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

FORM 20-F

(Mark One)

☐ **REGISTRATION STATEMENT PURSUANT TO SECTION 12(b) OR (g) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

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

For the fiscal year ended June 30, 2020

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 13(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

OR

☐ **SHELL COMPANY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

Date of event requiring this shell company report

Commission File Number 001-39387

RENALYTIX AI PLC
(Exact name of Registrant as specified in its charter and translation of Registrant's name into English)

ENGLAND AND WALES
(Jurisdiction of incorporation or organization)

Avon House 19 Stanwell Road
Penarth, Cardiff CF64 2EZ
United Kingdom
(Address of principal executive offices)

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Chief Executive Officer
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Securities registered or to be 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 Global Market**
Ordinary shares, nominal value £0.0025 per share	*****	**The Nasdaq Global Market***

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

Securities registered or to be registered pursuant to Section 12(g) of the Act. None.

Securities for which there is a reporting obligation pursuant to Section 15(d) of the Act. None.

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary Shares: 59,416,134 outstanding as of June 30, 2020**

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ 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, or an emerging growth company. See definition of "large accelerated filer, "accelerated filer," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☐ Non-accelerated filer ☒ Emerging growth company ☒

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, 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. ☐

† The term "new or revised financial accounting standard" refers to any update issued by the Financial Accounting Standards Board to its Accounting Standards Codification after April 5, 2012.

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. ☐

Indicate by check mark which basis of accounting the registrant has used to prepare the financial statements included in this filing:

U.S. GAAP ☒ International Financial Reporting Standards as issued by the International Accounting Standards Board ☐ Other ☐

If "Other" has been checked in response to the previous question, indicate by check mark which financial statement item the registrant has elected to follow. ☐ Item 17 ☐ Item 18

If this is an annual report, indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes ☒ No

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INTRODUCTION

Unless otherwise indicated, all references in this Annual Report on Form 20-F, or annual report, to the terms “Renalytix,” “Renalytix AI,” “Renalytix AI plc,” “the company,” “we,” “us” and “our” refer to Renalytix AI plc together with its subsidiaries.

This annual report includes trademarks, trade names and service marks, certain of which belong to us and others that are the property of other organizations. Solely for convenience, trademarks, trade names and service marks referred to in this annual report appear without the ®, ™ and SM symbols, but the absence of those symbols is not intended to indicate, in any way, that we will not assert our rights or that the applicable owner will not assert its rights to these trademarks, trade names and service marks to the fullest extent under applicable law. We do not intend our use or display of other parties’ trademarks, trade names or service marks to imply, and such use or display should not be construed to imply, a relationship with, or endorsement or sponsorship of us by, these other parties.

PRESENTATION OF FINANCIAL INFORMATION

Our consolidated financial statements are prepared in accordance with generally accepted accounting principles in the United States, or U.S. GAAP, and we present our financial statements in U.S. dollars. Renalytix AI plc’s and Renalytix AI, Inc.’s functional currency is their local currency. The functional currency of Renalytix Al plc and Verici Dx Limited is the pound sterling which, for purposes of our consolidated financial statements, is translated into the U.S. dollar for assets and liabilities at the exchange rate at the relevant balance sheet dates and revenue and expenses are translated at the weighted-average exchange rates during the relevant reporting period. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to accumulated other comprehensive income (loss), a component of shareholders’ equity.

All references in this annual report to “$” are to U.S. dollars and all references to “£” are to pounds sterling.

We have made rounding adjustments to some of the figures included in this annual report. Accordingly, numerical figures shown as totals in some tables may not be an arithmetic aggregation of the figures that preceded them.

INDUSTRY AND MARKET DATA

This annual report contains estimates, projections and other information concerning our industry, our business and the market for KidneyIntelX. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from our own internal estimates and research as well as from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources. The Boston Healthcare Associates study discussed in this annual report was commissioned by and prepared in collaboration with us. While we believe our internal company research as to such matters is reliable and the market definitions are appropriate, neither such research nor these definitions have been verified by any independent source.

In addition, assumptions and estimates of our and our industry’s future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled “Risk factors.” These and other factors could cause our future performance to differ materially from our assumptions and estimates. See “Special note regarding forward-looking statements.”

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. In some cases, you can identify forward-looking statements by the words “may,” “might,” “will,” “could,” “would,” “should,” “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;
- our plans to obtain and maintain regulatory approvals of KidneyIntelX;
- 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;
- estimates of our expenses, capital requirements and need for additional financing;
- 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 developments relating to our competitors;
- our ability to identify, recruit and retain key personnel;
- our plans and timing with respect to Verici Dx;
- our plans and timing with respect to Kantaro;
- the potential impact of the current COVID-19 pandemic on our business or operations; and
- the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations and capital expenditure requirements.

You should refer to the section of this annual report titled “Risk factors” for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this 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. 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 any stock exchange to which we are subject.

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. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. Selected Financial Data

The following selected consolidated financial data should be read in conjunction with our consolidated financial statements and the related notes which are included elsewhere in this annual report and "Item 5. Operating and Financial Review and Prospects" of this annual report. Our historical results for any prior period are not necessarily indicative of results to be expected for any future period. We prepare our consolidated financial statements in accordance with U.S. GAAP.

(in thousands, except share and per share amounts)	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
Consolidated statements of operation and comprehensive loss:			
Operating expenses:			
Acquired in-process research and development	$ —	$ 35,286	$ —
Research and development	4,565	4,316	193
General and administrative	5,750	2,737	374
Loss from operations	(10,315)	(42,339)	(567)
Equity in losses of affiliate	(63)	—	—
Other income (expense), net	534	38	(5)
Net loss	(9,844)	(42,301)	(572)
Net loss per ordinary share, basic and diluted	$ (0.17)	$ (0.99)	$ (0.03)
Weighted average ordinary shares, basic and diluted	59,079,522	42,561,600	20,000,000

(in thousands)	As of June 30, 2020	2019	2018
Consolidated balance sheet data:			
Cash, cash equivalents and short-term investments	$14,275	$9,195	$ 82
Total assets	20,883	9,700	115
Total liabilities	4,971	1,149	617
Total shareholders' equity	15,912	8,551	(502)

B. Capitalization and Indebtedness

Not applicable.

C. Reasons for the Offer and Use of Proceeds

Not applicable.

D. 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 United States Securities and Exchange Commission, or 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.

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 not yet generated revenue from sales of KidneyIntelX and we cannot guarantee that our commercialization and partnership efforts will result in significant revenue to us. 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 period from March 15, 2018 (inception) through June 30, 2018 and the fiscal years ended June 30, 2019 and 2020 were $0.6 million, $42.3 million and $9.8 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 prepare 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.

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, 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 our ongoing and planned clinical utility studies of KidneyIntelX in preparation for deployment with multiple healthcare provider partners and commercial sales at scale. We have submitted KidneyIntelX for regulatory review with the New York State Department of Health and voluntarily intend to seek Food and Drug Administration, or FDA, marketing authorization through the FDA's de novo classification process, which we refer to as "clearance" from the FDA. We expect to incur significant commercialization expenses related to product manufacturing, marketing, sales and distribution. We have begun to, and expect to 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.

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 expect that our cash, cash equivalents and short-term investments as of June 30, 2020, together with the net proceeds from our global offering in July 2020, will enable us to fund our operating expenses and capital expenditure requirements for at least the next 12 months, and to advance the KidneyIntelX platform through completion of the FDA clearance process. 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, 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;
- the degree to which any of our healthcare system partners order KidneyIntelX;
- the cost of any arrangements under which we may agree to pre-fund the supply of KidneyIntelX tests in anticipation of eventual reimbursement, which reimbursement may not occur at the level we anticipate or at all;
- 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, if any, 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, such as Kantaro, 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.

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 not yet commercially launched our partnership with Mount Sinai or any other healthcare system. 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 build a 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.

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. We are planning to initially market KidneyIntelX as an LDT and are concurrently pursuing marketing authorization from the FDA. Successfully scaling commercial activities with KidneyIntelX as an LDT and pursuing FDA clearance or approval will require us to be successful in a range of challenging activities, including:

- 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;
- expanding our manufacturing of commercial supply for KidneyIntelX;
- 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 gain regulatory clearance or 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.

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.

If we are required to conduct additional clinical studies or trials before expanding or continuing the commercial use of KidneyIntelX as an LDT, those studies or trials could lead to delays or future failure to obtain regulatory clearance or approval, which could cause significant delays in commercializing KidneyIntelX and harm our ability to achieve sustained profitability. 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.

If the FDA decides to require that we obtain clearance or approval to expand or continue commercialization of KidneyIntelX, we may be required to conduct additional clinical testing and analysis before submitting a regulatory notification or application for commercial sales. Clinical trials and studies must be conducted in compliance with FDA regulations or the FDA may take enforcement action or reject the data presented. The data collected from these clinical trials or studies may ultimately be used to support market clearance or approval for KidneyIntelX. It may take substantial time, up to several years, to conduct the requisite studies and trials to obtain clearance or approval from the FDA. Even if our trial and study work is completed as planned, we cannot be certain that their results will support our intended use and performance claims or that the FDA will agree with our conclusions. 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. If we are required to conduct additional clinical trials, whether using prospectively acquired samples or archival samples, delays in the commencement or completion of clinical testing could significantly increase our development costs and delay commercialization. Many of the factors that may cause or lead to a delay in the commencement or completion of future clinical trials and studies may also ultimately lead to delay or denial of regulatory clearance or approval. The commencement of clinical trials and studies may be delayed due to insufficient patient enrollment, which is a function of many factors, including the size of the patient population, the nature of the protocol, the proximity of patients to clinical sites and the eligibility criteria for clinical data generation.

Moreover, the clinical trial and study processes may fail to demonstrate that KidneyIntelX is effective for the proposed indicated use, which could cause us to abandon or delay development.

We may find it necessary to engage contract research organizations, or CROs, to perform data collection and analysis and other aspects of our clinical trials, which might increase the cost and complexity of our trials. We may also depend on clinical investigators, medical institutions and contract research organizations to perform the trials properly. If these parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, or if the quality, completeness or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or for other reasons, our clinical trials may have to be extended, delayed or terminated. It is possible that the COVID-19 pandemic may have an impact on the workforce of the third parties and contract research organizations on which we may rely, which could adversely impact our ability to perform data collection and analysis and other aspects of our clinical trials on expected timeframes or to complete such studies and trials. Many of these factors would be beyond our control. We may not be able to enter into replacement arrangements without undue delays or considerable expenditures. If there are delays in testing or approvals as a result of the failure to perform by third parties, our research and development costs would increase, and we may not be able to obtain regulatory clearance or approval for our current assays and our planned future assays. In addition, we may not be able to establish or maintain relationships with these parties on favorable terms, if at all. Each of these outcomes would harm our ability to market our assays or to achieve sustained profitability.

We are voluntarily seeking FDA clearance of KidneyIntelX. If we do not successfully complete this process and if the FDA were to require approval or clearance of KidneyIntelX, we could incur substantial costs and time delays associated with meeting requirements for premarket clearance or approval or we could experience decreased demand for, or reimbursement of, our products.

We intend to initially provide KidneyIntelX as an LDT under CLIA in our International Organization for Standardization, or ISO, 13485:2016 certified laboratory in Salt Lake City, Utah and through our New York City based laboratory facility. Historically, the FDA has exercised enforcement discretion with respect to most LDTs and has not required laboratories that offer LDTs to comply with the agency's requirements for medical devices (e.g., establishment registration, device listing, quality systems regulations, premarket clearance or premarket approval, and post-market controls). In recent years, however, the FDA has stated it intends to end its policy of enforcement discretion and regulate certain LDTs as medical devices. To this end, on October 3, 2014, the FDA issued two draft guidance documents, entitled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)" and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)", respectively, that set forth a proposed risk-based regulatory framework that would apply varying levels of FDA oversight to LDTs. The FDA has indicated that it does not intend to modify its policy of enforcement discretion until the draft guidance documents are finalized. In January 2017, the FDA announced that it would seek further comment from stakeholders on the oversight of LDTs. On January 13, 2017 the FDA issued a "Discussion Paper on Laboratory Developed Tests (LDTs)," which states that the material in the document does not represent a final version of the LDT draft guidance documents that were published in 2014 or position of the FDA. Similar to the FDA's 2014 draft guidance, the FDA's discussion paper proposes a risk-based framework that would require most LDTs to comply with most of the FDA's regulatory requirements for medical devices. Unlike the draft guidance, however, the discussion paper describes a framework where currently marketed LDTs would generally not be subject to FDA premarket review; instead, FDA would general require only new or modified tests to be approved or cleared by the agency. In the discussion paper, the FDA also states that there is "a growing consensus that additional oversight of LDTs is necessary." The timing of when, if at all, the draft guidance documents will be finalized is unclear, and even then, the new regulatory requirements are proposed to be phased-in. Nevertheless, the FDA may decide to regulate certain LDTs on a case-by-case basis at any time and/or may seek to regulate LDTs in a manner that differs from the phased-in approaches described in the draft guidance and discussion paper.

Legislative proposals have been introduced in Congress or publicly circulated, each of which would implement differing approaches to the regulation of LDTs. We cannot predict whether any of these legislative proposals will be enacted into law or the impact such new legal requirements would have on our business. In the meantime, we maintain our CLIA certification, which permits us to offer LDTs for diagnostic purposes.

FDA review, if required and successfully accomplished, would be expected to have some advantages. Certain health insurance payors have paid higher amounts over LDT prices for FDA approved or cleared tests, recognizing the additional costs of bringing a test through regulatory review. Some payors also accept FDA approval or clearance as a presumptive evidence of an assay's analytic validity and clinical validity, which can reduce the barriers to coverage since the payor can focus its review on clinical utility.

If we do not successfully complete the FDA clearance process for KidneyIntelX, a requirement of premarket review could negatively affect our business until such review is completed and clearance to market or approval is obtained. The FDA could require that we stop selling KidneyIntelX pending clearance or approval. If the FDA allows KidneyIntelX to remain on the market but there is uncertainty about it or if labeling claims the FDA allows us to make are very limited, orders from laboratory supply distributors and physicians, or reimbursement from third-party payors, may decline. The regulatory approval process may involve, among other things, successfully completing additional clinical trials and making a 510(k) submission or filing a premarket approval application or de novo request for classification with the FDA. If the FDA requires premarket review, KidneyIntelX may not be cleared or approved on a timely basis, if at all.

A breakthrough device designation by the FDA for KidneyIntelX may not lead to a faster development, regulatory review or clearance or approval process, and it may not increase the likelihood that KidneyIntelX will receive marketing authorization from the FDA.

In May 2019, we announced that the FDA granted breakthrough device designation for KidneyIntelX as an artificial intelligence-enabled *in vitro* diagnostics for kidney disease. The FDA's breakthrough devices program is a voluntary program for certain medical devices and device-led combination products that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. The goal of the program is to provide patients and health care providers with timely access to these medical devices by speeding up their development, assessment and review, while preserving the statutory standards for premarket approval, 510(k) clearance and de novo marketing authorization, consistent with the FDA's mission to protect and promote public health.

The receipt of a breakthrough device designation for KidneyIntelX may not result in a faster development process, review or approval compared to conventional FDA procedures and does not assure ultimate marketing authorization by the FDA. In addition, even if a product qualifies as a breakthrough device, the FDA may later decide that the product no longer meets the conditions for qualification.

If we obtain marketing authorization for KidneyIntelX, it will be subject to ongoing regulation and could be subject to post-marketing restrictions or withdrawal from the market.

If KidneyIntelX is authorized by the FDA for marketing in the United States, the test will be subject to the FDA's quality system regulation, or 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, assuming we receive FDA marketing clearance for KidneyIntelX, we will continue to expend time, money and effort in all areas of regulatory compliance.

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.

For example, in our half-year report published on March 3, 2020, we announced that our board of directors was considering the spin-off and admission to AIM of FractalDx, a technology portfolio of diagnostic and prognostic products in-licensed by us from Mount Sinai since late 2018. The FractalDx spin-off is being effected through the establishment of a new subsidiary, Verici Dx. Our board of directors has determined that the FractalDx spin-off may provide the opportunity to secure separate financial and management resources for the FractalDx portfolio, with the goal of enabling accelerated development of FractalDx products and achievement of commercial milestones. 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 is necessary to implement the distribution in specie as we currently have negative reserve balances, and will also improve our distributable reserves position. The reduction of capital was confirmed by the High Court in England and Wales on June 9, 2020. Our board of directors declared the distribution of shares in Verici Dx to effect the FractalDx spin-off on July 7, 2020, and the distribution occurred on July 10, 2020. We have based certain of our financial projections and allocation of resources on the assumption that we complete a financing transaction for FractalDx. Until such time as we secure separate financial and management resources for Verici Dx, members of our management team and board of directors will be responsible for the management of Verici Dx, which may result in management distraction from the development and commercialization of our KidneyIntelX platform and other execution challenges. In addition, the entity created to effect the spin-off is newly formed, and there is risk that not all of the relevant assets have been transferred appropriately, and risk that there may be other claims from shareholders or other stakeholders arising out of the spin-off with respect to the terms or structure of the spin-off. Failure to complete a financing transaction for FractalDx as planned and on a timely basis could require us to continue to expend resources on the FractalDx program, which may have a negative effect on our financial position and results of operation.

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. For example, in May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement to form 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 and 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.

For example, in the case of Kantaro, we have committed to lend up to $250,000 to Kantaro and provide services to Kantaro pursuant to an Advisory Agreement. Certain of our employees spend time and resources providing services to Kantaro and Erik Lium, Ph.D., a member of our board of directors, serves as chairman of the board of managers of Kantaro. These individuals are required to allocate time and resources between us and Kantaro. In addition, we may be subject to additional or unexpected claims or liability due to our participation in Kantaro. Moreover, if Kantaro is unsuccessful, we will have dedicated time, money and other resources that we are not able to recoup. Any of these risks could have an adverse effect on our business, financial condition or results of operations.

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.

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,

or 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 until December 2022, and we are currently undergoing a Medicare coverage determination process with results expected in calendar year 2021. Our success is highly dependent on receiving a positive 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 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, or 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. 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. 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. At the federal level, the Trump administration's budget proposal for fiscal year 2021 contains further price control measures that could be enacted during the budget process or in other future legislation sessions. While any proposed measures will require authorization through additional legislation to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs.

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.

Our commercial success depends on our ability to maintain coverage and adequate reimbursement from those payors that decide to cover and reimburse our products. 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 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 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 our products or reduce the reimbursement amounts for our 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. Further, due to the COVID-19 pandemic, millions of individuals have lost or will be losing employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

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 KidneyIntelX, 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 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, or collectively, 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 for our Utah and New York laboratories. 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.

For example, in New York, KidneyIntelX also must be approved by the New York State Department of Health before it is offered in New York. As part of this process, the State of New York requires validation of our tests. New York State requires additional regulatory approvals for laboratories producing clinical results through the oversight of the NYS-CLEP program. These approvals were received in June 2020.

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 Anti-Kickback Statute, or 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;
- the Health Insurance Portability and Accountability Act of 1996, or 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 the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH and their respective implementing regulations, which imposes certain requirements on certain covered healthcare providers, health plans, and healthcare clearinghouses as well as 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. 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 False Claims Act, or 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) and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made to certain non-physician providers such as physician assistants and nurse practitioners;
- federal physician self-referral prohibitions, commonly known as the Stark Law, which prohibits, among other things, physicians who have a financial relationship, including an investment, ownership or compensation relationship with an entity, from referring Medicare patients for designated health services, which include clinical laboratory services, unless an exception applies;
- 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%, or 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 remain judicial and Congressional challenges to certain aspects of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the ACA. Since January 2017, the president of the United States has signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the ACA.

On January 20, 2017, President Trump signed the first Executive Order, directing federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal burden on states or a cost, fee, tax, penalty or regulatory burden on individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. On October 13, 2017, President Trump signed the second Executive Order terminating the cost-sharing subsidies that reimburse insurers under the Affordable Care Act. The current administration has concluded that cost-sharing reduction, or CSR, payments to insurance companies required under the ACA have not received necessary appropriations from Congress and announced that it will discontinue these payments immediately until those appropriations are made. The loss of the CSR payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, the U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay to third-party payors more than $12 billion in ACA risk corridor payments that they argued were owed to them. However, on April 27, 2020, the United States Supreme Court reversed the Federal Circuit decision that previously upheld Congress's denial of $12 billion in risk corridor funding. The effects of

this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. 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 December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA will impact the ACA. Litigation over the ACA is likely to continue, with unpredictable and uncertain results.

In addition, other legislative changes have been proposed and adopted since the ACA was enacted. The Protecting Access to Medicare Act of 2014, or 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. 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 through 2030 unless additional congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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, or 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, or APMs, and the Merit-based Incentive Payment System, or 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 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 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 Foreign Corrupt Practices Act, or 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 changing privacy laws, information security laws, regulations, policies and contractual obligations related to data privacy and security. Our actual or perceived failure to comply with such obligations could harm our reputation, subject us to significant fines and liability, or otherwise adversely affect our business.

We collect, store, process and transmit sensitive data, including legally protected health information, or PHI, personally identifiable information, intellectual property and proprietary business information. As we seek to expand our business, we are, and will increasingly become, subject to numerous state, federal and foreign laws, regulations and standards, as well as contractual obligations, relating to the collection, use, retention, security, disclosure, transfer and other processing of sensitive and personal information in the jurisdictions in which we operate. In many cases, these laws, regulations and standards apply not only to third-party transactions, but also to transfers of information between or among us, our subsidiaries and other parties with which we have commercial relationships. These laws, regulations and standards may be interpreted and applied differently over time and from jurisdiction to jurisdiction, and it is possible that they will be interpreted and applied in ways that will materially and adversely affect our business, financial condition and results of operations. The regulatory framework for data privacy, data security and data transfers worldwide is rapidly evolving, and there has been an

increasing focus on privacy and data protection issues with the potential to affect our business, and as a result, interpretation and implementation standards and enforcement practices are likely to remain uncertain for the foreseeable future. Failure to comply with any of these laws and regulations could result in enforcement actions against us, including fines, imprisonment of company officials and public censure, claims for damages by affected individuals, damage to our reputation and loss of goodwill, any of which could have a material adverse effect on our business.

There are numerous U.S. federal and state laws and regulations related to the privacy and security of health information. These laws and regulations include HIPAA, as amended by HITECH, which establishes a set of national privacy and security standards for the protection of PHI, by health plans, healthcare clearinghouses and certain healthcare providers, referred to as covered entities, and the business associates with whom such covered entities contract for services. HIPAA requires covered entities and business associates to develop and maintain policies and procedures with respect to PHI that is used or disclosed, including the adoption of administrative, physical and technical safeguards to protect such information and ensure the confidentiality, integrity and availability of electronic PHI. HIPAA also implemented the use of standard transaction code sets and standard identifiers that covered entities must use when submitting or receiving certain electronic healthcare transactions, including activities associated with the billing and collection of healthcare claims. The United States Office of Civil Rights may impose penalties on a covered entity for a failure to comply with a requirement of HIPAA. Penalties will vary significantly depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. These penalties include significant civil monetary penalties, criminal penalties and, in certain instances, imprisonment. HIPAA also authorizes state attorneys general to file suit on behalf of their residents. Courts may 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 sue us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. Furthermore, in the event of a breach as defined by HIPAA, the covered entity has specific reporting requirements under HIPAA regulations. In the event of a significant breach, the reporting requirements could include notification to the general public. Enforcement activity can result in reputational harm, and responses to such enforcement activity can consume significant internal resources. Additionally, if we are unable to properly protect the privacy and security of PHI, we could be found to have breached our contracts. Determining whether PHI has been handled in compliance with applicable privacy standards and our contractual obligations can be complex and we cannot be sure how these regulations will be interpreted, enforced or applied to our operations.

In addition, many states in which we operate have laws that protect the privacy and security of sensitive and personal information. Certain state laws may be more stringent or broader in scope, or offer greater individual rights, with respect to sensitive and personal information than federal, international or other state laws, and such laws may differ from each other, which may complicate compliance efforts. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Further, in some cases where we process sensitive and personal information of individuals from numerous states, we may find it necessary to comply with the most stringent state laws applicable to any of the information. For example, the California Consumer Privacy Act of 2018, or the CCPA, which increases privacy rights for California residents and imposes stringent data privacy and security obligations on companies that process their personal information, came into effect on January 1, 2020. Among other things, the CCPA requires covered companies to provide new disclosures to California consumers and provide such consumers new data protection and privacy rights, including the ability to opt-out of certain sales of personal information. The CCPA provides for civil penalties for violations, as well as a private right of action for certain data breaches that result in the loss of personal information. This private right of action may increase the likelihood of, and risks associated with, data breach litigation. The CCPA was amended in September 2018 and November 2019, and it is possible that further amendments will be enacted, but even in its current form it remains unclear how various provisions of the CCPA will be interpreted and enforced. Despite the delay in adopting regulations, the California State Attorney

General will commence enforcement actions against violators beginning July 1, 2020. While any information we maintain in our role as a business associate may be exempt from the CCPA, other records and information we maintain on our customers may be subject to the CCPA. New legislation proposed or enacted in Illinois, Massachusetts, Nevada, New Jersey, New York, Rhode Island, Washington and other states, and a proposed right to privacy amendment to the Vermont Constitution, imposes, or has the potential to impose, additional obligations on companies that collect, store, use, retain, disclose, transfer and otherwise process confidential, sensitive and personal information, and will continue to shape the data privacy environment nationally. State laws are changing rapidly and there is discussion in Congress of a new federal data protection and privacy law to which we would become subject if it is enacted. All of these evolving compliance and operational requirements impose significant costs that are likely to increase over time, may require us to modify our data processing practices and policies, divert resources from other initiatives and projects, and could restrict the way products and services involving data are offered, all of which may have a material and adverse impact on our business, financial condition and results of operations.

Laws, regulations and standards in many foreign jurisdictions apply broadly to the collection, use, retention, security, disclosure, transfer and other processing of personal information, which impose significant compliance obligations. For example, in the EU and the United Kingdom, the processing of personal data, including clinical trial data, is governed by the provisions of the General Data Protection Regulation, or the GDPR. Following the United Kingdom's withdrawal from the EU on January 31, 2020, pursuant to the transitional arrangements agreed between the United Kingdom and EU, the GDPR will continue to have effect in U.K. law, until December 31, 2020, in the same fashion as was the case prior to that withdrawal as if the United Kingdom remained a member state of the EU for such purposes. Following December 31, 2020, it is likely that the data protection obligations of the GDPR will continue to apply to U.K.-based organization's processing of personal data in substantially unvaried form and fashion, for at least the short term thereafter. The GDPR came into effect in May 2018, superseding the European Union Data Protection Directive, and it applies to any company established in the EU as well as those outside the EU if they process personal data in relation to the offering of goods or services to individuals in the EU and/or the monitoring of their behavior. The GDPR imposes more stringent data privacy and security requirements on both processors and controllers of personal data, including health data from clinical trials. In particular, the GDPR imposes several requirements relating to ensuring there is a lawful basis for processing personal data, extends the rights of individuals to whom the personal data relates, materially expands the definition of what is expressly noted to constitute personal data, requires additional disclosures about how personal data is to be used, imposes limitations on retention of personal data, imposes strict rules on the transfer of personal data out of the EEA to third countries, creates mandatory data breach notification requirements in certain circumstances, and establishes onerous new obligations on service providers who process personal data simply on behalf of others. The GDPR authorizes competent authorities to impose penalties and fines for certain violations of up to 4% of an undertaking's total global annual revenue for the preceding financial year or €20 million, whichever is greater. In addition to administrative fines, a wide variety of other potential enforcement powers are available to competent authorities in respect of potential and suspected violations of the GDPR, including extensive audit and inspection rights, and powers to order temporary or permanent bans on all or some processing of personal data carried out by noncompliant actors. European data protection authorities may interpret the GDPR and national laws differently and impose additional requirements, which contributes to the complexity of processing personal data in or from the EEA or United Kingdom. Guidance on implementation and compliance practices is often updated or otherwise revised. Given the breadth and depth of changes in data protection obligations, complying with its requirements has caused us to expend significant resources and such expenditures are likely to continue into the near future as we respond to new interpretations, additional guidance, and potential enforcement actions and patterns. While we have taken steps to comply with the GDPR, and implementing legislation in applicable member states, we cannot assure you that our efforts to achieve and remain in compliance have been, and/or will continue to be, fully successful.

We make public statements about our use and disclosure of personal information through our privacy policy, self-certifications, information provided on our internet platform and press statements. Although we endeavor to comply with our public statements and documentation, we may at times fail to do so or be alleged to have failed

to do so. Moreover, despite our efforts, we may not be successful in achieving compliance if our employees or vendors fail to comply with our published policies, certifications and documentation. The publication of our privacy policy and other statements that provide promises and assurances about data privacy and security can subject us to potential government or legal action if they are found to be deceptive, unfair or misrepresentative of our actual practices. Any failure, real or perceived, by us to comply with our posted privacy policies or with any legal or regulatory requirements, standards, certifications or orders or other privacy or consumer protection-related laws and regulations applicable to us could cause our customers to reduce their use of our products and services and could materially and adversely affect our business, financial condition and results of operations. In many jurisdictions, enforcement actions and consequences for non-compliance can be significant and are rising. In addition, from time to time, concerns may be expressed about whether our products, services or processes compromise the privacy of customers and others. Concerns about our practices with regard to the collection, use, retention, security, disclosure, transfer and other processing of personal information or other privacy-related matters, even if unfounded, could damage our reputation and materially and adversely affect our business, financial condition and results of operations.

Many statutory requirements, both in the United States and abroad, include obligations for companies to notify individuals of security breaches involving certain personal information, which could result from breaches experienced by us or our third-party service providers. For example, laws in all 50 U.S. states and the District of Columbia require businesses to provide notice to consumers whose sensitive personal information has been disclosed as a result of a data breach. These laws are not consistent, and compliance in the event of a widespread data breach is difficult and may be costly. Moreover, states have been frequently amending existing laws, requiring attention to changing regulatory requirements. We also may be contractually required to notify customers or other counterparties of a security breach. Although we may have contractual protections with our third-party service providers, contractors and consultants, any actual or perceived security breach could harm our reputation and brand, expose us to potential liability or require us to expend significant resources on data security and in responding to any such actual or perceived breach. Any contractual protections we may have from our third-party service providers, contractors or consultants may not be sufficient to adequately protect us from any such liabilities and losses, and we may be unable to enforce any such contractual protections.

