aggregate purchase price of $8.8 million.

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 June 30, 2023, there were 14,246,664 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 granted as of June 30, 2023, 2,984,799 vest equally over twelve quarters following the grant date, 962,477 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary, 500,000 which vest 1/12th immediately and the remainder equally over the remaining eleven quarters, 471,300 which vest 25% on the one year anniversary, 50% on the two year anniversary, 25% on the three year anniversary, 40,000 which vest quarterly over two years and 10,000 which 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 years ended June 30, 2023 and 2022 (in thousands):

	Twelve Months Ended June 30,	
	2023	2022
Research and development	$ 312	$ 345
General and administrative	$ 2,612	4,276
Cost of revenue	$ 12	—
	$ 2,936	$ 4,621

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 years ended June 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 years ended June 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:

	Twelve Months Ended June 30,	
	2023	2022
Expected term (in years)	6.1	5.6
Expected volatility	66.9%	61.4%
Risk-free rate	3.2%	1.3%
Dividend yield	—%	—%

The weighted average fair value of the options granted during the years ended June 30, 2023 and 2022 was $1.19 and $6.60 per share, respectively.

The following table summarizes the stock option granted to employees and non-employees for the year ended June 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, 2022	4,599,899	$	5.06	8.1
Granted	571,300	$	1.91	
Exercised	—	$	-	
Forfeited	(202,623)	$	9.86	
Outstanding at June 30, 2023	4,968,576	$	4.50	6.7
Exercisable at June 30, 2023	4,008,293	$	4.39	6.2
Vested and expected to vest at June 30, 2023	4,968,576	$	4.50	6.7

As of June 30, 2023, there was $2.50 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 2.05 years. The aggregate intrinsic value of options outstanding and options exercisable at June 30, 2022 was nil, respectively.

Employee Share Purchase Plan

The Company's 2020 Employee Share Purchase Plan (the "ESPP") became effective on August 17, 2020. The ESPP authorizes the issuance of up to 850,000 shares of the Company's common stock. The number of shares of the Company's common stock that may be issued pursuant to rights granted under the ESPP shall automatically increase on January 1st of each year, commencing on January 1, 2021 and continuing for ten years, in an amount equal to the lesser of one percent of the total number of shares of the Company's common stock outstanding on December 31st of the preceding calendar year, and 2,000,000 ordinary shares, subject to the discretion of the board of directors or renumeration committee to determine a lesser number of shares shall be added for such year.

Under the ESPP, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the board of directors or renumeration committee. Eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of the Company's common stock on the first day of the offering period or on the purchase date. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not purchase more than $25,000 worth of the Company's common stock for each calendar year in which such rights is outstanding. During the years ended June 30, 2023 and 2022, 298,086 and 33,734 shares were purchased under the ESPP, respectively.

In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company's common stock at 85% of the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, share-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period. The Company recognized share-based compensation expense of $0.07 million and $0.07 million in general and administrative expense and $0.03 million and $0.04 million in research and development expense during the years ended June 30, 2023 and 2022, respectively, related to the ESPP.

Restricted Stock Units

Activity for restricted stock units for the year ended June 30, 2023 is as follows:

	Number of Restricted Stock Units	Weighted-average Grant Date Fair Value
Non-vested balance at June 30, 2022	—	$ -
Granted	135,000	$ 1.55
Vested	(82,800)	$ 1.44
Forfeited	(11,860)	$ 1.47
Non-vested balance at June 30, 2023	40,340	$ 1.72

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

At June 30, 2023, total unrecognized compensation expense related to non-vested restricted stock units was approximately $0.05 million. Unrecognized compensation expense relating to restricted stock units that are deemed probably of vesting is expected to be recognized over a weighted-average period of approximately 1.4 years.

14. Income taxes

Loss from operations before income taxes was comprised of the following (in thousands):

	Twelve Months Ended June 30, 2023	2022
United Kingdom and other	$ (712)	$ (13,061)
United States	$ (44,894)	(32,194)
	$ (45,606)	$ (45,255)

Due to the pretax losses reported in both the United Kingdom and United States for all periods since inception there is no income tax expense or benefit but for an immaterial amount of Ireland income tax expense for the period ended June 30, 2023.

A reconciliation of income tax benefit from continuing operations as reflected in the financial statements is as follows:

	Twelve Months Ended June 30, 2023	2022
U.K tax benefit at statutory rate	(20.5) %	(19.0) %
State taxes, net of federal benefit	(10.4)	(3.7)
Permanent differences	0.9	1.4
Research and development	—	—
Change in valuation allowance	31.2	24.1
Foreign rate differential	(1.1)	(2.6)
Other	(0.1)	(0.1)
Effective tax rate	0.0 %	0.1 %

The principal components of the Company's deferred tax assets and liabilities were as follows (in thousands):

	Twelve Months Ended June 30, 2023	2022
Deferred tax assets:		
Net operating losses	$ 37,740	$ 27,201
Capitalized research and development costs	2,826	—
Research and development licenses	2,814	3,150
Share-based compensation	1,327	1,025
Unrealized foreign exchange loss	—	—
Deferred interest expense	—	—
Accrued expenses	964	311
Mark-to-market securities	256	—
Lease liabilities	55	—
Other	73	4
Valuation allowances	(45,602)	(31,113)
Total deferred tax assets	453	578
Deferred tax liabilities:		
Depreciation	(386)	(473)
Mark-to-market securities	—	(89)
Right-of-use assets	(51)	—
Unrealized foreign exchange loss	(16)	(16)
Total deferred tax liabilities	(453)	(578)
Net deferred tax	$ —	$ —

The Company does not have unrecognized tax benefits as of June 30, 2023 and 2022. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

The Company's net operating loss carryforwards ("NOL") for U.K., U.S. federal and U.S. state income tax purposes consisted of the following (in thousands):

	Twelve Months Ended June 30, 2023	2022
United Kingdom	$ 26,569	$ 13,452
U.S. Federal	98,555	79,896
U.S. State and Local	177,306	120,146

The UK and federal net operating loss carryforwards have no expiration. The amount of UK annual profits that can be relieved by losses carried forward is limited to 50%, in excess of a threshold amount of £5 million of profits. Under the Tax Cuts and Jobs Act of 2017 as modified by the Coronavirus Aid, Relief, and Economic Security (CARES) Act, or collectively, the Tax Acts, U.S. federal net operating losses incurred taxable years beginning after December 31, 2017 may be carried forward indefinitely, but the deductibility of such federal net operating losses may be limited to 80% of taxable income in taxable years beginning after December 31, 2020. The federal NOL net operating loss amount will carry forward indefinitely. Certain state net operating loss carryforwards begin to expire in 2038. The Company recorded a valuation allowance on the deferred tax assets as of June 30, 2023 and 2022 because of the uncertainty of their realization. The valuation allowance increased by $14.5 million for the year ended June 30, 2023 and $10.1 million for the year ended June 30, 2022.

Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 as amended, if changes in ownership of the company have occur previously or occur in the future. Ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of 5-percent shareholders in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company experiences a Section 382 ownership change, the tax benefits related to the NOL carry forwards may be further limited or lost. The Company may also experience ownership changes as a result of shifts in share ownership, some of which are outside its control. Therefore, as a result of ownership changes with respect to ordinary shares, the ability to use current net operating losses and other pre-change tax attributes to offset post-change taxable income or taxes could be subject to limitation. The Company has not undertaken a Section 382 study.

For tax years beginning on or after January 1, 2022, the Tax Cuts and Jobs Act of 2017 ("TCJA") eliminates the option to currently deduct research and development expenses and requires taxpayers to capitalize and amortize them over five years for research activities performed in the United States and 15 years for research activities performed outside the United States pursuant to IRC Section 174.

The Company files income tax returns in the United Kingdom, Ireland the U.S. federal jurisdiction and various state jurisdictions. The Company's 2018 through 2022 tax years remain subject to examination. Carryforward attributes from prior years may be adjusted upon examination by tax authorities if they are used in an open period.

15. Related-party transactions

EKF Diagnostic Holdings

During the years ended June 30, 2023 and 2022, the Company incurred expenses of $0.1 million and $0.1 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 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 June 30, 2023 and 2022, amounts due to ISMMS totaled $3.4 million and $2.6 million, respectively. During the years ended June 30, 2023 and 2022, the Company incurred expenses of $3.3 million and $3.1 million, respectively, related to its obligations under the ISMMS license agreement.

Kantaro Biosciences LLC

In connection with the formation of Kantaro, the Company entered into a five-year Advisory Services Agreement (“Advisory Agreement”) pursuant to which the Company has agreed to provide certain advisory services to Kantaro. Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to the Company as the sole consideration for the services to be rendered by the Company under the Advisory Agreement. A portion of the Company’s units are subject to forfeiture if, prior to December 31, 2021, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services to be provided under the Advisory Agreement was $2.0 million and the fair value of the Class A units received from Kantaro was $2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions which include discount rates and future cash flows, among others. As a result of the prior year impairment charge discussed in Note 3, the carrying value of the Kantaro investment was written down to zero.

A contributing factor to the impairment consideration for Kantaro was lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees. Based on these circumstances, the Company adjusted the liability to perform services to Kantaro under the Advisory Agreement during the year ended June 30, 2021. On December 31, 2022, the members and managers of Kantaro decided that it was in the best interest of Kantaro to wind up the business and unanimously signed a termination agreement. As part of the termination agreement, the members agreed to wind up Kantaro's business and dissolve it reasonably promptly after the effective date of the termination agreement. The termination agreement relieved Renalytix of its obligation to provide services to Kantaro, and the total liability associated with the services was written off.

For the twelve months ended June 30, 2023, the Company recognized $0.02 million in the statement of operations related to services performed under the Advisory Agreement. For the twelve months ended June 30, 2023, $0.01 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $0.01 million were included in general and administrative expense. For the twelve months ended June 30, 2022, the Company recognized $0.1 million statements of operations related to services performed under the Advisory Agreement. For the twelve months ended June 30, 2022, $0.05 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $0.07 million were included within general and administrative expense.

In addition to the equity granted at formation, in May 2020 the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $0.3 million and an additional $0.5 million thereafter. The Company committed to lend an initial amount of $0.08 million and an additional $0.17 million thereafter. Each loan bears interest at a per year rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to the Company based on each investor’s proportionate ownership). The Company loaned Kantaro $0.25 million and initially recorded a note receivable. Upon liquidation of the joint venture, Kantaro paid Renalytix $0.2 million for repayment of the loan. Renalytix recognized income of $0.1 million in the statement of operations as the loan had a carrying value of approximately $0.075 million at the time of repayment.

Private Placement

On February 9, 2023, the Company entered into security purchase agreements to sell an aggregate of 3,699,910 Ordinary Shares, and 7,511,525 ADS, at a price of $2.17 per ADS and £0.90 per Ordinary Share. The private placement generated gross cash proceeds of $20.3 million, the net proceeds of which will be used for sales and marketing, clinical product development, and corporate support and financing costs. Certain related parties, directors of the Company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,382,489 new American Depositary Shares at $2.17 per ADS. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 346,375 Ordinary Shares at £0.90 per Ordinary Share.

In the year ended June 30, 2022, the Company also entered into a private placement agreement to sell, an aggregate of 2,428,688 shares of common stock (the “PIPE Shares”), for a purchase price of $3.625 per share and an aggregate purchase price of $8.8 million. Certain related parties, directors of the company and executive officers participated in the private placement. Mount Sinai subscribed for a total of 1,103,448 new ordinary shares at $3.625 per ordinary share. EKF Diagnostics Holdings, subscribed for a total of 137,930 new ordinary shares at $3.625 per ordinary share. Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 551,724 new ordinary shares at $3.625 per ordinary share. Timothy Scannell, Non-Executive Director, subscribed for a total of 68,964 new ordinary shares at $3.625 per ordinary share. Thomas McLain, President, subscribed for a total of 55,172 new ordinary shares at $3.625 per ordinary share.

16. 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 June 30, 2023 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.

For the fiscal year ended June 30, 2022, the diluted net loss per share calculation included the dilutive effect of convertible debt as well as the impact of the $3.9 million fair value gain related to the convertible debt, which further increase net loss used in the diluted loss per share calculation.

The following is a reconciliation of basic net loss per share to diluted net loss per share for the fiscal years ended June 30, 2023 and 2022.

	Year ended June 30,	
	2023	2022
Basic earnings per share	$ (0.55)	$ (0.62)
Average shares outstanding - basic	82,210,050	72,861,448
Convertible debt shares	-	976,048
Adjusted average shares outstanding - diluted	82,210,050	73,837,496
Diluted earnings per share	$ (0.55)	$ (0.67)

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:

	Twelve Months Ended June 30,	
	2023	2022
Stock options to purchase ordinary shares	4,968,576	4,554,901
Restricted stock units	40,340	—
Conversion of convertible note	5,441,198	—
	10,450,114	4,554,901

17. Subsequent Events

On July 17, 2023, the Company announced the repayment of $1.06 million of the Company's convertible bond through the issuance of 526,211 American Depositary Shares ("ADS"). 1,052,422 new ordinary shares of £0.0025 each in the capital of the Company (the "Ordinary Shares") were issued to settle the conversion of 526,211 ADSs, with each ADS representing two Ordinary Shares. After settlement of the repayment, the principal remaining under the convertible bond will be reduced by $1.06 million to $15.90 million.

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "Agreement') is entered into on October 22, 2018 and shall become effective on the date of admission of the entire issued share capital of Renalytix AI plc ("***Parent***") to trading on AIM, the market operated by London Stock Exchange plc (the "***Effective Date***"), by and among James McCullough (the "***Employee***") and Renalytix AI, Inc. ("***Renalytix DE***" or the "***Company***"), a Delaware corporation, and the Parent (collectively with Renalytix DE, the "***Group***").

On and from the Effective Date, the Company desires to employ the Employee as its Chief Executive Officer and, in connection therewith, to compensate the Employee for Employee's personal services to the Company; and

Employee wishes to be so employed by the Company and provide personal services and certain covenants to the Company in return for certain compensation and benefits.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position. Subject to the terms set forth herein, the Company agrees to employ Employee in the position of Chief Executive Officer, and Employee hereby accepts such employment. As Chief Executive Officer, Employee will serve as a member of the Board of Directors of the Company (the "***Board***") and its Executive Committee (if established), subject to approval of the Board and in accordance with the Company's By-laws, as amended from time-to-time. Continued tenure in the capacity as a director of Parent is subject to shareholder approval from time to time in accordance with the articles of association of Parent and Parent's corporate governance policies as in force from time to time (and for the avoidance of doubt retirement of Parent's directors will be put to shareholders on an individual director basis and not a plurality slated resolution).

1.2 Duties. Employee will report to the Board, performing such duties as are normally associated and commensurate with his position. During the term of Employee's employment with the Company, Employee will devote Employee's best efforts and substantially all of Employee's business time and attention to the business of the Group. Employee shall perform Employee's duties under this Agreement principally out of the Company's U.S. corporate headquarters in New York. In addition, Employee shall make such business trips to such places as may be necessary or advisable for the efficient operations of the Group.

1.3 Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Employee will be eligible to participate on the same basis as similarly situated employees in Renalytix DE's benefit plans in effect from time to time during his employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of the such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing,

in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COMPENSATION.

2.1 Salary. Employee shall receive for Employee's services to be rendered under this Agreement an initial base salary of $350,000 on an annualized basis, subject to review and increase by the Remuneration Committee of the Parent ("***RemCo***") in its sole discretion but in no event less than three percent (3%) per year, payable and subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

2.2 Annual Discretionary Bonus. Employee will be eligible for an annual cash bonus in the sole discretion of the RemCo, payable subject to standard payroll withholding requirements. Whether or not Employee earns any bonus will be dependent upon (a) the actual achievement by Employee and the Company of the applicable individual and corporate performance goals, as determined by the RemCo in its sole discretion, and (b) Employee's continuous performance of services to the Company through the date any such bonus is paid (which shall be no later than March 15 of the year following the year to which the bonus relates), except as set forth below in Section 6. The bonus may be greater or lesser than any target Bonus and may be zero should the Board determine that any performance criteria agreed with the Employee have not been met.

2.3 Expense Reimbursement. The Company will reimburse Employee for reasonable business expenses in accordance with the Company's standard expense reimbursement policy, as the same may be modified by the Board from time to time. The Company shall reimburse Employee for all customary and appropriate business-related expenses actually incurred and documented in accordance with Company policy as in effect from time to time as soon as practicable after Employee's submission of supporting documentation. For the avoidance of doubt, to the extent that any reimbursements payable to Employee are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

2.4 Vacation. Employee will be eligible to accrue a maximum of five (5) weeks paid vacation per year, in accordance with the Company's vacation policy, which shall be taken subject to the demands of the Company's business and Employee's obligations as an employee of the Company with a substantial degree of responsibility.

3. CONFIDENTIAL INFORMATION, INVENTIONS, NON-COMPETITION AND NON-SOLICITATION OBLIGATIONS. As a condition of employment, Employee agrees to execute and abide by the Employee Confidential Information, Inventions, Non-Competition and Non-Solicitation Agreement attached as Exhibit A ("***Confidential Information Agreement***"), which may be amended by the parties from time to time without regard to this Agreement. The Confidential Information Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4. OUTSIDE ACTIVITIES DURING EMPLOYMENT. Except with the prior written consent of the Company, which consent shall not unreasonably be withheld, Employee will not, while employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Employee's responsibilities and the performance of Employee's duties hereunder, except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Employee may wish to serve, (ii) reasonable time devoted to

activities in the non-profit and business communities consistent with Employee's duties, (iii) such other activities as may be specifically approved by the Company. This restriction shall not, however, preclude Employee (i) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (ii) from employment or service in any capacity with Affiliates of the Company. As used in this Agreement, "***Affiliates***" means an entity under common management or control with the Company.

5. **No Conflict with Existing Obligations**. Employee represents that Employee's performance of all the terms of this Agreement and as an Employee of the Company do not and will not breach any agreement or obligation of any kind made prior to Employee's employment by the Company, including agreements or obligations Employee may have with prior employers or entities for which Employee has provided services. Employee has not entered into, and Employee agrees that Employee will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. **Termination Of Employment.** The parties acknowledge that Employee's employment relationship with the Company is at-will. Either Employee or the Company may terminate the employment relationship for any reason whatsoever at any time, with or without cause or advance notice. The provisions in this Section govern the amount of compensation, if any, to be provided to Employee upon termination of employment and do not alter this at-will status.

6.1 **Termination by the Company Without Cause**.

(a) The Company shall have the right to terminate Employee's employment with the Company pursuant to this Section 6.1 at any time without "Cause" (as defined in Section 6.2(b) below) by giving notice as described in Section 7.1 of this Agreement. A termination pursuant to Section 6.5 below is not a termination without "Cause" for purposes of receiving the benefits described in this Section 6.1.

(b) If the Company terminates Employee's employment without Cause and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section l.409A-l(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), then Employee shall be entitled to receive the Accrued Obligations (defined below) and, subject to Employee's material compliance with the obligations in Section 6. l(c) below, Employee shall be eligible to receive the following severance benefits (the "***Severance Benefits***"):

(i) The Company will pay Employee an amount equal to Employee's then current Base Salary for twelve (12) months, less all applicable withholdings and authorized deductions, and paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in Section 6. l(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter. If any such payments are delayed due to the timing of the effectiveness of the Release, any such payments owed since the termination date shall be paid in the first payroll following the Release Effective Date.

(ii) If Employee timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Employee's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (A) twelve (12) months following the termination date (the "***COBRA Severance Period***"); (B) the date when Employee becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self employment; or (C) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "***COBRA Payment Period***"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Employee's

behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Employee on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Employee of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(iii) The Company will pay (i) any bonus earned from the year prior to the year in which the termination occurs, to the extent not previously paid, and (ii) a pro rata portion of the bonus for the year in which the termination occurs, in each case calculated by the Company in good faith with any individual goals deemed to have been achieved and such bonuses to be paid no later than March 15 of the year following the year to which the bonus relates.

(iv) The Company will accelerate (or cause to be accelerated) the vesting of that portion of Employee's equity held on the termination date that would have vested over the one year period following the termination date; provided that all unvested equity shall vest in the event of a Change in Control.

For purposes of this Agreement, a "**Change in Control**" means any of the following transactions: (i) a sale of all or substantially all of the assets of either the Company or the Parent in one or more transactions, (ii) a consolidation or merger of either the Company or the Parent with or into any other corporation or other entity, or any other corporate re-organization, as a result of which the current shareholders own capital stock of the entity surviving such merger, consolidation or reorganization representing less than fifty percent (50%) of the combined voting power of the outstanding securities of the surviving entity immediately after such consolidation, merger or reorganization, or (iii) the sale by the current shareholders of either in one or more transactions which results in the current shareholders owning less than fifty percent (50%) of the outstanding equity securities of either the Company or the Parent. For purposes of this Agreement, a "Change in Control" shall have the meaning given by the UK Takeover Code.

(c) Employee will be paid all of the Accrued Obligations on the Company's first payroll date after Employee's date of termination from employment or earlier if required by law. If eligible to receive the Severance Benefits pursuant to Section 6.l(b) of this Agreement, Employee will only receive such Severance Benefits if: (i) within the time period provided in the separation agreement (which shall be no longer than 60 days following the date of Employee's Separation from Service), he has signed and delivered to the Company an effective separation agreement that includes, among other terms, a general release of claims in favor of the Company and its affiliates and representatives, in a form reasonably acceptable to the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if he holds any other positions with the Company, he resigns such position(s) to be effective no later than the date of Employee's termination date (or such other date as requested by the Board); (iii) he returns all Company property; (iv) he complies with his post-termination obligations under this Agreement and the Confidential Information Agreement; and (v) he complies with the terms of the Release, including without limitation any non-disparagement (which shall be mutual to the extent applicable to the Company's officers while employed by the Company), confidentiality and cooperation provisions contained in Release. The Release shall not release the Company from the obligations under this Section, any vested rights under any employee benefit or compensation plan or indemnification obligations.

(d) For purposes of this Agreement, "***Accrued Obligations***" are (i) Employee's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred

by Employee payable in accordance with the Company's standard expense reimbursement policies, (iii) any accrued but not taken vacation pay and (iv) benefits owed to Employee under any qualified retirement plan or health and welfare benefit plan in which Employee was a participant in accordance with applicable law and the provisions of such plan.

(e) The Severance Benefits provided to Employee pursuant to this Section 6.1 are in lieu of, and not in addition to, any benefits to which Employee may otherwise be entitled under any Company severance plan, policy or program.

(f) Any damages caused by the termination of Employee's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Employee is eligible pursuant to Section 6.l(b) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

6.2 Termination by the Company for Cause.

(a) The Company shall have the right to terminate Employee's employment with the Company at any time for Cause by giving notice as described in Section 7.1 of this Agreement; provided that if such event is capable of cure in the opinion of the Company, the Company first provides written notice detailing the event and provides Employee with thirty (30) days in which to cure. If cured, the Company may not terminate Employee's employment for Cause.

(b) "***Cause***" for purposes of this Agreement shall mean that Employee has engaged in any of the following: (i) a material breach of any covenant or condition under this Agreement or any other agreement between the Company and Employee; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) material violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of Company; (vi) negligence in the performance of Employee's duties or failure to perform his material duties to the Company; (vii) failure to pass to the satisfaction of the Company, a preliminary background check or failure to submit proof of legal eligibility to work in the United States; or (viii) breach of fiduciary duty.

(c) In the event Employee's employment is terminated at any time for Cause, Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.3 Resignation by Employee (without Good Reason).

(a) Employee may resign from Employee's employment with the Company at any time by giving notice as described in Section 7.1.

(b) In the event Employee resigns from Employee's employment with the Company (other than for Good Reason as set forth in Section 6.4), Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.4 Resignation by Employee for Good Reason.

(a) Provided Employee has not previously been notified of the Company's intention to terminate Employee's employment, Employee may resign from employment with the Company for Good Reason (as defined in Section 6.4(6) below).

(b) "***Good Reason***" for purposes of this Agreement shall mean the occurrence of any of the following conditions without Employee's prior written consent after Employee's provision of written notice to the Company of the existence of such condition (which notice must be provided as described in Section 7.1 within ninety (90) days of the initial existence of the condition and must specify the particular condition in reasonable detail), provided that the Company has not first provided notice to Employee of its intent to terminate Employee's employment: (i) a material diminution of, or material reduction or material adverse alteration in, Employee's position, title, duties, or responsibilities; (ii) a material (greater than 10%) reduction by the Company of Employee's Base Salary (except in the case of either an across the board reduction in salaries or a temporary reduction due to financial exigency); or (iii) a relocation of Employee, or the Company's principal offices to which Employee is assigned more than fifty (50) miles from its then current location, except for required travel by Employee on the Company's business or (iv) a material breach of this Agreement by the Company. Notwithstanding the foregoing, Good Reason shall only exist if the Company is provided a thirty (30) day period to cure the event or condition giving rise to Good Reason, and it fails to do so within that cure period (and, additionally, Employee must resign for such Good Reason condition by giving notice as described in Section 7. l within ten (10) days after the period for curing the violation or condition has ended).

(c) In the event Employee resigns from Employee's employment for Good Reason, then Employee shall be entitled to the Accrued Obligations and, provided that Employee complies with the obligations in Section 6.1(c) of this Agreement (including the requirement to provide an effective Release), Employee shall be eligible to receive the same Severance Benefits as described in Section 6.1 and on the same conditions as if Employee had been terminated by the Company without Cause.

6.5 Termination by Virtue of Death or Disability of Employee.

(a) In the event of Employee's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll policies, pay to Employee's legal representatives all Accrued Obligations as well as payment for any bonus earned for the year prior to the year of termination, to the extent not paid, and a pro rata bonus for the year in which the termination occurs, each determined by the Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

(b) Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to Employee, to terminate this Agreement based on Employee's Disability. Termination by the Company of Employee's employment based on "***Disability***" shall mean termination because Employee is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 180 days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. One of the physicians shall be chosen by the Company and the other shall be chosen by the Employee, or by his or his representative. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Employee's employment is terminated based on Employee's Disability, Employee will not receive severance payments, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations as well as any payment for any bonus earned for the year prior to the year of termination to the extent not paid and a pro rata bonus for the year in which the termination occurs, each determined by the

Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

6.6 Application of Section 409A. It is intended that all of the severance payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "***Section 409A***") provided under Treasury Regulations Sections 1.409A-l(b)(4) and 1.409A-l(b)(9), and this Agreement will be construed in a manner that complies with Section 409A. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and payment terms. No severance payments will be made under this Agreement unless Employee's termination of employment constitutes a "separation from service" (as defined under Treasury Regulation Section l.409A-l(h)). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section l.409A-2(b)(2)(iii)), Employee's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. To the extent that any severance payments are deferred compensation under Section 409A, and are not otherwise exempt from the application of Section 409A, then, if the period during which Employee may consider and sign the Release spans two calendar years, the severance payments will not begin until the second calendar year. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Employee's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance will be delayed as follows: on the earlier to occur of (a) the date that is six months and one day after Employee's Separation from Service, and (b) the date of Employee's death (such earlier date, the "***Delayed Initial Payment Date***"), the Company will (i) pay to Employee a lump sum amount equal to the sum of the severance benefits that Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.6 and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Section 6.1. No interest shall be due on any amounts deferred pursuant to this Section 6.6.

6.7 280G Approval. To the extent the Parachute Payment Vote (as defined below) is permitted by the Regulations (as defined below), and Employee agrees to waive (as would be required under the Regulations) the right to all or any portion of the payment or benefit Employee would receive pursuant to a Change in Control as a result of the provisions of this Agreement that would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) be subject to the excise tax imposed by Section 4999 of the Code (the "**At-Risk Payments**), the Company shall use commercially reasonable efforts to timely solicit stockholder approval of the At Risk Payments (the "**Parachute Payment Vote**") in accordance with the requirements of Treasury Regulations § l .280G-l, Q&A-7 or any successor thereto (the "**Regulations**"***)***.

6.8 Cooperation With Company After Termination of Employment. Following termination of Employee's employment for any reason and for a period of two years thereafter, Employee shall reasonably cooperate with the Company in all matters relating to the winding up of Employee's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company. The Company will reimburse Employee for reasonable out-ofpocket expenses Employee incurs in connection with any such cooperation (excluding forgone wages, salary, or other compensation) and will make reasonable efforts to accommodate Employee's scheduling needs.

7. GENERAL PROVISIONS.

7.1 Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company payroll or to Employee's Company-issued email address, or at such other address as the Company or Employee may designate by ten (10) days advance written notice to the other.

7.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3 Survival. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Employee's employment, or otherwise, for such period as may be appropriate under the circumstances.

7.4 Waiver. If either party should waive any breach of any provisions of this Agreement, it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.5 Complete Agreement. This Agreement (together with the documents referred to herein) constitutes the entire agreement between Employee and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Employee and an authorized officer of the Company. The parties have entered into a separate Confidential Information Agreement and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Employee's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

7.6 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

7.7 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.8 Successors and Assigns. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all

of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Employee may not assign or transfer this Agreement or any rights or obligations hereunder, other than to his estate upon his death.

7.9 **Choice of Law**. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New York.

7.10 **Resolution of Disputes**. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Employee's employment with the Company or out of this Agreement, or the Employee's termination of employment or termination of this Agreement, may not be in the best interests of either the Employee or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Employee's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however*, that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy or to sexual harassment claims to the extent prohibited by applicable law. The location for the arbitration shall be the New York metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; *provided however*, that at the Employee's option, Employee may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Employee and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its **exclusive remedy**, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.** To the extent applicable law prohibits mandatory arbitration of sexual harassment claims, in the event you intend to bring multiple claims, including a sexual harassment claim, the sexual harassment may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

7.11 **Legal Fees and Costs**. In the event of a dispute under any agreement between the Company and the Employee, the prevailing party (meaning the party receiving substantially the relief sought) shall be entitled to be reimbursed for its reasonable attorneys' fees and costs incurred in connection with such dispute up to a limit of $25,000.

7.12 **Joint and Several Liability**. Renalytix DE and the Parent shall be jointly and severally liable for the obligations under this Agreement provided that the assumption of liability by the

Parent shall not constitute or be deemed to constitute the creation of an employment relationship between the Parent and the Employee and should the Parent discharge any obligation of Renalytix DE under this Agreement such discharge shall extinguish any similar claim against Renalytix DE and vice versa to the intent that no acceptable of joint and several liability shall constitute an ability to recover against both entities for a claim founded on the same facts.

In Witness Whereof, the parties have executed this Employment Agreement on the day and year first written above.

SIGNATURE PAGE FOLLOWS

RENALYTIX AI, INC.

By: /s/ Julian Baines
Name: Julian Baines
Title: Director

RENALYTIX AI PLC

By: /s/ Julian Baines
Name: Julian Baines
Title: Director

Employee**:**

By: /s/James McCullough
JAMES MCCULLOUGH

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "***Agreement***") is entered into on October 12, 2018 and shall become effective on the date of admission of the entire issued share capital of Renalytix AI plc ("***Parent***") to trading on AIM, the market operated by London Stock Exchange plc (the "***Effective Date***"), by and among Oliver James Sterling (the "***Employee***") and Renalytix AI, Inc. ("***Renalytix DE***" or the "***Company***"), a Delaware corporation, and the Parent (collectively with Renalytix DE, the "***Group***").

On and from the Effective Date, the Company desires to employ the Employee as its Chief Financial Officer and, in connection therewith, to compensate the Employee for Employee's personal services to the Company; and

Employee wishes to be so employed by the Company and provide personal services and certain covenants to the Company in return for certain compensation and benefits.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position. Subject to the terms set forth herein, the Company agrees to employ Employee in the position of Chief Financial Officer, and Employee hereby accepts such employment.

1.2 Duties. Employee will report to the Board of Directors of the Company (the "***Board***"), performing such duties as are normally associated and commensurate with his position. During the term of Employee's employment with the Company, Employee will devote Employee's best efforts and substantially all (subject to any agreement as to his Working Hours as defined below) of Employee's business time and attention to the business of the Group. Employee shall perform Employee's duties under this Agreement principally out of the Company's U.S. corporate headquarters in New York. In addition, Employee shall make such business trips to such places as may be necessary or advisable for the efficient operations of the Group.

1.3 Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Employee will be eligible to participate on the same basis as similarly situated employees in Renalytix DE's benefit plans in effect from time to time during his employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of the such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COMPENSATION.

2.1 Salary. Employee shall receive for Employee's services to be rendered under this Agreement a base salary calculated by reference to an initial full-time base salary of $275,000 on an annualized basis, subject to review and increase by the Remuneration Committee of the Parent ("***RemCo***") in its sole discretion but in no event less than three percent (3%) per year, payable and subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices. Unless otherwise agreed between the parties from time to time, the Employee shall work 75% of full-time hours (being his "***Working Hours***"), and accordingly shall receive an annual base salary of $206,250 ("***Base Salary***").

2.2 Annual Discretionary Bonus. Employee will be eligible for an annual cash bonus in the sole discretion of the RemCo, payable subject to standard payroll withholding requirements. Whether or not Employee earns any bonus will be dependent upon (a) the actual achievement by Employee and the Company of the applicable individual and corporate performance goals, as determined by the RemCo in its sole discretion, and (b) Employee's continuous performance of services to the Company through the date any such bonus is paid (which shall be no later than March 15 of the year following the year to which the bonus relates), except as set forth below in Section 6. The bonus may be greater or lesser than any target Bonus and may be zero should the Board determine that any performance criteria agreed with the Employee have not been met.

2.3 Expense Reimbursement. The Company will reimburse Employee for reasonable business expenses in accordance with the Company's standard expense reimbursement policy, as the same may be modified by the Board from time to time. The Company shall reimburse Employee for all customary and appropriate business-related expenses actually incurred and documented in accordance with Company policy as in effect from time to time as soon as practicable after Employee's submission of supporting documentation. For the avoidance of doubt, to the extent that any reimbursements payable to Employee are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

2.4 Vacation. Employee will be eligible to accrue a maximum of five (5) weeks paid vacation per year, in accordance with the Company's vacation policy, which shall be taken subject to the demands of the Company's business and Employee's obligations as an employee of the Company with a substantial degree of responsibility.

3. CONFIDENTIAL INFORMATION, INVENTIONS, NON-COMPETITION AND NON-SOLICITATION OBLIGATIONS. As a condition of employment, Employee agrees to execute and abide by the Employee Confidential Information, Inventions, Non-Competition and Non-Solicitation Agreement attached as Exhibit A ("***Confidential Information Agreement***"), which may be amended by the parties from time to time without regard to this Agreement. The Confidential Information Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4. Outside Activities During Employment. Except with the prior written consent of the Company, which consent shall not unreasonably be withheld, Employee will not, while employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Employee's responsibilities and the performance of Employee's duties hereunder, except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Employee may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Employee's duties, (iii) such other activities as may be specifically approved by the Company. This restriction shall not, however, preclude Employee (i) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (ii) from employment or service in any capacity with Affiliates of the Company. As used in this Agreement, "***Affiliates***" means an entity under common management or control with the Company.

5. No Conflict with Existing Obligations. Employee represents that Employee's performance of all the terms of this Agreement and as an Employee of the Company do not and will not breach any agreement or obligation of any kind made prior to Employee's employment by the Company, including agreements or obligations Employee may have with prior employers or entities for which Employee has provided services. Employee has not entered into, and Employee agrees that Employee will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. Termination Of Employment. The parties acknowledge that Employee's employment relationship with the Company is at-will. Either Employee or the Company may terminate the employment relationship for any reason whatsoever at any time, with or without cause or advance notice. The provisions in this Section govern the amount of compensation, if any, to be provided to Employee upon termination of employment and do not alter this at-will status.

6.1 Termination by the Company Without Cause.

(a) The Company shall have the right to terminate Employee's employment with the Company pursuant to this Section 6.1 at any time without "Cause" (as defined in Section 6.2(b) below) by giving notice as described in Section 7.1 of this Agreement. A termination pursuant to Section 6.5 below is not a termination without "Cause" for purposes of receiving the benefits described in this Section 6.1.

(b) If the Company terminates Employee's employment without Cause and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), then Employee shall be entitled to receive the Accrued Obligations (defined below) and, subject to Employee's material compliance with the obligations in Section 6.1(c) below, Employee shall be eligible to receive the following severance benefits (the "***Severance Benefits***"):

(i) The Company will pay Employee an amount equal to Employee's then current Base Salary for twelve (12) months, less all applicable withholdings and authorized deductions, and paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in Section 6.1(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter. If any such payments are delayed due to the timing of the effectiveness of the Release,

any such payments owed since the termination date shall be paid in the first payroll following the Release Effective Date.