In addition to the possibility of fines, lawsuits, regulatory investigations, public censure, other claims and penalties, and significant costs for remediation and damage to our reputation, we could be materially and adversely affected if legislation or regulations are expanded in a manner that requires changes in our data processing practices and policies or if governing jurisdictions interpret or implement their legislation or regulations in ways that negatively impact our business. Complying with these various laws could cause us to incur substantial costs or require us to change our business practices and compliance procedures in a manner adverse to our business. Any inability to adequately address data privacy or security-related concerns, even if unfounded, or to comply with applicable laws, regulations, standards and other obligations relating to data privacy and security, could result in additional cost and liability to us, harm our reputation and brand, damage our relationships with customers and have a material and adverse impact on our business.

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 we are unable to timely launch our commercial partnership with Mount Sinai or such 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, subject to execution of a further written clinical utility study agreement. If we do not ultimately enter into any such agreement, conduct the anticipated clinical utility study or receive the potential revenue of up to $6.0 million from the sales of tests to Mount Sinai in connection with such study, our ability to achieve our strategic goals and commercial objectives could be adversely affected. There can be no certainty that we will complete the anticipated 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, partnerships with other healthcare systems, our business would be adversely affected.

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 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, or 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 and Utah. 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 and New York 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 such as the current COVID-19 pandemic, 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 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 health 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.

The current 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. In March 2020, the World Health Organization declared the COVID-19 outbreak a pandemic, and the U.S. government imposed travel restrictions on travel between the United States, Europe and certain other countries. Further, the president of the United States declared the

COVID-19 pandemic a national emergency, invoking powers under the Stafford Act, the legislation that directs federal emergency disaster response. In response to the COVID-19 pandemic, many state, local and foreign governments have put in place quarantines, executive orders, shelter-in-place orders and similar government orders and restrictions in order to control the spread of the disease. We have implemented work-from-home policies for all employees with exceptions being made for essential laboratory personnel. Such orders and policies may negatively impact productivity, disrupt our business and delay our clinical programs and timelines, the magnitude of which will 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 may be affected by the COVID-19 pandemic. For example, our key partner, Mount Sinai, is located in New York and is currently dedicating substantial resources to the fight against this pandemic. Our planned clinical utility study with Mount Sinai is currently delayed. Moreover, when we are able to initiate this study, some patients may not be able to comply with study protocols if quarantines impede patient movement or interrupt healthcare services. Similarly, our ability to recruit and retain patients and principal investigators and site staff who, as healthcare providers, may have heightened exposure to COVID-19, could be adversely impacted.

The spread of COVID-19, which has caused a broad impact globally, may materially affect us economically. While the potential economic impact brought by, and the duration of, COVID-19 may be difficult to assess or predict, a widespread pandemic could result in significant disruption of global financial markets, reducing our ability to access capital, which could in the future negatively affect our liquidity. In addition, a recession or market correction resulting from the spread of COVID-19 could materially affect our business and the value of our ADSs and ordinary shares.

The global pandemic of COVID-19 continues to rapidly evolve. The ultimate impact of the COVID-19 pandemic or a similar health epidemic is highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts on our business, our clinical trials, healthcare systems or the global economy as a whole. However, these effects could have a material impact on our operations, and we will continue to monitor the COVID-19 situation closely.

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.

We depend on our information technology and telecommunications systems, and those of our third-party service providers, contractors and consultants, and any failure of these systems could harm our business.

We depend on our information technology and telecommunications systems and those of our third-party service providers, contractors and consultants for significant elements of our operations, including our KidneyIntelX platform, which is dependent upon Microsoft Azure cloud computing services. We have installed and are expanding a number of enterprise software systems that affect a broad range of business processes and functional areas, including, for example, systems handling human resources, financial controls and reporting, contract management, and other infrastructure operations. These information technology and telecommunications systems support a variety of functions, including laboratory operations, test validation, sample tracking, quality control, customer service support, billing and reimbursement, research and development activities, scientific and medical curation, and general administrative activities.

Despite the implementation of preventative and detective security controls, such information technology and telecommunications systems are vulnerable to damage or interruption from a variety of sources, including telecommunications or network failures or interruptions, system malfunction, natural disasters, malicious human acts, terrorism and war. Such information technology and telecommunication systems, including our servers, are additionally vulnerable to physical or electronic break-ins, security breaches from inadvertent or intentional actions by our employees, third-party service providers, contractors, consultants, business partners, and/or other third parties, or from cyber-attacks by malicious third parties (including the deployment of harmful malware, ransomware, denial-of-service attacks, social engineering, and other means to affect service reliability and threaten the confidentiality, integrity, and availability of information). The risk of a security breach or disruption, particularly through cyber-attacks or cyber intrusion, including by computer hackers, foreign governments, and cyber terrorists, has generally increased as the number, intensity, and sophistication of attempted attacks and intrusions from around the world have increased. We may not be able to anticipate all types of security threats, and we may not be able to implement preventive measures effective against all such security threats. The techniques used by cyber criminals change frequently, may not be recognized until launched, and can originate from a wide variety of sources, including outside groups such as external service providers, organized crime affiliates, terrorist organizations, or hostile foreign governments or agencies.

Failures or significant downtime of our information technology or telecommunications systems, or those used by our third-party service providers, contractors or consultants could prevent us, now or when we commercialize our products, from conducting our *in vitro* diagnostic tests, preparing and providing reports and data to physicians, billing payors, processing reimbursement appeals, handling patient or physician inquiries, conducting research and development activities, and managing the administrative aspects of our business. The costs related to significant security breaches or disruptions could be material and exceed the limits of any cybersecurity insurance we maintain against such risks. If the information technology systems of our third-party service providers and other contractors and consultants become subject to disruptions or security breaches, we may have insufficient recourse against such third parties and we may have to expend significant resources to mitigate the impact of such an event, and to develop and implement protections to prevent future events of this nature from occurring. Any disruption or loss of information technology or telecommunications systems on which critical aspects of our operations depend could have an adverse effect on our business, financial condition and results of operations.

Security breaches, loss of data, and other disruptions of our or our third-party service providers' or contractors' information technology or telecommunications systems could result in a material disruption of our services, compromise sensitive information related to our business or other personal information, prevent us from accessing critical information and expose us to liability, which could adversely affect our business and our reputation.

In the ordinary course of our business, we and our third-party service providers, contractors and consultants, including our third-party billing and collections provider, collect, store and transmit sensitive data, including legally PHI, personally identifiable information, intellectual property and proprietary business information owned or controlled by us or our customers, payors and partners. We manage and maintain our applications and data utilizing a combination of on-site systems, managed data center systems, and cloud-based data center systems. We also communicate, and facilitate the exchange of, sensitive patient data to and between customers and their contracted or affiliated healthcare providers through online customer-facing portals. These applications and related data encompass a wide variety of business-critical information including research and development information, commercial information, and business and financial information.

The secure processing, storage, maintenance, and transmission of sensitive data and confidential information is vital to our operations and business strategy. Although we have implemented security measures and a formal, dedicated enterprise security program to prevent unauthorized access to patient data and other sensitive data and confidential information, applications such as our online customer-facing portals are currently accessible through public web portals and may, in the future, be accessible through dedicated mobile applications, and there is no guarantee we can protect our online portals or our mobile applications from breach. In addition, our information technology and infrastructure, and that of our third-party service providers, contractors and consultants, may be vulnerable to attacks by hackers or malicious software, or as a result of physical break-ins, disruptions or breaches due to malfeasance or other inadvertent or intentional actions by our employees, third-party service providers, contractors, business partners, and/or other third parties. Any security breaches or disruptions of our information technology systems or those of our third-party service providers and other contractors could compromise the security or integrity of our networks or result in the loss, misappropriation, and/or unauthorized access, use, modification or disclosure of, or the prevention of access to, sensitive data or confidential information (including trade secrets or other intellectual property, proprietary business information, and personal information), which could result in financial, legal, business, and reputational harm to us. For example, any such event that leads to unauthorized access, use, or disclosure of personal information, including personal information regarding our customers or employees, could harm our reputation directly, compel us to comply with federal and/or state breach notification laws and foreign law equivalents, subject us to mandatory corrective action, and otherwise subject us to liability under laws and regulations that protect the privacy and security of personal information, which could disrupt our operations and result in significant legal and financial exposure and reputational damages that could potentially have a material adverse effect on our business, financial condition, results of operations and prospects. If we fail to make adequate or timely disclosures to the public or to

law enforcement agencies following any such event, whether due to delayed discovery or a failure to follow existing protocols, that could result in significant fines, penalties, orders, sanctions and proceedings or actions against us by governmental bodies and other regulatory authorities, clients or third parties, which could affect our financial condition, operating results and our reputation, and any such proceeding or action, and any related indemnification obligation, could damage our reputation, force us to incur significant expenses in defense of these proceedings, distract our management, increase our costs of doing business or result in the imposition of financial liability.

Cyber-attacks are increasing in frequency and evolving in nature. We are at risk of attack by a variety of adversaries, including state-sponsored organizations, organized crime, hackers or "hactivists" (activist hackers), through the use of increasingly sophisticated methods of attack, including long-term, persistent attacks referred to as advanced persistent threats. The techniques used to obtain unauthorized access or sabotage systems include, among other things, computer viruses, malicious or destructive code, ransomware, social engineering attacks (including phishing and impersonation), hacking and denial-of-service attacks. For example, we have been subject to phishing incidents and we may experience additional incidents in the future. Our systems are also subject to compromise from internal threats, such as theft or malfeasance by employees, vendors and other third parties with otherwise legitimate access to our systems. Given the unpredictability of the timing, nature and scope of information technology disruptions, and given that these techniques change frequently and are increasingly sophisticated, there can be no assurance that any security procedures and controls that we or our vendors have implemented will be sufficient to prevent cyber-attacks from occurring. Certain measures that could increase the security of our systems, such as data encryption (including data at rest encryption), heightened monitoring and logging, scanning for source code errors or deployment of multi-factor authentication, take significant time and resources to deploy broadly, and such measures may not be deployed in a timely manner or be effective against an attack. As cybersecurity threats continue to evolve, we may be required to expend significant additional resources to continue to modify or enhance our protective measures or to investigate and remediate any information security vulnerabilities. The inability to implement, maintain and upgrade adequate safeguards could have a material adverse effect on our business.

We have numerous vendors and other third parties who receive personal data from us in connection with the services we offer our clients. In addition, we have migrated certain data, and may increasingly migrate data, to a cloud hosted by third-party vendors. Some of these vendors and third parties also have direct access to our systems. Due to applicable laws and regulations or contractual obligations, we may be held responsible for any information security failure or cyber-attack attributed to our vendors that relates to the information we share with them. In addition, because we do not control our vendors and our ability to monitor their data security is limited, we cannot ensure the security measures they take will be sufficient to protect confidential, proprietary, or sensitive data, including personal data. We are at risk of a cyber-attack involving a vendor or other third party, which could result in a breakdown of such third party's data protection processes or the cyber-attackers gaining access to our infrastructure or data through the third party. Regardless of whether an actual or perceived cyber-attack is attributable to us or our vendors, such an incident could, among other things, result in improper disclosure of information, harm our reputation and brand, reduce the demand for our products and services, lead to loss of customer confidence in the effectiveness of our security measures, disrupt normal business operations or result in our systems or products and services being unavailable. In addition, it may require us to spend material resources to investigate or correct the breach and to prevent future security breaches and incidents, expose us to uninsured liability, increase our risk of regulatory scrutiny, expose us to legal liabilities, including litigation, regulatory enforcement, indemnity obligations or damages for contract breach, divert the attention of management from the operation of our business and cause us to incur significant costs, any of which could affect our financial condition, operating results and our reputation. Moreover, there could be public announcements regarding any such incidents and any steps we take to respond to or remediate such incidents, and if securities analysts or investors perceive these announcements to be negative, it could, among other things, have a substantial adverse effect on the price of our ADSs or ordinary shares. In addition, our remediation efforts may not be successful. Any of the foregoing events could have a material adverse effect on our business, financial condition and results of operations.

A security breach may cause us to breach customer contracts. Our agreements with certain customers may require us to use industry-standard or reasonable measures to safeguard sensitive personal information or confidential information. A security breach could lead to claims by our customers, their end-users, or other relevant stakeholders that we have failed to comply with such legal or contractual obligations. As a result, we could be subject to legal action or our customers could end their relationships with us. There can be no assurance that the limitations of liability in our contracts would be enforceable or adequate or would otherwise protect us from liabilities or damages.

In addition, litigation resulting from security breaches may adversely affect our business. Unauthorized access to our platform, systems, networks, or physical facilities could result in litigation with our customers, our customers' end users, or other relevant stakeholders. These proceedings could force us to spend money in defense or settlement, divert management's time and attention, increase our costs of doing business, or adversely affect our reputation. We could be required to fundamentally change our business activities and practices or modify our products and/or platform capabilities in response to such litigation, which could have an adverse effect on our business. If a security breach were to occur, and the confidentiality, integrity or availability of our data or the data of our partners, our customers or our customers' end-users was disrupted, we could incur significant liability, or our platform, systems or networks may be perceived as less desirable, which could negatively affect our business and damage our reputation.

We may not have adequate insurance coverage with respect to security breaches or disruptions. The successful assertion of one or more large claims against us that exceeds our available insurance coverage, or results in changes to our insurance policies (including premium increases or the imposition of large deductible or co-insurance requirements), could have an adverse effect on our business. In addition, we cannot be sure that our existing insurance coverage and coverage for errors and omissions will continue to be available on acceptable terms or that our insurers will not deny coverage as to any future claim.

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, 2020, we had U.S. federal net operating loss carryforwards of approximately $11.8 million and U.S. state and local net operating loss carryforwards of approximately $21.5 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, or 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, or 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 U.K. carryforward tax losses or tax credits to reduce future tax payments, or to 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, 2020, we had cumulative carryforward tax losses of approximately $3.6 million. Subject to any relevant 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 available to carry forward and offset against future operating profits. As a company that carries out extensive research and development activities, we may benefit from the U.K. research and development tax credit regime under the scheme for small and medium-sized enterprises, or SMEs, and also claim a Research and Development Expenditure Credit, or RDEC, to the extent that our projects are grant funded. Under the SME scheme, we are able to surrender some of our trading losses that arise from our qualifying research and development activities for a cash rebate of up to 33.35% of such qualifying research and development expenditures. The net tax benefit of the RDEC is expected to be 9.72%. Qualifying expenditures largely are comprised of employment costs for research staff, consumables, outsourced CRO costs and utilities costs incurred as part of research projects. Specified subcontracted qualifying research expenditures are eligible for a cash rebate of up to 21.67%. We may not be able to continue to claim payable research and development tax credits in the future if we cease to qualify as a small or medium-sized company, based on size criteria concerning employee headcount, turnover and gross assets.

In the event we generate revenues in the future, we may benefit from the U.K. “patent box” regime that allows profits attributable to revenues from patents or patented products to be taxed at an effective rate of 10%. We are the exclusive licensee or owner of one patent and several patent applications which, if issued, would cover our products, and accordingly, future upfront fees, milestone fees, product revenues and royalties could be taxed at this tax rate. When taken in combination with the enhanced relief available on our research and development expenditures, we expect a long-term lower effective rate of corporation tax to apply to us. If, however, there are unexpected adverse changes to the U.K. research and development tax credit regime 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, our business, results of operations, and financial condition may be adversely affected.

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 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 Base Erosion and Profit Shifting, or 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. 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, 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 liabilities. For example, Her Majesty's Revenue & Customs 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, 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, or 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, or PTAB, of the USPTO, such as post grant review, or 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, or 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 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;
- an inability to obtain additional financing;
- 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;
- 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 success or failure of Kantaro, our joint venture with Mount Sinai;
- 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, including the global and regional impacts of the COVID-19 pandemic;
- 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.

A substantial number of our total outstanding shares are restricted from immediate resale, but may be sold into the market in the near future. This 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 following the global offering, the market price of our ADSs and ordinary shares could decline significantly.

We had 59,416,134 ordinary shares outstanding as of June 30, 2020 and sold an additional 12,613,500 ordinary shares, including ordinary shares represented by ADSs, in our global offering in July 2020. As of October 14, 2020, after the expiration of lock-up agreements entered into by our directors, executive officers and certain of our shareholders in connection with the global offering, all of these ordinary shares (including ordinary shares represented by ADSs) will be available for sale in the public market. Sales of a substantial number of such ADSs or ordinary shares upon expiration of the lock-up agreements 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, the lock-up agreements described above and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

Additionally, the holders of an aggregate of approximately 15% of our ordinary shares, or their transferees, have rights, subject to some conditions, to require us to file one or more registration statements covering their shares or to include their shares in registration statements that we may file for ourselves or other shareholders. If we were to register the resale of these shares, they could be freely sold in the public market. If these additional shares 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 that we did not incur prior to our global offering, 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 $1.07 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, or Section 404;
- not being required to comply with any requirement that has or may be adopted by the Public Company Accounting Oversight Board, or 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 June 30 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, 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 recent global offering 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, cash equivalents and short-term investments, including the net proceeds from the global offering, 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, cash equivalents and short-term investments, including the net proceeds from the global offering, 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, or 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.

Upon completion of our global offering in July 2020, members of 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 28.4% of our outstanding ordinary shares, based on the number of ordinary shares outstanding as of June 30, 2020. 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. Investors seeking cash dividends should not purchase our ADSs or ordinary shares in the global offering.

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, or PFIC, 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, or 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 (as defined below in Item 10.E, “Taxation—Material U.S. federal income tax considerations for U.S. Holders”) 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.

Based on our current estimates of the composition of our income and valuation of our assets, including goodwill, we believe that we may be treated as a PFIC for our taxable year ended June 30, 2020. In addition, the FractalDx spin-off may cause us to incur additional passive income (based in part on the fair market value of the Verici Dx shares distributed to our shareholders) which could make it more likely that we are treated as a PFIC. However, no assurances regarding our PFIC status can be provided for any past, current or future taxable years. 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, including the global offering. We cannot provide any assurances 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. For further discussion of the PFIC rules and the adverse U.S. federal income tax consequences in the event we are classified as a PFIC, see Item 10.E, “Taxation—Material U.S. federal income tax considerations for U.S. Holders” in this annual report.

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.

We have identified material weaknesses in the design of our internal control over financial reporting. If we are unable to remediate these material weaknesses, or if we experience additional material weaknesses in the future or otherwise fail to maintain an effective system of internal controls, we may not be able to accurately or timely report our financial condition or results of operations, which may adversely affect investor confidence in us and, as a result, the value of our ADSs and ordinary shares.

In connection with the preparation of our consolidated financial statements for the years ended June 30, 2020, 2019, and the period from March 15, 2018 (inception) through June 30, 2018, we concluded that there were material weaknesses in the design of our internal control over financial reporting. 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 segregation of duties as well as our lack of formal processes and procedures and our lack of maintaining a sufficient complement of personnel commensurate with our accounting and reporting requirements. Currently, we have only two designated finance and accounting employees and rely primarily on consultants to provide many accounting, bookkeeping and administrative services. As of June 30, 2020, these material weaknesses remained unremediated. To address these material weaknesses, we will need to add personnel as well as implement new financial processes. We intend to take steps to remediate the material weaknesses described above through hiring additional qualified accounting and financial reporting personnel, and further evolving our accounting processes and policies. We will not be able to fully remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time.

Risks related to investing in a foreign private issuer or U.K. company

We qualify as a foreign private issuer and, as a result, we are not subject to U.S. proxy rules and are subject to Exchange Act reporting obligations that, to some extent, are more lenient and less frequent than those of a U.S. domestic public company.

As a foreign private issuer under the Exchange Act, we are exempt from certain provisions of the Exchange Act that are applicable to U.S. domestic public companies, including (i) the sections of the Exchange Act regulating the solicitation of proxies, consents or authorizations in respect of a security registered under the Exchange Act; (ii) the sections of the Exchange Act requiring insiders to file public reports of their share ownership and trading activities and liability for insiders who profit from trades made in a short period of time; and (iii) the rules under the Exchange Act requiring the filing with the SEC of quarterly reports on Form 10-Q containing unaudited financial and other specified information, or current reports on Form 8-K upon the occurrence of specified significant events. In addition, foreign private issuers are not required to file their annual report on Form 20-F until 120 days after the end of each fiscal year, while U.S. domestic issuers that are accelerated filers are required to file their annual report on Form 10-K within 75 days after the end of each fiscal year. Foreign private issuers also are exempt from Regulation Fair Disclosure, aimed at preventing issuers from making selective disclosures of material information. As a result of the above, you may not have the same protections afforded to shareholders of companies that are not foreign private issuers.

As a foreign private issuer, we are permitted to adopt certain home country practices in relation to corporate governance matters that differ significantly from Nasdaq corporate governance listing standards. These practices may afford less protection to shareholders than they would enjoy if we complied fully with Nasdaq corporate governance listing standards.

As a foreign private issuer listed on the Nasdaq Global Market, we are subject to corporate governance listing standards. However, Nasdaq rules permit a foreign private issuer like us to follow the corporate governance practices of its home country in lieu of certain Nasdaq corporate governance listing standards. Certain corporate governance practices in the United Kingdom, which is our home country, may differ significantly from Nasdaq corporate governance listing standards. For example, neither the corporate laws of the United Kingdom nor our articles of association require a majority of our directors to be independent; we can and intend to include non-independent directors as members of our nominations and remuneration committees; and our independent directors would not necessarily hold regularly scheduled meetings at which only independent directors are present. We are required to follow the AIM Rules for Companies published by London Stock Exchange plc, and have adopted the Corporate Governance Code published by the Quoted Companies Alliance. Therefore, our shareholders may be afforded less protection than they otherwise would have under Nasdaq corporate governance listing standards applicable to U.S. domestic issuers.

We may lose our foreign private issuer status, which would then require us to comply with the Exchange Act's domestic reporting regime and cause us to incur significant legal, accounting and other expenses.

As a foreign private issuer, we are not required to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers. We may no longer be a foreign private issuer as of December 31, 2020, which would require us to comply with all of the periodic disclosure and current reporting requirements of the Exchange Act applicable to U.S. domestic issuers as of July 1, 2021. In order to maintain our current status as a foreign private issuer, either (1) a majority of our voting securities must be either directly or indirectly owned of record by non-residents of the United States or (2)(a) a majority of our executive officers or directors cannot be U.S. citizens or residents, (b) more than 50% of our assets must be located outside the United States and (c) our business must be administered principally outside the United States.

If we lose our status as a foreign private issuer, we would be required to comply with the Exchange Act reporting and other requirements applicable to U.S. domestic issuers, which are more detailed and extensive than the requirements for foreign private issuers. We may also be required to make changes in our corporate governance

practices in accordance with various SEC and Nasdaq rules. The regulatory and compliance costs to us under U.S. securities laws if we are required to comply with the reporting requirements applicable to a U.S. domestic issuer may be significantly higher than the cost we would incur as a foreign private issuer. As a result, we expect that a loss of foreign private issuer status would increase our legal and financial compliance costs and would make some activities highly time consuming and costly. We also expect that if we were required to comply with the rules and regulations applicable to U.S. domestic issuers, it would make it more difficult and expensive for us to obtain director and officer liability insurance, and we may be required to accept reduced coverage or incur substantially higher costs to obtain coverage. These rules and regulations could also make it more difficult for us to attract and retain qualified members of our board of directors.

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, or 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. See Item 10.B – "Memorandum and Articles of Association —Differences in corporate law" for a description of the principal differences between the provisions of the Companies Act applicable to us and, for example, the Delaware General Corporation Law relating to shareholders' rights and protections.

Protections found in provisions under the U.K. City Code on Takeovers and Mergers, or the Takeover Code, 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, or 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. See Item 10.B – "Memorandum and Articles of Association" in this annual report for a description of various persons who are currently considered to be acting in concert with respect of our company.
- 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 £14,854.03 (plus an additional aggregate nominal amount of £5,739.24 to be used only in respect of the exercise of outstanding share options and other potential shares granted by us) from September 30, 2019 (being the date of our 2019 annual general meeting) until the conclusion of our 2020 annual general meeting, which authorization will need to be renewed or replaced upon expiration.

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 £14,854.03 (plus the allotment of shares on the exercise of share options granted by us) from September 30, 2019 (being the date of our 2019 annual general meeting) until the conclusion of our 2020 annual general meeting, 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. See Item 10.B – “Memorandum and Articles of Association.”

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.

Legal, political and economic uncertainty surrounding the exit of the United Kingdom from the EU may be a source of instability in international markets, create significant currency fluctuations, adversely affect our operations in the United Kingdom and pose additional risks to our business, revenue, financial condition, and results of operations.

Following the result of a referendum in 2016, the United Kingdom left the EU on January 31, 2020, commonly referred to as Brexit. Pursuant to the formal withdrawal arrangements agreed between the United Kingdom and the EU, the United Kingdom will be subject to a transition period until December 31, 2020, or the Transition Period, during which the United Kingdom will remain within the EU single market and customs union and EU rules will continue to apply in the United Kingdom. Negotiations between the United Kingdom and the EU are expected to continue in relation to the customs and trading relationship between the United Kingdom and the EU following the expiry of the Transition Period.

The lack of clarity on future United Kingdom laws and regulations (including financial laws and regulations, tax and free trade agreements, intellectual property rights, data protection laws, supply chain logistics, environmental, health and safety laws and regulations, immigration laws and employment laws) may negatively impact foreign direct investment in the United Kingdom, increase costs, depress economic activity and restrict access to capital.

The uncertainty concerning the United Kingdom's legal, political and economic relationship with the EU after the Transition Period may be a source of instability in the international markets, create significant currency fluctuations, and/or otherwise adversely affect trading agreements or similar cross-border co-operation arrangements (whether economic, tax, fiscal, legal, regulatory or otherwise).

These developments, or the perception that any of them could occur, have had, and may continue to have, a significant adverse effect on global economic conditions and the stability of global financial markets, and could significantly reduce global market liquidity and limit the ability of key market participants to operate in certain financial markets. In particular, it could also lead to a period of considerable uncertainty in relation to the U.K. financial and banking markets, as well as on the regulatory process in Europe. Asset valuations, currency exchange rates and credit ratings may also be subject to increased market volatility.

If the United Kingdom and the EU are unable to negotiate acceptable trading and customs terms or if other EU member states pursue withdrawal, barrier-free access between the United Kingdom and other EU member states or among the European Economic Area overall could be diminished or eliminated. The long-term effects of Brexit will depend on any agreements (or lack thereof) between the United Kingdom and the EU and, in particular, any arrangements for the United Kingdom to retain access to EU markets after the Transition Period.

Such a withdrawal from the EU is unprecedented, and it is unclear how the United Kingdom's access to the European single market for goods, capital, services and labor within the EU, or single market, and the wider commercial, legal and regulatory environment, will impact our U.K. operations and customers.

There may continue to be economic uncertainty surrounding the consequences of Brexit, following the Transition Period, which could adversely impact customer confidence resulting in customers reducing their spending

budgets on our products, which could adversely affect our business, revenue, financial condition, results of operations and could adversely affect the market price of our ADSs and ordinary shares.

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 Brexit, we expected to be able to benefit from the harmonization of certain regulatory requirements within the EU, which may no longer apply as a result of the United Kingdom leaving the EU. As a result, any future efforts to market our products in both the United Kingdom and the EU may require us to complete separate regulatory processes, which will increase the time and cost associated with addressing those markets. This will depend on the availability of transitional and future arrangements 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 4. Information on the Company

A. History and Development of the Company

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 Avon House, 19 Stanwell Road, Penarth, Cardiff, CF64 2EZ, 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, is our wholly owned subsidiary.

In 2019, we established a second laboratory in Salt Lake City, Utah. 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. This site will be used in addition to our laboratory in New York City, New York which was established for research, development and clinical testing. In 2020, 2019 and 2018 we spent $0.9 million, $0.3 million and $0.0 million respectively on Property, Plant & Equipment related to our sites. Additionally, in 2020 we spent $0.6 million in software and development costs related to software designed for use in our labs.

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.renalytixai.com. 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.

B. Business Overview

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

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The National Kidney Foundation, or 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 and kidney transplant. In 2016, more than 726,000 patients had end-stage kidney disease, or ESKD, with more than 500,000 requiring dialysis at least three times a week. More than 100,000 patients begin dialysis each year to treat ESKD. Once on dialysis, patients typically experience a five-year mortality rate of up to 65%, about the equivalent rate for brain cancer. Further, transplants are expensive and uncertain. As of July 2019, nearly 100,000 Americans were on the waiting list to receive a kidney transplant and 13 patients die in the United States while waiting for a kidney transplant every day.

Moreover, the kidney disease crisis is continuing to grow along with the increased prevalence of contributing risk factors. One of the most significant risk factors for developing CKD is diabetes. It is estimated that there are approximately over 12.6 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 tied to specific guideline-driven clinical recommendations. The ability to predict which patients will experience progressive kidney function decline, which includes rapid kidney function decline, or RKFD, sustained significant decline in kidney function, kidney failure, initiation of long-term dialysis or kidney transplant, is critical to changing patient outcomes and health economics. Current 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 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 our clinical validation studies in patients with DKD, we observed that the Kidney Disease: Improving Global Outcomes, or KDIGO, classification system, which is the standard clinical assessment to predict risk for progression of CKD, including DKD, only identified approximately 20% of patients that experienced an adverse kidney outcome as very high-risk patients with the recommendation of referral to a nephrologist, while KidneyIntelX identified nearly half of such patients. Lack of ability to accurately predict which patients are at higher risk 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.

We believe that the KidneyIntelX platform will be central to managing CKD, helping to identify which patients could benefit from clinical interventions at earlier stages of CKD before significant and irreversible kidney damage has taken place. For patients with CKD as a result of diabetes, obesity or other factors, early intervention can lower the risk of progressing to life-altering advanced disease, kidney failure, dialysis and diminished quality of life. For primary care physicians and specialists, KidneyIntelX provides an easy-to-understand, reportable patient risk score integrated with specific guideline-driven clinical recommendations designed to maximize patient treatment and compliance outcomes. For insurance payors, KidneyIntelX can help drive health economics gains over time. For population health and clinical medicine departments, KidneyIntelX provides a powerful prognostic tool to stratify CKD populations into low-, intermediate- and high-risk categories applied to a continuous scale, enabling physicians to optimize the choice of treatment and allocation of clinical resources to benefit patient outcomes and health economics. In our clinical validation studies to date, involving stored specimens from over 1,500 patients with DKD, KidneyIntelX demonstrated the ability to more accurately identify which patients would experience progressive kidney function decline over current clinical practice. We believe early risk stratification, using advanced technology implemented in partnership with healthcare systems and insurance payors, can help support a fundamental shift towards optimal treatment for the over 850 million people suffering from kidney disease worldwide.