(ii) If Employee timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Employee's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (A) twelve (12) months following the termination date (the "***COBRA Severance Period***"); (B) the date when Employee becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self-employment; or (C) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "***COBRA Payment Period***"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Employee's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Employee on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Employee of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(iii) The Company will pay (i) any bonus earned from the year prior to the year in which the termination occurs, to the extent not previously paid, and (ii) a pro rata portion of the bonus for the year in which the termination occurs, in each case calculated by the Company in good faith with any individual goals deemed to have been achieved and such bonuses to be paid no later than March 15 of the year following the year to which the bonus relates.

(iv) The Company will accelerate (or cause to be accelerated) the vesting of that portion of Employee's equity held on the termination date that would have vested over the one year period following the termination date; provided that all unvested equity shall vest in the event of a Change in Control.

For purposes of this Agreement, a **"Change in Control"** means any of the following transactions: (i) a sale of all or substantially all of the assets of either the Company or the Parent in one or more transactions, (ii) a consolidation or merger of either the Company or the Parent with or into any other corporation or other entity, or any other corporate re-organization, as a result of which the current shareholders own capital stock of the entity surviving such merger, consolidation or reorganization representing less than fifty percent (50%) of the combined voting power of the outstanding securities of the surviving entity immediately after such consolidation, merger or reorganization, or (iii) the sale by the current shareholders of either in one or more transactions which results in the current shareholders owning less than fifty percent (50%) of the outstanding equity securities of either the Company or the Parent. For purposes of this Agreement, a "Change in Control" shall have the meaning given by the UK Takeover Code.

(c) Employee will be paid all of the Accrued Obligations on the Company's first payroll date after Employee's date of termination from employment or earlier if

required by law. If eligible to receive the Severance Benefits pursuant to Section 6.1(b) of this Agreement, Employee will only receive such Severance Benefits if: (i) within the time period provided in the separation agreement (which shall be no longer than 60 days following the date of Employee's Separation from Service), he has signed and delivered to the Company an effective separation agreement that includes, among other terms, a general release of claims in favor of the Company and its affiliates and representatives, in a form reasonably acceptable to the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if he holds any other positions with the Company, he resigns such position(s) to be effective no later than the date of Employee's termination date (or such other date as requested by the Board); (iii) he returns all Company property; (iv) he complies with his post-termination obligations under this Agreement and the Confidential Information Agreement; and (v) he complies with the terms of the Release, including without limitation any non-disparagement (which shall be mutual to the extent applicable to the Company's officers while employed by the Company), confidentiality and cooperation provisions contained in Release. The Release shall not release the Company from the obligations under this Section, any vested rights under any employee benefit or compensation plan or indemnification obligations.

(d) For purposes of this Agreement, "***Accrued Obligations***" are (i) Employee's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred by Employee payable in accordance with the Company's standard expense reimbursement policies, (iii) any accrued but not taken vacation pay and (iv) benefits owed to Employee under any qualified retirement plan or health and welfare benefit plan in which Employee was a participant in accordance with applicable law and the provisions of such plan.

(e) The Severance Benefits provided to Employee pursuant to this Section 6.1 are in lieu of, and not in addition to, any benefits to which Employee may otherwise be entitled under any Company severance plan, policy or program.

(f) Any damages caused by the termination of Employee's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Employee is eligible pursuant to Section 6.1(b) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

6.2 <u>Termination by the Company for Cause</u>.

(a) The Company shall have the right to terminate Employee's employment with the Company at any time for Cause by giving notice as described in Section 7.1 of this Agreement; provided that if such event is capable of cure in the opinion of the Company, the Company first provides written notice detailing the event and provides Employee with thirty (30) days in which to cure. If cured, the Company may not terminate Employee's employment for Cause.

(b) "***Cause***" for purposes of this Agreement shall mean that Employee has engaged in any of the following: (i) a material breach of any covenant or condition under this Agreement or any other agreement between the Company and Employee; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony

under applicable law; (iv) material violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of Company; (vi) negligence in the performance of Employee's duties or failure to perform his material duties to the Company; (vii) failure to pass to the satisfaction of the Company, a preliminary background check or failure to submit proof of legal eligibility to work in the United States; or (viii) breach of fiduciary duty.

(c) In the event Employee's employment is terminated at any time for Cause, Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.3 Resignation by Employee (without Good Reason).

(d) Employee may resign from Employee's employment with the Company at any time by giving notice as described in Section 7.1.

(e) In the event Employee resigns from Employee's employment with the Company (other than for Good Reason as set forth in Section 6.4), Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.4 Resignation by Employee for Good Reason.

(f) Provided Employee has not previously been notified of the Company's intention to terminate Employee's employment, Employee may resign from employment with the Company for Good Reason (as defined in Section 6.4(b) below).

(g) "***Good Reason***" for purposes of this Agreement shall mean the occurrence of any of the following conditions without Employee's prior written consent after Employee's provision of written notice to the Company of the existence of such condition (which notice must be provided as described in Section 7.1 within ninety (90) days of the initial existence of the condition and must specify the particular condition in reasonable detail), provided that the Company has not first provided notice to Employee of its intent to terminate Employee's employment: (i) a material diminution of, or material reduction or material adverse alteration in, Employee's position, title, duties, or responsibilities; (ii) a material (greater than 10%) reduction by the Company of Employee's Base Salary (except in the case of either an across the board reduction in salaries or a temporary reduction due to financial exigency); or (iii) a relocation of Employee, or the Company's principal offices to which Employee is assigned more than fifty (50) miles from its then current location, except for required travel by Employee on the Company's business or (iv) a material breach of this Agreement by the Company. Notwithstanding the foregoing, Good Reason shall only exist if the Company is provided a thirty (30) day period to cure the event or condition giving rise to Good Reason, and it fails to do so within that cure period (and, additionally, Employee must resign for such Good Reason condition by giving notice as described in Section 7.1 within ten (10) days after the period for curing the violation or condition has ended).

(h) In the event Employee resigns from Employee's employment for Good Reason, then Employee shall be entitled to the Accrued Obligations and, provided that Employee complies with the obligations in Section 6.1(c) of this Agreement (including the requirement to provide an effective Release), Employee shall be eligible to receive the same

Severance Benefits as described in Section 6.1 and on the same conditions as if Employee had been terminated by the Company without Cause.

6.5 Termination by Virtue of Death or Disability of Employee.

(g) In the event of Employee's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll policies, pay to Employee's legal representatives all Accrued Obligations as well as payment for any bonus earned for the year prior to the year of termination, to the extent not paid, and a pro rata bonus for the year in which the termination occurs, each determined by the Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

(h) Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to Employee, to terminate this Agreement based on Employee's Disability. Termination by the Company of Employee's employment based on "***Disability***" shall mean termination because Employee is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 180 days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. One of the physicians shall be chosen by the Company and the other shall be chosen by the Employee, or by his or his representative. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Employee's employment is terminated based on Employee's Disability, Employee will not receive severance payments, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations as well as any payment for any bonus earned for the year prior to the year of termination to the extent not paid and a pro rata bonus for the year in which the termination occurs, each determined by the Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

6.6 Application of Section 409A. It is intended that all of the severance payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "***Section 409A***") provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9), and this Agreement will be construed in a manner that complies with Section 409A. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and payment terms. No severance payments will be made under this Agreement unless Employee's termination of employment constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h)). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Employee's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. To the extent that any severance payments are deferred compensation under Section 409A, and are not otherwise exempt from the application of Section 409A, then, if the period during which Employee may consider and sign the Release spans two calendar years, the

severance payments will not begin until the second calendar year. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Employee's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance will be delayed as follows: on the earlier to occur of (a) the date that is six months and one day after Employee's Separation from Service, and (b) the date of Employee's death (such earlier date, the "***Delayed Initial Payment Date***"), the Company will (i) pay to Employee a lump sum amount equal to the sum of the severance benefits that Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.6 and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Section 6.1. No interest shall be due on any amounts deferred pursuant to this Section 6.6.

6.7 280G Approval. To the extent the Parachute Payment Vote (as defined below) is permitted by the Regulations (as defined below), and Employee agrees to waive (as would be required under the Regulations) the right to all or any portion of the payment or benefit Employee would receive pursuant to a Change in Control as a result of the provisions of this Agreement that would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) be subject to the excise tax imposed by Section 4999 of the Code (the "**At-Risk Payments**), the Company shall use commercially reasonable efforts to timely solicit stockholder approval of the At-Risk Payments (the "**Parachute Payment Vote**") in accordance with the requirements of Treasury Regulations § 1.280G-1, Q&A-7 or any successor thereto (the "**Regulations**").

6.8 Cooperation With Company After Termination of Employment. Following termination of Employee's employment for any reason and for a period of two years thereafter, Employee shall reasonably cooperate with the Company in all matters relating to the winding up of Employee's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company. The Company will reimburse Employee for reasonable out-of-pocket expenses Employee incurs in connection with any such cooperation (excluding forgone wages, salary, or other compensation) and will make reasonable efforts to accommodate Employee's scheduling needs.

7. General Provisions.

7.1 Notices. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company payroll or to Employee's Company-issued email address, or at such other address as the Company or Employee may designate by ten (10) days advance written notice to the other.

7.2 Severability. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3 Survival. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Employee's employment, or otherwise, for such period as may be appropriate under the circumstances.

7.4 Waiver. If either party should waive any breach of any provisions of this Agreement, it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.5 Complete Agreement. This Agreement (together with the documents referred to herein) constitutes the entire agreement between Employee and the Company with regard to the subject matter hereof. This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Employee and an authorized officer of the Company. The parties have entered into a separate Confidential Information Agreement and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Employee's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

7.6 Counterparts. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

7.7 Headings. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.8 Successors and Assigns. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Employee may not assign or transfer this Agreement or any rights or obligations hereunder, other than to his estate upon his death.

7.9 Choice of Law. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New York.

7.10 Resolution of Disputes. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Employee's employment with the Company or out of this Agreement, or the Employee's termination of employment or termination of this Agreement, may not be in the best interests of either the Employee or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Employee's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; *provided however,* that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy or to sexual harassment claims to the extent prohibited by applicable law. The location for the arbitration shall be the New York metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; *provided however*, that at the Employee's option, Employee may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Employee and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its **exclusive remedy**, and each party expressly waives any right it might have to seek redress in any other forum, except as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury.** To the extent applicable law prohibits mandatory arbitration of sexual harassment claims, in the event you intend to bring multiple claims, including a sexual harassment claim, the sexual harassment may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

7.11 Legal Fees and Costs. In the event of a dispute under any agreement between the Company and the Employee, the prevailing party (meaning the party receiving substantially the relief sought) shall be entitled to be reimbursed for its reasonable attorneys' fees and costs incurred in connection with such dispute up to a limit of $25,000.

7.12 Joint and Several Liability. Renalytix DE and the Parent shall be jointly and severally liable for the obligations under this Agreement provided that the assumption of liability by

the Parent shall not constitute or be deemed to constitute the creation of an employment relationship between the Parent and the Employee and should the Parent discharge any obligation of Renalytix DE under this Agreement such discharge shall extinguish any similar claim against
Renalytix DE and vice versa to the intent that no acceptable of joint and several liability shall constitute an ability to recover against both entities for a claim founded on the same facts.

In Witness Whereof, the parties have executed this Employment Agreement on the day and year first written above.

SIGNATURE PAGE FOLLOWS

RENALYTIX AI, INC.

By: /s/ James R. McCullough
Name James R. McCullough
Title CEO

RENALYTIX AI PLC

By: /s/ James R. McCullough
Name James R. McCullough
Title CEO

Employee:

/s/ Oliver James Sterling
OLIVER JAMES STERLING

EMPLOYMENT AGREEMENT

This **EMPLOYMENT AGREEMENT** (the "***Agreement***") is entered into effective June 1, 2019 (the "***Effective Date***"), by and among Thomas McLain (the "***Employee***") and Renalytix AI, Inc. ("***Renalytix DE***" or the "***Company***"), a Delaware corporation, and Renalytix AI plc ("***Parent***" and collectively with Renalytix DE, the "***Group***").

The Company desires to continue to employ the Employee as its President and Head of Managed Care on the terms of this Agreement and, in connection therewith, to compensate the Employee for Employee's personal services to the Company; and

Employee wishes to be so employed by the Company and provide personal services and certain covenants to the Company in return for certain compensation and benefits.

Accordingly, in consideration of the mutual promises and covenants contained herein, the parties agree to the following:

1. EMPLOYMENT BY THE COMPANY.

1.1 Position. Subject to the terms set forth herein, the Company agrees to continue to employ Employee in the position of President and Head of Managed Care, and Employee hereby accepts such continued employment.

1.2 Duties. Employee will report to the Board of Directors of the Company (the "***Board***"), performing such duties as are normally associated and commensurate with his position. During the term of Employee's employment with the Company, Employee will devote Employee's best efforts and substantially all of Employee's business time and attention to the business of the Group. Employee shall perform Employee's duties under this Agreement principally from Florida or out of the Company's U.S. corporate headquarters in New York. In addition, Employee shall make such business trips to such places as may be necessary or advisable for the efficient operations of the Group.

1.3 Company Policies and Benefits. The employment relationship between the parties shall also be subject to the Company's personnel policies and procedures as they may be interpreted, adopted, revised or deleted from time to time in the Company's sole discretion. Employee will be eligible to participate on the same basis as similarly situated employees in Renalytix DE's benefit plans in effect from time to time during his employment. All matters of eligibility for coverage or benefits under any benefit plan shall be determined in accordance with the provisions of the such plan. The Company reserves the right to change, alter, or terminate any benefit plan in its sole discretion. Notwithstanding the foregoing, in the event that the terms of this Agreement differ from or are in conflict with the Company's general employment policies or practices, this Agreement shall control.

2. COMPENSATION.

2.1 Salary. Employee shall receive for Employee's services to be rendered under this Agreement an initial base salary of $300,000 on an annualized basis, subject to review and increase by the Company in its sole discretion but in no event less than three percent (3%) per year payable and subject to standard federal and state payroll withholding requirements in accordance with the Company's standard payroll practices ("***Base Salary***").

2.2 Annual Discretionary Bonus. Employee will be eligible for an annual cash bonus in the sole discretion of the Company, payable subject to standard payroll withholding requirements. Whether or not Employee earns any bonus will be dependent upon (a) the actual achievement by Employee and the Company of the applicable individual and corporate performance goals, as determined by the Board in its sole discretion, and (b) Employee's continuous performance of services to the Company through the date any such bonus is paid (which shall be no later than March 15 of the year following the year to which the bonus relates), except as set forth below in Section 6. The bonus may be greater or lesser than any target Bonus and may be zero should the Board determine that any performance criteria agreed with the Employee have not been met.

2.3 Expense Reimbursement. The Company will reimburse Employee for reasonable business expenses in accordance with the Company's standard expense reimbursement policy, as the same may be modified by the Board from time to time. The Company shall reimburse Employee for all customary and appropriate business-related expenses actually incurred and documented in accordance with Company policy as in effect from time to time as soon as practicable after Employee's submission of supporting documentation. For the avoidance of doubt, to the extent that any reimbursements payable to Employee are subject to the provisions of Section 409A of the Internal Revenue Code of 1986, as amended (the "***Code***"): (a) any such reimbursements will be paid no later than December 31 of the year following the year in which the expense was incurred, (b) the amount of expenses reimbursed in one year will not affect the amount eligible for reimbursement in any subsequent year, and (c) the right to reimbursement under this Agreement will not be subject to liquidation or exchange for another benefit.

2.4 Vacation. Employee will be eligible to accrue a maximum of four (4) weeks paid vacation per year, in accordance with the Company's vacation policy, which shall be taken subject to the demands of the Company's business and Employee's obligations as an employee of the Company with a substantial degree of responsibility.

3. CONFIDENTIAL INFORMATION, INVENTIONS, NON-COMPETITION AND NON- SOLICITATION OBLIGATIONS. As a condition of employment, Employee agrees to execute and abide by the Employee Confidential Information, Inventions, Non-Competition and Non- Solicitation Agreement attached as Exhibit A ("***Confidential Information Agreement***"), which may be amended by the parties from time to time without regard to this Agreement. The Confidential Information Agreement contains provisions that are intended by the parties to survive and do survive termination of this Agreement.

4. OUTSIDE ACTIVITIES DURING EMPLOYMENT. Except with the prior written consent of the Company, which consent shall not unreasonably be withheld, Employee will not, while

employed by the Company, undertake or engage in any other employment, occupation or business enterprise that would interfere with Employee's responsibilities and the performance of Employee's duties hereunder, except for (i) reasonable time devoted to volunteer services for or on behalf of such religious, educational, non-profit and/or other charitable organization as Employee may wish to serve, (ii) reasonable time devoted to activities in the non-profit and business communities consistent with Employee's duties, (iii) such other activities as may be specifically approved by the Company. This restriction shall not, however, preclude Employee (i) from owning less than one percent (1%) of the total outstanding shares of a publicly traded company, or (ii) from employment or service in any capacity with Affiliates of the Company. As used in this Agreement, "***Affiliates***" means an entity under common management or control with the Company.

5. **No Conflict With Existing Obligations**. Employee represents that Employee's performance of all the terms of this Agreement and as an Employee of the Company do not and will not breach any agreement or obligation of any kind made prior to Employee's employment by the Company, including agreements or obligations Employee may have with prior employers or entities for which Employee has provided services. Employee has not entered into, and Employee agrees that Employee will not enter into, any agreement or obligation, either written or oral, in conflict herewith.

6. **Termination of Employment**. The parties acknowledge that Employee's employment relationship with the Company is at-will. Either Employee or the Company may terminate the employment relationship for any reason whatsoever at any time, with or without cause or advance notice. The provisions in this Section govern the amount of compensation, if any, to be provided to Employee upon termination of employment and do not alter this at-will status.

6.1 **Termination by the Company Without Cause**.

(a) The Company shall have the right to terminate Employee's employment with the Company pursuant to this Section 6.1 at any time without "***Cause***" (as defined in Section 6.2(b) below) by giving notice as described in Section 7.1 of this Agreement. A termination pursuant to Section 6.5 below is not a termination without "***Cause***" for purposes of receiving the benefits described in this Section 6.1.

(b) If the Company terminates Employee's employment without Cause and provided that such termination constitutes a "separation from service" (as defined under Treasury Regulation Section 1.409A-1(h), without regard to any alternative definition thereunder, a "***Separation from Service***"), then Employee shall be entitled to receive the Accrued Obligations (defined below) and, subject to Employee's material compliance with the obligations in Section 6.1(c) below, Employee shall be eligible to receive the following severance benefits (the "***Severance Benefits***"):

(i) The Company will pay Employee an amount equal to Employee's then current Base Salary for six (6) months, less all applicable withholdings and authorized deductions, and paid in equal installments beginning on the Company's first regularly scheduled payroll date following the Release Effective Date (as defined in Section 6.1(c) below), with the remaining installments occurring on the Company's regularly scheduled payroll dates thereafter.

If any such payments are delayed due to the timing of the effectiveness of the Release, any such payments owed since the termination date shall be paid in the first payroll following the Release Effective Date.

(ii) If Employee timely elects continued coverage under COBRA for himself and his covered dependents under the Company's group health plans following such termination, then the Company shall pay the COBRA premiums necessary to continue Employee's and his covered dependents' health insurance coverage in effect for himself (and his covered dependents) on the termination date until the earliest of: (A) twelve (12) months following the termination date (the "***COBRA Severance Period***"); (B) the date when Employee becomes eligible for substantially equivalent health insurance coverage in connection with new employment or self- employment; or (C) the date Employee ceases to be eligible for COBRA continuation coverage for any reason, including plan termination (such period from the termination date through the earlier of (i)-(iii), (the "***COBRA Payment Period***"). Notwithstanding the foregoing, if at any time the Company determines that its payment of COBRA premiums on Employee's behalf would result in a violation of applicable law (including, but not limited to, the 2010 Patient Protection and Affordable Care Act, as amended by the 2010 Health Care and Education Reconciliation Act), then in lieu of paying COBRA premiums pursuant to this Section, the Company shall pay Employee on the last day of each remaining month of the COBRA Payment Period, a fully taxable cash payment equal to the COBRA premium for such month, subject to applicable tax withholding, for the remainder of the COBRA Payment Period. Nothing in this Agreement shall deprive Employee of his rights under COBRA or ERISA for benefits under plans and policies arising under his employment by the Company.

(iii) The Company will pay (i) any bonus earned from the year prior to the year in which the termination occurs, to the extent not previously paid, and (ii) a pro rata portion of the bonus for the year in which the termination occurs, in each case calculated by the Company in good faith with any individual goals deemed to have been achieved and such bonuses to be paid no later than March 15 of the year following the year to which the bonus relates.

(iv) The Company will accelerate (or cause to be accelerated) the vesting of that portion of Employee's equity held on the termination date that would have vested over the one year period following the termination date; provided that all unvested equity shall vest in the event of a Change in Control.

For purposes of this Agreement, a "***Change in Control***" means any of the following transactions: (i) a sale of all or substantially all of the assets of either the Company or the Parent in one or more transactions, (ii) a consolidation or merger of either the Company or the Parent with or into any other corporation or other entity, or any other corporate re-organization, as a result of which the current shareholders own capital stock of the entity surviving such merger, consolidation or reorganization representing less than fifty percent (50%) of the combined voting power of the outstanding securities of the surviving entity immediately after such consolidation, merger or reorganization, or (iii) the sale by the current shareholders of either in one or more transactions which results in the current shareholders owning less than fifty percent (50%) of the outstanding equity securities of either the Company or the Parent. For purposes of this Agreement, a "***Change in Control***" shall have the meaning given by the UK Takeover Code.

(c) Employee will be paid all of the Accrued Obligations on the Company's first payroll date after Employee's date of termination from employment or earlier if required by law. If eligible to receive the Severance Benefits pursuant to Section 6.1(b) of this Agreement, Employee will only receive such Severance Benefits if: (i) within the time period provided in the separation agreement (which shall be no longer than 60 days following the date of Employee's Separation from Service), he has signed and delivered to the Company an effective separation agreement that includes, among other terms, a general release of claims in favor of the Company and its affiliates and representatives, in a form reasonably acceptable to the Company (the "***Release***"), which cannot be revoked in whole or part by such date (the date that the Release can no longer be revoked is referred to as the "***Release Effective Date***"); and (ii) if he holds any other positions with the Company, he resigns such position(s) to be effective no later than the date of Employee's termination date (or such other date as requested by the Board); (iii) he returns all Company property; (iv) he complies with his post-termination obligations under this Agreement and the Confidential Information Agreement; and (v) he complies with the terms of the Release, including without limitation any non-disparagement (which shall be mutual to the extent applicable to the Company's officers while employed by the Company), confidentiality and cooperation provisions contained in Release. The Release shall not release the Company from the obligations under this Section, any vested rights under any employee benefit or compensation plan or indemnification obligations.

(d) For purposes of this Agreement, "***Accrued Obligations***" are (i) Employee's accrued but unpaid salary through the date of termination, (ii) any unreimbursed business expenses incurred by Employee payable in accordance with the Company's standard expense reimbursement policies, (iii) any accrued but not taken vacation pay and (iv) benefits owed to Employee under any qualified retirement plan or health and welfare benefit plan in which Employee was a participant in accordance with applicable law and the provisions of such plan.

(e) The Severance Benefits provided to Employee pursuant to this Section 6.1 are in lieu of, and not in addition to, any benefits to which Employee may otherwise be entitled under any Company severance plan, policy or program.

(f) Any damages caused by the termination of Employee's employment without Cause would be difficult to ascertain; therefore, the Severance Benefits for which Employee is eligible pursuant to Section 6.1(b) above in exchange for the Release is agreed to by the parties as liquidated damages, to serve as full compensation, and not a penalty.

6.2 Termination by the Company for Cause.

(a) The Company shall have the right to terminate Employee's employment with the Company at any time for Cause by giving notice as described in Section 7.1 of this Agreement; provided that if such event is capable of cure in the opinion of the Company, the Company first provides written notice detailing the event and provides Employee with thirty (30) days in which to cure. If cured, the Company may not terminate Employee's employment for Cause.

(b) "***Cause***" for purposes of this Agreement shall mean that Employee has engaged in any of the following: (i) a material breach of any covenant or condition under this

Agreement or any other agreement between the Company and Employee; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) material violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of Company; (vi) negligence in the performance of Employee's duties or failure to perform his material duties to the Company; (vii) failure to pass to the satisfaction of the Company, a preliminary background check or failure to submit proof of legal eligibility to work in the United States; or (viii) breach of fiduciary duty.

(c) In the event Employee's employment is terminated at any time for Cause, Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.3 Resignation by Employee (without Good Reason).

(a) Employee may resign from Employee's employment with the Company at any time by giving notice as described in Section 7.1.

(b) In the event Employee resigns from Employee's employment with the Company (other than for Good Reason as set forth in Section 6.4), Employee will not receive Severance Benefits, or any other severance compensation or benefits, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations.

6.4 Resignation by Employee for Good Reason.

(a) Provided Employee has not previously been notified of the Company's intention to terminate Employee's employment, Employee may resign from employment with the Company for Good Reason (as defined in Section 6.4(b) below).

(b) "***Good Reason***" for purposes of this Agreement shall mean the occurrence of any of the following conditions without Employee's prior written consent after Employee's provision of written notice to the Company of the existence of such condition (which notice must be provided as described in Section 7.1 within ninety (90) days of the initial existence of the condition and must specify the particular condition in reasonable detail), provided that the Company has not first provided notice to Employee of its intent to terminate Employee's employment: (i) a material diminution of, or material reduction or material adverse alteration in, Employee's position, title, duties, or responsibilities; (ii) a material (greater than 10%) reduction by the Company of Employee's Base Salary (except in the case of either an across the board reduction in salaries or a temporary reduction due to financial exigency); or (iii) a relocation of Employee, or the Company's principal offices to which Employee is assigned more than fifty (50) miles from its then current location, except for required travel by Employee on the Company's business or (iv) a material breach of this Agreement by the Company. Notwithstanding the foregoing, Good Reason shall only exist if the Company is provided a thirty (30) day period to cure the event or condition giving rise to Good Reason, and it fails to do so within that cure period (and, additionally, Employee must resign for such Good Reason condition by giving notice as

described in Section 7.1 within ten (10) days after the period for curing the violation or condition has ended).

(c) In the event Employee resigns from Employee's employment for Good Reason, then Employee shall be entitled to the Accrued Obligations and, provided that Employee complies with the obligations in Section 6.1(c) of this Agreement (including the requirement to provide an effective Release), Employee shall be eligible to receive the same Severance Benefits as described in Section 6.1 and on the same conditions as if Employee had been terminated by the Company without Cause.

6.5 Termination by Virtue of Death or Disability of Employee.

(a) In the event of Employee's death while employed pursuant to this Agreement, all obligations of the parties hereunder shall terminate immediately, and the Company shall, pursuant to the Company's standard payroll policies, pay to Employee's legal representatives all Accrued Obligations as well as payment for any bonus earned for the year prior to the year of termination, to the extent not paid, and a pro rata bonus for the year in which the termination occurs, each determined by the Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

(b) Subject to applicable state and federal law, the Company shall at all times have the right, upon written notice to Employee, to terminate this Agreement based on Employee's Disability. Termination by the Company of Employee's employment based on "***Disability***" shall mean termination because Employee is unable due to a physical or mental condition to perform the essential functions of his position with or without reasonable accommodation for 180 days in the aggregate during any twelve (12) month period or based on the written certification by two licensed physicians of the likely continuation of such condition for such period. One of the physicians shall be chosen by the Company and the other shall be chosen by the Employee, or by his or his representative. This definition shall be interpreted and applied consistent with the Americans with Disabilities Act, the Family and Medical Leave Act, and other applicable law. In the event Employee's employment is terminated based on Employee's Disability, Employee will not receive severance payments, or any other severance compensation or benefit, except that, pursuant to the Company's standard payroll policies, the Company shall pay to Employee the Accrued Obligations as well as any payment for any bonus earned for the year prior to the year of termination to the extent not paid and a pro rata bonus for the year in which the termination occurs, each determined by the Company in good faith and paid no later than March 15 of the year following the year to which the bonus relates.

6.6 Application of Section 409A. It is intended that all of the severance payments payable under this Agreement satisfy, to the greatest extent possible, the exemptions from the application of Section 409A of the Code and the regulations and other guidance thereunder and any state law of similar effect (collectively, "***Section 409A***") provided under Treasury Regulations Sections 1.409A-1(b)(4) and 1.409A-1(b)(9), and this Agreement will be construed in a manner that complies with Section 409A. If not so exempt, this Agreement (and any definitions hereunder) will be construed in a manner that complies with Section 409A, and incorporates by reference all required definitions and payment terms. No severance payments will be made under this Agreement unless Employee's termination of employment constitutes a "separation from service"

(as defined under Treasury Regulation Section 1.409A-1(h)). For purposes of Section 409A (including, without limitation, for purposes of Treasury Regulations Section 1.409A-2(b)(2)(iii)), Employee's right to receive any installment payments under this Agreement (whether severance payments or otherwise) shall be treated as a right to receive a series of separate payments and, accordingly, each installment payment hereunder shall at all times be considered a separate and distinct payment. To the extent that any severance payments are deferred compensation under Section 409A, and are not otherwise exempt from the application of Section 409A, then, if the period during which Employee may consider and sign the Release spans two calendar years, the severance payments will not begin until the second calendar year. If the Company determines that the severance benefits provided under this Agreement constitutes "deferred compensation" under Section 409A and if Employee is a "specified employee" of the Company, as such term is defined in Section 409A(a)(2)(B)(i) of the Code at the time of Employee's Separation from Service, then, solely to the extent necessary to avoid the incurrence of the adverse personal tax consequences under Section 409A, the timing of the Severance will be delayed as follows: on the earlier to occur of (a) the date that is six months and one day after Employee's Separation from Service, and (b) the date of Employee's death (such earlier date, the "***Delayed Initial Payment Date***"), the Company will (i) pay to Employee a lump sum amount equal to the sum of the severance benefits that Employee would otherwise have received through the Delayed Initial Payment Date if the commencement of the payment of the severance benefits had not been delayed pursuant to this Section 6.6 and (ii) commence paying the balance of the severance benefits in accordance with the applicable payment schedule set forth in Section 6.1. No interest shall be due on any amounts deferred pursuant to this Section 6.6.

6.7 280G Approval. To the extent the Parachute Payment Vote (as defined below) is permitted by the Regulations (as defined below), and Employee agrees to waive (as would be required under the Regulations) the right to all or any portion of the payment or benefit Employee would receive pursuant to a Change in Control as a result of the provisions of this Agreement that would (i) constitute a "parachute payment" within the meaning of Section 280G of the Code, and (ii) be subject to the exercise tax imposed by Section 4999 of the Code (the "**At-Risk**" Payments), the Company shall use commercially reasonable efforts to timely solicit stockholder approval of the At-Risk Payments (the "**Parachute Payment Vote**") in accordance with the requirements of Treasure Regulations § 1.280G-1, Q&A-7 or any successor thereto (the "**Regulations**").

6.8 Cooperation With Company After Termination of Employment. Following termination of Employee's employment for any reason and for a period of two years thereafter, Employee shall reasonably cooperate with the Company in all matters relating to the winding up of Employee's pending work including, but not limited to, any litigation in which the Company is involved, and the orderly transfer of any such pending work to such other employees as may be designated by the Company. The Company will reimburse Employee for reasonable out-of- pocket expenses Employee incurs in connection with any such cooperation (excluding forgone wages, salary, or other compensation) and will make reasonable efforts to accommodate Employee's scheduling needs.

7. General Provisions.

7.1 **Notices**. Any notices required hereunder to be in writing shall be deemed effectively given: (a) upon personal delivery to the party to be notified, (b) when sent by electronic mail or confirmed facsimile if sent during normal business hours of the recipient, and if not, then on the next business day, (c) five (5) days after having been sent by registered or certified mail, return receipt requested, postage prepaid, or (d) one (1) day after deposit with a nationally recognized overnight courier, specifying next day delivery, with written verification of receipt. All communications shall be sent to the Company at its primary office location and to Employee at Employee's address as listed on the Company payroll or to Employee's Company-issued email address, or at such other address as the Company or Employee may designate by ten (10) days advance written notice to the other.

7.2 **Severability**. Whenever possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be invalid, illegal or unenforceable in any respect under any applicable law or rule in any jurisdiction, such invalidity, illegality or unenforceability will not affect any other provision or any other jurisdiction, but this Agreement will be reformed, construed and enforced in such jurisdiction as if such invalid, illegal or unenforceable provisions had never been contained herein.

7.3 **Survival**. Provisions of this Agreement which by their terms must survive the termination of this Agreement in order to effectuate the intent of the parties will survive any such termination, whether by expiration of the term, termination of Employee's employment, or otherwise, for such period as may be appropriate under the circumstances.

7.4 **Waiver**. If either party should waive any breach of any provisions of this Agreement, it shall not thereby be deemed to have waived any preceding or succeeding breach of the same or any other provision of this Agreement.

7.5 **Complete Agreement**. This Agreement (together with the documents referred to herein) constitutes the entire agreement between Employee and the Company with regard to the subject matter hereof (and for the avoidance of doubt, replaces the employment agreement entered into between the Employee, the Company and the Parent dated June 1, 2019, which agreement shall have no further force and effect as of the date hereof). This Agreement is the complete, final, and exclusive embodiment of their agreement with regard to this subject matter and supersedes any prior oral discussions or written communications and agreements. This Agreement is entered into without reliance on any promise or representation other than those expressly contained herein, and it cannot be modified or amended except in writing signed by Employee and an authorized officer of the Company. The parties have entered into a separate Confidential Information Agreement and have or may enter into separate agreements related to equity. These separate agreements govern other aspects of the relationship between the parties, have or may have provisions that survive termination of Employee's employment under this Agreement, may be amended or superseded by the parties without regard to this Agreement and are enforceable according to their terms without regard to the enforcement provision of this Agreement.

7.6 **Counterparts**. This Agreement may be executed in separate counterparts, any one of which need not contain signatures of more than one party, but all of which taken together will constitute one and the same Agreement.

7.7 **Headings**. The headings of the sections hereof are inserted for convenience only and shall not be deemed to constitute a part hereof nor to affect the meaning thereof.

7.8 **Successors and Assigns**. The Company shall assign this Agreement and its rights and obligations hereunder in whole, but not in part, to any Company or other entity with or into which the Company may hereafter merge or consolidate or to which the Company may transfer all or substantially all of its assets, if in any such case said Company or other entity shall by operation of law or expressly in writing assume all obligations of the Company hereunder as fully as if it had been originally made a party hereto, but may not otherwise assign this Agreement or its rights and obligations hereunder. The Employee may not assign or transfer this Agreement or any rights or obligations hereunder, other than to his estate upon his death.

7.9 **Choice of Law**. All questions concerning the construction, validity and interpretation of this Agreement will be governed by the laws of the State of New York.

7.10 **Resolution of Disputes**. The parties recognize that litigation in federal or state courts or before federal or state administrative agencies of disputes arising out of the Employee's employment with the Company or out of this Agreement, or the Employee's termination of employment or termination of this Agreement, may not be in the best interests of either the Employee or the Company, and may result in unnecessary costs, delays, complexities, and uncertainty. The parties agree that any dispute between the parties arising out of or relating to the negotiation, execution, performance or termination of this Agreement or the Employee's employment, including, but not limited to, any claim arising out of this Agreement, claims under Title VII of the Civil Rights Act of 1964, as amended, the Civil Rights Act of 1991, the Age Discrimination in Employment Act of 1967, the Americans with Disabilities Act of 1990, Section 1981 of the Civil Rights Act of 1966, as amended, the Family Medical Leave Act, the Employee Retirement Income Security Act, and any similar federal, state or local law, statute, regulation, or any common law doctrine, whether that dispute arises during or after employment, shall be settled by binding arbitration in accordance with the National Rules for the Resolution of Employment Disputes of the American Arbitration Association; provided however, that this dispute resolution provision shall not apply to any separate agreements between the parties that do not themselves specify arbitration as an exclusive remedy or to discrimination or sexual harassment claims to the extent prohibited by applicable law. The location for the arbitration shall be the New York metropolitan area. Any award made by such panel shall be final, binding and conclusive on the parties for all purposes, and judgment upon the award rendered by the arbitrators may be entered in any court having jurisdiction thereof. The arbitrators' fees and expenses and all administrative fees and expenses associated with the filing of the arbitration shall be borne by the Company; provided however, that at the Employee's option, Employee may voluntarily pay up to one-half the costs and fees. The parties acknowledge and agree that their obligations to arbitrate under this Section survive the termination of this Agreement and continue after the termination of the employment relationship between Employee and the Company. The parties each further agree that the arbitration provisions of this Agreement shall provide each party with its exclusive remedy, and each party expressly waives any right it might have to seek redress in any other forum, except

as otherwise expressly provided in this Agreement. By election arbitration as the means for final settlement of all claims, **the parties hereby waive their respective rights to, and agree not to, sue each other in any action in a Federal, State or local court with respect to such claims, but may seek to enforce in court an arbitration award rendered pursuant to this Agreement. The parties specifically agree to waive their respective rights to a trial by jury, and further agree that no demand, request or motion will be made for trial by jury**. To the extent applicable law prohibits mandatory arbitration of discrimination or sexual harassment claims, in the event the Employee intends to bring multiple claims, including a discrimination and/or sexual harassment claim, such claim(s) may be publicly filed with a court, while any other claims will remain subject to mandatory arbitration.