We believe that the utilization of KidneyIntelX across large patient populations will have a significant impact on overall healthcare costs. Health economic benefits are projected to be derived from three key areas of benefit: (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 clinically validated, *in vitro* diagnostic test, KidneyIntelX is able to help predict which patients will experience progressive kidney function decline within a five-year timeframe, equipping physicians with the information they need to properly assess risk and stratify patients, more efficiently allocate treatments and clinical resources for high-risk patients, and intensify or pivot treatment over time as a patient's risk evolves. We have partnered with Boston Healthcare Associates, or BHA, to develop a health economic model analyzing the cost and care pathway for patients with DKD at all stages of the disease and the potential cost savings of implementing and utilizing KidneyIntelX. According to the BHA study, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in under 24 months and deliver a cost savings of up to $1.3 billion over five years per 100,000 patients with DKD.

Several federal policy and economic events, including the U.S. Presidential Executive Order on Advancing American Kidney Health issued in July 2019 and recent changes in U.S. reimbursement law, are helping disrupt the kidney disease clinical and commercial environment and highlighting the pressing need for solutions such as KidneyIntelX. We believe this shift will benefit us as we continue to expand our insurance payor coverage, pursue clearance from the FDA for KidneyIntelX, and seek to leverage partnerships with healthcare systems and relevant payors to drive commercial adoption. We have already achieved a number of reimbursement and regulatory milestones critical to these goals, including:

- receiving a CPT code for KidneyIntelX, which can be used to report the use of KidneyIntelX to private and public payors throughout the United States for reimbursement;

- the Centers for Medicare & Medicaid Services, or CMS, including KidneyIntelX on the Final 2020 Clinical Laboratory Fee Schedule, or CLFS, and setting the national price for KidneyIntelX at $950 per reportable test;
- Capital District Physicians' Health Plan, Inc., a physician-led health insurance payor, issuing a positive coverage determination for KidneyIntelX for certain patients with DKD;
- Noridian Healthcare Solutions, the regional Medicare Administrative Contractor with responsibility for overseeing facilities and providers located in the western United States, approving our application for a Medicare Provider Transaction Access Number, or PTAN, which qualifies us as a provider and allows us to bill for services provided to patients with Medicare and Medicaid health insurance coverage in the United States;
- becoming a provider in the America's Choice Provider Network, a preferred provider network in the United States;
- the FDA granting breakthrough device designation for KidneyIntelX;
- receiving a Clinical Laboratory Improvement Amendments , or CLIA, Certificate of Registration for our newly established commercial laboratory operation in Salt Lake City, Utah, which we believe will support scale-up test volumes, optimize processing costs and accelerate payor coverage determinations; and
- receiving a clinical laboratory permits from the states of New York, California and Pennsylvania to provide commercial testing of KidneyIntelX. With licensed CLIA commercial laboratories in Utah and New York, we can now provide KidneyIntelX testing services in 49 states (Maryland application pending); and
- submitting our final package to FDA seeking clearance of KidneyIntelX.

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 are focused on building integrated partnerships with healthcare systems and the engagement and support of their clinical leadership teams, which will allow us to efficiently initiate and deploy our solution. Integration of the KidneyIntelX software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting. 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.

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, or ISO, quality management systems, population health, clinical medicine 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 from Mount Sinai Health System, the Harvard Medical School, the Harvard School of Public Health, Johns Hopkins Medicine, University of Chicago, University of Washington, Wake Forest University and the NKF.

Recent developments

Commercial launch of KidneyIntelX at Mount Sinai

In September 2020, we announced the commercial launch of the KidneyIntelX clinical test reporting platform within the Mount Sinai Health System (Mount Sinai) in New York City. KidneyIntelX risk assessment of

progressive decline in kidney function or kidney failure, including education support for treating clinicians, is now commercially available for patients with early stage DKD. In addition to patient testing and risk assessment, a central component of this launch milestone was the physician education and support program developed in close collaboration with leadership of the Mount Sinai Departments of Medicine and Population Health Science and Policy, with input from patient advocacy groups and the broader clinical community. This expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website, www.kidneyintelx.com. We believe this education and support program will be an important resource to help improve care for early stage DKD patients at Mount Sinai and support future deployments of KidneyIntelX.

Agreements with Laboratory Corporation of America and a national medical logistics provider were established to support sample collection at five patient service centers servicing Mount Sinai patients. We intend to scale this process with laboratory service providers and logistics providers across multiple territories in the United States to ensure patient blood samples can be efficiently and securely delivered to RenalytixAI laboratories in New York, New York and Salt Lake City, Utah.

Submission to FDA seeking clearance of KidneyIntelX

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

COVID-19 studies

The current COVID-19 pandemic has had a devastating impact around the world. Many reports indicate that acute kidney injury occurs in approximately 20% to 40% of patients hospitalized with COVID-19, is often severe (including need for acute dialysis), and data from Mount Sinai during the initial U.S. surge indicated that 70% of patients that develop acute kidney injury in the setting of COVID-19 either die in the hospital or do not recover kidney function by discharge. Given the ongoing pandemic, we have announced plans to study the KidneyIntelX platform in patients with COVID-19. We plan to investigate the use of KidneyIntelX for patients with COVID-19 in two clinical studies. The first study, entitled “Pred-MAKER” (Prediction of Major Adverse Kidney Events and Recovery) involves acutely ill patients with COVID-19 admitted to Mount Sinai. The goal of the study is to improve the understanding of mechanisms of COVID-19-associated kidney disease, and to leverage the KidneyIntelX platform to deploy machine learning-based prediction models that utilize clinical data along with plasma and urine biomarkers to risk stratify COVID-19 patients for major adverse kidney events, including need for acute dialysis and recovery of kidney function after discharge. The second study, “MASKeD-COVID” (Multi-center Assessment of Survivors for Kidney Disease after COVID-19) involves multiple major academic institutions, including Mount Sinai, University of Michigan, Johns Hopkins, Yale University and Rutgers University. The goal of this study is to understand the long-term kidney epidemiology of CKD in survivors of COVID-19 and validate KidneyIntelX for prediction of long-term kidney outcomes post-COVID hospitalization that will inform further prevention, treatment and clinical care.

Pharmaceutical partnerships

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

We expect to release more details on the initial pharmaceutical partnership in conjunction with public dissemination of the top line data from the primary analyses that are currently ongoing.

FractalDx spin-off

We held exclusive license to FractalDx, a technology portfolio of diagnostic and prognostic products in-licensed from Mount Sinai since late-2018. The FractalDx technology is based principally on sequencing biomarkers from a patient's blood using widely available instrument platforms. We have been developing two products from the portfolio: a prognostic test performed prior to kidney transplant to predict which transplant recipients are most at risk of acute rejection and a diagnostic test for evidence of rejection of the transplanted kidney in advance of any clinical symptoms.

On March 3, 2020, we announced that our board of directors was considering options for the spin-off of FractalDx to provide the opportunity to secure separate financial and management resources for the FractalDx portfolio, with the goal of enabling accelerated development of FractalDx products and achievement of commercial milestones.

We have implemented the FractalDx spin-off in advance of a proposed admission to AIM of our newly established subsidiary, Verici Dx Limited. In May 2020, we transferred the in-licensed FractalDx technology and associated assets to Verici Dx. The reduction of share capital necessary to implement the FractalDx spin-off was approved by our shareholders at a general meeting held on May 15, 2020 and confirmed by the High Court in England and Wales on June 9, 2020. Our board of directors declared the distribution of shares to effect the FractalDx spin-off on July 7, 2020, and the distribution occurred on July 10, 2020. Prior to completion of a possible admission to AIM or an equivalent financing transaction, Renalytix will continue to finance Verici Dx under a convertible note instrument executed in May 2020. As a result of our level of control, we anticipate Verici Dx will continue to be included in our consolidated financial statements and notes thereto.

We announced on July 8, 2020 that the share capital of Verici Dx had been re-designated into 59,416,134 A Shares of £0.001 each and one golden share of £0.001 (the "Golden Share") and that Renalytix would retain the Golden Share and its associated controlling voting rights. Subsequent to that announcement, we entered into a declaration of trust whereby Renalytix AI plc has declared that it holds the Golden Share as nominee and on trust for Fergus Fleming, Erik Lium, James McCullough, Christopher Mills, Barbara Murphy and Chirag Parikh, the Directors of RenalytixAI, and accordingly the Company itself has no ongoing beneficial interest in Verici Dx shares. This change has been made so as to comply with EIS/VCT eligibility for Verici.

Joint venture with Mount Sinai for production of COVID-19 antibody tests

In May 2020, we and Mount Sinai entered into an operating agreement, or the Kantaro Operating Agreement, in order to form a joint venture, Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing test kits for laboratories for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into an advisory services agreement, or the Advisory Agreement, pursuant to which we have agreed to provide certain advisory services to Kantaro. Kantaro has partnered with Bio-Techne Corporation to develop the new kit with the goal of commercially launching the clinical kit in the coming months, subject to regulatory approval. The tests are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. In August, Kantaro launched the research use only (RUO) version of the test, and the company has submitted to the FDA for emergency use authorization of the clinical kit. See "—Our key agreements—Kantaro Biosciences LLC" for additional information.

University of Michigan research collaboration

In June 2020, we entered into a research agreement, or the UM Agreement, with the Regents of the University of Michigan, or the University of Michigan, pursuant to which we will work collaboratively with the University of Michigan to perform certain research projects to examine the feasibility of incorporating the biomarker urinary Epithelial Growth Factor, or uEGF, into the KidneyIntelX platform using samples from the George M. O'Brien Michigan Kidney Translational Core Center's Clinical Phenotyping Resource and Biobank Core, a large repository of longitudinally followed CKD patients with matched urine and plasma samples coupled with extensive medical records. This research program is designed to help us explore the potential role of uEGF in predicting progressive kidney function decline in patients with DKD and possible extended applications of the KidneyIntelX platform to patients with non-diabetic CKD or at risk of developing CKD. Under the UM Agreement, we were granted an option to license any patents filed by the University of Michigan covering certain intellectual property owned by the University of Michigan or developed jointly by us and the University of Michigan.

Nasdaq dual listing

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

Proposed Medicare coverage rule that could benefit the Company if adopted

In October 2019, President Trump issued an executive order ("Executive Order on Protecting and Improving Medicare for Our Nation's Senior") directing the Secretary of the U.S. Department of Health and Human Services ("HHS") to issue regulations to streamline the approval, coverage, and coding process for certain innovative products, including breakthrough medical devices. As such, in August 2020, the U.S. Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS, submitted for public comment a rule ("Medicare Coverage of Innovative Technology") which, if finalized, would provide an automatic National Medicare Coverage Determination for diagnostic devices that have received Breakthrough Device designation upon the effective date of the promotional approval by the FDA. The automatic coverage period shall continue for a period of four years, during which manufacturers of breakthrough devices may develop additional evidence regarding the applicability of their products to the Medicare population, so they might continue Medicare coverage beyond the initial four years. As we already have a designated Medicare reimbursement code and pricing in effect and were awarded Breakthrough Device designation in May of 2019, we believe that this new proposed CMS rule making, if adopted in its current form, could have a material positive impact on addressable market population with insurance coverage for KidneyIntelX if we obtain FDA clearance for KidneyIntelX. We

estimate that the number of DKD patients covered under Medicare exceeds 12 million. However, as a proposed regulation, additional authorization of the Medicare Coverage and Innovative Technology rule is required to become effective. Additionally, we cannot assure you as to the ultimate content, timing, or effect of this proposed rule, if finalized, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could have on the future sales of our products.

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. To achieve this goal, we plan to:

- ***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 software platform with healthcare systems' EHR systems and clinical workflow. In September 2020, we announced the commercial launch of our partnership with Mount Sinai Health System, including initiation of patient testing. Integrated partnerships such as this are designed to allow KidneyIntelX 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 believe that the potential of KidneyIntelX to improve patient outcomes and promote benefits in health economics for patients, physicians and payors provides a strong foundation for our reimbursement strategy. Moreover, early and ongoing engagement with insurance payors will be key to supporting the deployment of KidneyIntelX. 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.
- ***Continue to Pursue Medicare Coverage.*** Following the receipt of national Medicare pricing at $950 per reportable test for KidneyIntelX in January 2020, we are actively pursuing Medicare coverage determination under the Molecular Diagnostics Services, or MolDX, Program, which would expand our Medicare coverage and expedite the claims payment process. 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. We estimate that Medicare currently provides insurance coverage for approximately 14 million patients with CKD. We currently anticipate a coverage determination decision under MolDX in calendar year 2021.
- ***Obtain FDA Clearance of KidneyIntelX to Further Drive Commercial Adoption in the United States.*** While not required for commercialization as an LDT, we are seeking marketing authorization from the FDA through the de novo classification process, which we refer to as "clearance" from the FDA, as part of our strategy to produce a product capable of becoming the new, long-term standard of care for patients with CKD. We have designed KidneyIntelX under a quality-controlled product development process to support our FDA clearance application, and to take advantage of the dynamic capability of machine learning applied to large datasets through regulated, versioned product releases. KidneyIntelX was granted breakthrough device designation from the FDA in May 2019. In addition, we believe that preparing for and potentially obtaining FDA clearance could support our efforts to obtain regulatory

approvals of KidneyIntelX in the United Kingdom, European Union, China and other major global market territories, provide support for the adoption of KidneyIntelX across clinical disciplines and assist with the establishment of private third-party and government-based reimbursement.

- ***Build Substantial Repository of Kidney Disease-Related Data.*** We intend to build 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, 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. We have tested this capability in our clinical validation studies involving stored specimens from over 1,500 patients with DKD from the Mount Sinai Health System and University of Pennsylvania Health System biobanks. As we continue to build our data repository, we believe our predictive capabilities will continue to improve, and we expect that we will have the most comprehensive kidney disease data repository geared toward early identification of high-risk patients and optimization of care pathways.
- ***Launch in Major International Markets.*** We plan to pursue the launch of KidneyIntelX in major medical markets outside of the United States, including in the United Kingdom, European Union and China, which have large and growing populations of CKD patients and are facing cost and clinical management challenges similar to the United States. According to a recent report published by NHS Kidney Care, in the United Kingdom, treatment for CKD costs more than breast, lung, colon and skin cancer combined. We plan to pursue foreign regulatory approval pathways, continue data accumulation and study development with ex-U.S. clinical investigators and seek integrated medical center opportunities for addressing CKD patient populations outside of the United States, subject to obtaining the required marketing authorizations.
- ***Expand Our Product Portfolio.*** We believe there are significant opportunities to expand our technology platform through incremental version releases of KidneyIntelX as well as through extending KidneyIntelX application into additional populations of CKD patients beyond those with diabetes, including patients of African ancestry with the *APOL1* high-risk genotype. We also intend to develop solutions for use in other large chronic disease patient populations, like cardiovascular disease. KidneyIntelX has been designed within a regulated, manufacturing-quality environment 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 and quality management systems, will enable our KidneyIntelX platform to rapidly generate exponential data growth and new clinical use cases, with a clearer path to achieving the regulated and reimbursed introduction and subsequent product improvements of an artificial intelligence-powered *in vitro* diagnostic.

Ultimately, we believe KidneyIntelX will be a powerful prognostic tool that can help 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 are building a body of 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 recommendation designed to maximize patient treatment and compliance, can have a measurable positive impact on patient quality of life. 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 developing a detailed understanding of the clinical practice environment, we believe KidneyIntelX will help ease suffering and improve outcomes for patients living with CKD.

Our competitive strengths

The KidneyIntelX platform has the following key strengths:

- ***Novel, Artificial Intelligence-enabled Platform to Identify Kidney Disease Risk***. KidneyIntelX is the first artificial intelligence-enabled *in vitro* diagnostic 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 37 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 over 12.6 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***. KidneyIntelX has received national Medicare pricing and its first private insurance payor positive coverage determination. We believe these positive outcome are the result of several factors: (1) our rigorous approach to a product development and 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***. We have designed KidneyIntelX 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 clinically validated, *in vitro* diagnostic test, KidneyIntelX is able to help predict which patients will experience progressive kidney function decline within a five-year timeframe, equipping physicians with the information they need to properly risk stratify patients, more efficiently allocate treatments and allocate treatments and clinical resources for high-risk patients, and intensify or pivot treatment over time as a patient's risk evolves. According to a study conducted by BHA, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in under 24 months and deliver a cost savings of up to $1.3 billion over five years per 100,000 patients with DKD.
- ***Partnered Business Model at Population Health Level***. 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. KidneyIntelX has had the support of clinical leadership, with the primary focus of quickly and efficiently deploying an effective prognostic solution to their DKD patients. As a result, we believe KidneyIntelX will be able to reach and potentially benefit significant patient populations without employing a large, traditional sales force on a provider-level basis. 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. In addition, integration of the KidneyIntelX software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting.

- ***Partnership with Mount Sinai Health System.*** Our company was founded through a collaborative effort with Mount Sinai Health System, one of our significant shareholders and our launch partner for KidneyIntelX. Mount Sinai Health System encompasses the Icahn School of Medicine at Mount Sinai and eight hospital campuses in the New York metropolitan area. It is a pioneer in kidney health and devoted to discovering causes, prevention and treatment of kidney disorders. Our collaborative research studies with Mount Sinai utilize the Mount Sinai Bio*Me* biobank. Bio*Me* is designed to enable researchers to conduct genetic, epidemiologic, molecular and genomic studies using research specimens from consented participants, which are linked with each participant's de-identified health information. All Bio*Me* participants have consented to allow their de-identified data and samples to be used for research purposes. As of January 2020, the Bio*Me* biobank had over 52,000 participants. For KidneyIntelX, this 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. In September 2020, we announced the commercial launch of our partnership with Mount Sinai Health System, including initiation of patient testing.
- ***Regulatory-compliant Versioning Approach***. KidneyIntelX is designed as a scalable platform that can be optimized and deployed into clinical use on a validated-version by validated-version basis. Because we are operating as the Manufacturer of Record, KidneyIntelX is designed and manufactured under an *in vitro* diagnostics, quality-controlled process following FDA requirements and ISO guidelines. As a result, and with support from recent FDA policy initiatives, KidneyIntelX may conduct a version-controlled process to optimize algorithmic performance and expand clinical indications on an iterative basis. We believe this regulatory framework could potentially provide KidneyIntelX with the following competitive advantages: (1) more rapid machine-learning algorithm optimization as additional biomarker and patient EHR data are aggregated at a logarithmic rate, (2) a simplified pathway to expanded indications for use, including therapeutic drug response monitoring, and (3) more personalized patient diagnostic information as the heterogeneity of data density is better analyzed.
- ***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. As we expand coverage, we believe that the velocity of data aggregation will continue to increase, leading to greater KidneyIntelX fidelity and therefore greater competitive barriers to entry.

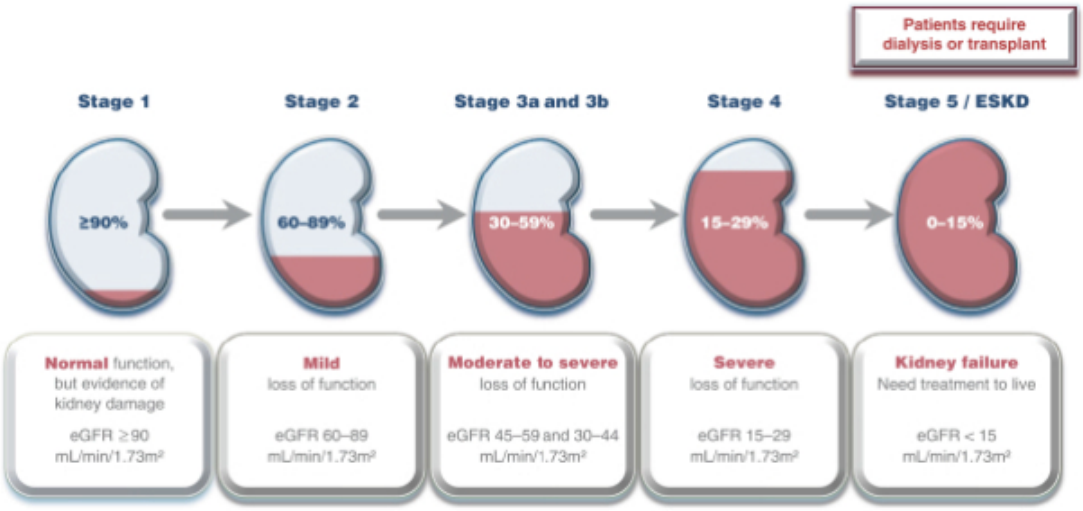
Industry background

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, or CDC, CKD affects approximately 37 million people in the United States alone, and the NKF estimates that one third of adults in the United States are at risk of developing kidney disease.

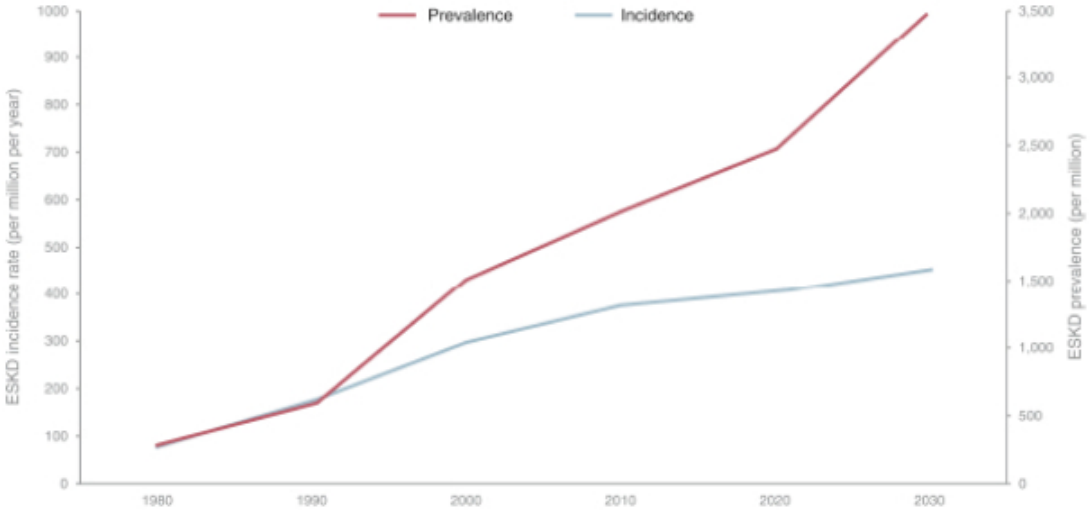
CKD, also called chronic kidney failure, is the gradual loss of kidney function. Advanced kidney disease is generally not reversible. There are five stages of CKD, from mild kidney damage in Stage 1 to complete kidney failure in Stage 5. The stages of kidney disease are based on how well the kidneys can filter waste and extra fluid out of the blood, as measured by an individual's estimated glomerular filtration rate, or 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, or 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 not functioning properly. 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.



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 2016, more than 726,000 patients had ESKD, with more than 500,000 requiring dialysis at least three times a week. More than 100,000 patients begin dialysis each year to treat ESKD. The incidence and prevalence rates of ESKD are projected to increase significantly as set forth in the graph below.



Once on dialysis, patients typically experience a five-year mortality rate of up to 70%, about the equivalent rate for brain cancer. According to the NKF, over two million people worldwide currently receive treatment with dialysis or a kidney transplant to stay alive, yet this number may only represent 10% of people who actually need treatment to live. 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 ethnicity 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. Genetic studies have identified the *APOL1* genotype that is responsible for much of the increased risk for CKD and ESKD in individuals of African ancestry. The *APOL1* high-risk genotypes (two copies of the *APOL1* kidney disease risk variants; G1/G1; G2/G2 or G1/G2) have been shown to be associated with increased ESKD risk, CKD progression, eGFR decline and CKD incidence.

Chronic kidney disease, obesity and diabetes

One of the most significant risk factors for developing CKD is type 2 diabetes. 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.

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, or 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.

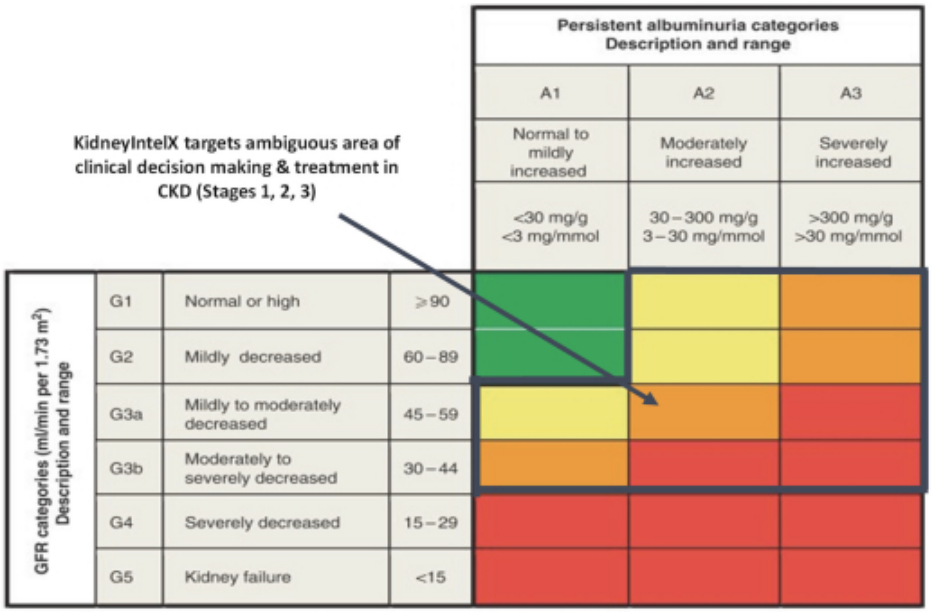
Significant healthcare system costs associated with CKD

According to the United States Renal Data System's 2019 Annual Data Report, 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 EKSD. Treatment for kidney failure consumes 6.7% of the total Medicare budget to care for less than 1% of the covered population. In the United States, dialysis 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 RKFD, especially in earlier stages of DKD (Stages 1 through 3). In our clinical validation studies in patients with DKD, we observed that the KDIGO classification system only identified approximately 20% of patients that experienced an adverse kidney outcome as very high-risk patients with the recommendation of referral to a nephrologist, while KidneyIntelX identified nearly half of such patients.

Moreover, recommendations from the American Diabetes Association, or the ADA, do not provide guidance on patients with earlier stage DKD (Stages 1 through 3), which represent 95% of the total U.S. DKD population. The ADA guidelines only suggest that a treating clinician refer the patient for “uncertainty about etiology of CKD, difficult management issues, or Stage 4 CKD.” Most experts agree that Stage 4 of the disease is too late to intervene for DKD, and that better preventive and treatment options are needed to be applied to patients with earlier stages of DKD (Stages 1 through 3).

Further, lack of ability to accurately predict which patients are at high risk of RKFD 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. The high burden and lack of available time for each patient do not allow these physicians to fully assess the vast amount of data from the EHR to enable proper risk stratification and treatment. 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, or SGLT2, inhibitors, 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 progressing to RKFD 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

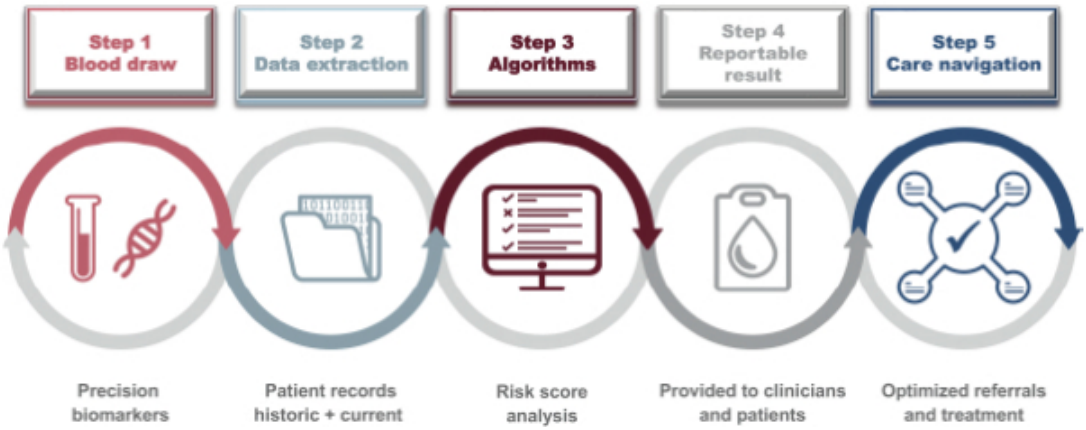
Our goal is to improve quality of life and lower healthcare costs by transforming the paradigm for kidney disease risk assessment and clinical management through our KidneyIntelX platform. We believe the use of KidneyIntelX will drive improved patient outcomes and significantly lower healthcare costs.

According to the CDC, in the United States alone, CKD affects approximately 37 million people and DKD, the most common type of CKD, affects approximately 12.6 million adults. Based on the Centers for Medicare & Medicaid Services, or CMS, national price for KidneyIntelX of $950 per reportable test, this represents a potential market opportunity of approximately $12 billion assuming one test per patient. The initial commercial launch version of KidneyIntelX is indicated for a subset of these patients, specifically patients 21 years of age or older with earlier stage DKD (Stages 1 through 3). We believe many patients will benefit from the use of KidneyIntelX for multiple tests throughout the course of treatment to provide ongoing risk assessment, enabling care pathway optimization, escalation of treatment and long-term disease management. Further, published data suggests the population of patients that could benefit from our solutions will continue to grow along with the anticipated increase in the occurrence of type 2 diabetes, a significant risk factor for developing CKD, and obesity, the primary driver of type 2 diabetes. We also intend to extend KidneyIntelX application into additional populations of CKD patients beyond those with diabetes, including patients of African ancestry with the *APOL1* high-risk genotype.

Our technology platform solution

Overview

We have designed KidneyIntelX, our first-in-class diagnostic platform, to enable risk prediction of progressive kidney function decline in patients with CKD. KidneyIntelX 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 score, categories of risk classification and specific guideline-driven clinical actions, as depicted in the graphic below.