7.11 Legal Fees and Costs. In the event of a dispute under any agreement between the Company and the Employee, the prevailing party (meaning the party receiving substantially the relief sought) shall be entitled to be reimbursed for its reasonable attorneys' fees and costs incurred in connection with such dispute up to a limit of $25,000.

7.12 Joint and Several Liability. Renalytix DE and the Parent shall be jointly and severally liable for the obligations under this Agreement provided that the assumption of liability by the Parent shall not constitute or be deemed to constitute the creation of an employment relationship between the Parent and the Employee and should the Parent discharge any obligation of Renalytix DE under this Agreement such discharge shall extinguish any similar claim against Renalytix DE and vice versa to the intent that no acceptable of joint and several liability shall constitute an ability to recover against both entities for a claim founded on the same facts.

In Witness Whereof, the parties have executed this Employment Agreement on the day and year first written above.

SIGNATURE PAGE FOLLOWS

RENALYTIX AI, INC.

By: /s/ O. James Sterling
Name: O. James Sterling
Title: CFO

RENALYTIX AI PLC

By: /s/ O. James Sterling
Name: O. James Sterling
Title: CFO

Employee:

/s/ Thomas McLain
THOMAS MCLAIN

EXHIBIT 10.9

Dated 2 NOVEMBER 2018

(1) RENALYTIX AI PLC

(2) FERGUS FLEMING

DIRECTORS SERVICE AGREEMENT

Berry Smith
Haywood House
Dumfries Place
Cardiff
CF10 3GA

THIS AGREEMENT is made the 2 day of November 2018

BETWEEN:

(1) RENALYTIX AI PLC Registered Number 11257655 whose registered office is at Avon House, 19 Stanwell Road, Penarth, Cardiff CF64 2EZ (**"the Company"**); and

(2) FERGUS FLEMING of 12 Talbots Grove, Freshford Road, Kilkenny, R95 C99E ("**the Executive**").

1 Interpretation

1.1 In this Agreement the following expressions have the following meanings:

Board means the Board of Directors of the Company from time to time including any committee of the Board duly appointed by it and any representative of the Board duly appointed by it.

Commencement date means 1 November 2018.

Conditions means the conditions to Completion, being the matters set out in clause 2.

Continuous employment means the date from which the Executive began the period of continuous employment defined by s210-219 Employment Rights Act 1996 with the Company or its predecessors.

Group Company means any parent undertaking or subsidiary undertaking or any associated company from time to time of the Company (for which purpose "parent undertaking" and "subsidiary undertaking" are to be defined in accordance with section 1162 of the Companies Act 2006 and associated company means any company which any such parent undertaking or subsidiary undertaking holds or controls more than 20 per cent of the equity share capital).

Listing means the successful application and admission of all or any of the shares in the capital of the Company, on the AIM market operated by the London Stock Exchange plc, or to any recognised investment exchange (as defined in section 285 of the Financial Services and Markets Act 2000 (as amended)).

Longstop Date means 31st December 2018 or such later date as may be agreed in writing by the Company and the Executive.

Termination date means the date on which the Executive's employment under this Agreement terminates and references to "from the Termination Date" mean from and including the date of termination.

1.2 The headings are included in this Agreement for convenience only and do not affect its construction.

1.3 Any references to a statutory provision shall be deemed to include all modifications and/or re-enactment of it and all subordinate legislation made under it.

2 Conditions

2.1 The continued employment of the Executive by the Company is subject to and conditional upon a Listing.

2.2 If the Condition referred to in clause 2.1 is not fully satisfied by the Longstop Date, this agreement shall automatically terminate with immediate effect.

3 Previous agreements and warranties

3.1 This Agreement contains the entire and only agreement and will govern the relationship between the Company and the Executive from the Commencement Date in substitution for all previous agreements and arrangements whether written, oral or implied between the Company or any Group Company and the Executive relating to the services of the Executive all of which will be deemed to have terminated by consent with effect from the Commencement Date.

3.2 The Executive and the Company acknowledge that in entering into this Agreement neither has relied on any representation or undertaking by the other whether oral or in writing except as expressly incorporated in the Agreement. The Company will not be liable for any misrepresentation by it or any Group Company before the Commencement Date made innocently or negligently and any remedy of the Executive in respect of any representation which is untrue made before the Commencement Date will be limited to damages for breach of contract.

3.3 The Executive warrants and represents to the Company that he will not breach any existing or former terms of employment applicable to him whether express or implied or any other obligation binding on him by reason of entering into this Agreement or performing any of his duties and obligations under it.

3.4 The Executive warrants and represents that he has, prior to entering into this Agreement, disclosed to the Company in writing all previous convictions other than spent convictions.

4 Appointment, duration and notice

4.1 Subject to the provisions of clause 2, the Company will employ the Executive and the Executive will serve the Company as Chief Technology Officer and such other role commensurate with the Executive's status as the Board may from time to time direct.

4.2 Subject to the provisions of clause 2, the appointment will commence on the Commencement Date and will continue subject as follows, unless and until the employment is terminated either by the Company giving to the Executive not less than 12 months written notice or by the Executive giving to the Company not less than 12 months written notice to expire at any time.

4.3 Without prejudice to clauses 19.1 and 19.3 at its absolute discretion the Company may upon receipt of the Executive's written notice in accordance with clause 4.2, or as an alternative to providing notice in accordance with clause 4.2, terminate this Agreement and the Executive's employment with immediate effect at any time by giving him written notice of such termination and paying him his basic salary in lieu of the notice required under clause 4.2 in full and final settlement of all claims which he has or may have against the Company or any Group Company, under or arising out of his employment with the Company or any such Group Company, the termination of his employment (including without limitation his right to notice pursuant to clause 4.2) or otherwise. For the avoidance of doubt the Executive's employment will terminate on the date specified in the notice given by the Company pursuant to this clause.

4.4 The Executive's continuous employment with the Company commenced on the Commencement Date

5 Duties

5.1 The Executive will faithfully and diligently perform such duties and functions (including, but not limited to the statutory statement of directors' duties set out in the Companies Act 2006), exercise such powers and comply with such instructions in connection with the business of the Company and the Group as the Board reasonably determines and shall comply with all the Company's rules, regulations and policies and procedures from time to time in force.

5.2 The Executive will, if and as long as he is so required by the Company, carry out duties for and/or act as a director, officer or employee of any other Group Company. The duties attendant on any such appointment will be carried out by the Executive as if they were duties to be performed by him on behalf of the Company under this Agreement.

5.3 The Executive will do such things as are necessary to ensure compliance by himself and any relevant Group Company with the UK Corporate Governance Code (as amended from time to time).

5.4 The Executive will comply with all requirements, recommendations or regulations, as amended from time to time, of the UK Listing Authority (including the Model Code for transactions in securities by directors and certain senior executives of listed companies), the FCA and all regulatory authorities relevant to any Group Company.

5.5 The Executive will comply with the requirements under both legislation and regulation as to the disclosure of inside information.

5.6 The Executive will comply with the Company's anti-corruption and bribery policy and related procedures.

5.7 Without prejudice to clauses 5.1 and 19.3 the Board may at any time require the Executive to cease performing and exercising all or any of such duties, functions or powers and/or the Board may appoint any person or persons to act jointly with the Executive to discharge his duties and functions under the Agreement.

5.8 The Executive shall not without the prior written consent of the Board:

5.8.1 incur any capital expenditure in excess of such sums as may be authorised from time to time; or

5.8.2 enter into on behalf of the Company or any Group Company any commitment, contract or arrangement or otherwise than in the normal course of business or outside the scope of his normal duties, or of an unusual, onerous or long-term nature.

5.9 The Executive accepts and confirms that he has a duty to report any wrongdoing by any employee or director of which he becomes aware (even where this necessarily involves disclosing the Executive's own misconduct). He should report any such wrongdoing to the Board.

6 Other interests

6.1 The Executive will not (except with the prior written consent of the Board not to be unreasonably withheld) whether paid or unpaid, be directly or indirectly engaged, concerned or interested in any other business or occupation or in the setting up of any other business or occupation provided that the Executive may hold/or be interested in:

6.1.1 any securities listed on a recognised stock exchange or dealt in on any other public securities market (for the purpose of investment only and which amount to not more than (3%) of the issued share capital, debentures or other securities of any company) and will disclose to the Board any like matters relating to his spouse, partner, children, stepchildren or parents;

6.1.2 any other business occupation (including as an executive or non-executive director) or public office which, prior to the commencement of this Agreement or prior to the Executive's holding of an interest in such business, occupation or public office, has been disclosed in writing by the Executive and agreed to by the Board.

provided that, in all circumstances, any such interest under clause 6.1.1 or 6.1.2 shall not conflict with the business interests of the Company or any Group Company and which will not require the Executive to devote such time as would be inconsistent with his obligations under this Agreement.

6.2 The Board reserves the right to withdraw its consent to any of the matters referred to in sub-clause 6.1 if they relate to matters that are in competition with or potentially compete with the Company or any Group Company. The Executive confirms that he has fully disclosed to the Company in writing, all circumstances in respect of which there is, or there might be, a conflict of interest between the Company or any Group Company, and the Executive and he agrees to fully disclose to the Board any such circumstances which may arise during his employment under this Agreement.

6.3 The Executive shall not be entitled to receive or obtain directly or indirectly any discount, rebate, commission or other benefit in respect of any business transacted (whether or not by him), by or on behalf of the Company or any Group Company and if any other company or business entity in which he is interested shall directly or indirectly obtain any such discount, rebate, fee, gratuity, commission, payment

or other benefit, the Executive will immediately account to the Company or Group company for the amount received or value of the benefit obtained.

7 Place of work

The Executive will perform his duties principally from Kilkenny, Ireland but may from time to time be required to travel both inside and outside Ireland and the United Kingdom in the course of his duties. For the avoidance of doubt, the Company will not require the Executive to change his place of residence without his prior consent.

8 Hours of work

In signing this Agreement, the Executive agrees that he has no standard hours of work and he is expected to work such hours (including at weekends) as may be reasonably necessary to properly fulfil his duties. The parties agree that in view of the Executive's seniority and managerial duties and responsibilities, his working time cannot be measured and accordingly, that his employment falls within the scope of Regulation 20 of the Working Time Regulations.

9 Remuneration

9.1 The Company will pay the Executive a salary at the rate of €200,000.00 per annum which shall accrue from day to day and be payable in arrears by equal monthly instalments on the 28th day of each month.

9.2 The Executive's salary will be subject to review by the Board from time to time. Any increase in the Executive's salary will be determined at the absolute discretion of the Remuneration Committee of the Parent ("**RemCo**"). The fact that the Executive's salary may be increased in any year or years during his employment does not confer any right on the Executive to receive any increase in any subsequent year or years.

9.3 The Executive's salary will be inclusive of any director's fees to which the Executive may be entitled as a director of the Company or of any Group Company.

10 Pension

10.1 The Executive will be entitled to become a member of any pension scheme operated by the employer from time to time ("the Scheme") subject always to the trust deed and rules of the pension scheme from time to time in effect (including without limitation any powers of alteration and discontinuance). Any rules relating to the pension scheme can be obtained from the Company Secretary.

10.2 If the Executive joins the Scheme, the Company will contribute an amount, being equivalent to 5% of the basic salary of the Executive to the Scheme during each year that the Executive remains employed under this Agreement on terms notified by the Company to the Executive from time to time in writing. The Company's contributions to the Scheme shall be payable in equal monthly instalments in arrears, and shall be subject to the rules of the Scheme and the tax reliefs and exemptions available from HM Revenue & Customs, as amended from time to time.

10.3 There is no contracting out certificate in force in respect of the Executive's employment under the provisions of the Pension Schemes Act 1993 (as amended from time to time).

10.4 The Company at its absolute discretion reserves the right to replace or amend the benefit under this clause 10.

11 Car Allowance

11.1 Provided that the Executive holds a current driving licence the Executive shall receive a car allowance for use of the Executive's own car of €5,000.00 a year which shall be payable together with and in the same manner as the salary in accordance with clause 9.1. The car allowance shall not be treated as part of the basic salary for any purpose and shall not be pensionable.

11.2 The Executive shall immediately inform the Company if he is disqualified from driving and shall cease to be entitled to receive the allowance under clause 11.1.

12 Other Benefits

12.1 During this employment the Executive will be entitled to participate at the Company's expense in the Company's private medical expenses insurance scheme for the benefit of the Executive.

12.2 The Executive's membership of the scheme detailed at 12.1 above is subject to:

12.2.1 the rules of the above scheme from time to time (and any replacement schemes provided by the Company); and

12.2.2 the Executive being eligible to participate in or benefit from such scheme pursuant to their rules.

12.3 If the scheme provider (including but not limited to any insurance company) refuses for any reason (whether based on its own interpretation of the terms of the insurance policy or otherwise) to provide any benefits to the Executive the

Company is not liable to provide replacement benefit of the same or similar kind or compensation in lieu of such benefit.

12.4 The Executive will be entitled to become a participant in an annual employee bonus scheme, if one is established and operated by the Company from time to time subject always to the terms and conditions of any such scheme. The award and determination of any such bonus shall be in the absolute discretion of the RemCo.

13 Expenses

The Executive will be reimbursed all out of pocket expenses reasonably and properly incurred by him in the performance of his duties under this Agreement on hotel, travelling, entertainment and other similar items provided that he produces to the Company satisfactory evidence of expenditure.

14 Holidays

14.1 The Executive shall be entitled to 25 working days paid holiday in each year, in addition to normal public holidays, such holidays to be taken at such time or times as may be approved by the Board.

14.2 The Company shall also close between Christmas and New Year and the Executive shall receive holiday pay for this period, however, with the exception of the normal public holidays, this shall not come out of the Executive's entitlement as set out in clause 14.1.

14.3 The Company's holiday year runs from 1st January to 31st December.

14.4 Any holiday entitlement which is not taken by the end of the holiday year to which it relates will be lost and may not be carried forward without express approval from the Board.

14.5 The Executive's entitlement to paid holiday in the holiday year in which his employment terminates will be calculated on a pro-rata basis rounded to the nearest half day.

14.6 Where the Executive has taken more or less than his holiday entitlement in the year his employment terminates, a proportionate adjustment will be made by way of addition to or deduction from (as appropriate) his final gross pay calculated on a pro-rata basis. Such payment in lieu shall be 1/260th of the Executive's salary for each day.

15 Incapacity

If the Executive is absent from his duties as a result of illness or injury he will notify the Company Secretary as soon as possible and complete any self-certification forms which are required by the Company. If the incapacity continues for a period of 7 days or more he will produce to the Company a medical certificate to cover the duration of such absence.

16 Confidentiality

16.1 The Executive acknowledges that in the ordinary course of his employment he will be exposed to information about the business of the Company and the Group and that of the Company's and the Group's suppliers and customers which amounts to trade secrets, is confidential or is commercially sensitive and which may not be readily available to others engaged in a similar business to that of the Company or any of the Group Companies or to the general public and which if disclosed will be liable to cause significant harm to the Company or such Group Companies. The Executive has therefore agreed to accept the restrictions in this clause 16.

16.2 For the purposes of this clause and by way of illustration and not limitation, information will prima facie be secret and confidential if it relates to:

16.2.1 raw materials;

16.2.2 research and development;

16.2.3 inventions;

16.2.4 formulae and formulations;

16.2.5 methods of treatment, processing, manufacture or production, process and production controls including quality controls;

16.2.6 suppliers and their production and delivery capabilities;

16.2.7 customers and details of their particular requirements;

16.2.8 costings, profit margins, discounts, rebates and other financial information;

16.2.9 marketing strategies and tactics;

16.2.10 current activities and current and future plans relating to all or any of development, production or sales including the timing of all or any such matters;

16.2.11 the development of new products;

16.2.12 production or design secrets; or

16.2.13 technical design or specifications of the Company's products.

16.3 The Executive will not during the period of his employment with the Company obtain or seek to obtain any financial advantage (direct or indirect) from the disclosure of information acquired by him in the course of his employment with the Company.

16.4 The Executive will not either during his employment (including without limitation any period of absence or of exclusion/garden leave pursuant to clause 19.3) or after its termination, without limit in time, for his own purposes or for any purposes other than those of the Company or any Group Company for any reason and in any manner use or divulge or communicate to any person, firm, company or organisation, except to officials of any Group Company who are entitled to know, any secret or confidential information or information constituting a trade secret acquired or discovered by him in the course of his employment with the Company relating to the private affairs or business of the Company or any Group Company or suppliers, customers, management or shareholders.

16.5 The restrictions contained in this clause do not apply to:

16.5.1 any disclosure authorised by the Board or required in the ordinary and proper course of the Executive's employment or required by the order of a court of competent jurisdiction or by an appropriate regulatory authority or as otherwise required by law;

16.5.2 any information which the Executive can demonstrate is in the public domain otherwise than as a result of a breach by him of this clause; or

16.5.3 protected disclosures made pursuant to and in accordance with the Public Interest Disclosure Act 1998 and/or any policy on disclosure operated by the Company from time to time.

17 Intellectual property

17.1 For the purposes of this Agreement:

17.1.1 “Employment Inventions” means any Invention which is made wholly or partially by the Executive at any time during the course of his employment with the Company (whether or not during working hours or using Company premises or resources, and whether or not recorded in material form) which relates to or affects the business of the Company or any Group Company.

17.1.2 “Employment IPRs” means Intellectual Property Rights created by the Executive in the course of his employment with the Company (whether or not during working hours or using Company premises or resources).

17.1.3 “Intellectual Property Rights” means patents, rights to Inventions, copyright and related rights, trade marks, trade names and domain names, rights in get-up, goodwill and the right to sue for passing off, unfair competition rights, rights in designs, rights in computer software, database rights, topography rights, rights to use and preserve the confidentiality of information (including know-how and trade secrets) and any other intellectual property rights, in each case whether registered or unregistered and including all applications (or rights to apply) for and be granted, renewals or extensions of, and rights to claim priority from, such rights and all similar or equivalent rights or forms of protection which subsist or will subsist now or in the future in any part of the world.

17.1.4 “Invention” any invention, idea, discovery, development, improvement or innovation, whether or not patentable or capable of registration, and whether or not recorded in any medium.

17.2 The Executive acknowledges that all Employment IPRs, Employment Inventions and all materials embodying them shall automatically belong to the Company to the fullest extent permitted by law. To the extent that they do not vest in the Company automatically, the Executive holds them on trust for the Company.

17.3 The Executive acknowledges that, because of the nature of his duties and the particular responsibilities arising from the nature of his duties, the Executive has, and shall have at all times while he is employed by the Company, a special obligation to further the interests of the Company.

17.4 To the extent that legal title in and to any Employment IPRs or Employment Inventions does not vest in the Company by virtue of clause 17.2, the Executive agrees, immediately on creation of such rights and Inventions, to offer to the Company in writing a right of first refusal to acquire them on arm’s length terms to

be agreed between the parties. If the parties cannot agree on such terms within 30 days of the Company receiving the offer, the Company shall refer the dispute for determination to an expert who shall be appointed by the President of London Court of International Arbitration. The expert's decisions shall be final and binding on the parties in the absence of manifest error, and the costs of arbitration shall be borne equally by the parties.

17.5 The Executive agrees:

17.5.1 to give the Company full written details of all Employment Inventions promptly on their creation;

17.5.2 at the Company's request and in any event on the termination of his employment to give to the Company all originals and copies of correspondence, documents, papers and records on all media which record or relate to any of the Employment IPRs;

17.5.3 not to attempt to register any Employment IPR nor patent any Employment Invention unless requested to do so by the Company; and

17.5.4 to keep confidential each Employment Invention unless the Company has consented in writing to its disclosure by him.

17.6 The Executive waives all his present and future moral rights which arise under the Copyright Designs and Patents Act 1988, and all similar rights in other jurisdictions relating to any copyright which forms part of the Employment IPRs, and agree not to support, maintain or permit any claim for infringement of moral rights in such copyright works.

17.7 The Executive acknowledges that, except as provided by law, no further remuneration or compensation other than that provided for in this Agreement is or may become due to him in respect of his compliance with this clause. This clause is without prejudice to the Executive's rights under the Patents Act 1977.

17.8 The Executive undertakes to use his best endeavours to execute all documents and do all acts both during and after his employment by the Company as may, in the opinion of the Company, be necessary or desirable to vest the Employment IPRs in the Company, to register them in the name of the Company and to protect and maintain the Employment IPRs and the Employment Inventions. Such documents may, at the Company's request, include waivers of all and any statutory moral rights relating to any copyright works which form part of the Employment

IPRs. The Company agrees to reimburse his reasonable expenses of complying with this clause17.8.

17.9 The Executive agrees to give all necessary assistance to the Company to enable it to enforce its Intellectual Property Rights against third parties, to defend claims for infringement of third party Intellectual Property Rights and to apply for registration of Intellectual Property Rights, where appropriate throughout the world, and for the full term of those rights.

17.10 The Executive irrevocably authorises the Company to appoint a person to execute any documents and to do everything necessary to effect his obligations under this clause on his behalf.

18 Restrictive covenants

18.1 In this clause the following expressions have the following meanings:

"Critical Person"	any person who was an employee, agent, director, consultant or independent contractor employed, appointed or engaged by the Company or any Relevant Group Company at any time within the Relevant Period who by reason of such employment, appointment or engagement and in particular his/her seniority and expertise or knowledge of trade secrets or confidential information of the Company or any Group Company or knowledge of or influence over the clients, customers or suppliers of the Company or any Group Company is likely to be able to assist or benefit a business in or proposing to be in competition with the Company or any Relevant Group Company;
"Products or Services"	products or services which are of the same kind as or of a materially similar kind to or competitive with any products or services sold or supplied by the Company or any Relevant Group Company within the Relevant Period;

“Relevant Customer”	any person, firm, company or organisation who or which at any time during the Relevant Period is or was: (i) negotiating with the Company or a Relevant Group Company for the sale or supply of Relevant Products or Services; or (ii) a client or customer of the Company or any Relevant Group Company for the sale or supply of Relevant Products or Services; or (iii) in the habit of dealing with the Company or any Relevant Group Company for the sale or supply of Relevant Products or Services and in each case with whom or which the Executive was directly concerned or connected or of whom or which the Executive had personal knowledge during the Relevant Period in the course of his employment;
“Relevant Group Company”	any Group Company (other than the Company) for which the Executive has performed services under this Agreement or for which he has had operational/management responsibility at any time during the Relevant Period;
“Relevant Period”	the period of 12 months immediately before the Termination Date or (where such provision is applied) the commencement of any period of exclusion/garden leave pursuant to clause 19.3 if earlier;
“Relevant Products or Services”	Products or Services with which sale or supply the Executive was directly concerned or connected during the Relevant Period in the course of his employment.

18.2 The Executive will not without the prior written consent of the Company directly or indirectly and whether alone or in conjunction with or on behalf of any other person and whether as a principal, shareholder, director, employee, agent, consultant, partner or otherwise:

18.2.1 for a period of 9 months from the Termination Date be employed, engaged, concerned or interested in or provide technical, commercial or professional advice to any other business which supplies Products or Services in competition with the Company or any Relevant Group Company provided that this restriction does not apply to prevent the Executive from:

(a) undertaking duties or activities which are materially different from those undertaken by him during the Relevant Period in the performance of his duties; or

(b) holding shares or other securities in any company which is quoted, listed or otherwise dealt in on a recognised investment exchange or other securities market and which confer not more than 3% per cent. of the votes which could be cast at a general meeting of such company;

18.2.2 for a period of 9 months from the Termination Date be employed, engaged, concerned or interested in any business which is or was at any time during the Relevant Period a Relevant Customer of the Company or any Relevant Group Company and/or do or attempt to do anything which causes or may cause the Relevant Customer to cease or materially to reduce its orders or contracts with the Company or any Relevant Group Company; or

18.2.3 for a period of 9 months from the Termination Date so as to compete with the Company or any Relevant Group Company canvass, solicit or approach or cause to be canvassed, solicited or approached any Relevant Customer for the sale or supply of Relevant Products or Services or endeavour to do so; or

18.2.4 for a period of 9 months from the Termination Date so as to compete with the Company or any Relevant Group Company deal or contract with any Relevant Customer in relation to the sale or supply of any Relevant Products or Services, or endeavour to do so; or

18.2.5 for a period of 9 months from the Termination Date solicit, induce or entice away from the Company or any Relevant Group Company or, in connection with any business in or proposing to be in competition with the Company or any Relevant Group Company, employ, engage or appoint or in any way cause to be employed, engaged or appointed a Critical Person whether or not such person would commit any breach of his or her contract of employment or engagement by leaving the service of the Company or any Relevant Group Company; or

18.2.6 use in connection with any business any name which includes the name of the Company or any Group Company or any colourful imitation of it.

18.3 Whilst the restrictions in this clause 18 are regarded by the parties as fair and reasonable and necessary to protect the Company's legitimate business interests, the parties declare that each of the restrictions in this clause 18 are intended to be separate and severable. If any restriction is held to be unreasonably wide but would be valid if part of the wording (including in particular but without limitation the defined expressions referred to in clause 18.1) were deleted, such restriction will apply with so much of the wording deleted as may be necessary to make it valid.

18.4 The parties agree that the periods referred to in sub-clause 18.2 above will be reduced by one day for every day during which at the Company's direction and pursuant to clause 19.3 below the Executive has been excluded from the Company's premises and/or has not carried out any duties or has carried out duties other than his normal duties.

18.5 For the purposes of clauses 16 and 18 the Company has entered into this Agreement as agent for and trustee of all Relevant Group Companies and all Group Companies respectively.

18.6 If the Executive applies for or is offered new employment, appointment or engagement, before entering into any related contract the Executive will bring the terms of this clause and clauses 4, 5, 16, 16.2 and 19.3 to the attention of a third party proposing directly or indirectly to employ, appoint or engage him.

19 Termination

19.1 Notwithstanding the provisions of clause 4.2 above, the Company may terminate this Agreement with immediate effect without payment of compensation (notwithstanding that the Company may have on a former occasion waived its rights under this clause) if the Executive:

19.1.1 commits, repeats or continues any serious breach of this Agreement or his obligations under it;

19.1.2 in the performance of his duties under this Agreement or otherwise commits any act of gross misconduct or serious/gross incompetence;

19.1.3 prejudices or because of his behaviour is likely in the reasonable opinion of the Board to prejudice the interests or reputation of the Executive, the Company or any Group Company;

19.1.4 has committed/is charged with/is convicted of any criminal offence other than an offence which does not in the reasonable opinion of the Board affect his position under this Agreement;

19.1.5 becomes bankrupt or enters into or makes any arrangement or composition with, or for the benefit of his creditors generally;

19.1.6 becomes prohibited by law from being a director of a company or if the Executive ceases to be a director of the Company without the consent or concurrence of the Board;

19.1.7 becomes incapacitated from performing all or any of his duties under this Agreement by illness or injury (physical or mental) for a period exceeding (in total) 52 weeks (or such longer period as the Company may agree) in any period of 12 months; or

19.1.8 infringes or the Company has reasonable suspicion that he has infringed any rules or regulations by any regulatory or other external authority or professional body applicable to his employment or which regulate the performance of his duties or fails to possess any qualifications or meet any condition or requirement laid down by any applicable regulatory authority, professional body or legislation.

19.2 The Company shall have the right to suspend the Executive (subject to the continued payment of salary and full contractual benefits) pending any investigation into any potential dishonesty, gross misconduct or any other circumstances which may give rise to a right to the Company to terminate pursuant to clause 19.1 for such period as it thinks fit.

19.3 Without prejudice to clause 5.1 after notice of termination has been given by either party under clause 4.2 or if the Executive seeks to or indicates an intention to resign as a director of the Company or any Group Company or terminate his employment

without notice, provided that the Executive continues to be paid and enjoys his full contractual benefits until his employment terminates in accordance with the terms of this Agreement, the Board may in its absolute discretion without breaking the terms of this Agreement or giving rise to any claim against the Company or any Group Company for all or part of the notice period required under clause 4.2:

19.3.1 exclude the Executive from the premises of the Company and/or any Group Company;

19.3.2 require the Executive to work from home and/or to carry out specified duties or special projects outside the scope of his normal duties and responsibilities or to carry out no duties;

19.3.3 announce to employees, suppliers and customers and to any relevant regulatory information service that the Executive has been given notice of termination or has resigned (as the case may be);

19.3.4 instruct the Executive not to communicate orally or in writing with suppliers, customers, employees, agents or representatives of the Company or any Group Company until his employment under this Agreement has terminated.

19.4 For the avoidance of doubt, the Executive's duties and obligations under clauses 5, 6, 16 and 16.2 and those to be implied into this Agreement at common law continue to apply during any period of exclusion/garden leave.

19.5 On commencement of any period of exclusion/garden leave pursuant to clause 19.3 the Executive will:

19.5.1 on request deliver up to the Company all property belonging to it or any Group Company (except any property necessary to complete any duties assigned to the Executive); and

19.5.2 resign in accordance with clause 19 from all offices and appointments he holds in the Company and any Group Company.

19.6 Before and after termination of the Executive's employment, the Executive will provide the Company and/or any Group Company with reasonable assistance regarding matters of which he has knowledge and/or experience in any proceedings or possible proceedings in which the Company and/or Group Company is or may be a party.

19.7 The Executive agrees that at the expense and request of the Company and in any event on termination of his employment, he will transfer or procure the transfer of all shares held by him in trust or as a nominee by virtue of his employment with the Company, to such person or persons as the Company may direct. If the Executive fails to do so within 7 days of any such request, or the termination of his employment (as the case may be), the Company is irrevocably authorised to appoint a person or persons to execute all necessary transfer forms and other documentation on his behalf.

19.8 The Executive shall not at any time after the termination of his employment with the Company represent himself as being in any way connected with, or interested with the Company or any of the Group Companies or their respective businesses unless the particulars are specifically agreed in writing with the Company.

20 Resignation as director

20.1 The Executive will on termination of his employment for any reason, at the request of the Board, give notice resigning immediately without claim for compensation (but without prejudice to any claim he may have for damages for breach of this Agreement):

20.1.1 as a director of the Company and all such Group Companies of which he is a director; and

20.1.2 all trusteeships held by him of any pension scheme or other trusts established by the Company or any Group Company or any other company with which the Executive has had dealings as a consequence of his employment with the Company.

20.2 If notice pursuant to clause 20.1 is not received by the relevant Company within 7 days of a request by the Company, the Company is irrevocably authorised to appoint a person to execute any documents and to do everything necessary to effect such resignation or resignations on the Executive's behalf.

20.3 Except with the prior written agreement of the Board, the Executive will not during his employment under this Agreement resign his office as a director of the Company or any Group Company and if he does so without the consent or concurrence of the Board, the Company will be entitled to terminate his employment pursuant to clause 19.1.6, or at the Company's absolute discretion, to treat such resignation as notice of termination given by the Executive to the

Company pursuant to clause 4.2 and to suspend the Executive pursuant to clause 19.3.

21 Delivery of documents and property

On termination of this agreement for any reason (or earlier if requested) the Executive will immediately deliver up to the Company all property (including but not limited to any hardware, documents and software, credit cards, mobile phone, keys and security passes) belonging to it or any Group Company in the Executive's possession or under his control. Documents and software include (but are not limited to) correspondence, diaries, address books, databases, files, reports, minutes, plans, records, documentation or any other medium for storing information. The Executive's obligations under this clause include the return of all copies, drafts, reproductions, notes, extracts or summaries (however stored or made) of all documents and software. The Company may withhold any monies then owing to the Executive in any respect pending him providing, if so requested, his written undertaking that he has complied with this obligation.

22 Deductions

The Executive authorises the Company to deduct from his remuneration (which for this purpose includes salary, pay in lieu of notice, commission, bonus, holiday pay and sick pay) all debts owed by the Executive to the Company or any Group Company, including but without limitation the balance outstanding of any loans (and interest where appropriate) advanced by the Company to the Executive.

23 Sale or reconstruction of the Company

If the Executive's employment by the Company under this Agreement is terminated by reason of the liquidation of the Company for the purposes of reconstruction or amalgamation or as part of any arrangement (not involving insolvency) for the reconstruction, amalgamation or transfer of the undertaking of the Company and the Executive is offered employment with the reconstructed or amalgamated company or transferee of the undertaking on terms generally not less favourable than the terms of this Agreement then (whether or not he accepts the offer) the Executive shall have no claim against the Company in respect of the termination of his employment by the Company.

24 Interception of Communications

The Executive acknowledges and agrees that the Company may monitor and/or record the Executive's communications (including but not limited to e-mails, Internet access and telephone communications) during the Employment. The Executive agrees to abide, at

all times, with any relevant policy or procedure issued by the Company (or any Group Company) from time to time.

25 Disciplinary and grievance procedures

25.1 The Company shall operate a dismissal disciplinary and grievance rules and procedures. The spirit and principles of these procedures apply to the Executive suitably adapted to reflect his seniority and status but these procedures do not form part of the Executive's terms and conditions of employment.

25.2 The Company may invoke the disciplinary procedure at any stage from the imposition of a final written warning, it being recognised that warnings will not generally be appropriate in view of the Executive's seniority.

26 Notices

Notices under this Agreement by the Executive to the Company should be addressed to the Company and left at its registered office or sent by first class post or by facsimile transmission or other form of electronic delivery to its registered office and notices given by the Company to the Executive should be served personally or sent by first class post or sent by facsimile transmission or other form of electronic delivery to his usual or last known place of residence. In case of service by post, the day of service will be 72 hours after posting and in the case of facsimile transmission or other electronic delivery the day of service will be the day of transmission by the sender.

27 Data protection

27.1 The Company will collect and process information relating to the Executive in accordance with the privacy notice issued to the Executive. The Executive is required to sign and date the privacy notice, and return to the Company Secretary.

27.2 The Executive shall comply with the Privacy standard/Data protection policy when handling personal data in the course of employment including personal data relating to any employee, worker, contractor, customer, client, supplier or agent of the Company. The Employee will also comply with the Company's other policies and procedures.

27.3 Failure to comply with the Privacy standard/Data protection policy or any of the policies may be dealt with under the Company's disciplinary procedure and, in serious cases, may be treated as gross misconduct leading to summary dismissal.

28 Third party rights

Apart from the provisions of this Agreement which are expressly or impliedly entered into by the Company for itself and as agent of and trustee for any Group Company the parties do not intend that this Agreement should confer any right or benefit on any third party.

29 Miscellaneous

29.1 As of the date of this Agreement, this Agreement shall supersede and replace the directors service contract entered into by the parties dated 22 October 2018 (the "**Former Agreement**") and the Former Agreement shall cease to have any effect.

29.2 This Agreement will be governed by and interpreted in accordance with the law of England and Wales.

29.3 The parties to this Agreement submit to the exclusive jurisdiction of the English Courts in relation to any claim, dispute or matter arising out of or relating to this Agreement.

29.4 Any delay by the Company in exercising any of its rights under this Agreement will not constitute a waiver of such rights.

29.5 There are no collective agreements which directly affect the Executive's terms and conditions of employment.

29.6 This Agreement may be executed in any number of counterparts, each of which, when executed, shall constitute a duplicate original but all the counterparts together shall constitute the one Agreement.

THIS AGREEMENT has been executed as a deed and is delivered and takes effect on the date stated at the beginning of it.

Executed as a deed by
James McCullough for and on behalf of RENALYTIX AI PLC.

/s/ James McCullough

Director

in the presence of:

/s/ O. James Sterling_

SIGNATURE OF WITNESS

NAME: O. James Sterling

ADDRESS: [***]

OCCUPATION: CFO

Signed as a deed by Fergus Fleming

/s/ Fergus Fleming_____

SIGNATURE OF EXECUTIVE

in the presence of:

/s/ O. James Sterling_

SIGNATURE OF WITNESS

NAME: O. James Sterling

ADDRESS: [***]

OCCUPATION: CFO

EXHIBIT 10.10

December 12, 2020

Michael J. Donovan PhD MD
601 NE 27th St., Apt. 1707
Miami, FL 33137

Dear Michael:

Renalytix AI, Inc. (the "Company") is pleased to offer you the position of Chief Medical Officer, reporting directly to CEO James McCullough. 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.