KidneyIntelX™

Test Report

Ordered by	Dr. Fran Lake
Collection Date	8/14/2020
Report Date	8/19/2020
Specimen ID	665544

PATIENT INFORMATION

NAME	SEX	DATE OF BIRTH	MEDICAL RECORD #
Jane Lee	F	1/1/1960	00998877

RISK OF PROGRESSIVE DECLINE IN KIDNEY FUNCTION

95

Patients with a **high** KidneyIntelX score have an elevated risk of progressive decline in kidney function

The KidneyIntelX score ranges from 0-100 and correlates with the probability of progressive decline in kidney function in the study population. Risk classification is provided to guide interpretation of the risk score using cut-offs related to clinical outcomes.

SIGNED	DATE	TIME

Laboratory Director: Michael J. Donovan PhD, MD. CLIA, Renalytix AI, 101 6th Ave, 3rd Floor, Room 324 New York, NY 10013 CLIA Number: 33D2156875

This test was developed and its performance characteristics determined by Renalytix AI, Inc. It has not been cleared or approved by the FDA nor is it currently required to be. The laboratory is regulated under CLIA as qualified to perform high-complexity testing. The test is used for clinical purposes. It should not be regarded as investigational or for research. See page 2 for further details.

EXAMPLE OF CLINICAL PATHWAY WITH KIDNEYINTELX

Frequency of Monitoring / Referral[1]		Comprehensive Strategy to Maximize Protection for Diabetic Kidney Disease Progression and Cardiovascular Disease[2,3]	
Monitoring 3x/year	Nephrology Referral	Titrate ACEi or ARB to maximally tolerated dose	Strongly consider SGLT2 inhibitor therapy unless contraindicated

[1] KDIGO 2012 Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease https://kdigo.org/wp-content/uploads/2017/02/KDIGO_2012_CKD_CL.pdf
[2] Executive Summary of the 2020 KDIGO Diabetes Management in CKD Guideline. https://doi.org/10.1016/j.kint.2020.06.024
[3] ADA guidelines. https://care.diabetesjournals.org/content/43/Supplement_1/S135

RENALYTIX AI

Potential benefits of KidneyIntelX

We believe that the KidneyIntelX platform will be central to managing CKD, helping to identify which patients could benefit from clinical interventions at earlier stages of CKD before significant and irreversible kidney damage has taken place. In particular, we believe KidneyIntelX could provide the following benefits:

- **For patients**, with CKD as a result of diabetes, obesity or other factors, early intervention can lower the risk of progressing to life-altering advanced disease, kidney failure, dialysis, suffering and diminished quality of life. Patients that are designated to be low- or intermediate-risk, requiring lower intensity of treatments, can continue care with their existing primary care physician or endocrinologist. For example, healthcare providers may be able to use a wider range of preventative and therapeutic measures such as dietary advice (optimizing intake of salt, proteins, fluids and supplements), lifestyle changes (weight management and smoking cessation) and medication. High-risk patients are able to receive appropriate referral to a specialist, increased monitoring intervals, improved awareness of kidney health, referral to dieticians, reinforcement of usage of antagonists of the renin angiotensin aldosterone system, and increased motivation to start recently approved medications, including SGLT2 inhibitors to slow disease progression. All of these factors can result in the delay or prevention of ESKD and may reduce the occurrence of dialysis crashes. In addition, earlier engagement with clinical specialists may also allow for more time to advise and educate patients about home-based dialysis and pre-emptive or early kidney transplant.
- **For primary care physicians and specialists**, KidneyIntelX provides an easy-to-understand, reportable patient risk score integrated with specific guideline-driven clinical recommendations designed to maximize patient treatment and compliance outcomes. Primary care physicians are empowered to continue to treat low-risk patients with actionable guidelines, and high-risk patients are appropriately referred to specialist care.
- **For insurance payors**, KidneyIntelX can help drive health economics gains over time by (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. According to the BHA study, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in under 24 months and deliver cost savings of up to $1.3 billion over five years per 100,000 DKD patients.
- **For population health and clinical medicine departments**, KidneyIntelX provides a powerful diagnostic tool to stratify kidney disease populations into low-, intermediate- and high-risk categories applied to a continuous scale, enabling physicians to optimize the choice of treatment and allocation of clinical resources to benefit patient outcomes and health economics.

These benefits are primarily driven by the following:

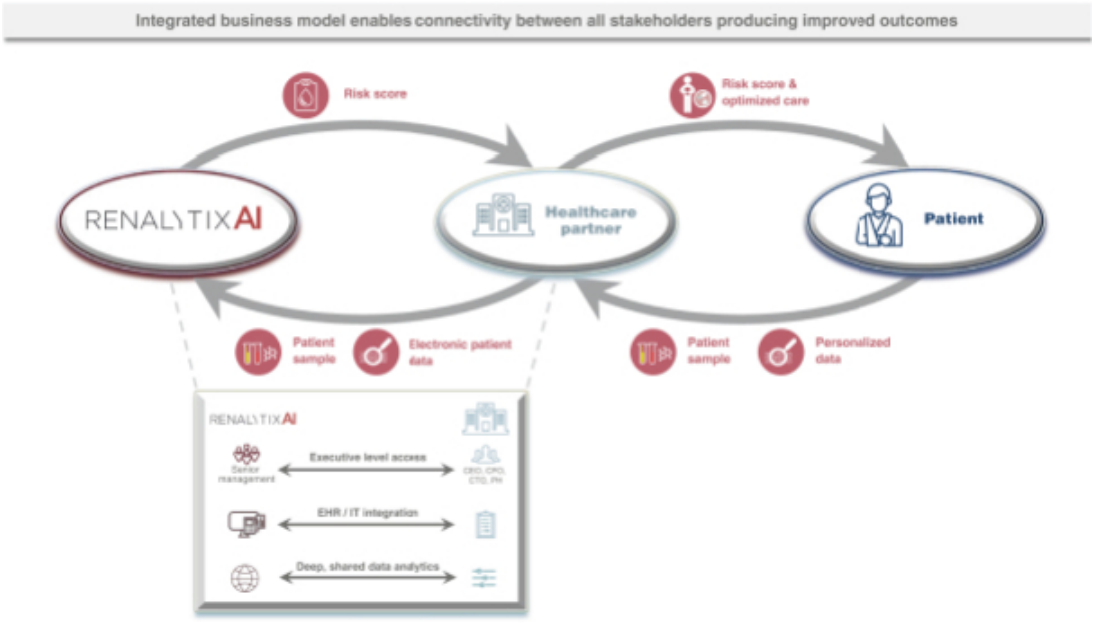
- *Improved Patient Risk Stratification in Earlier Stage CKD.* The machine learning-enabled patient risk score generated by KidneyIntelX, unlike static CKD risk classification systems, is able to take into account the continuous values of key inputs, including eGFR and uACR (the two measures utilized by the KDIGO classification system), other kidney-related laboratory values (such as serum sodium, potassium, calcium, bicarbonate, urea nitrogen, phosphate and hemoglobin), physiologic variables (such as age, weight and blood pressure), and combine them with predictive blood-based biomarkers. In clinical studies, KidneyIntelX demonstrated the ability to more accurately identify potentially fast-progressing CKD in individuals with type 2 diabetes and those of African ancestry over current clinical practice. In addition to the individual features themselves, combinations and interactions of these features, called meta-features, can add to the predictive performance of the model and can be deployed in clinical practice for the first time.
- *Advanced Data Analytics for Earlier Stage CKD.* The deployment of KidneyIntelX in the partnership model setting with healthcare systems and insurance payors presents an opportunity to

improve outcomes. Specifically, we believe the partnership model can highlight how early CKD risk stratification integrates into health system clinical workflows to slow or prevent disease progression and kidney failure and improve efficiency of care delivery. To maximize insight, we are bringing together a multi-disciplinary team that includes data science, health economics, behavioral economics and clinical specialists for initial deployments. This team consists of both our internal employee base and third-party groups that have experience examining large quantities of population-based data.

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.

KidneyIntelX is initially indicated for patients 21 years of age or older with earlier stage DKD (Stages 1 through 3). The initial commercial launch version of KidneyIntelX will combine validated proprietary blood-based biomarkers and personalized patient data from EHR systems to generate a risk score unique to each patient, which is intended as an aid to assess the risk of progressive kidney function decline over a five-year timeframe. The test is not intended as a screening or stand-alone diagnostic. We believe that KidneyIntelX will be the first clinical-grade, quality-controlled and validated product to enable risk prediction in earlier stages of DKD.



Validated 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 demonstrate consistent associations of soluble Tumor Necrosis Factor, or TNFR, 1 and 2 and plasma Kidney Injury Molecule-1, or 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 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 versions of KidneyIntelX 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 algorithm to address different target populations. For example, the next generation test is being developed to address the increased incidence in kidney disorders amongst individuals of African ancestry by incorporating genotyping for *APOL1*.

KidneyIntelX is designed to update risk assessment through dynamic EHR data analyses, potentially providing a clinician and his or her patient with the most up to date information about kidney disease status and risk of progression through the course of treatment over time. We plan to further clinically validate KidneyIntelX with repeat testing in additional clinical validation studies being initiated in the second half of the calendar year 2020.

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 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 1,500 patients with DKD from the Mount Sinai Health System and University of Pennsylvania Health System biobanks.

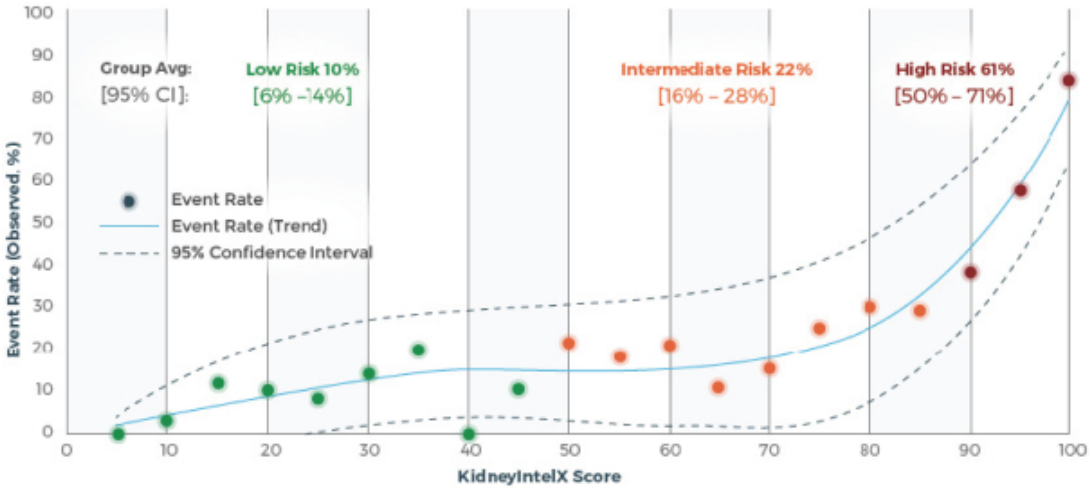
- *EHR Data Harmonization.* EHR data from different institutions can be entered and stored in different formats. To overcome this significant limitation, we have developed a proprietary machine learning-enabled algorithm that can convert the diverse data (specifically laboratory values and medication 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 study, to ensure that the kidney disease outcomes for KidneyIntelX were accurately classified and did not represent random non-disease variation, all kidney function changes over time and all clinical outcomes were independently adjudicated by examining the trajectory of kidney function over their longitudinal course of treatment to the outcome. This clinical adjudication and knowledge base has been codified into the overall workflow for KidneyIntelX 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.

Patient-specific continuous risk score

The KidneyIntelX artificial intelligence-enabled algorithm integrates the composite of feature inputs into a continuous patient risk score, which is reported to the treating clinician on a scale from 0 to 100 and also categorized into low-, intermediate- and high-risk strata.

The graph below shows the probability of the composite kidney endpoint by quantile of the KidneyIntelX risk score in our multi-center validation study discussed below. The event rate of the composite kidney endpoint,

which represents the five-year progression of disease, includes three categories of progressive kidney function decline: (1) RKFD, which is defined as eGFR decline of at least 5 ml/min/1.73m^2/year, (2) sustained 40% decline in eGFR and (3) one of the following: (a) kidney failure, defined as a sustained eGFR < 15 ml/min/1.73m^2, (b) long-term dialysis or (c) kidney transplant.



PPV: positive predictive value
NPV: negative predictive value

This novel capability of using machine learning to generate a continuous risk score enables the timely and accurate prediction of risk of disease progression in the earlier stages of DKD (Stages 1 through 3), where active intervention has the most potential to delay or prevent progression to ESKD and the need for dialysis or kidney transplant.

In addition, the KidneyIntelX risk score will 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 extract from the EHR system the information required for each ordered test, which is then combined with biomarker data to generate the risk score and test report. We anticipate that future versions of KidneyIntelX will enable periodically updated patient risk scores through repeat testing, and integration of the risk score back into the EHR as part of the permanent medical record of the patient. 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 on the effects of changes in care management and patient behavior on kidney health.

We anticipate that the kidney disease risk score will be provided to the clinician at the point-of-care through standard approaches for reporting, mobile device and/or the RenalytixAI provider portal. In addition, we plan to

be able to provide the kidney disease risk score directly to patients via access to the RenalytixAI patient portal and patient-facing mobile device applications.

All personal health information captured by the KidneyIntelX 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.

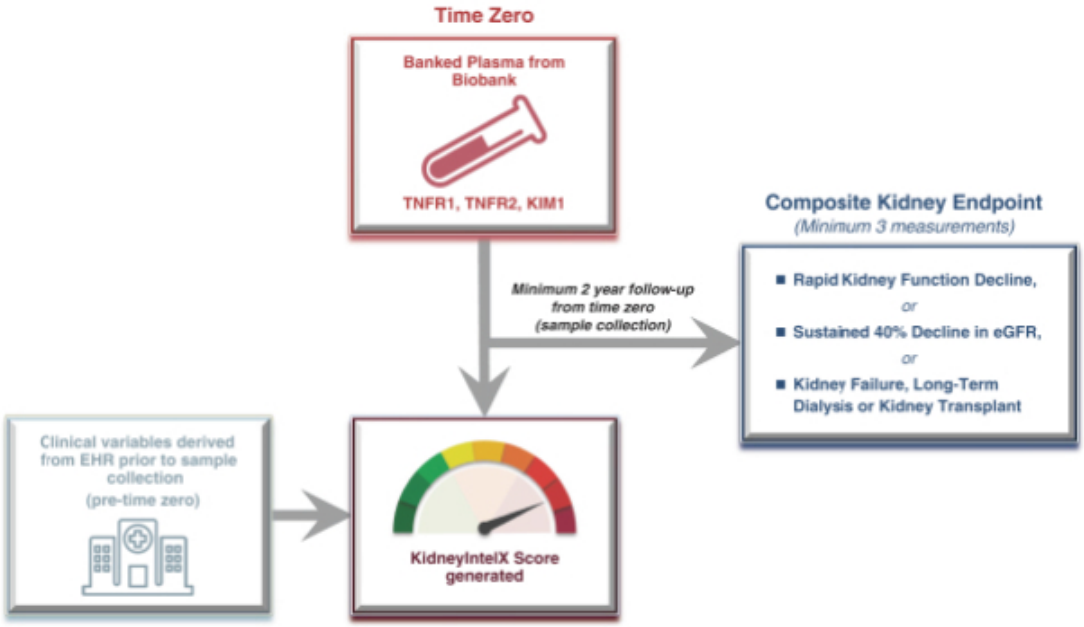
We have been working with Persistent Systems Limited, or Persistent Systems, to develop secure, cloud-based data integration software architecture and secure, high-performance algorithms for our platform. Persistent Systems is a leader in software development and has long-standing relationships with several healthcare providers that manage our target patient populations, including Mount Sinai Health System, Johns Hopkins, Yale, Montefiore, UCLA Health and New York Presbyterian Hospital.

Clinical validation studies

We have completed two clinical validation studies using blood biobank facilities with integrated patient EHR data over a multi-year period from Mount Sinai Health System and University of Pennsylvania Health System. We are also evaluating KidneyIntelX in an ongoing collaboration with University Medical Center Groningen, Netherlands in patients included in a completed large, randomized control trial for a novel treatment for DKD.

Completed clinical validation studies

The primary objective of each completed validation study was to accurately predict the rate of occurrence of progressive kidney function decline based on the KidneyIntelX risk score and probability-based categorical cutoffs, with results compared to standard clinical models. These studies measured the event rate of the composite kidney endpoint, which represents the progression of disease, and includes three categories of progressive kidney function decline over a five-year timeframe: (1) RKFD, which is defined as eGFR decline of at least 5 ml/min/1.73m^2/year, (2) sustained 40% decline in eGFR and (3) one of the following: (a) kidney failure, defined as a sustained eGFR < 15 ml/min/1.73m^2, (b) long-term dialysis or (c) kidney transplant. The following is a graphical representation of the study design for both of the validation studies:



These two completed validation studies and their results are significant in a number of ways:

- We believe this is the first demonstration of a machine learning-enabled patient risk score applied to a CKD population.
- These studies leveraged three plasma biomarkers that have established strong association with CKD progression and RKFD or kidney failure in other patient groups and settings, but had not previously been analyzed for clinical utility as demonstrated with the KidneyIntelX continuous and categorical risk score.
- Although several other studies of biomarkers for prediction of CKD progression or RKFD or kidney failure exist, the majority have focused on broad measures of association versus patient-specific clinical utility metrics.
- These studies leveraged two biobanks linked to longitudinal de-identified EHR data with over five years of participant follow up for these analyses, which is in contrast to most biobanks that do not have stored plasma and linkage to robust longitudinal EHR data.
- These studies assessed clinical utility through application of a composite risk score that effectively divides patients into low-, intermediate- and high-risk groups. Results demonstrate that KidneyIntelX achieves high positive predictive value in the high-risk group and high negative predictive value in the

low-risk group with performance that is statistically superior to existing standard of care tools such as the KDIGO classification system or other validated clinical models.

- Our first clinical validation study also highlighted the potential for the utility of KidneyIntelX in non-diabetic patients of African ancestry with the high-risk *APOL1* genotype, which is the second largest population accounting for ESKD in the United States.

Validation Study 1—Mount Sinai Health System

In our clinical validation study with Mount Sinai Health System, completed in March 2019, we selected two subpopulations of high-risk individuals: 871 patients with type 2 diabetes and 498 patients of African ancestry with the *APOL1* high-risk genotype, with a baseline eGFR ³ 45 ml/min/1.73m2 from the Mount Sinai Bio*Me* biobank. Plasma levels of soluble TNFR1/2 and KIM-1 were measured and a series of supervised machine learning approaches were employed to combine the biomarker data with longitudinal clinical variables.

The following table presents a summary of key demographic data for patients in this study with type 2 diabetes and patients of African ancestry with the high-risk *APOL1* genotype:

	Patients with Type 2 Diabetes (n=871)	Patients of African Ancestry (n=498)
Mean Age (years)	61	56
Median baseline estimated eGFR	74 ml/min/1.73m2	83 ml/min/1.73m2
Median uACR	13 mg/g	11 mg/g
Median follow-up (years)	4.6	5.9
Median additional retrospective* data available (years)	2.3	3.1

* Prior to time zero (sample collection).

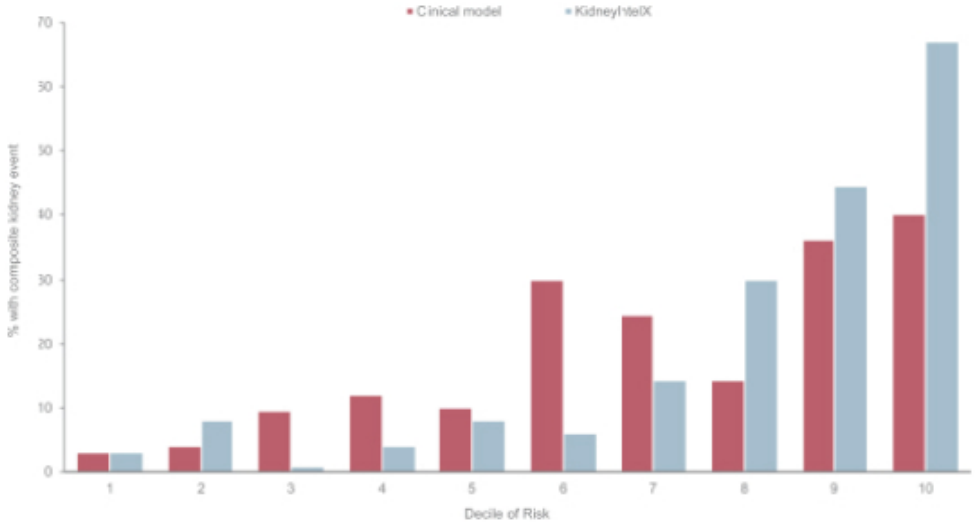
The observations in this study demonstrated that, in patients with type 2 diabetes or patients of African ancestry with the high-risk *APOL1* genotype, KidneyIntelX significantly improved prediction of eGFR decline or kidney failure over standard clinical models.

The observed composite kidney endpoint by deciles of risk with KidneyIntelX compared to the standard clinical models are shown in the figures below. For patients with type 2 diabetes, the KidneyIntelX area under receiver operator characteristic curve, or AUC, in the training set (80%, n=697) for the composite kidney endpoint was 0.81 (95% CI: 0.80-0.82) and 0.77 (95% CI: 0.75-0.79) in the test set (20%, n=174). By comparison, the clinical model had an AUC of 0.66 (95% CI: 0.65-0.67) in the entire cohort (n=871).

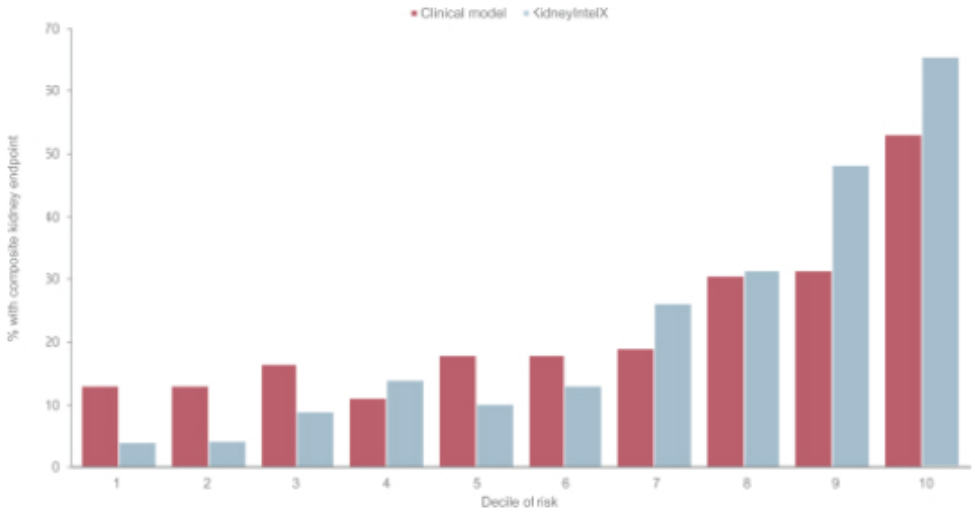
For the patients with *APOL1* high risk genotype, the AUC for KidneyIntelX in the training set (80%, n=398) was 0.86 (95% CI: 0.84-0.87) and 0.80 (95% CI: 0.77-0.83) in the test set (20%, n=99). The clinical model had an AUC of 0.72 (95% CI: 0.71-0.73) in the *APOL1*-HR cohort (n=498).

At the upper end of the scores, KidneyIntelX identifies more adverse kidney events than clinical model, and at the lower end of the scores, fewer patients with low-risk KidneyIntelX scores have adverse kidney events compared to low-risk scores with the clinical model.

Proportion with the composite kidney endpoint by deciles of predicted risk via KidneyIntelX vs. clinical model in Type 2 Diabetes



Proportion with the composite kidney endpoint by deciles of predicted risk via KidneyIntelX vs. clinical model in *APOL1*



The table below summarizes the results of this study, including the high- and low-strata risk cutoffs, sensitivity and specificity levels, positive predictive value, or PPV, and negative predictive value, or NPV, for each model evaluated.

KidneyIntelX thresholds for the composite kidney endpoint with sensitivity, specificity, PPV and NPV for Type 2 Diabetes and *APOL1* high-risk populations in high- and low-risk strata

	Risk Cutoff	Sensitivity	Specificity	PPV	NPV
Type 2 Diabetes KidneyIntelX					
Bottom 50%	0.192	0.82	0.59	0.38	0.92
Top 20%	0.444	0.50	0.89	0.58	0.86
Top 15%	0.555	0.40	0.93	0.62	0.84
Top 10%	0.707	0.29	0.96	0.68	0.82
Type 2 Diabetes Clinical Model					
Bottom 50%	0.148	0.58	0.55	0.31	0.85
Top 20%	0.240	0.38	0.85	0.43	0.82
Top 15%	0.278	0.30	0.89	0.46	0.81
Top 10%	0.338	0.23	0.94	0.54	0.80
***APOL 1*-HR KidneyIntelX**					
Bottom 50%	0.209	0.88	0.58	0.32	0.96
Top 20%	0.438	0.60	0.89	0.56	0.91
Top 15%	0.489	0.52	0.93	0.62	0.90
Top 10%	0.546	0.36	0.96	0.66	0.87
***APOL 1*-HR Clinical Model**					
Bottom 50%	0.151	0.79	0.57	0.29	0.93
Top 20%	0.322	0.42	0.85	0.38	0.87
Top 15%	0.387	0.32	0.87	0.39	0.85
Top 10%	0.448	0.22	0.93	0.4	0.84

Validation Study 2—Mount Sinai Health System and University of Pennsylvania Health System

In our multi-center clinical validation study with Mount Sinai Health System and University of Pennsylvania Health System, completed in December 2019, we selected patients specifically with prevalent DKD (G3a-G3b, A1-A3 or G1-G2, A2-A3) and banked plasma patients from two EHR-linked biobanks, the Mount Sinai Health System Bio*Me* biobank and the Penn Medicine Biobank. We measured plasma levels of soluble TNFR 1/2 and KIM-1 at baseline with a high sensitivity, analytically validated assay. EHR data for patients was integrated and harmonized to ensure data consistency. Patients were randomly divided into a derivation, or train set, consisting of 686 patients, and a validation, or test set, consisting of 460 patients. A machine learning model was trained and performance assessed using standard metrics and compared to an optimized clinical model and current KDIGO risk categories.

We also compared KidneyIntelX to a published validated clinical model consisting of a regression equation for 40% eGFR decline prediction, including age, sex, race, eGFR, cardiovascular disease, smoking, hypertension, BMI, and UACR insulin use, diabetes medications, and glycated hemoglobin (or HbA1c).

The following table presents a summary of key demographic data for the DKD patients in this study:

	Patients with DKD (n=1,146)
Median baseline estimated eGFR	54 ml/min/1.73m^2
Median uACR	61 mg/g
Median follow-up (years)	4.3

Of these patients, 241, or 21%, experienced the composite kidney endpoint within the 5 year follow-up period. The risk model had an AUC of 0.77 (95% CI 0.74-0.79) with comparable AUC result in the validation set of 0.77 (95% CI 0.76-0.79). By comparison, the AUC for an optimized clinical model was 0.62 (95% CI 0.61-0.63) in the derivation set and 0.61 (95% CI 0.60-0.63) in the validation set.

Using cutoffs from the derivation set, KidneyIntelX stratified patients into low-, intermediate- and high-risk groups. As demonstrated, the PPV for the top strata in KidneyIntelX range from 55% to 70% while the PPV for the optimized clinical model range from 31% to 38%. The predictive values of KidneyIntelX and the clinical model are summarized in the table below.

Risk score	KidneyIntelX				Risk score	Clinical Model			
Low risk	Population	Sens	Spec	NPV	Low Risk	Population	Sens	Spec	NPV
0.04	Lowest 32%	88%	38%	91%	0.142	Lowest 32%	74%	33%	86%
0.061	Lowest 46%	81%	54%	91%	0.171	Lowest 46%	67%	48%	88%
0.0712	Lowest 48%	77%	58%	90%	0.175	Lowest 48%	67%	51%	89%
High risk	**Population**	**Sens**	**Spec**	**PPV**	**High risk**	**Population**	**Sens**	**Spec**	**PPV**
0.241	Top 21%	50%	88%	55%	0.288	Top 21%	41%	82%	31%
0.302	Top 16.5%	45%	93%	62%	0.319	Top 16.5%	37%	88%	37%
0.401	Top 12%	31%	96%	70%	0.361	Top 12%	28%	91%	38%

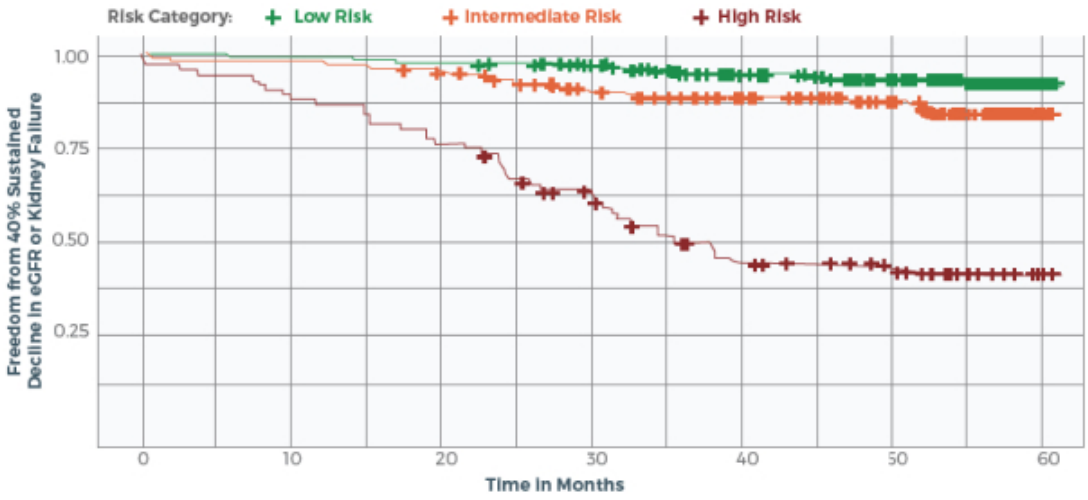
We also compared KidneyIntelX to KDIGO risk strata:

	KidneyIntelX	KDIGO
Risk Stratification with KidneyIntelX:		
High-risk stratification	16%	
Intermediate-risk stratification	37%	
Low-risk stratification	47%	
Predictive Value:		
Positive predictive value in high-risk category	**62%**	**41%**
Negative predictive value in low-risk category	**91%**	**85%**

The net reclassification index for events into high-risk group for KidneyIntelX, compared to the KDIGO classification system, was 41% ($p<0.05$).