In the Chief Medical Officer role, you will serve as the Company's medical expert and be responsible for strategic development and tactical implementation of clinical studies for our diagnostic programs. This will include providing direct medical/physician oversight for clinical studies, and clinician input into all aspects of our diagnostic test development. You will help ensure that all products developed and marketed by Renalytix AI conform to high quality standards in accordance with all related regulatory requirements. Additional duties and responsibilities may be assigned in consultation with the CEO.

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 January 4, 2020. You will be a remote employee but will be expected to travel frequently to our clinical laboratories in the United States and other U.S. and international company, customer, health system and other locations when required (approx. 40% travel time).

The position will include a base salary of $304,000 per year for 80% of your full-time work hours (i.e., 80% of full-time rate of $380,000), plus you will be eligible for annual bonus subject to approval of the board, and company benefits. Please see the appendix on the last page of this letter for a summary list of benefits.

In addition, you will receive a one-time sign-on bonus of $50,000, paid through the first available payroll cycle. This payment will be subject to all applicable taxes and withholdings. In the event that you should separate from the Company prior to one (1) year of employment (except through a workforce reduction job elimination or other mutually agreeable terms), the bonus will be repayable on a pro-rata basis.

If you choose to accept this job offer, please sign a copy of this letter where indicated below and return it to me by December 15, 2020. 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. Should the Company choose to terminate your employment for reasons other than Cause, you shall be entitled to severance payment equal to one month's base salary for each full month of employment, up to a maximum severance payment equal to six months of then-current base salary. "Cause for purposes of this letter shall mean that you have engaged in any of the following: (i) a material breach of any covenant or condition under this offer letter or any agreement between the Company and you; (ii) any act constituting dishonesty, fraud, immoral or disreputable conduct; (iii) any conduct which constitutes a felony under applicable law; (iv) material violation of any Company policy or any act of misconduct; (v) refusal to follow or implement a clear and reasonable directive of Company; (vi) negligence in the performance of your duties or failure to perform your material duties to the Company; (vii) failure to pass to the satisfaction of the Company, a preliminary background check or failure to submit proof of legal eligibility to work in the United States; or (viii) breach of fiduciary duty. In the event your employment is terminated at any time for Cause, you will not receive severance benefits, or any other severance compensation or benefits.

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 will 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.

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 your join the team during this exciting time in Renalytix AI's development.

Sincerely,

……
Trent D Bingham
Chief Human Resources Officer

About Renalytix AI

Renalytix AI 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 AI's 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 AI expects to launch 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 AI plc.

****

I hereby accept the chief medical officer position as described herein.

Michael J. Donovan
Full legal name

/s/ Michael J. Donovan
Signature

12/18/2020
Date

EXHIBIT 10.16

EXECUTION VERSION

DATED 30 OCTOBER 2018

RENALYTIX AI PLC

AND

ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI

AND

NPLUS1 SINGER ADVISORY LLP

RELATIONSHIP AGREEMENT

Cooley (UK) LLP DASHWOOD, 69 OLD BROAD STREET, LONDON EC2N 1QS, UK
T: +44 (0) 20 7583 4055 f: +44 (0) 20 7785 9355 WWW.COOLEY.COM

THIS AGREEMENT is made on 30 October 2018

BETWEEN:

(1) **RENALYTIX AI PLC**, incorporated and registered in England and Wales with company number 11257655, whose registered office is at Avon House, 19 Stanwell Road, Penarth, Cardiff CF64 2EZ (the "**Company**"); and

(2) **ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI**, a New York not-for-profit education corporation with a place of business at One Gustave L. Levy Place, New York, New York 10029 ("**Mount Sinai**"); and

(3) **NPLUS1 SINGER ADVSORY LLP**, a limited liability partnership incorporated and registered in England (Registered No. OC364131), whose registered office is at One Bartholomew Lane, London EC2N 2AX ("**N+1 Singer**").

BACKGROUND:

(A) The Company intends to apply for its entire issued share capital to be admitted to trading on AIM.

(B) Upon Admission, Mount Sinai is expected to hold approximately 14% - 15% of the issued share capital of the Company.

(C) The parties have agreed to enter into this Agreement for the purpose of documenting and regulating the terms of the relationship between the Company and Mount Sinai and its Associated Undertakings and ensuring that the Company can operate independently of Mount Sinai and accordingly be a company suitable for admission to AIM.

(D) This Agreement replaces the Management Rights Letter, which shall cease and terminate on the Effective Date.

THE PARTIES AGREE THAT:

1. **Interpretation**

1.1 Definitions

In this Agreement:

"Admission" means admission of the entire issued share capital of the Company to trading on AIM.

"AIM" means the market of that name operated by the London Stock Exchange.

"AIM Rules" means the AIM Rules for Companies published by the London Stock Exchange in force at the date of this Agreement or, where the context requires, as amended, modified or reissued after the date of this Agreement.

"Applicable Laws" means Companies Act 2006, the Financial Services and Markets Act 2000, the AIM Rules, the Nomad Rules, the City Code on Takeovers and Mergers, the Market Abuse Regulation and the QCA Code.

"Articles" means the articles of association of the Company from time to time.

"Associated Undertaking" means, in relation to a company, a subsidiary undertaking or parent undertaking of such company, any other company over which such company or any parent undertaking of such company has Control or any Company whose board of directors are accustomed to act in accordance with the directions or instructions of the relevant company.

"Board" means the board of directors of the Company or a duly authorised committee thereof.

"Business Day" means any day other than a Saturday, Sunday or public holiday in England.

"Control" means, in relation to any Undertaking, for the purposes of this Agreement only, the right directly or indirectly to (i) control the exercise of 50% or more of the Voting Rights or (ii) control (by way of the exercise of Voting Rights or otherwise) the appointment or removal of a majority of the board of directors of the relevant Undertaking.

"Directors" means the directors of the Company at the date of this Agreement or, where the context requires, in office from time to time.

"Effective Date" means the date of Admission.

"Group" means, in relation to a company, the company and its subsidiary undertakings from time to time, any parent undertaking of the company for the time being and any subsidiary undertakings of any such parent undertaking.

"Independent Director" means any person appointed as a Director from time to time who is considered by the Board to be independent for the purposes of any corporate governance regime complied with by the Company and shall include the chair of the Board provided he or she was considered by the Board to be independent upon appointment.

"London Stock Exchange" means London Stock Exchange plc.

"Market Abuse Regulation" means the Market Abuse Regulation (EU 596/2014).

"Management Rights Letter" means the agreement between the Company and Mount Sinai of that name.

"Mount Sinai Director" has the meaning given to it in clause 4.1.

"Mount Sinai Indemnitors" has the meaning given to it in clause 4.8.

"Mount Sinai Initial Director" means Erik Lium.

"Mount Sinai Minimum Shareholding" means 5% by nominal value of the issued ordinary share capital of the Company.

"New Mount Sinai Appointee" has the meaning given to it in clause 4.2.

"Nomad" means N+1 Singer or such other nominated adviser appointed by the Company from time to time.

"Nomad Engagement Letter" means the letter of engagement between N+1 Singer and the Company dated 28 August 2018 (or, to the extent that N+1 Singer is no longer the nominated adviser to the Company, any other engagement letter entered into between the Company and the nominated adviser appointed by the Company from time to time).

"Nomad Rules" means the AIM Rules for Nominated Advisers published by the London Stock Exchange in force from time to time.

"Ordinary Shares" means the Company's ordinary shares of £0.0025, having the rights and being subject to the restrictions set out in the Articles as in force at the date of this Agreement.

"Previous Mount Sinai Appointee" has the meaning given to it in clause 4.2.

"QCA Code" means the Corporate Governance Code published by the Quoted Companies Alliance or such other corporate governance regime complied with by the Company.

"Undertaking" means a company, body corporate, or other economic enterprise carrying on a business (whether or not for profit).

"Voting Rights" means, in relation to any Undertaking the voting rights attaching to securities of the relevant Undertaking which are generally exercisable at meetings of shareholders of the relevant Undertaking.

1.2 Construction of certain references

In this Agreement:

(a) words and phrases, the definitions of which are contained or referred to in the Companies Act 2006, shall be construed as having the meanings so attributed to them;

(b) references to statutory provisions shall be construed as references to those provisions and all statutory instruments and other subordinate legislation made thereunder, as amended or re-enacted or as their application is modified by other provisions from time to time, and shall include references to any provisions of which they are re-enactments (whether with or without modification);

(c) references to times, unless otherwise expressly stated, are references to London times;

(d) references to "clauses" are references to clauses of this Agreement;

(e) references to the singular shall include the plural and vice versa, and references to the any gender shall include any other gender;

(f) headings are included for convenience only and shall be disregarded in its interpretation;

(g) general words shall not be given a restrictive meaning by reason of their being preceded or followed by words indicating a particular class of acts, matters or things, and the word “including” shall be construed without limitation; and

(h) “person” includes any individual, partnership, body corporate, corporation sole or aggregate, a state or agency of a state and any unincorporated association or organisation in each case whether or not having a separate legal personality.

2. Conditionality and duration

2.1 Condition

This Agreement and the obligations of the parties hereto, are conditional upon Admission occurring on or before 30 November 2018, or such later date as the Nomad and the Company may agree. If this condition is not satisfied by such date as specified or agreed this Agreement will automatically terminate and be of no further force or effect.

2.2 Duration

Subject to clause 2.1, this Agreement shall continue from the Effective Date until such time as Mount Sinai and its Associated Undertakings together cease to hold as beneficial owner any Ordinary Shares, whereupon this Agreement shall terminate automatically with immediate effect, without prejudice to any rights and obligations that have accrued under it prior to termination, or it is terminated in accordance with clause 2.3.

2.3 Termination

Either Mount Sinai or the Company may terminate this Agreement with immediate effect by written notice to the other parties on or at any time after:

(a) the Company passing a resolution for its winding up or a court of competent jurisdiction making an order for the Company’s winding up or dissolution;

(b) the making of an administration order in relation to the Company or the appointment of a receiver over, or an encumbrancer taking possession of or selling, an asset of the Company; or

(c) the Company making an arrangement or composition with its creditors generally or making an application to a court of competent jurisdiction for protection from its creditors generally.

Such termination will be without prejudice to any rights and obligations that have accrued under it prior to termination.

3. Mount Sinai obligations

3.1 Independence of the Company

During the term of this Agreement and for so long as (i) Mount Sinai and its Associated Undertakings hold as beneficial owner, in aggregate, at least the Mount Sinai Minimum Shareholding; and (ii) the Company’s Ordinary Shares are admitted to trading on AIM, Mount

Sinai severally undertakes to the Company and the Nomad to procure (so far as it is able with respect to its Associated Undertakings) that:

(a) it shall not take any action that is intended to prevent the Board from operating independently of Mount Sinai and its Associated Undertakings;

(b) subject to clause 3.1(a), it will not take any action that would have the effect of preventing or might reasonably be expected to prevent any member of the Company's Group from complying with its obligations under any of the Applicable Laws including, without limitation, AIM Rule 13;

(c) Mount Sinai and its Associated Undertakings will exercise their Voting Rights in the Company (if any) so as to ensure (so far as they are reasonably able) that:

(i) the terms of this Agreement are implemented in full;

(ii) Mount Sinai and its Associated Undertakings perform and comply with their obligations under this Agreement and the Articles;

(iii) no variations are made to any provision of the Articles that it knows (or might reasonably expect) would be contrary to the terms of this Agreement or which it knows (or might reasonably expect) would otherwise have an impact on the Company's ability to operate independently from Mount Sinai and any of its Associates; and

(iv) the composition of the Board and the audit, nomination and remuneration committees of the Board is in compliance with the corporate governance regime adopted by the Company from time to time.

(d) Without limitation to their obligations under clause 3.1(c):

(i) neither Mount Sinai nor any of its Associated Undertakings will exercise any of their Voting Rights in the Company or be counted in any quorum at any meeting of the Company; and

(ii) the Mount Sinai Directors will not vote or be counted in any quorum at any meeting of the Board (or any committee thereof),

in each case, in relation to:

(A) any actual or proposed transaction, agreement or arrangement between the Company and any member of Mount Sinai's Group (including as to the amendment, enforcement or implementation of the same);

(B) any matter in which any member of Mount Sinai's Group or any Associated Undertaking thereof is interested; or

(C) any decision by the Company concerning the enforcement of its rights under, and the operation of, this Agreement,

and it is acknowledged and agreed that such matters referred to in (A), (B) and (C) above shall (i) be dealt with on behalf of the Company by a committee of the Board comprising the Independent Directors, and (ii) shall be assessed by the Nomad for the purposes of the AIM Rules in relation to Related Party Transactions (being Rule 13 of the AIM Rules as at the date of this Agreement) prior to any approval.

(e) Mount Sinai and its Associated Undertakings will not undertake any activity in violation of the terms of this Agreement;

(f) Mount Sinai and its Associated Undertakings will not exercise their Voting Rights to call a general meeting of the Company to propose a resolution to:

(i) de-list the Company from AIM (unless such delisting is supported by a majority of the Company's independent shareholders (as evidenced by the delivery of proxies in relation to a proposed delisting) or in circumstances where such resolution is being proposed in connection with (i) an offer by a bona fide third party to acquire the entire issued share capital of the Company or (ii) a recommended offer by Mount Sinai and/or its Associated Undertakings to acquire the entire issued share capital of the Company (excluding any shares already held by the Mount Sinai (and/or any of its Associated Undertakings));

(ii) remove an Independent Director from the Board where a replacement director, acceptable to the Nomad, has not been identified and engaged subject only to their formal appointment.

3.2 Mount Sinai voting and other rights

(a) Notwithstanding any other provision of this Agreement, Mount Sinai shall have the right to exercise its Voting Rights in respect of any proposed resolution to amend the Articles in circumstances where such amendments are not inconsistent with the terms of this Agreement.

(b) Notwithstanding any other provision of this Agreement, nothing in this agreement is intended to, or shall prevent Mount Sinai or any Associated Undertaking from:

(i) exercising the rights attaching to its or their Ordinary Shares as it or they see fit in its or their absolute discretion (save as expressly prohibited in this agreement); or

(ii) acquiring or disposing of any securities of the Company (save to the extent otherwise required by law or regulation).

3.3 Adjudication of Disputes

Any disputes between Mount Sinai and the Company relating to either the management of the Company, the operation of the Board of Directors or any transaction, agreement or arrangement referred to in clause 3.1(b) shall be passed to, and dealt with on behalf of the Company by, a committee comprising only of the Independent Directors following consultation with the Nomad.

4. **Appointment of Mount Sinai Directors**

4.1 Mount Sinai shall have the right to appoint one Director to the Board (the "Mount Sinai Director"). For so long as the Company's Ordinary Shares are admitted to trading on AIM, Mount Sinai will only be entitled to exercise this right at any time when it and its Associated Undertakings together hold as beneficial owner at least the Mount Sinai Minimum Shareholding.

4.2 The Company shall procure that the Mount Sinai Initial Director shall be appointed as a non-executive Director conditional upon Admission in accordance with the terms of his letter of appointment in a form agreed with Mount Sinai. It is acknowledged and agreed that the appointment of any person as a Director who is employed by or otherwise associated with Mount Sinai or any of its Associated Undertakings and who is not appointed by Mount Sinai as a Mount Sinai Director pursuant to this clause 4 shall not constitute such person as a Mount Sinai Director or affect Mount Sinai's right to appoint a Director under this clause 4.

4.3 Substitution

Subject to clause 4.1, Mount Sinai may by notice given to the Company at any time request that a person (a "**New Mount Sinai Appointee**") be appointed as a non-executive Director in place of any person previously appointed as the Mount Sinai Director (a "**Previous Mount Sinai Appointee**"), subject to the Nomad being satisfied as to the suitability of such New Mount Sinai Appointee in accordance with the Nomad Rules (provided the Company's Ordinary Shares are at the relevant time admitted to trading on AIM) and, subject to Mount Sinai procuring the resignation of the Previous Mount Sinai Appointee (unless s/he shall have already ceased to hold office) without any compensation being payable by the Company to such Director in respect of such cessation of office and with a full waiver of all and any claims such director may have against the Company (excluding for the avoidance of doubt any accrued but unpaid fees and expenses which have not been reimbursed at the relevant time) and the Company shall thereupon procure that the New Mount Sinai Appointee is appointed as a non-executive Director and the New Mount Sinai Appointee will enter into an individual letter of appointment on substantially similar terms to the Previous Mount Sinai Appointee (or on such other terms as Mount Sinai and the Company may then agree following consultation with the Nomad).

4.4 Maintenance in office

The Company shall procure that (unless Mount Sinai otherwise requires) the Mount Sinai Director is proposed and recommended by the Board (subject to the Directors' fiduciary duties) for re-election at the first annual general meeting of the Company after his appointment and at each subsequent annual general meeting of the Company at which such Director becomes liable to retire by rotation.

4.5 Replacement appointee - in the event that the Previous Mount Sinai Appointee ceased to hold office if they failed to be re-elected or have been removed as a Director at any general meeting, the New Mount Sinai Appointee shall be a person other than the Previous Mount Sinai Appointee.

4.6 Conflicts of interest

For the avoidance of doubt, the exercise by Mount Sinai or its Associated Undertakings of their voting rights solely for the purpose of maintaining the level of their shareholding in the Company (expressed as a percentage of the nominal value of the ordinary (or other voting) share capital of the Company) shall not be considered to be a conflict of interest.

4.7 Fees and expenses

In consideration for the services of the Mount Sinai Director, the Company shall pay Mount Sinai (or the Mount Sinai Director if so directed by Mount Sinai) a fee equal to the basic level payable to a non-executive director of the Company, which at Admission is £20,000 per annum. In addition, the Company will reimburse the reasonable costs incurred by any Mount Sinai Director and any Observer appointed pursuant to clause 5 below in performing his or her duties as a Director or Observer, as the case may be, including without limitation reasonable travel and accommodation costs to attend the Board meetings.

4.8 Indemnification and insurance

(a) The Company shall execute and deliver an indemnification agreement between the Company and any individual serving as a Mount Sinai Director in the form reasonably agreed to by Mount Sinai upon any such appointment.