Finally, KidneyIntelX demonstrated accurate risk prediction for a modified, time-to-event based composite kidney endpoint of 40% sustained decline or kidney failure, with a nine-fold difference in risk between the high-risk and low-risk strata for this clinical and objective endpoint, as shown in the graph below.

Kaplan-Meier curves by risk strata for the endpoint of sustained 40% decline in eGFR or kidney failure in the validation set



Validation Study 3— Evaluation of KidneyIntelX in a randomized controlled clinical trial

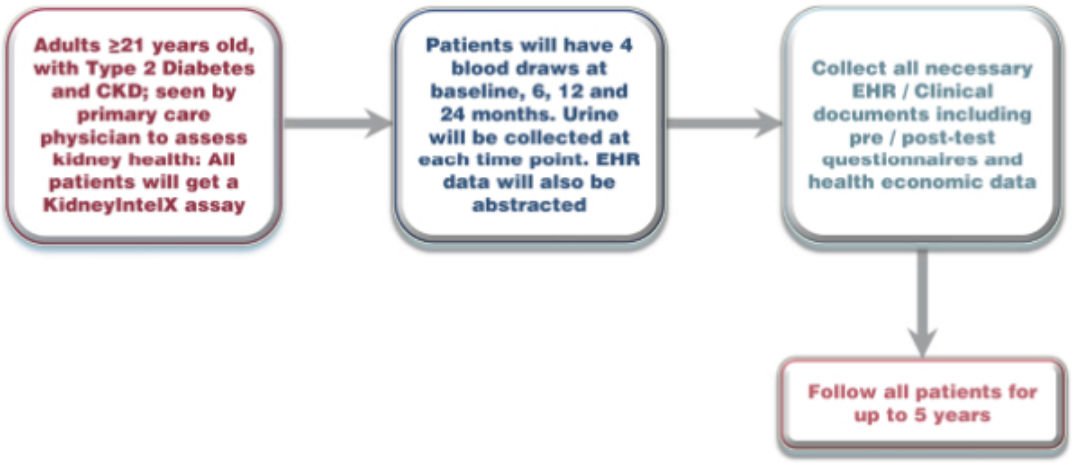
We are also evaluating the performance of KidneyIntelX in 3,500 patients with type 2 diabetes from the a large, randomized, controlled trial in collaboration with University Medical Center Groningen, Netherlands.

The collaborative study involves multiple components, including: (1) how effectively KidneyIntelX predicts which patients experience progressive decline in kidney function in both placebo and treatment arms; (2) whether KidneyIntelX can predict at baseline those most likely to benefit from treatment and (3) the effect of treatment on changes on the KidneyIntelX risk score over time. Stored blood specimens were collected longitudinally out to six years in the trial participants, with over 9,000 blood specimens in total. Moreover, extensive clinical data was collected at each study visit and has been shared under a data sharing agreement, which allows for robust inputs into the KidneyIntelX algorithm for risk score generation. Results from this study have been submitted for presentation at ASN Kidney Week, 2020 and will also be submitted for presentation at the World Congress of Nephrology sponsored by the International Society of Nephrology in April 2021.

Planned clinical utility study program

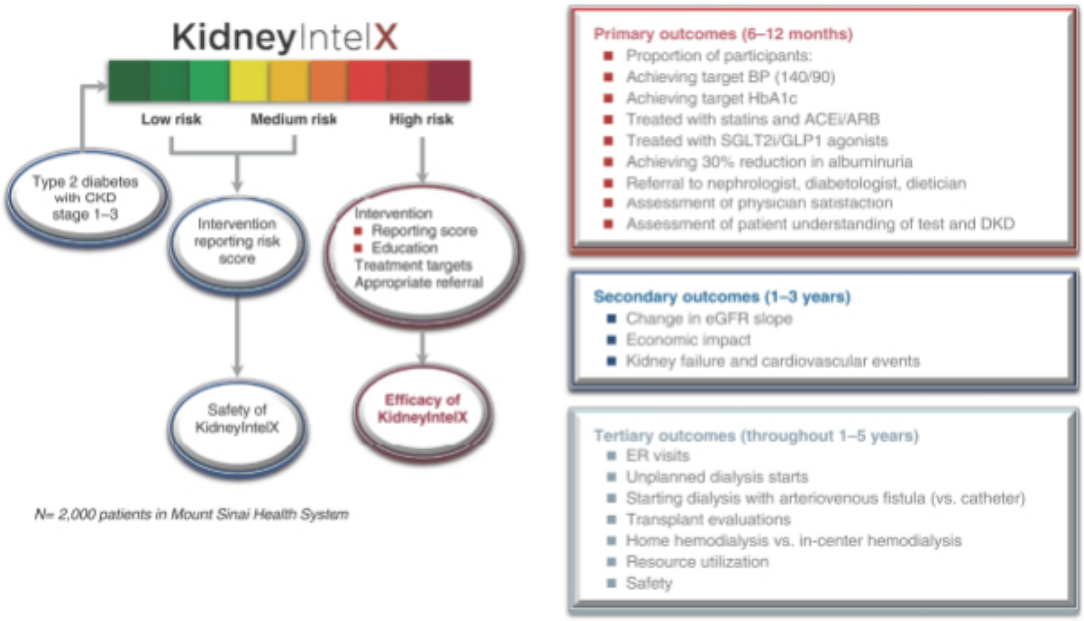
As part of a comprehensive, multi-center clinical utility program, we plan to initiate a clinical utility study at Mount Sinai Health System in fiscal 2nd quarter, which is designed to evaluate how the results of KidneyIntelX impact the clinical management of patients with type 2 diabetes identified as having increased risk of progressive kidney function decline within a five-year timeframe. Specific clinical decisions such as referral to a nephrologist, or initiating treatment (e.g. SGLT2 inhibitors, angiotensin-converting enzyme inhibitors, or ACEi, angiotensin II receptor blockers, or ARBs, statins) will be tracked along with measurable clinical endpoints such as lowering of blood pressure and reduction in levels of Hb1Ac. Urine will also be collected as part of this study given the well-established importance of urine as the source of a biological signal for kidney health.

This study will be a prospective, interrupted time series, shared decision-impact and health-economic assessment study. The target accrual is 2,000 patients seen for a regularly scheduled evaluation. All enrolled patients will have the KidneyIntelX test and results will be provided to both patient and the clinician provider. The design of the clinical utility study is depicted below.



All enrolled patients will receive the KidneyIntelX test reports and will be asked to consent for blood and urine collection and to complete a patient questionnaire at time of each visit. Additionally, at the time of baseline, a reflex order of a uACR will be placed in the EHR (to be collected and measured in the study center lab) if not already present within the past six months. This will be done since all guidelines (NKF, ADA) recommend uACR screening in these patients, but are not performed approximately 50% of the time.

Clinician providers will also be asked to assure review of the KidneyIntelX results report in real-time and to respond to a provider-specific questionnaire. Data collection, clinical evaluation and biospecimen acquisition will take place at: baseline (time of consent), 6 months, 12 months and 24 months. We will allow a +/- 30 day tolerance window around the six-month visit and a +/- two-month tolerance window around the 12- and 24-month visits. Anticipated study design and endpoints are highlighted below.



It is anticipated that up to five clinical sites within Mount Sinai Health System will serve as participating sites. The selected sites will have an existing infrastructure to conduct clinical research, including the ability to recruit, enroll and perform clinical data and biospecimen collections over serial study visits. Selected investigators will be experienced in clinical research and in the provision of care to patients with type 2 diabetes. The sites will be responsible for general oversight including efficient operation with regards to recruitment and follow-up activities. Sites will be responsible for timely shipment of collected samples to our laboratory.

COVID-19 clinical studies

We plan to investigate the utility and validation of KidneyIntelX for patients with COVID-19 in two clinical studies.

Pred-MAKER study

The first study, referred to as Pred-MAKER (Prediction of Major Adverse Kidney Events and Recovery), will explore clinical features and biomarkers, including multiple plasma biomarkers and urine proteomics and RNA sequences, as predictors of major adverse kidney events in approximately 700 patients hospitalized with COVID-19 at Mount Sinai.

The goal of the study is to improve the understanding of mechanisms of COVID-19-associated kidney disease, and to leverage the KidneyIntelX platform to deploy machine learning-based prediction models that utilize clinical data along with plasma and urine biomarkers to risk stratify COVID-19 patients major adverse kidney events, including need for acute dialysis and recovery of kidney function after discharge.

The samples have been collected, assays are in process, and the biomarker concentrations will be merged with the clinical data that has recently been cleaned and linked to the patients with the biospecimens in preparation for full analyses of a machine-learning model incorporating the various inputs.

MASKeD-COVID (Multi-center Assessment of Survivors for Kidney Disease after COVID-19) Study

This study involves multiple major academic institutions, including Mount Sinai, University of Michigan, Johns Hopkins, Yale University and Rutgers University. The goal of this study is to understand the long-term kidney epidemiology of CKD in survivors of COVID-19 and validate KidneyIntelX for prediction of long-term kidney outcomes post-COVID hospitalization that will inform further prevention, treatment and clinical care.

Several hundred COVID-19 survivors have been seen post-hospitalization and had samples collected. We plan to conduct assays on the blood and urine specimens in early Q4 and assess the performance of KidneyIntelX in this novel population. We believe KidneyIntelX is well-positioned to assist with risk prediction in this patient population as the COVID pandemic continues into the fall and winter of 2020-2021.

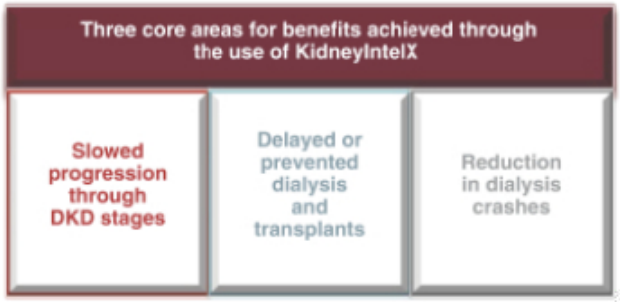
Health economics

We believe that the utilization of KidneyIntelX across large patient populations will have a significant impact on overall healthcare costs. We have partnered with BHA to develop a health economic model analyzing the cost and care pathway for patients with DKD at all stages of the disease and the potential cost savings provided by KidneyIntelX. The preliminary evaluation of payer budget impact associated with the use of KidneIntelX to modify DKD progression was selected for a late-breaking podium presentation at the NKF Spring Clinical Meeting in March 2020 where it was presented later that month.

The study analysis was based on a hypothetical cohort of 100,000 patients with type 2 diabetes and DKD (Stages 1 through 3), which was followed for up to five years, and discussed results on the following objectives:

- identify incremental costs to payers associated with KidneyIntelX implementation compared to standard of care;
- identify incremental benefit from the use of KidneyIntelX compared to standard of care and monetize this benefit; and
- calculate net savings associated with KidneyIntelX use.

The total savings were calculated based on the three core areas of expected benefit, as depicted below.



The model compared differences in the following treatment costs between KidneyIntelX and standard of care patients: (1) costs of preventative measures (treatments and office visits) in KidneyIntelX high-risk patients (DKD Stages 1 through 3); (2) costs of each DKD stage; (3) costs of dialysis, transplants (including post-transplant care), and dialysis crashes; and (4) costs of KidneyIntelX test ($1,050, including $950 per reportable

test and $100 administration cost). Peer-reviewed published data was used to estimate annual costs associated with each stage of DKD, annual incremental costs to standard of care associated with the actionable results of the KidneyIntelX test, cost of preventative measures for the KidneyIntelX group, and cost of dialysis, transplants, and dialysis crashes. All costs were based on published U.S. estimates and inflation-adjusted to 2019 dollars.

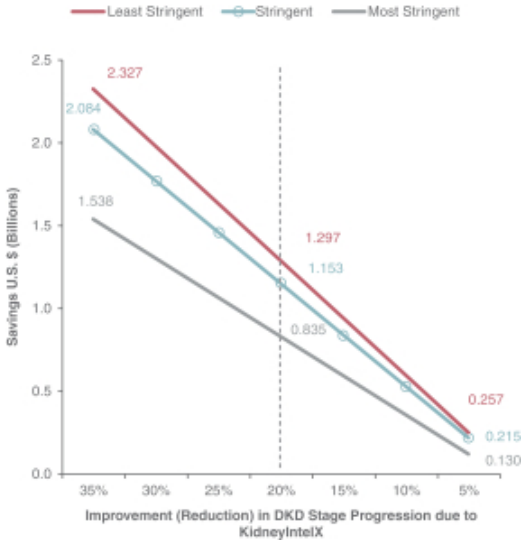
Of the 100,000 patients in the cohort, 16% were assumed to have a high-risk patient score and receive additional medical management and preventative measures. Patients undergoing risk assessment with KidneyIntelX using KidneyIntelX were assumed to have a 20% slowed progression rate through DKD stages compared to standard of care, based on our completed validation studies. A sensitivity analysis was conducted by changing this slowed progression rate over a range from 5% to 35%. 100% adherence to preventative measures was assumed in these patients. A sensitivity analysis was also conducted using three different definitions of 'progression' to the next DKD stage:

- Least Stringent: ³1 eGFR value(s) in the next stage.
- Stringent: ³2 eGFR values three months apart in next stage.
- Most Stringent: ³2 eGFR values three months apart in the next stage, only in the 21% of patients that ultimately experienced RFKD or kidney failure (79% stable).

Therefore, in the least stringent definition of progression, more patients were assumed to progress through DKD stages, resulting in more cost savings compared to the most stringent definition.

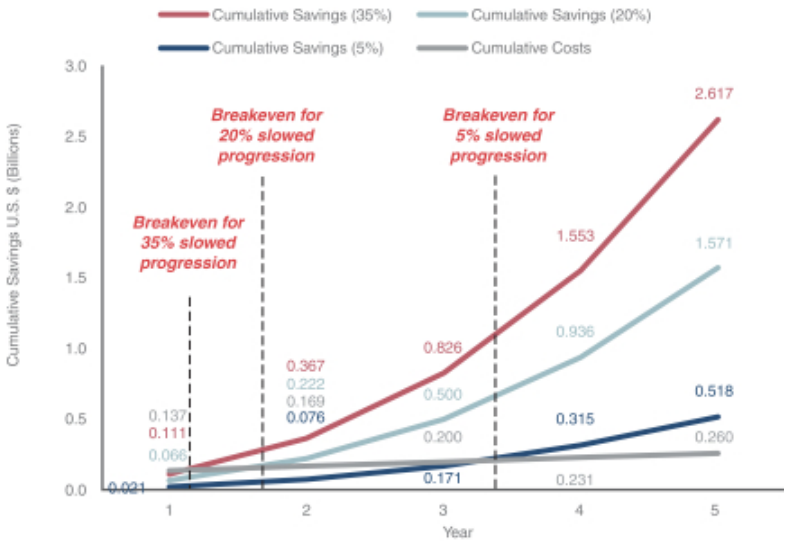
As shown in the graph below, the net present value of five-year payor savings associated with KidneyIntelX adoption for the 100,000 patient cohort was estimated to range between $835 million and $1.3 billion over a five-year time horizon for the most stringent and least stringent definitions of progression, respectively. The estimated savings realized for the stringent definition of progression (or base-case) was $1.15 billion.

Net present value of savings (discounted) over five years due to KidneyIntelX



Furthermore, according to the study analysis, the estimated time to breakeven for KidneyIntelX adoption occurs between 12 and 24 months following implementation, assuming the stringent definition of progression (or base-case). As the graph below shows, after the breakeven point, the cumulative savings are expected to start increasing compared to the costs of implementation.

Cumulative (undiscounted) savings vs cost of KidneyIntelX implementation



The majority of the savings over five years are expected to be attributable to slowed progression through DKD stages owing to the use of KidneyIntelX compared to savings from other categories. We believe that KidneyIntelX will help slow progression of patients with DKD to the next stage of disease by:

- accurately predicting which patients with earlier stage DKD (Stages 1 through 3) are at high-risk (top 16%) of experiencing progressive kidney function decline within a five-year timeframe;
- enabling optimization of the patient care pathway at earlier stages of DKD leading to improved outcomes and quality of life;
- empowering primary care physicians to continue to treat low-risk (bottom 46%) DKD patients, which enables health systems to better allocate scarce specialist resources to patients most in need;
- arming primary care physicians and all levels of specialty practice with a diagnostic and predictive tool tied to specific guideline-driven clinical actions, including timely referral to a clinical specialist;
- increasing compliance through diagnostic and prescriptive kidney care protocols and improved clinical workflows and care coordination for DKD patients;
- achieving clinical and actuarial risk mitigation at both the individual and population levels; and
- supporting scaled implementation at a population-health level.

Recent and upcoming studies, presentations or publications

We intend to continue a robust data development and clinical study program for KidneyIntelX through scaled commercial activities and expanded product version introductions. We are currently working with a global network that includes, among others, the leading clinical society organization, the American Society of Nephrology, major academic medical centers, clinical investigators, patient advocacy organizations, including the NKF, and relevant payors to design studies for KidneyIntelX to measure real-world utility, clinical work-flow implications, health economics, patient behavior impacts and short- and long-term disease outcomes of KidneyIntelX. Recent or upcoming presentations or publications include:

- *Evaluation of Payer Budget Impact Associated with the Use of Artificial Intelligence in vitro Diagnostic, KidneyIntelX, to Modify DKD Progression*. As described above, an economic analysis

performed by BHA of the impact of KidneyIntelX was selected for a late-breaking podium presentation at the National Kidney Foundation Spring Clinical Meeting in March 2020. The presentation highlighted the significant cost savings potential from the implementation of KidneyIntelX as modeled in large healthcare system patient populations in the United States. NKF's Spring Clinical Meeting gathers more than 3,000 nephrology healthcare professionals from across the United States to learn about the newest developments related to all aspects of nephrology practice. The full manuscript is under peer review at BMC Nephrology.

- *Derivation and validation of a machine-learning risk score using biomarker and EHR data to predict rapid progression of diabetic kidney disease*. This manuscript demonstrated that of KidneyIntelX, a machine learned model combining plasma biomarkers and EHR data, significantly improved prediction of RKFD or kidney failure within five years over KDIGO risk strata and standard clinical models in 1,146 patients with earlier-stage DKD. Over 60% of patients classified as "high risk" by KidneyIntelX experienced the composite kidney endpoint, compared to less than 10% classified as "low risk." For the FDA-accepted endpoint of a sustained 40% decline in kidney function or kidney failure, those with KidneyIntelX high-risk scores had a nine-fold higher risk than those classified as low-or intermediate-risk. This manuscript is under revise and resubmit status after peer and editorial review at Diabetologia. These findings were also presented at the American Diabetes Association 80th Scientific Session in June 2020 in Chicago, Illinois and were published on the preprint server for health sciences, MedRxiv.
- *Initial Validation of a Machine Learning-Derived Prognostic Test (KidneyIntelX) Integrating Biomarkers and Electronic Health Record Data To Predict Longitudinal Kidney Outcomes*. Findings from the study examining the ability of KidneyIntelX machine-learning combining blood biomarkers and EHR data to predict the composite kidney endpoint in two distinct populations from the Mount Sinai BioMe biobank: one group with type 2 diabetes and relatively preserved kidney function, and the second group of approximately 500 patients of African ancestry with the APOL1 high-risk genotype were submitted for publication. In both patient groups, KidneyIntelX outperformed standard clinical models for predicting progression of kidney disease. As in the multi-center validation study, the positive predictive value exceeded 60% in the high-risk strata, and the negative predictive value exceeded 90% in both populations. These data were presented at ASN Kidney Week 2019 in Washington, DC and were published in the American Society of Nephrolog Journal Kidney360 in August of 2020.
- *Association between the inflammatory markers TNFR-1, TNRF-2, and KIM-1 with kidney and cardiovascular outcomes* and *The SGLT2 Inhibitor Canagliflozin Reduces the Plasma Markers TNFR-1, TNFR-2, and KIM-1 in the CANVAS Trial* have both been accepted at the ASN Kidney Week 2020. We have generated data from 3,500 participants from a randomized controlled trial of a therapeutic intervention in type 2 diabetes with 10,000 blood samples collected longitudinally.

Our key agreements

Mount Sinai Health System

In May 2018, we entered into a license agreement, or 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, or EKF, entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or 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, or 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.

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro for the purpose of developing and commercializing laboratory tests for the detection of antibodies against

SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into the Advisory Agreement, pursuant to which we have 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 us in respect of the services to be rendered by us under the Advisory Agreement. A portion of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum 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 us).

All services provided by us under the Advisory Agreement are subject to the oversight and direction of the board of managers of Kantaro. If, as circumstances develop, we believe that any of Kantaro's functions require a level of effort or expense that could not have reasonably been anticipated as of the date of the Advisory Agreement, the parties will consult together regarding such circumstances and the board of managers of Kantaro will determine whether the terms of the Advisory Agreement should be adjusted to take account of such circumstances; provided, however, that we shall not be required by any such adjustment to increase our level of effort or bear any expense in any material respect to an extent that exceeds those originally contemplated unless the parties have mutually agreed upon how such efforts and expenses shall be borne by the parties. It is the goal of the parties that Kantaro build its internal operational capabilities in order to eventually be self-sustaining, and certain of the aforementioned services are expected to sunset as Kantaro achieves such self-sustainability.

The sole consideration due to us for performance of these services is the issuance of the 250 Class A Units as described above.

The term of the Advisory Agreement will continue until the fifth anniversary of the execution thereof, unless earlier terminated. The Advisory Agreement may be terminated by either party upon an uncured material breach of the Advisory Agreement by the other party or in the event the other party is unable to perform under the Advisory Agreement for a specified period of time due to a force majeure event. Kantaro may also terminate the Advisory Agreement by notice to us if we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai.

AstraZeneca

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

The agreement will terminate upon completion of the activities under the AZ SOW.

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, care navigation and specialist educational programs. In addition, by deploying KidneyIntelX at a population health and clinical medicine level, we are able to deduce fixed operating costs associated with hiring and maintaining a direct sales force.

We are focused on hiring and training 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.

Recent reimbursement and regulatory developments

We have recently 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.
- ***Proposed Medicare coverage rule that could benefit the Company.*** In October 2019, President Trump issued an executive order ("Executive Order on Protecting and Improving Medicare for Our Nation's Senior") directing the Secretary of the U.S. Department of Health and Human Services ("HHS") to issue regulations to streamline the approval, coverage, and coding process for certain innovative products, including breakthrough medical devices. As such, in August 2020, the U.S. Centers for Medicare & Medicaid Services ("CMS"), an agency within HHS, submitted for public comment a rule ("Medicare Coverage of Innovative Technology") which, if finalized, would provide an automatic National Medicare Coverage Determination for diagnostic devices that have received Breakthrough Device designation upon the effective date of the promotional approval by the FDA. The automatic coverage period shall continue for a period of four years, during which manufacturers of breakthrough devices may develop additional evidence regarding the applicability of their products to the Medicare population, so they might continue Medicare coverage beyond the initial four years. As we already have a designated Medicare reimbursement code and pricing in effect and were awarded Breakthrough Device designation in May of 2019, we believe that this new proposed CMS rule making, if adopted in its current form, could have a material positive impact on addressable market population with insurance coverage for KidneyIntelX if we obtain FDA clearance for KidneyIntelX. We estimate that the number of DKD patients covered under Medicare exceeds 12 million. However, as a proposed regulation, additional authorization of the Medicare Coverage and Innovative Technology rule is required to become effective. Additionally, we cannot assure you as to the ultimate content, timing, or effect of this proposed rule, if finalized, nor is it possible at this time to estimate the impact of any such potential legislation; however, such changes or the ultimate impact of changes could have on the future sales of our products.

- ***FDA Breakthrough Device Designation Received.*** In May 2019, the FDA granted breakthrough device designation for KidneyIntelX.
- ***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 and New York, we can now provide KidneyIntelX testing services in 47 states (excluding California, Maryland and Pennsylvania).
- ***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.
- ***Submission to FDA seeking clearance of KidneyIntelX.*** We filed a submission seeking clearance of KidneyIntelX with the FDA in August 2020.
- ***ISO Compliance.*** In March 2020, we successfully passed the ISO-13485:2016 inspection. We have been recommended for certification by the notified body.

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. Further, due to the COVID-19 pandemic, millions of individuals have lost, or will be losing, employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

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 and any 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.

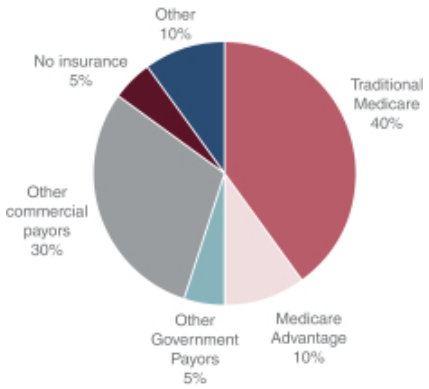
Our coverage and reimbursement strategy

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. We currently anticipate a coverage determination decision under MolDX in calendar year 2021. 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.

In 2020 and 2021, we also plan to accelerate credentialing and coverage contracts with Medicaid programs and providers. We also expect to execute a U.S. Government Services Administration Contract in 2021. This will allow us to provide testing to individual Veterans Administration, or VA, health systems and Department of Defense, or DoD, facilities as we work to secure coverage with the TriCare programs (DoD) and regional VA programs in 2021 and 2022.

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. 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.

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

In June 2019, we announced that multiple production-scale lots of the critical materials had been successfully produced and had met the stringent quality control specifications required to scale up manufacturing for commercial production. This milestone results from a successful collaboration with Meso Scale Diagnostics, LLC, based in Rockville, Maryland, a leading provider of highly sensitive multiplex immunoassays.

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, or 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.

We also have an option with Chirag Parikh and Dennis Moledina to negotiate a non-exclusive license to certain United States pending patent applications that claim methods of detecting markers associated with interstitial nephritis. This option will expire May 25, 2021.

Finally, we have an option with the Icahn School of Medicine at Mount Sinai to negotiate a non-exclusive license to certain United States pending patent applications that claim methods of automated medical diagnosis generally and automated diagnosis of patients with CKD. This option will expire in May 2021.

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, or 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 Registration for our Utah laboratory that allows us to now perform non-waived (moderate and/or high complexity) testing at that site. In 2020, the laboratory is expected to be inspected by the Utah Department of Health to determine its compliance with CLIA regulations. After a successful inspection, CMS will issue a Certificate of Compliance for our Utah laboratory. There will be subsequent annual inspections run by the Utah Department of Health. In June 2020, we also received CLIA certification for our New York laboratory through the New York State Department of Health. Following completion of a volume expansion project in the Utah laboratory, that certification will be transferred to the Utah laboratory.

In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate and use proprietary tests referred to as laboratory developed tests, or 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. In June 2020, we successfully received CLIA certification for our New York laboratory through the New York State Department of Health. We have also initiated the application process for our Utah laboratory in Maryland and expect to initiate the application process for California, Pennsylvania and Rhode Island in the first half of calendar year 2020.

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, or 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). We believe KidneyIntelX qualifies as an LDT and, thus, is currently subject to the FDA's enforcement discretion and not subject to the FDA's active oversight.

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 for us to continue to offer LDTs or to develop and introduce new tests as LDTs. For example, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, in July 2014, the FDA notified the U.S. Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. In October 2014, the FDA issued two draft guidance documents titled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Reporting Guidance. The Framework Guidance stated that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT.

Although the FDA halted finalization of these guidance documents in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017, the FDA could ultimately modify its current approach to LDTs in a way that would subject LDTs to additional regulatory requirements. Legislative measures could likewise result in a

change to the approach to FDA's regulation over LDTs, including a requirement for premarket review of LDTs, among other things. For example, on March 5, 2020, Congress introduced legislation entitled the Verifying Accurate, Leading-edge IVCT Development Act, or VALID Act, which would create a new test product category, *in vitro* clinical tests, or IVCTs, including LDTs and test kits, and would give FDA authority to review and approve such IVCTs. Currently it is unclear whether or in what form such legislation will be enacted.

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. Although we currently intend to market KidneyIntelX as an LDT, we could be subject to more onerous FDA compliance obligations in the future. Specifically, if the FDA begins to actively regulate LDTs, then, 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, or PMA, application, or a de novo request for classification, or 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.

In May 2019, the FDA granted breakthrough device designation for KidneyIntelX. The Breakthrough Devices Program is a voluntary program intended to expedite the review, development, assessment and review of certain medical devices that provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human diseases or conditions for which no approved or cleared treatment exists or that offer significant advantages over existing approved or cleared alternatives. All submissions for devices designated as breakthrough devices will receive priority review, meaning that the review of the submission is placed at the top of the appropriate review queue and receives additional review resources, as needed. Although breakthrough designation or access to any other expedited program may expedite the development or approval process, it does not change the standards for approval. Breakthrough designation may also be withdrawn by the FDA if it believes that the designation is no longer supported by data from our clinical development program. Additionally, breakthrough designation does not ensure that we will ultimately obtain FDA clearance or approval.

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).

Over the last several years, the FDA has proposed reforms to its 510(k) clearance process, and such proposals could include increased requirements for clinical data and a longer review period, or could make it more difficult for manufacturers to utilize the 510(k) clearance process for their products.

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.

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, or 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, or 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, or the FCA, which can result in additional civil and criminal penalties.

Federal and state anti-kickback laws

The federal Anti-Kickback Statute, or the AKS, makes it a felony for a person or entity, including a clinical laboratory, 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, or 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, or 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.

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) and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members. As of January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because our service offerings are currently limited to LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot guarantee, however, that the government will agree with our determination, and 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.

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, or 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 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

Health Insurance Portability And Accountability Act

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, requirements relating to the privacy, security and transmission of protected health information, or PHI, on covered entities including certain healthcare providers, health plans, and health clearinghouses, as well as 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. 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 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. Further, various states, such as California

and Massachusetts, have implemented similar privacy laws and regulations that impose restrictive requirements regulating the use and disclosure of health information and other personally identifiable information. For example, on June 28, 2018, California enacted the California Consumer Privacy Act, or CCPA, which became effective on January 1, 2020. The CCPA creates new individual privacy rights for California consumers (as defined in the law) and places increased privacy and security obligations on entities handling personal data of consumers or households. The CCPA requires covered companies to provide certain disclosures to consumers about its data collection, use and sharing practices, and to provide affected California residents with ways to opt-out of certain sales or transfers of personal information. As of March 28, the California State Attorney General has proposed varying versions of companion draft regulations which are not yet finalized. Despite the delay in adopting regulations, the California State Attorney General will commence enforcement actions against violators beginning July 1, 2020. While any information we maintain in our role as a business associate may be exempt from the CCPA, other records and information we maintain on our customers may be subject to the CCPA. Where state laws are more protective than HIPAA, we must comply with the state laws we are subject to, in addition to HIPAA. In certain cases, it may be necessary to modify our planned operations and procedures to comply with these more stringent state laws. Not only may some of these state laws impose fines and penalties upon violators, but also some, unlike HIPAA, may afford private rights of action to individuals who believe their personal information has been misused. In addition, state laws are changing rapidly, and there is discussion of a new federal privacy law or federal breach notification law, to which we may be subject.

Numerous other federal, state and foreign laws, including consumer protection laws and regulations, govern the collection, dissemination, use, access to, confidentiality and security of patient health information. We intend to continue to comprehensively protect all personal information and to comply with all applicable laws regarding the protection of such information.

The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

We are committed to information technology and data security. Given the AI-derived algorithm that incorporates features from a patient's EHR, we have access to patient data that requires high standards for data integrity. Therefore, we are undergoing compliance activities to submit ISO/IEC 27001:2013 certification, which specifies the requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of the organization. It also includes requirements for the assessment and

treatment of information security risks tailored to the needs of the organization. We expect certification to this standard in the last half of 2020.

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 Affordable Care Act 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 remain judicial and Congressional challenges to certain provisions of the ACA, as well as efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress has 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 Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas, or Texas District Court Judge, ruled that the entire Affordable Care Act is invalid based primarily on the fact that the Tax Cuts and Jobs Act of 2017 repealed the tax-based shared responsibility payment imposed by the ACA, on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate". Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. It is unclear how such litigation and other efforts to repeal and replace the ACA 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 2030 unless additional Congressional action is taken. These Medicare sequester reductions will be suspended from May 1, 2020 through December 31, 2020 due to the COVID-19 pandemic. 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. 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.

C. Organizational structure

The following is a list of our subsidiaries as of October 27, 2020:

Name of Subsidiary	Country of Incorporation	Proportion of Ownership Interest
Renalytix AI, Inc.	United States	100%
Verici Dx Limited (1)	United Kingdom	100%

(1) We announced on July 8, 2020 that the share capital of Verici Dx had been re-designated into 59,416,134 A Shares of £0.001 each and one golden share of £0.001 (the "Golden Share") and that Renalytix would retain the Golden Share and its associated controlling voting rights. Subsequent to that announcement, we entered into a declaration of trust whereby Renalytix AI plc has declared that it holds the Golden Share as nominee and on trust for Fergus Fleming, Erik Lium, James McCullough, Christopher Mills, Barbara Murphy and Chirag Parikh, the Directors of RenalytixAI, and accordingly the Company itself has no ongoing beneficial interest in Verici Dx shares. This change has been made so as to comply with EIS/VCT eligibility for Verici.

D. Property, plants and equipment

We lease office and laboratory space in New York City, New York on short-term leases that automatically renew. In addition, we lease laboratory space in Salt Lake City, Utah, which lease expires in October 2024.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

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, or 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 Diagnostics Holding Plc, or 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 an initial public offering, or IPO, on Nasdaq Global Market, in which we issued and sold 12.6 million ordinary shares which converted into 6.3 million American depository shares at a public offering price of $13.50 per share. In addition, 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.

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

Our Key Agreements

Mount Sinai Health System

In May 2018, we entered into a license agreement, or the Mount Sinai Agreement, with the Icahn School of Medicine at Mount Sinai, or 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 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 entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or 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 use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD, or 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.

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into an Advisory Agreement pursuant to which we have 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 us as the sole consideration for the services to be rendered by us under the Advisory Agreement. A portion of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum 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 us). Through June 30, 2020 we funded $83,333 of our financing contract and incurred $63,139 in losses.

The term of the Advisory Agreement will continue until the fifth anniversary of the execution thereof, unless earlier terminated. The Advisory Agreement may be terminated by either party upon an uncured material breach of the Advisory Agreement by the other party or in the event the other party is unable to perform under the Advisory Agreement for a specified period of time due to a force majeure event. Kantaro may also terminate the Advisory Agreement by notice to us if we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. See “Item 5—Our key agreements—Kantaro Biosciences LLC” for additional information.

Financial operations overview

Revenues

Since our inception, we have not generated any revenue from the sale of KidneyIntelX tests. We have initiated efforts in 2020 to begin deploying KidneyIntelX to patient populations with DKD, on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems’ patients. If these strategic partners fail to meet their key contractual obligations or to purchase KidneyIntelX tests, that will likely have a material adverse effect on us and our ability to achieve our commercial objectives, potentially including the attainment of sales volumes leading to profitability.

Acquired in-process research and development expenses

Acquired in-process research and development expense consists of initial up-front payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under Accounting Standard Codification Topic 805, *Business Combinations. Acquired in-process research and development expense reflects the cash paid or the estimated fair value of the equity consideration given.*

Research and development expenses

Research and development costs consist primarily of costs incurred in connection with the development of KidneyIntelX, in addition to costs associated with FractalDx. 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. In April 2020, we announced our intentions to pursue a spin-off and potential admission to AIM of Verici Dx in order to secure separate financial and management resources for the FractalDx portfolio with the goal of enabling accelerated development. Through June 30, 2020, expenses associated with FractalDx were primarily related to the acquisition of the license and reimbursement of Mount Sinai for patent costs of $1.0 million and $0.3 million, respectively. In addition, we paid an annual maintenance license fee of $25,000 during the year ended June 30, 2020. Our board of directors declared the distribution of shares in Verici Dx to effect the FractalDx spin-off on July 7, 2020, and the distribution occurred on July 10, 2020. Prior to completion of a possible admission to AIM or an equivalent financing transaction, and the establishment of an independent Verici Dx board of directors and independent management team, we retain control of Verici Dx. As a result of our level of control, Verici Dx will continue to be included in our consolidated financial statements and notes thereto.

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 development and 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;
- ability to achieve FDA clearance under our current Breakthrough Device designation process;
- 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. In addition, as part of our long-term strategy we plan to seek FDA clearance or approval so we can sell KidneyIntelX outside a CLIA Certificate of Registration laboratory; however, we would need to conduct additional clinical validation activities on our assays before we can submit an application for FDA approval or clearance.

General and administrative expenses

General and administrative expenses consist principally of legal fees relating to patent and corporate matters; salaries and other personnel-related costs including share-based compensation; professional fees for accounting, auditing, tax and administrative consulting services; 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.

We anticipate that our general and administrative expenses will increase in the future as we increase our headcount to support the continued development and commercialization of KidneyIntelX and any future products. We also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor and public relations expenses associated with maintaining compliance with stock exchange listing and SEC requirements, accounting and investor relations costs, and director and officer insurance premiums associated with being a company that is both publicly listed in the United States and admitted to trading on AIM in the United Kingdom.

Equity losses in affiliate

Equity losses in affiliate represents the recognition of our proportionate share of losses in Kantaro.

Other income (expense)

Other income primarily consists of realized gains on the sale of short-term investments, foreign currency income (losses) due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency, and the sale of excess supplies. The income is offset by the interest expense related to our related party borrowings from EKF that were repaid in their entirety in November 2018.

Consolidated results of operations

(in thousands)	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
Operating expenses:			
Acquired in-process research and development	$ —	$ 35,286	$ —
Research and development	4,565	4,316	193
General and administrative	5,750	2,737	374
Loss from operations	(10,315)	(42,339)	(567)
Equity losses in affiliate	(63)	—	—
Other income, net	534	38	(5)
Net loss	$ (9,844)	$(42,301)	$ (572)

Comparison of years ended June 30, 2020 and 2019

Acquired in-process research and development expenses

During the year ended June 30, 2019, we recognized $35.3 million in acquired in-process research and development expenses in connection with the upfront payments to acquire exclusive licenses from Mount Sinai of $11.0 million and the estimated fair value of our ordinary shares issued to EFK upon assignment of the license with Joslin of $24.3 million. Given the timing of the assignment of the Joslin license in October 2018 and our IPO in November 2018, the estimated fair value of our ordinary shares issued to EKF was estimated to be equal to the IPO price.

Research and development expenses

Research and development expenses increased by $0.3 million from $4.3 million for the year ended June 30, 2019 to $4.6 million for year ended June 30, 2020. The increase was attributable to an increase of $1.1 million in compensation and related benefits, including share-based payments, due to increased headcount, $0.4 million increase in consulting and professional fees, $0.2 million increase for facility leases, offset by $0.9 million decrease in clinical expenses and lab supplies purchases and $0.5 million decrease in lab supplies purchases.

General and administrative expenses

General and administrative expenses increased $3.1 million from $2.7 million for the year ended June 30, 2019 to $5.8 million for the year ended June 30, 2020. The increase was due to an increase of $1.6 million in compensation and related benefits, including share-based payments, due to increased headcount, $0.9 million increase in consulting and professional fees and an increase of $0.6 million in marketing, facility and other operating expenses in preparation of product launch.

Equity losses in affiliate

During the year ended June 30, 2020, we recognized $63,139 in losses which represents our proportionate share of losses in Kantaro.

Other income (expense)

We received $34,000 of interest income during the year ended June 30, 2019 as a result of interest earned on cash deposits and incurred $16,000 in interest expense on our related-party note with EKF. The related-party note was repaid in November 2018. We recognized a realized foreign exchange gain of $20,000 during the year ended June 30, 2019. During the year ended June 30, 2020, we received $0.1 million of interest income as a result of interest earned on cash deposits and realized gains of $0.1 million on the sale of U.S. Treasury securities. We also recognized unrealized foreign exchange gains of $0.2 million and other income of $0.1 million related to the sale of excess supplies during the year ended June 30, 2020.

Comparison of year ended June 30, 20219 and the period from March 15, 2018 (inception) through June 30, 2018

Acquired in-process research and development expenses

During the year ended June 30, 2019, we recognized $35.3 million in acquired in-process research and development expenses in connection with the upfront payments to acquire exclusive licenses from Mount Sinai of $11.0 million and the estimated fair value of our ordinary shares issued to EFK upon assignment of the license with Joslin of $24.3 million. Given the timing of the assignment of the Joslin license in October 2018 and our IPO in November 2018, the estimated fair value of our ordinary shares issued to EKF was estimated to be equal to the IPO price.

Research and development expenses

Research and development expenses increased by $4.1 million from $0.2 million for the period from March 15, 2018 (inception) through June 30, 2018 to $4.3 million for the year ended June 30, 2019. In the year ended June 30, 2019, we incurred $3.6 million of research and development expenses as we commenced our clinical validation studies for KidneyIntelX. We also incurred $0.7 million in personnel-related expenses due to increased headcount, of which $0.3 million was share-based compensation expense associated with the options we granted in November 2018.

General and administrative expenses

General and administrative expenses increased $2.4 million from $0.4 million for the period from March 15, 2018 (inception) through June 30, 2018 to $2.8 million for the year ended June 30, 2019. The increase was due to an increase of $0.7 million in professional fees, primarily related to legal, accounting , and consulting services as we operate as a publicly traded company in the United Kingdom, $0.8 million in compensation and related benefits due to increased headcount, $0.4 million of travel expenses, $0.5 million of marketing, facility and other operating expenses.

Other income (expense)

We incurred $5,000 of interest expense on our related party note with EKF for the period from March 15, 2018 (inception) through June 30, 2018. We received $34,000 of interest income during the year ended June 30, 2019 as a result of interest earned on cash deposits and incurred $16,000 in interest expense on our related-party note with EKF. The related-party note was repaid in November 2018. We recognized a realized foreign exchange gain of $20,000 during the year ended June 30, 2019.

Liquidity and capital resources

Since our inception, we have incurred net losses. We incurred net losses of $9.8 million and $42.3 million for the years ended June 30, 2020 and 2019, respectively. We incurred a net loss of $0.6 million for the period from March 15, 2018 (inception) through June 30, 2018. As of June 30, 2020, we had an accumulated deficit of $52.7 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, particularly 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, upon the completion of our offering of stock on Nasdaq in July 2020, 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, timing and outcome of entering into and maintaining partnership agreements with healthcare systems for the commercial sale of KidneyIntelX;
- 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, if any, 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, such as Kantaro, although we currently have no other commitments or agreements to complete any such transactions.

To date, we have primarily financed our operations through equity financings. As of June 30, 2020, we had cash, cash equivalents and short-term investments of $14.3 million. We believe that our existing cash, cash equivalents and short-term investments, along with approximately $76.1 million of net proceeds from the sale of ordinary shares in July 2020 will enable us to fund our current operating plan for at least the next 12 months. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Until such time, if ever, as we can generate substantial revenue from sales of KidneyIntelX tests, we expect 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. 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. Historically, we have not obtained traditional debt financing. EKF provided short-term debt financing that was repaid in November 2018 and we received a loan in an aggregate principal amount of $255,000 pursuant to the Paycheck Protection Program (the "PPP") under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. 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 the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. 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, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
Net cash used in operating activities	$ (9,522)	$ (6,156)	$ (427)
Net cash used in investing activities	$ (1,174)	$ (12,300)	$ —
Net cash provided by financing activities	$ 15,938	$ 27,383	$ 508
Effect of exchange rate changes on cash	$ (150)	$ (808)	$ 1

Net cash used in operating activities

During the year ended June 30, 2020, net cash used in operating activities was $9.5 million and was primarily attributable to our $9.8 million net loss and $0.7 million in the net change in our operating assets and liabilities that was offset by $1.0 million in noncash charges. The change in our operating assets and liabilities was

primarily attributable to $0.5 million decrease in our accrued expenses and other current liabilities due to the timing of payment to our vendors. Noncash charges were primarily related to share-based compensation expense of $1.2 million.

During the year ended June 30, 2019, net cash used in operating activities was $6.2 million and was primarily attributable to our $42.3 million net loss that was offset by $35.8 million in noncash charges and $0.3 million in the net change in our operating assets and liabilities. Noncash charges were primarily related to the in-process research and development charge of $35.3 million and our share-based compensation expense of $0.5 million. Our upfront payments to Mount Sinai of $11.0 million were recognized as outflow investing activities and then immediately expensed as a non-cash operating inflow activities as these expenses were determined to have no alternative future use and not eligible to be capitalized. We also recognized an in-process research and development expense of $24.3 million in connection with the estimated fair value of our ordinary shares issued to EKF in exchange for acquiring the license with Joslin. The change in our operating assets and liabilities was primarily attributable to $0.5 million increase in our payables and accrued expenses and due to the timing of payment to our vendors.

During the period from March 15, 2018 (inception) through June 30, 2018, net cash used in operating activities was $0.4 million and was primarily attributable to our $0.6 million net loss that was offset by $0.2 million in the net change in our operating assets and liabilities as we had limited operating activity from our inception date of March 15, 2018 through June 30, 2018.

Net cash provided by and used in investing activities

During the year ended June 30, 2020 net cash used in investing activities was $1.2 million and primarily attributable to $0.8 million for the purchase of lab and office equipment and $0.4 million of software development costs. In addition, we had net purchases of $0.1 million related to our short-term investments and advanced $83,333 to Kantaro.

During the year ended June 30, 2019, net cash used in investing activities was $12.3 million and primarily attributable to licenses purchased from Mount Sinai of $11.0 million and $0.3 million for the purchase of lab equipment. In addition, we had net proceeds of $1.0 million related to our short-term investments. We had no investing activities during the period from March 15, 2018 (inception) through June 30, 2018.

Net cash provided by financing activities

During the year ended June 30, 2020, net cash provided by financing activities was $15.9 million and was primarily attributable to $16.4 million of net proceeds of secondary public offering on AIM and proceeds of $0.3 million from the PPP loan offset by payments of $0.8 million for offering costs related to our initial public offering on the Nasdaq Global Market.

During the year ended June 30, 2019, net cash provided by financing activities was $27.4 million and was primarily attributable to net proceeds of $27.8 million in connection with our IPO in November 2018. We also received $0.6 million in additional borrowings with EKF. Upon completion of the IPO, we made payments of $1.0 million to EKF to repay all outstanding borrowings.

During the period from March 15, 2018 (inception) through June 30, 2018, net cash provided by financing activities was $0.5 million and primarily attributable to the $0.4 million in borrowings from EKF to fund our operations until we completed our IPO. We also received $66,000 in cash proceeds in May 2018 upon issuing our ordinary shares in connection with our formation.

Contractual obligations and commitments

See Item 5.F, “—Tabular Disclosure of Contractual Obligations” below.

Off-balance sheet arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

Critical accounting policies

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.

Equity method investment

We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro. In connection with the formation of Kantaro, we entered into a five-year Advisory Services Agreement ("Advisory Agreement") pursuant to which we agreed to provide certain services to Kantaro. We 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 requires several judgments and assumptions which include discount rates and future cash flows, among others.

Research and development expenses

Research and development expenses consist primarily of costs incurred in connection with the development of KidneyIntelX, in addition to costs associated with FractalDx. 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.

Acquired in-process research and development

Acquired in-process research and development expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of diagnostic products that do not meet the definition of a business under Accounting Standard Codification Topic 805, *Business Combinations*. Consideration paid in connection with asset acquisitions are expensed immediately if they have no alternative future use or have not achieve technological feasibility at the time of acquisition.

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.

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.

Qualitative and quantitative disclosures about market risk

We report our consolidated financial results in U.S. dollars. Renalytix AI plc’s, Renalytix AI, Inc.’s and Verici Dx Limited’s function currency is their local currency. The functional currency of Renalytix Al plc and Verici Dx Limited is the pound sterling which is translated into the U.S. dollar for assets and liabilities at the exchange rate at the balance sheet dates and revenue and expenses are translated at the weighted-average exchange rates during the reporting period. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to accumulated other comprehensive income (loss), a component of shareholders’ (deficit) equity.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

We are exposed to market risk related to changes in interest rates. As of June 30, 2020, we had cash, cash equivalents and short-term investments of $14.3 million consisting of bank deposits and U.S. Treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities.

Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase. Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our available-sale-securities until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

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 are in the process of evaluating 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 may 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 $1.07 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.

C. Research and Development

For a discussion of our research and development activities, see "Item 4.B—Business Overview" and "Item 5.A—Operating Results."

D. Trend Information

For a discussion of trends, see "Item 4.B—Business Overview," "Item 5.A—Operating Results" and "Item 5.B—Liquidity and Capital Resources."

E. Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any relationships with unconsolidated entities or financial partnerships, including entities sometimes referred to as structured finance or special purpose entities that were established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purposes. We do not engage in off-balance sheet financing arrangements. In addition, we do not engage in trading activities involving non-exchange traded contracts. We therefore believe that we are not materially exposed to any financing, liquidity, market or credit risk that could arise if we had engaged in these relationships.

F. Tabular Disclosure of Contractual Obligations

The following table summarizes our contractual obligations at June 30, 2020 (in thousands):

	Total	Less than 1 year	1 to 3 years	3 to 5 years	Greater than 5 years
Operating leases(1)	$482	$ 205	$249	$ 28	$ —
Note payable(2)	$255	$ 120	$135	$—	$ —
Total	$737	$ 325	$384	$ 28	$ —

(1) Reflects obligations related to our commercial laboratory operation in Salt Lake City, Utah and our JLabs lab facility in New York City, New York.
(2) Reflects obligations related to repayment of the PPP loan.

The commitment amounts in the table above are associated with contracts that are enforceable and legally binding and that specify all significant terms, including fixed or minimum services to be used, fixed, minimum or variable price provisions, and the approximate timing of the actions under the contracts. Payments due upon cancellation consisting only of payments for services provided or expenses incurred, including non-cancellable obligations of our service providers, up to the date of cancellation are not included in the preceding table as the amount and timing of such payments are not known.

Under the terms of the Mount Sinai license and sponsored research agreements 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. In addition, 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 from a sublicensee. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

Under the terms of the Mount Sinai license agreement for FractalDx we are obligated to pay Mount Sinai $0.3 million upon receipt of certain regulatory clearance and approval, $0.3 million upon receipt of U.S. CMS reimbursement code or PAMA reimbursement approval. In addition, we are obligated to pay Mount Sinai $1.0 million and $4.0 million in commercial milestone payments upon achieving worldwide net sales of FractalDx of $50.0 million and $250.0 million, respectively. We are also obligated to pay Mount Sinai a 6% to 8% royalty on net sales of FractalDx, subject to customary reductions. Moreover, we are obligated to pay Mount Sinai between 15% and 70% of any consideration received from a sublicensee.

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 from a sublicensee.

The contractual obligations table does not include any potential royalty or milestone payments that we may be required to make under our license agreements with Mount Sinai and Joslin. We excluded these royalty and milestone payments given that the timing of any such payments cannot be reasonably estimated at this time.

G. Safe Harbor

This annual report contains forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act and as defined in the Private Securities Litigation Reform Act of 1995. See “Special Note Regarding Forward-Looking Statements.”

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors, including their ages as of October 1, 2020.

Name	Age	Position(s)
Executive Officers:		
James McCullough	52	Chief Executive Officer and Director
Fergus Fleming	53	Chief Technical Officer and Director
Thomas McLain	62	President and Chief Commercial Officer
O. James Sterling	50	Chief Financial Officer
Michael J. Donovan, Ph.D., M.D.	66	Chief Medical Officer
Non-Executive Directors:		
Erik Lium, Ph.D.	52	Non-Executive Director
Christopher Mills	67	Non-Executive Director
Barbara Murphy, M.D.	56	Non-Executive Director
Chirag R. Parikh, Ph.D., M.D.	47	Non-Executive Director

Executive officers

James McCullough has served as our co-founder and Chief Executive Officer since our inception. Mr. McCullough has leadership experience building emerging technology companies in both the public and private sectors with specific expertise in the life-sciences industry. From 2008 to 2014, he served as chief executive officer of Exosome Diagnostics Inc., a venture backed personalized medicine company developing non-invasive liquid biopsy diagnostics in cancer that was acquired by Bio-Techne Corporation in 2018. Since 2014, Mr. McCullough has also served as a managing partner of Renwick Capital, LLC, a management consulting firm specializing in assisting emerging healthcare technology companies with strategic planning and business execution. He received his B.A. from Boston University and an MBA from Columbia Business School.

Fergus Fleming has served as our Chief Technical Officer since our inception. Mr. Fleming has served as managing director of FF Consulting Limited, providing Product Development and Commercialization support to Medical Devices and Diagnostics companies since June 2013. Roles in this period include Head of Business Development for Oncomark Limited from November 2016 to October 2018 and from 2013, he served in various roles at EKF Diagnostics plc. He has over 30 years of experience in the life sciences sector, including leadership positions with Baxter Healthcare, Boston Scientific and Trinity Biotech plc. Mr. Fleming received a degree in Science from University College Galway, Ireland.

Thomas McLain has served as our President and Chief Commercial Officer since July 2019. Prior to joining Renalytix AI, he held leading positions, including as Chief Executive Officer, of Exosome Diagnostics Inc. from July 2014 to July 2019. Mr. McLain has also served as President and Chief Executive Officer of Vermillion, Inc., Chief Executive Officer of Claro Scientific LLC, Chairman, Chief Executive Officer and President of Nabi Biopharmaceuticals and Vice President at Bausch & Lomb. Mr. McLain received his B.A. in Economics at College of the Holy Cross and his MBA at the William E. Simon Graduate School of Business Administration at University of Rochester.

O. James Sterling, MBA, has served as our Chief Financial Officer since our inception. Since May 2015, Mr. Sterling has also served as a managing partner of Renwick Capital, LLC. Previously, he served as a managing director at SF Sentry Securities, Brock Capital Group LLC and Aleutian Capital Group. Mr. Sterling also has experience as a management consultant at Booz Allen Hamilton. He received his B.A. in geography (alternative energy and environmental science) from Boston University and an MBA from Columbia Business School.

Michael J. Donovan, Ph.D., M.D. has served as our Chief Medical Officer since our inception. Since November 2011, Donovan has also served as a Professor of Experimental Pathology and Director of the Biorepository and Pathology core at the Icahn School of Medicine at Mount Sinai. In addition to an academic career at Harvard Medical School and Boston Children's Hospital, Dr. Donovan has over 20 years' experience in the biotechnology industry, serving in various senior management roles at Millennium Pharmaceuticals and Incyte Pharmaceuticals. He most recently served as Chief Clinical Officer of Vigilant Biosciences, Inc., Chief Medical Officer of MetaStat, Inc. and Chief Medical Officer of Exosome Diagnostics, Inc. Dr. Donovan received a B.S. in Zoology, an M.S. in Endocrinology and a Ph.D. in Cell and Developmental Biology from Rutgers University. He received his M.D. from the University of Medicine and Dentistry of New Jersey.

Non-executive directors

Christopher Mills has served as a member of our board of directors since our inception. Mr. Mills founded Harwood Capital Management in 2011, a successor from its former parent company J.O. Hambro Capital Management, which he co-founded in 1993. He is chief executive officer and investment manager of North Atlantic Smaller Companies Investment Trust plc and chairman and chief executive officer of Harwood Capital Management Ltd. Prior to that, Mr. Mills was a Director of Invesco MIM, where he was head of North American Investments and Venture Capital, and of Samuel Montagu International. Mr. Mills currently serves on the board of a number of public companies, including EKF Diagnostics plc, Sureserve Group plc, Augean plc and MJ Gleeson plc. Mr. Mills received a B.A. in Business Studies from Guildhall University.

Erik Lium, Ph.D. has served as a member of our board of directors since November 2018. Since March 2014, Dr. Lium has served in various roles at Mount Sinai, where he is currently the president of Mount Sinai Innovation Partners, and the executive vice president and chief commercial innovation officer of the Mount Sinai Health System. Dr. Lium represents Mount Sinai on several private company boards and previously served as a member of the investment review committee for the Accelerate NY Seed Fund. Dr. Lium also serves as chairman of the board of managers of Kantaro. Prior to joining Mount Sinai, Dr. Lium served as the assistant vice chancellor of Innovation, Technology & Alliances at the University of California, San Francisco (UCSF), the UCSF principal investigator for the Bay Area National Science Foundation I-Corps node, and assistant vice chancellor of Research. Dr. Lium served as president of LabVelocity Inc. prior to its acquisition in 2004. He pursued postdoctoral research at UCSF in the laboratory of J. Michael Bishop, M.D., earned a Ph.D. from the Integrated Program in Cellular, Molecular and Biophysical Studies at Columbia University in the laboratory of Dr. Saul J. Silverstein, and holds a B.S. in Biology from Gonzaga University.

Barbara Murphy, M.D. has served as a member of our board of directors since November 2018. Since 2013, Dr. Murphy has served as the Murray M. Rosenberg Professor of Medicine, chair of the Department of Medicine for Mount Sinai and Dean for Clinical Integration and Population Health. Her area of interest is transplant immunology, focusing on the use of high throughput genomic technologies as a means to understand the immune mechanisms that lead to graft injury and loss, with the aim of identifying gene expression profiles and or genetic variants that may be used to predict those at greatest risk. Dr. Murphy belongs to a number of professional societies including the American Society of Transplantation and the American Society of Nephrology, and has held many leadership roles at a national level. She is a past President of the American Society of Transplantation and is currently on Council for the American Society of Nephrology. Dr. Murphy earned her M.B. B.A.O. B.Ch. from The Royal College of Surgeons in Ireland and completed her postdoctoral training with a fellowship in Nephrology at Brigham and Women's Hospital, Harvard Medical School.

Chirag R. Parikh, Ph.D., M.D. has served as a member of our board of directors since October 2019. Since July 2018, Dr. Parikh has served as a Professor of Medicine and the Division Director of Nephrology at Johns Hopkins University. Dr. Parikh also served a faculty member at Yale University where he directed the Program of Applied Translational Research. Dr. Parikh's research focuses on the translation and validation of novel biomarkers for the diagnosis and prognosis of kidney diseases. He has assembled multicenter longitudinal prospective cohorts for translational research studies across several clinical settings of acute kidney injury and

chronic kidney disease for the efficient translation of novel biomarkers. Dr. Parikh received his medical degree from Seth G.S. Medical College and KEM Hospital in Mumbai, India and subsequently completed his Nephrology fellowship and a Ph.D. in Clinical Investigation at the University of Colorado Health Sciences Center.

Family Arrangements and Selection Arrangements

There are no family relationships between any of our executive officers or directors, nor are there any arrangements or understandings with major shareholders, customers, suppliers or others, pursuant to which any executive officer or director was selected as such.

B. Compensation

Director Compensation

The remuneration of our non-executive directors is proposed by the remuneration committee and determined by our board of directors as a whole, based on a review of current practices in other companies. The remuneration paid to our non-executive directors during the year ended June 30, 2020 is set forth in the table below.

Name	Salary and fees
Julian Baines, MBE(1)	$ 14,892
Richard Evans(2).	—
Christopher Mills	22,378
Barbara Murphy, M.D.	41,605
Mount Sinai(3)	25,215
Chirag R. Parikh, Ph.D., M.D.(4)	18,030

(1) Mr. Baines resigned from our board of directors in July 2020.
(2) Mr. Evans resigned from our board of directors in July 2020.
(3) Dr. Lium sits on our board as a representative of the Icahn School of Medicine at Mount Sinai. This fee is invoiced annually by Mt. Sinai.
(4) Dr. Parikh joined our board of directors in October 2019.

In addition to their fees for acting as a non-executive director and as a chair and/or member of any of our board committees, certain of our non-executive directors have been granted options over our ordinary shares under our Share Option Plan. The following tables set forth the options held by non-executive directors as of June 30, 2020:

Name	Number of ordinary shares underlying options	Option price per ordinary share
Julian Baines, MBE	—	£ —
Richard Evans.	—	—
Christopher Mills	—	—
Barbara Murphy, M.D.	269,081	1.21
Mount Sinai(1)	204,501	1.21
Chirag R. Parikh, Ph.D., M.D.	130,724	1.71

(1) Dr. Lium sits on our board as a representative of the Icahn School of Medicine at Mount Sinai. Mount Sinai receives all fees payable in respect of Erik Lium's service as a non-executive director, and Mount Sinai has been granted an option under our Share Option Plan in relation to such service.

In addition, each of the non-executive directors is entitled to be reimbursed for reasonable and properly documented expenses incurred in performing their duties as a director.