(b) The Company hereby acknowledges that a Mount Sinai Director may have certain rights to indemnification, advancement of expenses and/or insurance provided by Mount Sinai and certain of its Associated Undertakings (collectively, the "**Mount Sinai Indemnitors**"). The Company hereby agrees (a) that it is the indemnitor of first resort in relation to all matters pertaining to the Company (such that its obligations to any such Mount Sinai Director are primary and any obligation of the Mount Sinai Indemnitors to advance expenses or to provide indemnification for the same expenses or liabilities incurred by such Mount Sinai Director are secondary), (b) that it shall be required to advance and/or pay (as required) the full amount of expenses incurred by such Mount Sinai Director in relation to his services as a director of the Company and shall be liable for the full amount of all such expenses, judgments, penalties, fines and amounts paid by a Mount Sinai Indemnitor in settlement by or on behalf of any such Mount Sinai Director in relation to matters pertaining to the Company to the extent legally permitted and as required by the Articles (or any agreement between the Company and such Mount Sinai Director), without regard to any rights such Mount Sinai Director may have against the Mount Sinai Indemnitors, and, (c) that it irrevocably waives, relinquishes and releases the Mount Sinai Indemnitors from any and all claims against the Mount Sinai Indemnitors for contribution, subrogation, or any other recovery of any kind in respect of the matters pertaining to the Company referred to above. The Company further agrees that no advancement or payment by the Mount Sinai Indemnitors on behalf of any such

Mount Sinai Director with respect to any claim for which such Mount Sinai Director has sought indemnification from the Company shall affect the foregoing and the Mount Sinai Indemnitors shall have a right of contribution and/or be subrogated to the extent of such advancement or payment to all of the rights of recovery of such Mount Sinai Director against the Company. The Mount Sinai Director and the Mount Sinai Indemnitors are intended third party beneficiaries of this clause 4.8(b) and shall have the right, power and authority to enforce the provisions of this clause 4.8(b) as though they were a party to this agreement.

(c) The Company will put in place directors' liability insurance with financially sound and reputable insurers to the reasonable satisfaction of Mount Sinai on and with effect from the date of appointment of a Mount Sinai Director and must ensure such insurance remains current and in full force and effect for the duration of the Mount Sinai Director's appointment.

5. **Observer**

For so long as Mount Sinai and its Associated Undertakings together hold as beneficial owner at least the Mount Sinai Minimum Shareholding, whether or not there is a Mount Sinai Director appointed to the Board, Mount Sinai may appoint (by notice in writing to the Company) an individual to attend meetings of the Board and any sub-committee meetings of the Board (an "**Observer**"). The Observer shall only be entitled to speak at any meetings of the Board or any sub-committee of the Board if the Mount Sinai Director is not present and shall not be entitled to vote at any meetings of the Board or any sub-committee of the Board. The Observer shall be provided with all notices and, subject to any legal or regulatory restrictions, Board materials as if he or she were a duly appointed Mount Sinai Director.

6. **Warranty**

Each of the Company and Mount Sinai warrants to the other party that it has all necessary power and authority to enter into and perform its obligations under this Agreement in accordance with its terms without any sanction or consent and that this Agreement when entered into will constitute a legally binding obligation on such party enforceable in accordance with its terms.

7. **Confidentiality**

7.1

(a) Mount Sinai and the Company shall keep confidential, and shall procure that each of their directors, officers, employees and agents shall keep confidential, all Confidential Information (as defined in clause 7.2) and shall not disclose the same to any other person (other than to such of its directors, senior employees or advisers to the extent only that they strictly need to know the same for the proper performance of their duties and on the basis that they are to comply with this clause 7 which each party shall use their best endeavours to procure) and each party shall not make use of any Confidential Information for their own purposes, and this obligation shall continue without limit of time and notwithstanding the termination of this Agreement or Mount Sinai ceasing to hold any shares or other securities of the Company.

(b) To the extent Confidential Information is disclosed by the Company to the Nomad pursuant to clause 3.1(d), clause 3.3 or this clause 7.1, the Nomad shall have a duty of confidentiality to the Company and Mount Sinai on the same terms as are provided for by the Nomad Engagement Letter as if each reference therein to the Company referred to each of the Company and Mount Sinai. N+1 Singer's obligations with regard to all Confidential Information shall always be governed by clause 5 of the Terms and Conditions of the Nomad Engagement Letter.

7.2 Definition of "Confidential Information"

For the purpose of this clause 7 "Confidential Information" means all information of whatever kind which either party may impart or cause to be imparted to the other party or to either of the other party's directors, senior employees or advisers, or to Mount Sinai appointees to the Board, which is imparted on the understanding that it is to be kept confidential, or is imparted or otherwise obtained by any of such persons and is marked as being confidential, or however imparted or obtained, is of a nature which would be expected to be kept confidential or by its nature is "inside information" within the meaning of the Criminal Justice Act 1993, the Financial Services and Markets Act 2000 or the Market Abuse Regulation ("**Inside Information**"). For the avoidance of doubt, Confidential Information shall include information disclosed by Mount Sinai to the Company or its directors, senior employees or advisers, notwithstanding that Mount Sinai will generally not seek to make such information available beyond the Company and its directors unless other parties need to receive it in connection with their contractual obligations to the Company.

7.3 Exclusions

The obligation in clause 7.1 shall not apply in respect of any Confidential Information which:

(a) is required to be disclosed by law;

(b) is in the lawful possession of, or was lawfully furnished to any party (as applicable) by another person without any breach of any obligation of confidentiality; or

(c) is for the time being in the public domain, otherwise than by any breach by Mount Sinai or their respective directors, senior employees or advisers.

7.4 Price sensitive information

To the extent that any of the Confidential Information is inside information (as defined in clause 7.2) Mount Sinai undertakes to bring that fact to the attention of any person to whom it may disclose the same to the extent permitted by this clause 7.

7.5 Disclosure of information to Mount Sinai

(a) The Mount Sinai Director and any Observer shall be entitled to disclose information he or she receives from the Company to Mount Sinai and any Associated Undertaking and any officer, employee or professional adviser of Mount Sinai and any Associated Undertaking who strictly need to know such information for the purpose it is being disclosed (and in accordance with the confidentiality obligations) provided that a Mount Sinai Director or Observer may not disclose:-

(i) sensitive and confidential information relating to the Company's negotiating position in relation to any contract, arrangement or transaction with Mount Sinai or an Associated Undertaking, the disclosure of which would be prejudicial to the Company's position or where to do so would be a breach of a bona fide confidentiality obligation owed by the Company or any subsidiary to a third party;

(ii) Inside Information unless in compliance with the Market Abuse Regulation and other applicable laws and regulations. Mount Sinai acknowledges that such information may give rise to obligations on it under applicable law and regulations, including, without limitation, under the Market Abuse Regulation. Mount Sinai further acknowledges that for the purposes of MAR the Mount Sinai Director and Observer shall be placed on the Company's permanent insider list as prescribed by MAR.

(b) The parties agree that the Board (acting without the Mount Sinai Director) may at any time serve on the Mount Sinai Director and the Observer a written notice requiring the Mount Sinai Director and the Observer to cease supplying specified information that is Inside Information to Mount Sinai (a "Stop Notice") in circumstances where the supply of such Inside Information to Mount Sinai (i) would be contrary to applicable law or regulation or (ii) relates to a matter affecting all shareholders of the Company and would therefore, in the opinion of the Board (acting without the Mount Sinai Director), be inappropriate. Mount Sinai shall instruct the Mount Sinai Director and the Observer to undertake to comply with this clause 7.5(b) and to comply with the relevant Stop Notice for so long as it is outstanding and has not been withdrawn in writing by the Board.

(c) The Company undertakes to Mount Sinai that it will not enter into confidentiality obligations with third parties in bad faith to prevent disclosure of information by a Mount Sinai Director or Observer pursuant to clause 7.5(a).

(d) Subject to the Company's legal and regulatory obligations including, without limitation, the requirements of the AIM Rules and the Market Abuse Regulation, the Company shall procure that Mount Sinai and its Associated Undertakings are provided with such financial and other information as may be reasonably requested by Mount Sinai to complete any tax return or other filing which may be required by law or regulation, for any audit or regulatory reason, or to meet their financial reporting requirements.

8. **Waiver and Amendment**

8.1 No waiver

No waiver of any term, provision or condition of this Agreement shall be effective unless such waiver is evidenced in writing and signed by the waiving party (and in the case of any waiver of the provisions of clause 7.1(b) by Mount Sinai) and then only in the instance and for the purpose of which it is given.

8.2 Effect of delay

No failure or delay on the part of any party in exercising any right, power or privilege under this Agreement shall operate as a waiver thereof, nor shall any single or partial exercise of any such right, power or privilege preclude any other or further exercise thereof or of any other right, power or privilege. The rights and remedies herein provided are cumulative with and not exclusive of any rights or remedies provided by law.

8.3 Variation in writing

No variation to this Agreement shall be effective unless made in writing and signed by all the parties and unless any such variation is previously discussed with the Nomad.

9. **General**

9.1 Notices

(a) Any notice (which term in this clause 9.1 shall include any other communication) required to be given under, or in connection with any matter contemplated by this Agreement, shall be in writing in the English language.

(b) Subject to clause 9.1(d) any notice shall be addressed as provided in clause 9.1(c) and:

(i) any such notice shall be delivered by hand or sent by fax transmission or pre-paid first class post and if delivered by email shall conclusively be deemed to have been received when the recipient, by an email sent to the email address for the sender stated in this clause 9 or by a notice delivered by another method in accordance with this clause 9, acknowledges having received that email, with an automatic “read receipt” not constituting acknowledgment of an email for purposes of this clause 9, and if sent by post shall conclusively be deemed to have been received three (3) Business Days after posting; and

(ii) if any deemed receipt under clause 9.1(b)(i) occurs before 9.00 a.m. on any Business Day, the notice shall be deemed to have been received at 9.00 a.m. on that day, and if deemed receipt occurs after 5.00 p.m. on any Business Day or on any day which is not a Business Day, the notice shall be deemed to have been received at 9.00 a.m. on the next Business Day.

(c) The addresses and other details of the parties to this Agreement are:

The Company:

Address: Its registered office from time to time

For the attention of: The Company Secretary

Email address: [***]

Mount Sinai:

Address: Icahn School of Medicine at
Mount Sinai

One Gustave L. Levy Place, Box 1675
New York, New York 10029

For the attention of: Senior Vice President

Email address: [***]

With a copy of
legal notices to: Icahn School of Medicine at Mount Sinai
One Gustave L. Levy Place, Box 1675
New York, New York 10029

For the attention of: Office of General Counsel

Email address: [***]

(d) Any party to this Agreement may notify the other parties of any change to the address or any of the other details specified in clause 9.1(c) provided that such notification shall only be effective on the date specified in such notice or five Business Days after the notice is given whichever is the later and provided also that any new address shall be in the United Kingdom.

9.2 Time of the essence

Subject to clause 8.3, any time, date or period referred to in this Agreement may be extended by mutual agreement between the parties but as regards any time, date or period as originally fixed or so extended, time shall be of the essence.

9.3 Rights cumulative and other matters

(a) It is understood and agreed by the parties that monetary damages would not be a sufficient remedy for any breach of this Agreement that resulted in the disenfranchisement of the other parties Shares and each party shall be entitled to seek injunctive relief and specific performance as a remedy for any such breach by the other.

(b) The rights, powers and remedies provided in this Agreement are cumulative and are not exclusive of any rights, powers or remedies provided by law or otherwise.

(c) Save as expressly provided in this Agreement, no failure to exercise nor any delay in the exercising, by any party to this Agreement, of any right, privilege or remedy under this Agreement shall impair or operate as a waiver thereof.

(d) No single or partial exercise of any right power or remedy under this Agreement shall prevent any further or other exercise thereof or the exercise of any other right or remedy.

(e) No time or other indulgence granted, to, or release or compromise of the liability of, any party to this Agreement shall affect the liability of any other party to this Agreement.

(f) Each party's liability to the other howsoever arising under or in connection with this Agreement shall not extend to any special, indirect or consequential loss or damage whatsoever.

(g) Any liability or obligation of any party that is accrued and is not performed in full as of the date of termination of this Agreement shall survive such termination until performed in full.

9.4 Entire Agreement

This Agreement (from the Effective Date) constitutes the whole agreement between the parties relating to its subject matter as at its date and supersedes and extinguishes any prior drafts, agreements, undertakings, representations, warranties and arrangements of any nature, whether in writing or oral, relating to such subject matter, including the Management Rights Letter.

9.5 Contracts (Rights of Third Parties) Act 1999

No person who is not a party to this Agreement other than a Mount Sinai Indemnitor, the Mount Sinai Director and the Nomad shall have any right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement. This Agreement may be varied or terminated without consent from and without reference to any Mount Sinai Indemnitor who is not a party to this Agreement.

9.6 Other rights

The provisions of this Agreement are without prejudice to any liabilities which any of the parties may have under any law.

9.7 Invalidity

If any provision of this Agreement shall be held to be illegal or unenforceable, the enforceability of the remainder of this Agreement shall be unaffected.

9.8 Assignment

This Agreement is not assignable by any of the parties hereto.

9.9 Costs

Subject to Admission the Company shall bear all costs in relation to the preparation, negotiation and completion of this Agreement.

9.10 No partnership

Nothing in this Agreement and no action taken by the parties under this Agreement shall constitute a partnership, association, joint venture or other co-operative entity between the parties.

9.11 Further assurance

The parties shall from time to time (both during the term of this Agreement and after) do or procure to be done all such acts (including exercising all voting rights and powers (direct and indirect) available to it in relation to any person and/or the Company) and execute or procure the execution of all such documents and things as may be reasonably necessary to give effect to the provisions of this Agreement.

9.12 Overriding obligations

The obligations of the parties pursuant to this Agreement shall at all times be subject to the requirements of the Articles and all relevant legal and regulatory requirements and obligations of the parties, including under applicable companies legislation, the AIM Rules and the Market Abuse Regulation. Each party shall act in accordance with such requirements and no party shall be required to take any action in breach of such requirement or obligation.

10. **Counterparts**

10.1 Counterparts

This Agreement may be executed in any number of counterparts and by the parties to it on separate counterparts, each of which when executed and delivered shall be an original but all the counterparts shall together constitute one and the same document.

10.2 Delivery of counterparts

Delivery of an executed signature page of a counterpart in Adobe Portable Document Format (PDF) sent by email shall take effect as delivery of an executed counterpart of this Agreement. If either method is adopted without prejudice to the validity of such agreement, each party shall provide the others with the original of such page as soon as reasonably practicable thereafter.

11. **Law and Jurisdiction**

11.1 English Law

This Agreement and all matters arising from it (including any dispute relating to the existence, validity, or termination of this Agreement or any contractual or non-contractual obligation) shall be governed by, and construed in accordance with, English law.

11.2 Arbitration

(a) Any and all disputes, controversies and claims between the parties arising out of or in relation to this Agreement shall be amicably and promptly settled by negotiation and consultation among them. In the event that the parties are unable to settle such dispute, controversy or claim by negotiation and consultation within sixty (60) days, any party shall submit the dispute to arbitration in accordance with the terms of this clause 11.2. All arbitrations shall be conducted in London, or such other location as may be mutually agreed by the parties, and in accordance with the Rules of the London Court of International Arbitration (the "Rules") as administered by the London Court of International Arbitration. All disputes submitted to arbitration shall be arbitrated in English. All decisions of the panel of arbitrators on any matter submitted

for arbitration in accordance with this Agreement shall be final and binding on the parties. Damages for which a party may be liable shall include loss of property, out of pocket expenses and third party liability. The number of arbitrators shall be three and shall be appointed in accordance with the Rules.

(b) The parties agree that information concerning or arising out of any arbitration, including information concerning any arbitration award, shall be used only for the purposes of the arbitration and be treated as confidential and not disclosed to any person other than a party without the prior consent in writing of all of the parties unless any of the exclusions specified in clause 7.3 applies or the disclosure is to a person intended to be called as a witness in the arbitration by the party disclosing the information, for the purpose of preparing the witness statement of such witness, provided that in any such case a written confidentiality undertaking has first been obtained from such person. The restrictions contained in this clause 9.2(B) shall survive the termination of this Agreement and shall continue without limit of time.

This Agreement is executed as a deed and is delivered and takes effect at the date written above.

Executed as a deed by
RENALYTIX AI PLC
acting by _____,
a director, in the presence of:

/s/ Julian Baines
Director

/s/ Colin Anderson
Witness signature

Collin Anderson
Name

Accountant
Occupation

Address:

Executed as a deed by
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI
acting by its Executive Vice President who is permitted to execute for **ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI** under the laws of New York

/s/ Erik K. Lium
Erik K. Lium, Executive Vice President
Authorised Signatory

Executed as a deed by
NPLUS1 SINGER ADVISORY LLP
acting by James Maxwell,
a member, in the presence of:

/s/ James Maxwell
Member

/s/ James White
Witness signature

James White
Occupation
Name
Chartered Accountant

Address:

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	Jurisdiction
Renalytix AI, Inc.	United States
Renalytix AI Limited	Ireland

Exhibit 23.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Registration Statement on Form S-8 (File No. 333-248741) pertaining to the Share Option Plan for Employees with Non-Employee Sub-Plan and U.S. Sub-Plan, 2020 Employee Share Purchase Plan, and 2020 Equity Incentive Plan of Renalytix plc of our report dated September 28, 2023, with respect to the consolidated financial statements of Renalytix plc included in this Annual Report (Form 10-K) for the year ended June 30, 2023.

/s/ Ernst & Young LLP
Iselin, New Jersey

September 28, 2023

Exhibit 31.1

CERTIFICATIONS

I, James McCullough, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: September 28, 2023

/s/ James McCullough

James McCullough

Chief Executive Officer

Exhibit 31.2

CERTIFICATIONS

I, O. James Sterling, certify that:

1. I have reviewed this Annual Report on Form 10-K 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: September 28, 2023

/s/ O. James Sterling

O. James Sterling

Chief Financial Officer

EXHIBIT 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

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 certifies that, to the best of his knowledge:

1. The Company's Annual Report on Form 10-K for the fiscal year ended June 30, 2023, to which this Certification is attached as Exhibit 32.1 (the "Report"), fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: September 28, 2023

/s/ James McCullough

Name: James McCullough
Title: Chief Executive Officer
(Principal Executive Officer)

/s/ O. James Sterling

Name: O. James Sterling
Title: Chief Financial Officer
(Principal Financial Officer)

This certification accompanies the Report 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 Exchange Act (whether made before or after the date of the Report), irrespective of any general incorporation language contained in such filing.