Non-executive director agreements

We have entered into a letter of appointment with each of our non-executive directors. The appointment of our non-executive directors can be terminated at any time by either us or the applicable non-executive director by giving six months' written notice. On termination of the appointment, the non-executive director shall only be entitled to such fees as may have accrued to the date of termination, together with reimbursement in the normal way of any expenses properly incurred prior to that date. We may also terminate an appointment with immediate effect if the non-executive director: (1) commits a material breach of his or her obligations under the letter of appointment; (2) commits a serious or repeated breach or non-observance of his obligations to our company; (3) is guilty of any fraud or dishonesty or acts in a manner which, in our opinion, brings or is likely to bring him or us into disrepute or is materially adverse to our interests; or (4) is convicted of an arrestable criminal offense other than a road traffic offense for which a fine or non-custodial penalty is imposed.

Executive Officer Compensation

For the year ended June 30, 2020, the aggregate compensation paid to the members of our board of directors and our executive officers for services in all capacities was $2,784,417. This amount includes the following compensation paid to our executive directors:

Executive Director	Salary and Consulting Fees	Non-Equity Incentive Plan Compensation(1)	Other Compensation	Total
James McCullough	$ 470,271	$ —	$ 17,450(2)	$487,721
Fergus Fleming	$ 320,256(3)	$ —	$ 19,690	$339,946

(1) The amounts reflect the full grant date fair value of option grants under our Share Option Plan, computed in accordance with ASC Topic 718, *Compensation—Stock Compensation*.
(2) Consists of our contributions towards Mr. McCullough's 401(k) plan and life insurance premiums.
(3) Mr. Fleming's salary is paid in euros. The amount in the table is based on the exchange rate on June 28, 2019 of £1.00 = $1.1237.

The amounts paid to each of the non-executive members of our board of directors is set forth below under "—Non-executive director remuneration."

During the year ended June 30, 2020, our executive officers participated in performance-based compensation programs and we paid amounts to provide pension and healthcare benefits to our executive officers.

During the year ended June 30, 2020, options to purchase 1,011,743 ordinary shares were awarded to our executive officers and directors. As of June 30, 2020, our executive officers and directors held options to purchase 1,684,445 ordinary shares. Our executive officers and directors did not exercise options to purchase ordinary shares during the year ended June 30, 2020.

We periodically grant share options to employees, directors and consultants to enable them to share in our successes and to reinforce a corporate culture that aligns their interests with that of our shareholders. During the fiscal year ended June 30, 2020, we did not grant options to purchase ordinary shares to any employees or consultants who are not directors or executive officers.

Executive officer employment agreements

Employment agreement of James McCullough

James McCullough, our Chief Executive Officer, is employed by Renalytix AI, Inc., our wholly owned U.S. subsidiary, and entered into an employment agreement with Renalytix AI, Inc. in November 2018. Mr. McCullough also entered into a separate appointment letter with us in October 2018, which governs the terms of his appointment as a director. He receives no compensation or benefits for his service as a director above those that are provided under the employment agreement.

Pursuant to the terms of the employment agreement, Mr. McCullough is entitled to annual base salary, initially $350,000, which is subject to annual review by our remuneration committee and to a minimum annual increase of 3%. Our remuneration committee has approved an increase to Mr. McCullough's annual base salary to $589,000, effective on and from the date our ADSs begin trading on Nasdaq. Under the terms of the employment agreement, Mr. McCullough is also: (1) eligible for an annual cash bonus in the sole discretion of the remuneration committee; (2) entitled to participate on the same basis as similarly situated employees in our benefit plans in effect from time to time during his employment; and (3) entitled to five weeks' holiday per annum.

Mr. McCullough is employed at-will. If his employment is terminated by us without "Cause," as defined in the employment agreement, and in circumstances constituting a "separation from service," as defined in the U.S. Treasury Regulation Section 1.409A-1(h), or by Mr. McCullough with "Good Reason," as defined in the employment agreement, Mr. McCullough is entitled to be paid his salary and benefits in the usual way up to his termination date and, provided he complies with certain conditions including execution of a release, is entitled to receive the following severance benefits:

- 12 months' base salary;
- if elected, continued coverage under the Consolidated Omnibus Budget Reconciliation Act of 1985, or COBRA, for himself and his covered dependents for up to 12 months following termination;
- any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked; and
- accelerated vesting of the portion of equity awards held by Mr. McCullough which would have vested within 12 months following the termination date had Mr. McCullough remained in employment for such period, or full vesting of all equity in the event of a "Change in Control," as defined in the employment agreement.

In the event that Mr. McCullough's employment is terminated by us due to his death or "Disability," as defined in the employment agreement, he is entitled to receive any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked.

Mr. McCullough has also entered into an employee confidential information and invention assignment agreement with Renalytix AI, Inc., which governs matters related to confidentiality, intellectual property and post-termination covenants. Mr. McCullough is subject to confidentiality obligations which remain in place following termination of employment, and to non-solicitation and non-compete restrictive covenants for a period of 12 months post-termination of his employment.

Employment agreement of Fergus Fleming

Fergus Fleming, our Chief Technology Officer, entered into an employment agreement with us in November 2018, which agreement also governs the terms of his appointment as a director.

Pursuant to the terms of the employment agreement, Mr. Fleming is entitled to an annual base salary, initially €200,000, which is subject to annual review by our remuneration committee. Our remuneration committee has approved an increase to Mr. Fleming's annual base salary to €340,000, effective on and from the date our ADSs begin trading on Nasdaq. Under the terms of the employment agreement, Mr. Fleming is also: (1) eligible to join any pension scheme we operate from time to time and, should he so join, we will make contributions to such pension scheme at a rate of 5% of Mr. Fleming's annual base salary each year; (2) entitled to a car allowance of €5,000 per year, for so long as he holds a driving license; (3) entitled to participate, at our expense, in our private medical expenses insurance scheme; and (4) entitled to 25 days' holiday per annum, plus holiday pay during the period between Christmas and New Year each year.

Mr. Fleming's employment is terminable by either party on not less than 12 months' prior written notice. We may elect to terminate Mr. Fleming's employment prior to the expiration of any such notice by notifying him of such and paying him his basic salary in lieu of the remaining period of notice in full and final settlement of any claims he may have against us or any of our subsidiaries. We may elect to put Mr. Fleming on garden leave for all or part of any period of notice, or if or if he seeks to or indicates an intention to resign as a director or any of our subsidiaries or terminate his employment without notice.

The employment agreement contains standard assignment provisions relating to the ownership of intellectual property. Mr. Fleming is subject to confidentiality obligations which remain in place following termination of employment, and to non-solicitation and non-compete restrictive covenants for a period of nine months post-termination of his employment.

Employment agreement of Thomas McLain

Thomas McLain, our President and Chief Commercial Officer, is employed by Renalytix AI, Inc. and entered into an employment agreement with Renalytix AI, Inc. in June 2019.

Pursuant to the terms of the employment agreement, Mr. McLain is entitled to an annual base salary, initially $300,000, which is subject to annual review by our remuneration committee and to a minimum annual increase of 3%. Our remuneration committee has approved an increase to Mr. McLain's annual base salary to $408,000, effective on and from the date our ADSs begin trading on Nasdaq. Mr. McLain is also: (1) eligible for an annual cash bonus in the sole discretion of our remuneration committee; (2) entitled to participate on the same basis as similarly situated employees in our benefit plans in effect from time to time during his employment; and (3) entitled to five weeks' holiday per annum.

Mr. McLain is employed at-will. If his employment is terminated by us without "Cause," as defined in the employment agreement, and in circumstances constituting a "separation from service," as defined in the U.S. Treasury Regulation Section 1.409A-1(h), or by Mr. McLain with "Good Reason," as defined in the employment agreement, Mr. McLain is entitled to be paid his salary and benefits in the usual way up to his termination date and, provided he complies with certain conditions, including execution of a release, is entitled to receive the following severance benefits:

- six months' base salary;
- if elected, continued coverage under COBRA for himself and his covered dependents for up to 12 months following termination;
- any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked; and
- accelerated vesting of the portion of equity awards held by Mr. McLain which would have vested within one year following the termination date had Mr. McLain remained in employment for such period, or full vesting of all equity in the event of a "Change in Control," as defined in the employment agreement.

In the event that Mr. McLain's employment is terminated by our U.S. subsidiary due to his death or "Disability," as defined in the employment agreement, he is entitled to receive any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked.

Mr. McLain has also entered into an employee confidential information and invention assignment agreement with Renalytix AI, Inc., which governs matters related to confidentiality, intellectual property and post-termination covenants. Mr. McLain is subject to confidentiality obligations which remain in place following termination of employment, and to non-solicitation and non- compete restrictive covenants for a period of 12 months post-termination of his employment.

Employment agreement of O. James Sterling

O. James Sterling, our Chief Financial Officer, is employed by Renalytix AI, Inc. and entered into an employment agreement with Renalytix AI, Inc. in November 2018.

Pursuant to the terms of the employment agreement, Mr. Sterling is entitled to an annual base salary, initially $275,000, which is subject to annual review by our remuneration committee and to a minimum annual increase of 3%. Our remuneration committee has approved an increase to Mr. Sterling's annual base salary to $420,000, effective on and from the date our ADSs begin trading on Nasdaq. Mr. Sterling is also: (1) eligible for an annual cash bonus in the sole discretion of our remuneration committee; (2) entitled to participate on the same basis as similarly situated employees in our benefit plans in effect from time to time during his employment; and (3) entitled to five weeks' holiday per annum.

Mr. Sterling is employed at-will. If the employment is terminated by us without "Cause," as defined in the employment agreement and in circumstances constituting a "separation from service," as defined in the U.S. Treasury Regulation Section 1.409A-1(h) or by Mr. Sterling with "Good Reason," as defined in the service agreement, Mr. Sterling is entitled to be paid his salary and benefits in the usual way up to his termination date and, provided he complies with certain conditions, including execution of a release, is entitled to receive the following severance benefits:

- 12 months' base salary;
- if elected, continued coverage under COBRA for himself and his covered dependents for up to 12 months following termination;
- any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked; and
- accelerated vesting of the portion of equity awards held by Mr. Sterling which would have vested within one year following the termination date had Mr. Sterling remained in employment for such period, or full vesting of all equity in the event of a Change in Control," as defined in the employment agreement.

In the event that Mr. Sterling's employment is terminated by us due to his death or "Disability," as defined in the employment agreement, he is entitled to receive any accrued but unpaid bonus in relation to any prior year's employment, together with a pro rata bonus in respect of the portion of the then current year worked.

Mr. Sterling has also entered into an employee confidential information and invention assignment agreement with Renalytix AI, Inc., which governs matters related to confidentiality, intellectual property and post-termination covenants. Mr. Sterling is subject to confidentiality obligations which remain in place following termination of employment, and to non-solicitation and non- compete restrictive covenants for a period of 12 months post-termination of his employment.

Contractor Agreement of Michael J. Donovan, Ph.D., M.D.

Michael J. Donovan, Ph.D., M.D., our Chief Medical Officer, provides services to us pursuant to an independent contractor services agreement entered into with Renalytix AI, Inc. in November 2018.

Pursuant to the terms of this agreement, Dr. Donovan is entitled to: $10,000 per month, or part thereof; and the grant of an option over our ordinary shares as detailed in his option grant.

The agreement is terminable by either party at any time on 10 days' written notice. On such termination, Dr. Donovan is entitled to receive fees accrued prior to the date of termination.

The agreement contains standard assignment provisions relating to the ownership of intellectual property. Dr. Donovan is subject to confidentiality obligations which remain in place following termination of his engagement.

Limitations on Liability and Indemnification Matters

To the extent permitted by the Companies Act, we are empowered to indemnify our directors against any liability they incur by reason of their directorship. We maintain directors' and officers' insurance to insure such persons against certain liabilities. We have entered into a deed of indemnity with each of our directors and executive officers. In addition to such indemnification, we provide our directors and executive officers with directors' and officers' liability insurance.

Insofar as indemnification of liabilities arising under the Securities Act may be permitted to our board, executive officers or persons controlling us pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Equity Incentive Plans

The principal features of our equity incentive plans are summarized below. These summaries are qualified in their entirety by reference to the actual text of the plan, each of which are filed as exhibits to this annual report.

2020 Equity Incentive Plan

Our board of directors has adopted and our shareholders have approved our 2020 Equity Incentive Plan, or EIP, as of July 2020.

Eligibility and administration

Our employees and directors, who are also our employees, and employees of our subsidiaries are eligible to receive awards under the 2020 EIP. Our consultants and directors, who are not employees, and those of our subsidiaries, are eligible to receive awards under the 2020 Non-Employee Sub-Plan to the 2020 EIP described below. Persons eligible to receive awards under the 2020 EIP (including the 2020 Non-Employee Sub-Plan) are together referred to as service providers below. Except as otherwise specified, references below to the 2020 EIP include the 2020 Non-Employee Sub-Plan.

The 2020 EIP is administered by our board of directors, which may delegate its duties and responsibilities to one or more committees of our directors and/or officers (referred to as the Plan Administrator below), subject to certain limitations imposed under the 2020 EIP, and other applicable laws and stock exchange rules. The Plan Administrator has the authority to take all actions and make all determinations under the 2020 EIP, to interpret the 2020 EIP and award agreements and to adopt, amend and repeal rules for the administration of the 2020 EIP as it deems advisable. The Plan Administrator also has the authority to determine which eligible service providers receive awards, grant awards, set the terms and conditions of all awards under the 2020 EIP, including any vesting and vesting acceleration provisions, subject to the conditions and limitations in the 2020 EIP.

Shares available for awards

The maximum number of ordinary shares that may be issued under our 2020 EIP is 8,500,000 ordinary shares. No more than 25,500,000 ordinary shares may be issued under the 2020 EIP upon the exercise of incentive share options. In addition, the number of ordinary shares reserved for issuance under our 2020 EIP will automatically increase on January 1 of each year, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to 5 % of the total number of ordinary shares outstanding on December 31 of the

preceding calendar year. Our board may act prior to January 1 of a given year to provide that there will be no increase for such year or that the increase for such year will be a lesser number of ordinary shares, ordinary shares issued under the 2020 EIP may be new shares, shares purchased on the open market or treasury shares.

If an award under the 2020 EIP, expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited, any unused shares subject to the award will, as applicable, become or again be available for new grants under the 2020 EIP.

If an option granted under the Share Option Plan prior to the effective date expires, lapses or is terminated, exchanged for cash, surrendered, repurchased, cancelled without having been fully exercised or forfeited on or after the effective date, any unused shares subject to the option will, as applicable, become available for new grants under the 2020 EIP.

Awards granted under the 2020 EIP in substitution for any options or other equity or equity-based awards granted by an entity before the entity's merger or consolidation with us or our acquisition of the entity's property or stock will not reduce the number of ordinary shares available for grant under the 2020 EIP, but will count against the maximum number of ordinary shares that may be issued upon the exercise of incentive stock options.

Awards

The 2020 EIP provides for the grant of market value options, market value share appreciation rights, or SARs, restricted shares, restricted share units, or RSUs, performance restricted share units, or PSUs, and other share-based awards. All awards under the 2020 EIP will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms, change of control provisions and post-termination exercise limitations. A brief description of each award type follows.

Options and SARs. Options provide for the purchase of our ordinary shares in the future at an exercise price set at no less than the market value of an ordinary share on the grant date. SARs entitle their holder, upon exercise, to receive from us an amount equal to the appreciation of the shares subject to the award between the grant date and the exercise date. The Plan Administrator will determine the number of shares covered by each option and SAR, and the conditions and limitations applicable to the exercise of each option and SAR.

Restricted shares, RSUs and PSUs. Restricted shares are an award of non-transferable ordinary shares that remain forfeitable unless and until specified conditions are met and which may be subject to a purchase price. RSUs and PSUs are contractual promises to deliver our ordinary shares in the future, which may also remain forfeitable unless and until specified conditions are met. The Plan Administrator may provide that the delivery of the shares underlying RSUs will be deferred on a mandatory basis or at the election of the participant. The terms and conditions applicable to restricted shares, RSUs and PSUs will be determined by the Plan Administrator, subject to the conditions and limitations contained in the 2020 EIP.

Other share-based awards. Other share-based awards are awards of fully vested ordinary shares and other awards valued wholly or partially by referring to, or otherwise based on, our ordinary shares or other property. Other share-based awards may be granted to participants and may also be available as a payment form in the settlement of other awards, as standalone payments and as payment in lieu of compensation to which a participant is otherwise entitled. The Plan Administrator will determine the terms and conditions of other share-based awards, which may include any purchase price, performance goal, transfer restrictions and vesting conditions.

Performance criteria

The Plan Administrator may select performance criteria for an award to establish performance goals for a performance period.

Certain transactions

In connection with certain corporate transactions and events affecting our ordinary shares, including a change of control, another similar corporate transaction or event, another unusual or nonrecurring transaction or event affecting us or our financial statements or a change in any applicable laws or accounting principles, the Plan Administrator has broad discretion to take action under the 2020 EIP to prevent the dilution or enlargement of intended benefits, facilitate the transaction or event or give effect to the change in applicable laws or accounting principles. This includes canceling awards for cash or property, accelerating the vesting of awards, providing for the assumption or substitution of awards by a successor entity, adjusting the number and type of shares subject to outstanding awards and/or with respect to which awards may be granted under the 2020 EIP and replacing or terminating awards under the 2020 EIP. In addition, in the event of certain non-reciprocal transactions with our shareholders, the Plan Administrator will make equitable adjustments to the 2020 EIP, the limits thereunder and outstanding awards as it deems appropriate to reflect the transaction.

Plan amendment and termination

Our board of directors may amend or terminate the 2020 EIP at any time; however, no amendment, other than an amendment that increases the number of shares available under the 2020 EIP, may materially and adversely affect an award outstanding under the 2020 EIP without the consent of the affected participant and shareholder approval will be obtained for any amendment to the extent necessary to comply with applicable laws. Further, the Plan Administrator cannot, without the approval of our shareholders, amend any outstanding option or SAR to reduce its price per share or cancel any outstanding option or SAR in exchange for cash or another award under the 2020 EIP with an exercise price per share that is less than the exercise price per share of the original option or SAR. The 2020 EIP will remain in effect until the tenth anniversary of its effective date unless earlier terminated by our board of directors. No awards may be granted under the 2020 EIP after its termination.

Transferability and participant payments

Except as the Plan Administrator may determine or provide in an award agreement, awards under the 2020 EIP are generally non-transferrable, except by will or the laws of descent and distribution, or, subject to the Plan Administrator's consent, pursuant to a domestic relations order, and are generally exercisable only by the participant. With regard to tax withholding obligations arising in connection with awards under the 2020 EIP, and exercise price obligations arising in connection with the exercise of options under the 2020 EIP, the Plan Administrator may, in its discretion, accept cash, wire transfer or check, our ordinary shares that meet specified conditions, a promissory note, a "market sell order," such other consideration as the Plan Administrator deems suitable or any combination of the foregoing.

Non-U.S. and Non-U.K. participants

The Plan Administrator may modify awards granted to participants who are non-U.S. or U.K. nationals or employed outside the U.S. and the U.K. or establish sub-plans or procedures to address differences in laws, rules, regulations or customs of such international jurisdictions with respect to tax, securities, currency, employee benefit or other matters or to enable awards to be granted in compliance with a tax favorable regime that may be available in any jurisdiction.

2020 Non-Employee sub-plan

The 2020 Non-Employee Sub-Plan governs equity awards granted to our non-executive directors, consultants, advisers and other non-employee service providers and provides for awards to be made on identical terms to awards made under our 2020 EIP.

2020 Employee Share Purchase Plan

Our board of directors has adopted and our shareholders have approved our 2020 Employee Share Purchase Plan, or 2020 ESPP, as of July 2020.

Purpose

The purpose of the 2020 ESPP is to provide a means by which our employees may be given an opportunity to purchase ordinary shares, to assist us in retaining the services of our employees, to secure and retain the services of new employees and to provide incentives for such persons to exert maximum efforts for our success. The rights to purchase ordinary shares granted under the 2020 ESPP are intended to qualify as options issued under an "employee stock purchase plan" as that term is defined in Section 423(b) of the Code.

Administration

Our board of directors has the power to administer the 2020 ESPP and may also delegate administration of the 2020 ESPP to a committee comprised of one or more members of our board of directors. Our board of directors has delegated administration of the 2020 ESPP to the remuneration committee of our board of directors, but may, at any time, revest in itself some or all of the powers previously delegated to the remuneration committee. Our Board and the remuneration committee are each considered to be a Plan Administrator as such term in used herein. The Plan Administrator has the final power to construe and interpret both the 2020 ESPP and the rights granted under it. The Plan Administrator has the power, subject to the provisions of the 2020 ESPP, to determine when and how rights to purchase our ordinary shares will be granted, the provisions of each offering of such rights (which need not be identical), and whether employees of any of our parent or subsidiary companies will be eligible to participate in the 2020 ESPP.

Ordinary Shares Subject to the 2020 ESPP

Subject to adjustment for certain changes in our capitalization, the maximum number of ordinary shares that may be issued under the 2020 ESPP is 850,000 ordinary shares. In addition, the number of ordinary shares reserved for issuance under our 2020 ESPP will automatically increase on January 1 of each year, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the lesser of 1% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, and 2,000,000 ordinary shares. If any rights granted under the 2020 ESPP terminate without being exercised in full, the ordinary shares not purchased under such rights again become available for issuance under the 2020 ESPP. The ordinary shares issuable under the 2020 ESPP will be new shares.

Offerings

The 2020 ESPP will be implemented by offerings of rights to purchase ordinary shares to all eligible employees. The Plan Administrator will determine the duration of each offering period, provided that in no event may an offering period exceed 27 months. The Plan Administrator may establish separate offerings which vary in terms (although not inconsistent with the provisions of the 2020 ESPP or the requirements of applicable laws). Each offering period will have one or more purchase dates, as determined by the Plan Administrator prior to the commencement of the offering period. The Plan Administrator has the authority to alter the terms of an offering prior to the commencement of the offering period, including the duration of subsequent offering periods. When an eligible employee elects to join an offering period, he or she is granted a right to purchase ordinary shares on each purchase date within the offering period. On the purchase date, all contributions collected from the participant are automatically applied to the purchase of our ordinary shares, subject to certain limitations (which are described further below under "**Eligibility**").

The Plan Administrator has the discretion to structure an offering so that if the fair market value of our ordinary shares on the first trading day of a new purchase period within the offering period is less than or equal to the fair market value of our ordinary shares on the first day of the offering period, then that offering will terminate immediately as of that first trading day, and the participants in such terminated offering will be automatically enrolled in a new offering beginning on the first trading day of such new purchase period.

Eligibility

Any individual who is employed by us (or by any of our parent or subsidiary companies if such company is designated by the Plan Administrator as eligible to participate in the 2020 ESPP) may participate in offerings under the 2020 ESPP, provided such individual has been employed by us (or our parent or subsidiary, if applicable) for such continuous period preceding the first day of the offering period as the Plan Administrator may require, but in no event may the required period of continuous employment be equal to or greater than two years. In addition, subject to applicable law, the Plan Administrator may provide that an employee will not be eligible to be granted purchase rights under the 2020 ESPP unless such employee is customarily employed for more than 20 hours per week and five months per calendar year. The Plan Administrator may also provide in any offering that certain of our employees who are "highly compensated" as defined in the Code are not eligible to participate in the 2020 ESPP.

No employee will be eligible to participate in the 2020 ESPP if, immediately after the grant of purchase rights, the employee would own, directly or indirectly, shares possessing 5% or more of the total combined voting power or value of all classes of our shares or of any of our parent or subsidiary companies, including any shares which such employee may purchase under all outstanding purchase rights and options. In addition, no employee may purchase more than US$25,000 worth of our ordinary shares (determined based on the fair market value of the shares at the time such rights are granted) under all our employee share purchase plans and any employee share purchase plans of our parent or subsidiary companies for each calendar year during which such rights are outstanding.

Participation in the 2020 ESPP

An eligible employee may enroll in the 2020 ESPP by delivering to us, prior to the date selected by the Plan Administrator as the beginning of an offering period, an agreement authorizing contributions which may not exceed the maximum amount specified by the Plan Administrator, but in any case which may not exceed 15% of such employee's earnings during the offering period. Each participant will be granted a separate purchase right for each offering in which he or she participates. Unless an employee's participation is discontinued, his or her purchase right will be exercised automatically at the end of each purchase period at the applicable purchase price.

Purchase Price

The purchase price per share at which our ordinary shares are sold on each purchase date during an offering period will not be less than the lower of (i) 85% of the fair market value of an Ordinary Share on the first day of the offering period or (ii) 85% of the fair market value of an Ordinary Share on the purchase date.

Payment of Purchase Price; Payroll Deductions

The purchase of shares during an offering period generally will be funded by a participant's payroll deductions accumulated during the offering period. A participant may change his or her rate of contributions, as determined by the Plan Administrator in the offering. All contributions made for a participant are credited to his or her account under the 2020 ESPP and deposited with our general funds.

Purchase Limits

In connection with each offering made under the 2020 ESPP, the Plan Administrator may specify (i) a maximum number of ordinary shares that may be purchased by any participant pursuant to such offering, (ii) a maximum number of ordinary shares that may be purchased by any participant on any purchase date pursuant to such offering, (iii) a maximum aggregate number of ordinary shares that may be purchased by all participants pursuant to such offering, and/or (iv) a maximum aggregate number of ordinary shares that may be purchased by all participants on any purchase date pursuant to such offering. If the aggregate purchase ordinary shares issuable

upon exercise of purchase rights granted under such offering would exceed any such maximum aggregate number, then the Plan Administrator will make a pro rata allocation of available shares in a uniform and equitable manner.

Withdrawal

Participants may withdraw from a given offering by delivering a withdrawal form to us and terminating their contributions. Such withdrawal may be elected at any time prior to the end of an offering, except as otherwise provided by the Plan Administrator. Upon such withdrawal, we will distribute to the employee his or her accumulated but unused contributions without interest, and such employee's right to participate in that offering will terminate. However, an employee's withdrawal from an offering does not affect such employee's eligibility to participate in subsequent offerings under the 2020 ESPP.

Termination of Employment

A participant's rights under any offering under the 2020 ESPP will terminate immediately if the participant either (i) is no longer employed by us or any of our parent or subsidiary companies (subject to any post-employment participation period required by law) or (ii) is otherwise no longer eligible to participate. In such event, we will distribute to the participant his or her accumulated but unused contributions without interest.

Restrictions on Transfer

Rights granted under the 2020 ESPP are not transferable except by will, by the laws of descent and distribution, or if permitted by us, by a beneficiary designation. During a participant's lifetime, such rights may only be exercised by the participant.

Changes in Capitalization

In the event of certain changes in our share capitalization, the Plan Administrator will appropriately adjust: (i) the class(es) and maximum number of securities subject to the 2020 ESPP; (ii) the class(es) and number of securities subject to, and the purchase price applicable to outstanding purchase rights; and (iii) the class(es) and number of securities that are the subject of any purchase limits under each ongoing offering.

Effect of Certain Corporate Transactions

In the event of a corporate transaction (as defined in the 2020 ESPP and described below), (i) any acquiring company (or its parent company) may assume or continue outstanding purchase rights granted under the 2020 ESPP or may substitute similar rights (including a right to acquire the same consideration paid to the shareholders in the corporate transaction) for such outstanding purchase rights, or (ii) if any acquiring company (or its parent company) does not assume or continue such outstanding purchase rights or does not substitute similar rights for such outstanding purchase rights, then the participants' accumulated contributions will be used to purchase ordinary shares within ten business days prior to the corporate transaction under such purchase rights, and such purchase rights will terminate immediately after such purchase.

For purposes of the 2020 ESPP, a corporate transaction generally will be deemed to occur in the event of the consummation of: (i) a sale or other disposition of all or substantially all of our consolidated assets; or (ii) a change of Control (as defined in section 995(2) of the UK Income Tax Act 2007) of the company.

Non-US Participants

The Plan Administrator may adopt such procedures and sub-plans as are necessary or appropriate to permit participation in the 2020 ESPP by eligible employees who are resident or employed outside the United States.

Duration, Amendment and Termination

The Plan Administrator may amend or terminate the 2020 ESPP at any time. However, except in regard to certain capitalization adjustments, any such amendment must be approved by our shareholders if such approval is required by applicable law or listing requirements.

Any outstanding purchase rights granted before an amendment or termination of the 2020 ESPP will not be materially impaired by any such amendment or termination, except (i) with the consent of the employee to whom such purchase rights were granted, (ii) as necessary to comply with applicable laws, listing requirements or governmental regulations (including Section 423 of the Code), or (iii) as necessary to obtain or maintain favorable tax, listing or regulatory treatment.

Notwithstanding anything in the 2020 ESPP or any offering to the contrary, the Plan Administrator will be entitled to: (i) establish the exchange ratio applicable to amounts withheld in a currency other than U.S. dollars; (ii) permit contributions in excess of the amount designated by a participant in order to adjust for mistakes in the processing of properly completed contribution elections; (iii) establish reasonable waiting and adjustment periods and/or accounting and crediting procedures to ensure that amounts applied toward the purchase of our ordinary shares for each participant properly correspond with amounts withheld from the participant's contributions; (iv) amend any outstanding purchase rights or clarify any ambiguities regarding the terms of any offering to enable such purchase rights to qualify under and/or comply with Section 423 of the Code; and (v) establish other limitations or procedures as the Plan Administrator determines in its sole discretion advisable that are consistent with the 2020 ESPP. Any such actions by the Plan Administrator will not be considered to alter or impair any purchase rights granted under an offering as they are part of the initial terms of each offering and the purchase rights granted under each offering.

Federal Income Tax Information

The following is a summary of the principal United States federal income taxation consequences to participants and us with respect to participation in the 2020 ESPP. This summary is not intended to be exhaustive and does not discuss the income tax laws of any local, state or foreign jurisdiction in which a participant may reside. The information is based upon current federal income tax rules and therefore is subject to change when those rules change. Because the tax consequences to any participant may depend on his or her particular situation, each participant should consult the participant's tax adviser regarding the federal, state, local, and other tax consequences of the grant or exercise of a purchase right or the sale or other disposition of ordinary shares acquired under the 2020 ESPP. The 2020 ESPP is not qualified under the provisions of Section 401(a) of the Code and is not subject to any of the provisions of the Employee Retirement Income Security Act of 1974, as amended.

Rights granted under the 2020 ESPP are intended to qualify for favorable federal income tax treatment associated with rights granted under an "employee stock purchase plan" which qualifies under the provisions of Section 423 of the Code.

A participant will be taxed on amounts withheld for the purchase of ordinary shares as if such amounts were actually received. Otherwise, no income will be taxable to a participant as a result of the granting or exercise of a purchase right until a sale or other disposition of the acquired shares. The taxation upon such sale or disposition will depend upon the holding period of the acquired shares.

If the shares are sold or otherwise disposed of more than two years after the beginning of the offering period and more than one year after the shares are transferred to the participant, then the lesser of the following will be treated as ordinary income: (i) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price; or (ii) the excess of the fair market value of the shares as of the beginning of the offering period over the purchase price (determined as of the beginning of the offering period). Any further gain or any loss will be taxed as a long-term capital gain or loss.

If the shares are sold or otherwise disposed of before the expiration of either of the holding periods described above, then the excess of the fair market value of the shares on the purchase date over the purchase price will be treated as ordinary income at the time of such sale or disposition. The balance of any gain will be treated as capital gain. Even if the shares are later sold or otherwise disposed of for less than its fair market value on the purchase date, the same amount of ordinary income is attributed to the participant, and a capital loss is recognized equal to the difference between the sales price and the fair market value of the shares on such purchase date. Any capital gain or loss will be short-term or long-term, depending on how long the shares have been held.

There are no federal income tax consequences to us by reason of the grant or exercise of rights under the 2020 ESPP. We are entitled to a deduction to the extent amounts are taxed as ordinary income to a participant for shares sold or otherwise disposed of before the expiration of the holding periods described above (subject to the requirement of reasonableness and the satisfaction of tax reporting obligations).

New Plan Benefits

Participation in the 2020 ESPP is voluntary and each eligible employee will make his or her own decision regarding whether and to what extent to participate in the 2020 ESPP. In addition, our Board and the remuneration committee of our Board have not granted any purchase rights under the 2020 ESPP that are subject to shareholder approval. Accordingly, the benefits or amounts that will be received by or allocated to our executive officers and other employees under the 2020 ESPP, as well as the benefits or amounts which would have been received by or allocated to our executive officers and other employees for our current financial year if the 2020 ESPP had been in effect, are not determinable. Our non-executive directors will not be eligible to participate in the 2020 ESPP.

Share option plan

On September 11, 2018, our board adopted our Share Option Plan, which was subsequently approved by our shareholders on October 23, 2018, to incentivize certain of our employees, directors and other service providers, and those of our subsidiaries.

As of June 30, 2020, options to purchase 3,028,858 shares were outstanding, at a weighted-average exercise price of £1.63 per share.

The principal features of the Share Option Plan are outlined below.

Eligibility, awards and administration

The Share Option Plan provides for the grant of both tax-advantaged Enterprise Management Incentive, or EMI, options and non-tax advantaged options to our employees and those of our subsidiaries, subject to exercise conditions as summarized below.

In the case of tax-advantaged EMI options, full-time working requirements must be met, which means that the employee must be required to work 25 hours per week or if less, 75% of the employee's working time for us or our subsidiaries. Employees who have a material interest in our company cannot be granted EMI options. A material interest is either beneficial ownership of, or the ability to control directly or indirectly, more than 30% of our ordinary share capital.

The Share Option Plan has a Non-Employee Sub-Plan for the grant of options to our and our subsidiaries' advisors, consultants, non-executive directors, and entities providing services, through an individual such as advisory, consultancy, or office holder services and a U.S. Sub-Plan for the grant of options to eligible participants in the Share Option Plan and the Non-Employee Sub-Plan who are U.S. residents and U.S. taxpayers. Save as otherwise specified, references below to the Share Option Plan include the Non-Employee Sub-Plan and the U.S. Sub-Plan.

The Share Option Plan is operated by our board of directors, or a duly authorized committee of our board and some powers have been delegated to our remuneration committee.

General terms of options

Options may be granted within 42 days immediately following the end of a closed period, which has the same meaning as in Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on market abuse, and within any other period that our remuneration committee has decided options should be granted as exceptional circumstances exist.

No consideration is payable on the grant of options. The remuneration committee determines the exercise price of options before they are granted, which shall not be less than the nominal value of an ordinary share.

None of the benefits which may be received under the Share Option Plan will be taken into account when determining any pension or similar entitlements.

Each option is personal to the option holder and any transfer of, or the creation of any charge, pledge or other encumbrance over, the option will cause it to lapse (other than in respect of a transfer to an option holder's personal representative on or following their death).

An option holder does not have any shareholder rights with respect to an option until the option has vested and been exercised and the option holder has received the corresponding ordinary shares.

Where a tax liability arises on the exercise of an option, we may require the option holder to make payment to us or the option holder's employer to meet such liability, or to enter into other arrangements in respect of the satisfaction of such liability. If such payments or arrangements are insufficient (or are not made) we may sell as many of the option holder's ordinary shares as are necessary to cover the liability. The option holder may be required to bear the cost of secondary UK National Insurance contributions, or similar liability for social security contributions in any jurisdiction, to the extent applicable.

Vesting and exercise

Options can normally only be exercised on satisfaction of the conditions relating to time or the achievement of challenging performance targets over a specified period that have the intention of enhancing shareholder value as determined by the remuneration committee at grant. The remuneration committee may subsequently waive or vary such conditions, provided any varied condition is considered to be a fairer measure of performance and no more difficult to satisfy than the original condition.

Option holders who exercise an option under the Share Option Plan are required to pay the applicable option exercise price in a manner determined by the board of directors.

The last date for exercise of an option will be the day before the tenth anniversary of its grant.

Limitations on awards

The number of ordinary shares that may be issued or are issuable pursuant to the exercise of the options and any other options granted, or awards made, under all of the discretionary share option plans operated by us may not exceed 10% of our issued share capital.

Ordinary shares transferred from treasury to satisfy options will count as newly issued shares for these purposes.

Options which have lapsed or been surrendered or which were capable of exercise prior to admission of our ordinary shares to AIM will not count towards these dilution limits.

A maximum of 6,000,000 ordinary shares may be issued under the U.S. Sub-Plan upon the exercise of incentive stock options, as defined in Section 422 of the Code.

Leavers

ln the case of death, an option holder's personal representatives may exercise his or her options within 12 months after the date of death to the extent the exercise conditions have been satisfied, save that the remuneration committee may waive the exercise conditions in these circumstances. If an option holder ceases to be an employee by reason of injury, ill health, disability, retirement, redundancy or sale of the option holder's employing company or business, options are exercisable to the extent the exercise conditions have been satisfied during the 90 days from the date of cessation, save that the remuneration committee may waive the exercise conditions in these circumstances. If an option holder ceases to be an employee for any other reason, options may, at the discretion of the remuneration committee, be exercisable to the extent the exercise conditions have been satisfied during the 90 days from the date of cessation, save that the remuneration committee may waive the exercise conditions in these circumstances. If an option holder ceases to be an employee on or after the normal vesting date applicable to that option for any reason other than summary dismissal, the option may be exercised during the 90 day period following the date of cessation.

Certain transactions

ln the event of a takeover, scheme of arrangement, change of control or voluntary winding up of the company, options may be exercised to the extent the board determines that exercise conditions have been met, save that the remuneration committee may waive the exercise conditions in these circumstances in full. If options are not exercised within an appropriate period, generally 90 days of the relevant event, they will lapse. There is a provision allowing for the roll-over (assumption with consent) of options with agreement from the acquirer provided that, in the case of EMI options, such new options continue to meet EMI qualifying conditions.

Changes to capital structure

ln the event of any variation of share capital by way of capitalization, rights issue, consolidation, sub-division or reduction of share capital or other variation, affecting the value of options to option holders, the number and description of ordinary shares comprised in subsisting options and the exercise price may be adjusted by the board in such manner that the board deems to be fair and appropriate in their reasonable opinion.

Amendment and termination

The remuneration committee may make amendments to the rules of the Share Option Plan provided the amendment does not: (a) apply to options granted before the amendment was made; or (b) materially adversely affect the interests of option holders (unless the relevant option holders consent to such amendment). Further, no deletion, amendment or addition may be made except with the prior approval of our shareholders in general meeting if the deletion, amendment or addition is in relation to (a) the definition of 'employee'; or (b) the Share Option Plan's grant limits; or (c) the variation of share capital. No options may be granted under the Share Option Plan after the tenth anniversary of its adoption.

Non-Employee Sub-Plan

Under the Non-Employee Sub-Plan, options may be granted to our advisers, consultants and non- executive directors and entities providing, through an individual, such advisory, consultancy, or office holder services, on terms comparable to those described above. These options will not be EMI Options.

U.S. Sub-Plan

The U.S. Sub-Plan permits the grant of options to eligible participants under the Share Option Plan and the Non-Employee Sub-Plan who are U.S. residents and U.S. taxpayers, including potentially tax efficient incentive

stock options. The exercise price of options granted under the U.S. Sub- Plan shall not be less than 100% of the fair market value of an ordinary share on the date of grant, determined in accordance with Section 409A of the Code.

C. Board Practices

Composition of our board of directors

Our board of directors currently has six members. Under the rules and regulations of Nasdaq, a director will qualify as "independent" if our board of directors affirmatively determines that he or she has no material relationship with us (either directly or as a partner, shareholder or officer of an organization that has a relationship with us). Our board of directors has determined that, of our six directors, no director, other than James McCullough and Fergus Fleming, has a relationship that would interfere with the exercise of independent judgment in carrying out his or her responsibilities as a director and that each of these directors is "independent" as that term is defined under Nasdaq rules.

In accordance with our articles of association, at every annual general meeting, there shall retire from office any director who has been appointed by our board of directors since the last annual general meeting or who shall have been a director at each of the preceding two annual general meetings and who was not re-appointed at either such meeting or who has held office (other than in an executive position) for a continuous period of nine years or more. A retiring director shall be eligible for re-appointment. A director retiring at a meeting shall, if he is not re-appointed at such meeting, retain office until the meeting appoints someone in his place, or if it does not do so, until the conclusion of such meeting. See Item 10.B—"Memorandum and Articles of Association."

Committees of our board of directors

Our board of directors has three standing committees: an audit committee, a remuneration committee and a nomination committee.

Audit committee

Our audit committee consists of Erik Lium, Ph.D., Christopher Mills and Barbara Murphy, M.D., and assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. Dr. Lium serves as chairman of the audit committee. The audit committee consists exclusively of members of our board who are financially literate, and Mr. Mills is considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The audit committee is governed by a charter that complies with Nasdaq rules.

The audit committee's responsibilities include:

- monitoring the integrity of our financial and narrative reporting;
- reviewing accounting policies and key estimates and judgments;
- reviewing the appropriateness and completeness of the internal controls;
- recommending the appointment, re-appointment or removal of the independent auditor to the annual general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;

- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing and discussing with the executive officers, the board of directors and the independent auditor our financial statements and our financial reporting process; and
- reviewing procedures for detection of fraud, whistleblowing and prevention of bribery, and reports on systems for internal financial control, financial reporting and risk management.

Remuneration committee

Our remuneration committee consists of Erik Lium, Ph.D. and Chirag Parikh, Ph.D., M.D. and assists the board of directors in determining executive officer compensation. Dr. Lium serves as chairman of the remuneration committee.

The remuneration committee's responsibilities include:

- identifying, reviewing and proposing policies relevant to executive officer compensation;
- evaluating each executive officer's performance in light of such policies and reporting to the board;
- analyzing the possible outcomes of the variable remuneration components and how they may affect the remuneration of the executive officers;
- recommending any equity long-term incentive component of each executive officer's compensation in line with the remuneration policy and reviewing our executive officer compensation and benefits policies generally; and
- reviewing and assessing risks arising from our compensation policies and practices.

Nomination committee

Our nomination committee consists of Barbara Murphy, M.D. and Chirag Parikh, Ph.D., M.D., and assists our board of directors in identifying individuals qualified to become members of our board and executive officers consistent with criteria established by our board and in developing our corporate governance principles. Dr. Murphy serves as chairperson of the nomination committee.

The nomination committee's responsibilities include:

- drawing up selection criteria and appointment procedures for directors;
- reviewing and evaluating the size and composition of our board and making a proposal for a composition profile of the board of directors at least annually;
- recommending nominees for election to our board of directors and its corresponding committees;
- assessing the functioning of individual members of board and executive officers and reporting the results of such assessment to the board of directors; and
- developing and recommending to the board rules governing the board, reviewing and reassessing the adequacy of such rules governing the board and recommending any proposed changes to the board of directors.

Code of business conduct and ethics

We have adopted a Code of Business Conduct and Ethics, or Code of Ethics, 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 current copy of the Code of Ethics is posted on our website, which is located at www.renalytixai.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report and is not incorporated by reference herein.

D. Employees

As of June 30, 2020, we had 19 employees, including 17 full-time employees employed by our U.S. subsidiary, Renalytix AI, Inc., and 2 part-time employees employed directly by Renalytix AI plc. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

E. Share Ownership

For information regarding the share ownership of our directors and executive officers, see "Item 6.B—Compensation" and "Item 7.A—Major Shareholders."

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of September 15, 2020 for:

- each beneficial owner of 5% or more of our outstanding ordinary shares;
- each of our directors and executive officers; and
- all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of September 15, 2020. Percentage ownership calculations are based on 72,029,634 ordinary shares outstanding as of September 15, 2020.

Except as otherwise indicated, all of the shares reflected in the table are ordinary shares and all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. Our major shareholders do not have different voting rights than other holders of our ordinary shares. The information is not necessarily indicative of beneficial ownership for any other purpose.

Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are care of Renalytix AI plc, Avon House 19 Stanwell Road, Penarth, Cardiff, CF64 2EZ, United Kingdom.

Name of Beneficial Owner	Number of ordinary shares beneficially owned	Percentage of ordinary shares beneficially owned
5% or Greater Shareholders (other than Executive Officers and Directors):		
Icahn School of Medicine at Mount Sinai(1)	10,785,010	15.0%
Christopher Mills(2)	9,918,573	13.8%
Gilder Gagnon Howe & Co. LLC(3)	4,800,000	6.7%

Name of Beneficial Owner	Number of ordinary shares beneficially owned	Percentage of ordinary shares beneficially owned
Executive Officers and Directors:		
James McCullough(4).	2,870,110	4.0%
Fergus Fleming(5)	943,251	1.3%
Thomas McLain(6).	224,232	*
O. James Sterling(7)	1,902,640	2.6%
Michael J. Donovan, Ph.D., M.D.(8)	179,384	*
Erik Lium, Ph.D.	—	—
Barbara Murphy, M.D.(9).	330,184	*
Chirag R. Parikh, Ph.D., M.D.(10)	70,482	*
Christopher Mills(2)	9,918,573	13.8%
All current directors and executive officers as a group (9 persons)(11)	16,438,856	22.5%

(1) Includes 34,083 shares underlying options exercisable within 60 days of September 15, 2020. The address of Mount Sinai is 1 Gustave L. Levy Place, New York, New York, 10029.
(2) Consists of (i) 247,500 shares held by Mr. Mills and his immediate family members, (ii) 746,072 shares held by Harwood Capital Nominees Limited ("Harwood"), (iii) 6,145,001 shares held by North Atlantic Smaller Companies Investment Trust plc ("NASCIT"), of which Harwood Capital LLP is investment manager and (iv) 2,780,000 shares held by Oryx International Growth Fund Limited ("Oryx"), of which Harwood Capital LLP is an investment advisor. Mr. Mills is a partner and the chief investment officer at Harwood. The address of Harwood, NASCIT and Oryx is 6 Stratton St, Mayfair, London W1J 8LD, United Kingdom.
(3) The address of Gilder Gagnon Howe & Co. LLC is 475 10th Avenue, 12th Floor, New York, New York 10018.
(4) Consists of shares held by Mr. McCullough.
(5) Consists of (i) 584,481 shares held by Mr. Fleming and (ii) 358,770 shares underlying options exercisable within 60 days of September 15, 2020.
(6) Consists of shares underlying options exercisable within 60 days of September 15, 2020 held by Mr. McLain.
(7) Consists of shares held by Mr. Sterling.
(8) Consists of shares underlying options exercisable within 60 days of September 15, 2020 held by Dr. Donovan.
(9) Consists of (i) 150,800 shares held by Dr. Murphy and (ii) 179,384 shares underlying options exercisable within 60 days of September 15, 2020.
(10) Consists of shares underlying options exercisable within 60 days of September 15, 2020 held by Dr. Parikh.
(11) Consists of (i) 15,426,604 shares and (ii) 1,012,252 shares underlying options exercisable within 60 days of September 15, 2020.

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2019 are as a result of dilution from our July 2020 global offering in which we issued and sold 12,583,500 ordinary shares in our U.S. IPO, which converted into 6,291,750 ADSs, and 30,000 ordinary shares in a concurrent private placement in Europe.

Shareholders in the United States

As of September 30, 2020, to the best of our knowledge, 28,196,799 of our outstanding ordinary shares (including ordinary shares in the form of ADSs) were held by 17 shareholders of record in the United States. The

actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Participation in Global Offering

In our U.S. IPO, Mount Sinai purchased 948,750 of our ADSs at the public offering price, for aggregate gross proceeds of approximately $12.8 million.

EKF Diagnostics Holdings

In October 2018, we purchased the Joslin Agreement and other assets from EKF in exchange for 15,427,704 ordinary shares. See "Item 5—Our key agreements—Joslin Diabetes Center."

Prior to our admission to AIM, we received loans from EKF bearing interest at an annual rate of 5%. The loans were due on or within seven business days following the consummation of our initial public offing. Upon our admission to trading on AIM in November 2018, all borrowings and accrued interest were paid in their entirety.

Renwick Capital, LLC

Prior to our admission to AIM in November 2018, James McCullough, our Chief Executive Officer, and O. James Sterling, our Chief Financial Officer, provided their respective services through a consulting arrangement between us and Renwick Capital, LLC. During the period from March 15, 2018 (inception) through June 30, 2018 and for the year ended June 30, 2019, we incurred consulting services of $0.1 million and $0.2 million, respectively. Upon our admission to AIM, Mr. McCullough and Mr. Sterling became employees and the consulting agreement with Renwick Capital, LLC was terminated.

Icahn School of Medicine at Mount Sinai

In May 2018, we entered into the Mount Sinai Agreement. See "Item 5—Our key agreements—Mount Sinai Health System." As part of that partnership, Mount Sinai acquired 6,730,784 of our ordinary shares. Mount Sinai also purchased 1,288,202 of our ordinary shares as part of our admission to AIM, and an additional 834,440 ordinary shares in July 2019. Additionally, in connection with the FractalDx portfolio, we paid $1.0 million for the acquisition of the related license and $0.3 million for the reimbursement of patent costs.

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into the Advisory Agreement, pursuant to which we have agreed to provide certain services to Kantaro. See "Item 5—Our key agreements—Kantaro Biosciences LLC" for additional information.

In June 2020, we and Mount Sinai entered into a registration rights agreement pursuant to which we have granted Mount Sinai the following registration rights:

- *Demand Registration on Form F-3*—Mount Sinai is entitled to demand registrations on Form F-3, if we are then eligible to register shares on Form F-3, including up to two underwritten offerings in any 12-month period.
- *Demand Registration on Form F-1 or Form S-1*—At any time following one year after the completion of the global offering, if we are not eligible to register shares on Form F-3 or S-3, Mount Sinai is entitled to a maximum of one demand registration on Form F-1 or Form S-1 during any 12-month period, subject to specified exceptions.

- *Piggyback Registration*—Mount Sinai is entitled to certain piggyback registration rights, subject to certain marketing and other limitations in the context of an underwritten offering.
- *Expenses*—We will pay all registration expenses incident to the performance of our obligations under the registration rights agreement.

Mount Sinai's registration rights will terminate at such time as Rule 144, or another similar exception under the Securities Act, is available for the unlimited public sale of all of Mount Sinai's registrable securities without any volume or manner of sale limitations, subject to specified exceptions.

Agreements with our executive officers and directors

We have entered into employment agreements with certain of our executive officers and appointment letters with our non-executive directors. See Item 6.B, "Compensation—Director Compensation" and "Compensation—Executive Officer Compensation." These agreements contain customary provisions and representations, including confidentiality, non-competition, non-solicitation and inventions assignment undertakings by the executive officers. However, the enforceability of the non-competition provisions may be limited under applicable law.

Indemnification agreements

We have entered into deeds of indemnity with our directors and we expect to enter into a new deed of indemnity with each of our directors and executive officers in connection with the listing of our ADSs on Nasdaq. The deeds of indemnity and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

Related person transaction policy

We have adopted a related person transaction policy that sets forth our procedures for the identification, review, consideration and approval or ratification of related person transactions. For purposes of our policy only, a related person transaction is a transaction, arrangement or relationship, or any series of similar transactions, arrangements or relationships, in which we or any of our subsidiaries and any related person are, were or will be participants in which the amount involved exceeds $120,000 or which is unusual in its nature or conditions. Transactions involving compensation for services provided to us as an employee or director are not covered by this policy. A related person is any executive officer, director or beneficial owner of more than 5% of any class of our voting securities, including any of their immediate family members and any entity owned or controlled by such persons.

The related person transaction policy also covers related party transactions under the AIM Rules for Companies published by the London Stock Exchange, or the AIM Rules, which contains a different definition of a related party to the definition of a related person set out above for U.S. purposes. The AIM Rules require that any transaction with a related party (pursuant to the definition in the AIM Rules) that exceeds 5% in any of the class tests set out in the AIM Rules, taking into account certain provisions relating to aggregation of transactions, should be announced without delay as soon as the terms of the transaction are agreed, and that the announcement should include certain specified information including a statement that our directors (with the exception of any director who is involved in the transaction as a related party) consider, having consulted with our nominated adviser for AIM, that the terms of the transaction are fair and reasonable insofar as our shareholders are concerned.

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

Our consolidated financial statements are appended at the end of this annual report, starting at page F-1, and are incorporated by reference herein.

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.

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.

B. Significant Changes

See Item 4.B, “Business Overview—Recent Developments.”

Item 9. The Offer and Listing

A. Offer and Listing Details

Our ADSs have been listed on the Nasdaq Global Market under the symbol “RNLX” since July 17, 2020. Prior to that date, there was no public trading market for our ADSs. Our ordinary shares have traded on AIM, a market operated by the London Stock Exchange, under the symbol “RENX,” since November 6, 2018.

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Stockholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

General

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 Avon House, 19 Stanwell Road, Penarth, Cardiff, CF64 2EZ, United Kingdom, and the telephone number of our registered office is +44 20 3139 2910.

Since November 6, 2018, our ordinary shares have been traded on AIM under the symbol “RENX”. Our website address is www.renalytixai.com. The information contained on, or that can be accessed from, our website does not form part of this annual report. Our agent for service of process in the United States is Renalytix AI, Inc.

As of June 30, 2020, we had 59,416,134 ordinary shares outstanding, with a nominal value of £0.0025 per ordinary share. Each issued ordinary share is fully paid.

Ordinary shares

In accordance with our articles of association, the following summarizes the rights of holders of our ordinary shares:

- each holder of our ordinary shares is entitled to one vote per ordinary share on all matters to be voted on by shareholders generally;
- the holders of the ordinary shares shall be entitled to receive notice of, attend, speak and vote at our general meetings; and
- holders of our ordinary shares are entitled to receive such dividends as are recommended by our directors and declared by our shareholders.

See also “Articles of association—Shares and rights attaching to them” below.

Options

As of June 30, 2020, there were options to purchase 3,028,858 ordinary shares outstanding with a weighted average exercise price of £1.63 per ordinary share. The options generally lapse after ten years from the date of the grant.

Share register

We are required by the Companies Act to keep a register of our shareholders. Under the laws of England and Wales, the ordinary shares are deemed to be issued when the name of the shareholder is entered in our share register. The share register therefore is prima facie evidence of the identity of our shareholders, and the shares that they hold. The share register generally provides limited, or no, information regarding the ultimate beneficial owners of our ordinary shares. Our share register is maintained by our registrar, Link Asset Services Limited.

Holders of our ADSs are not treated as one of our shareholders and their names therefore are not entered in our share register. The depositary, the custodian or their nominees are the holder of the shares underlying our ADSs. Holders of our ADSs have a right to receive the ordinary shares underlying their ADSs.

Under the Companies Act, we must enter an allotment of shares in our share register as soon as practicable and in any event within two months of the allotment. We also are required by the Companies Act to register a transfer of shares (or give the transferee notice of and reasons for refusal) as soon as practicable and in any event within two months of receiving notice of the transfer.

We, any of our shareholders or any other affected person, may apply to the court for rectification of the share register if:

- the name of any person, without sufficient cause, is wrongly entered in or omitted from our register of members; or
- there is a default or unnecessary delay in entering on the register the fact of any person having ceased to be a member or on which we have a lien, provided that such refusal does not prevent dealings in the shares taking place on an open and proper basis.

Preemptive rights

The laws of England and Wales generally provide shareholders with preemptive rights when new shares are issued for cash; however, it is possible for the articles of association, or shareholders in a general meeting, 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 resolution, if the disapplication is by shareholder resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years).

On September 30, 2019, our shareholders approved the disapplication of preemptive rights for the period up to the conclusion of our next annual general meeting, which disapplication allows for the issue of ordinary shares up to the aggregate nominal amount of £14,854.03 (plus the issue of shares on the exercise of share options granted by us), and that will need to be renewed upon expiration to remain effective.

On July 13, 2020, our shareholders approved the disapplication of preemptive rights for the allotment of ordinary shares in connection with the global offering.

Articles of association

Shares and rights attaching to them

Objects

The objects of the company are unrestricted.

Share rights

Subject to the Companies Act and any rights attaching to shares already in issue, our shares may be issued with or have attached to them any rights and restrictions as we may by ordinary resolution of the shareholders determine or, in the absence of any such determination, as our board of directors may determine.

Voting rights

Subject to any rights or restrictions attached to any shares from time to time, the general voting rights attaching to shares are as follows:

- any resolution put to the vote of a general meeting must be decided exclusively on a poll;
- on a poll, every shareholder who is present in person or by proxy or corporate representative shall have one vote for each share of which they are the holder. A shareholder, proxy or corporate representative entitled to more than one vote need not, if they vote, use all their votes or cast all the votes in the same way; and
- if two or more persons are joint holders of a share, then in voting on any question the vote of the senior who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holders. For this purpose, seniority shall be determined by the order in which the names of the holders stand in the share register.

Restrictions on voting

No shareholder shall be entitled to vote at any general meeting or at any separate class meeting in respect of any share held by him unless all calls or other sums payable by him in respect of that share have been paid.

The board may from time to time make calls upon the shareholders in respect of any money unpaid on their shares and each shareholder shall (subject to at least 14 days' notice specifying the time or times and place of payment) pay at the time or times so specified the amount called on their shares.

Dividends

We may by ordinary resolution of shareholders declare dividends out of profits available for distribution in accordance with the respective rights of shareholders, but no such dividend shall exceed the amount recommended by the board of directors.

The board of directors may from time to time pay shareholders such interim dividends as appears to the board to be justified by the profits available for distribution (including any dividends at a fixed rate). If the share capital is divided into different classes, the board of directors may pay interim dividends on shares which confer deferred or non-preferred rights with regard to dividend as well as on shares which confer preferential rights with regard to dividend, but no interim dividend shall be paid on shares carrying deferred or non-preferred rights if, at the time of payment, any preferential dividend is in arrears.

The board of directors may deduct from any dividend or other money payable to any person on or in respect of a share all such sums as may be due from such shareholder to the company on account of calls or otherwise in relation to the shares of the company. Sums so deducted can be used to pay amounts owing to the company in respect of the shares.

Subject to any special rights attaching to or the terms of issue of any share, no dividend or other moneys payable by us on or in respect of any share shall bear interest against us. Any dividend unclaimed after a period of 12 years from the date such dividend became due for payment shall be forfeited and shall revert to us.

Dividends may be declared or paid in any currency and the board may decide the rate of exchange for any currency conversions that may be required, and how any costs involved are to be met.

The board of directors may, by ordinary resolution of the company, direct (or in the case of an interim dividend may without the authority of an ordinary resolution direct) that payment of any dividend declared may be satisfied wholly or partly by the distribution of assets, and in particular of paid up shares or debentures of any other company, or in any one or more of such ways.

Change of control

There is no specific provision in our articles of association that would have the effect of delaying, deferring or preventing a change of control.

Distributions on winding up

On a winding up, the liquidator may, with the sanction of a special resolution of shareholders and any other sanction required by law, divide amongst the shareholders in specie the whole or any part of the assets of the company and may, for that purpose, value any assets and determine how the division shall be carried out as between the shareholders or different classes of shareholders. The liquidator may, with the like sanction, vest the whole or any part of the assets in trustees upon such trusts for the benefit of the shareholders as he may with the like sanction determine, but no shareholder shall be compelled to accept any assets upon which there is a liability.

Variation of rights

All or any of the rights and restrictions attached to any class of shares issued may be varied or abrogated with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class (excluding any shares held as treasury shares) or by special resolution passed at a separate general meeting of the holders of such shares, subject to the Companies Act and the terms of their issue. The Companies Act provides a right to object to the variation of the share capital by the shareholders who did not vote in favor of the variation. Should an aggregate of 15% of the shareholders of the issued shares in question apply to the court to have the variation cancelled, the variation shall have no effect unless and until it is confirmed by the court.

Alteration to share capital

We may, by ordinary resolution of shareholders, consolidate all or any of our share capital into shares of larger amount than our existing shares, or sub-divide our shares or any of them into shares of a smaller amount. We may, by special resolution of shareholders, confirmed by the court, reduce our share capital or any capital redemption reserve or any share premium account in any manner authorized by the Companies Act. We may redeem or purchase all or any of our shares as described in "—Other English law considerations—Purchase of own shares."

Allotment of shares and preemption rights

In accordance with the Companies Act, the board of directors may be generally and unconditionally authorized to exercise all the powers of the company to allot shares up to an aggregate nominal amount equal to the amount stated in the relevant ordinary resolution authorizing such allotment. The following such authorities to allot shares in the company and to grant rights to subscribe for or to convert any security into shares in the company were granted at the company's annual general meeting on September 30, 2019 and remain in force at the date of this annual report:

- up to a maximum nominal amount of £5,739.24 for the purposes of the exercise of outstanding share options and other potential shares granted by the company only; and

- up to an aggregate nominal amount of £14,854.03 (in addition to the authority above), representing approximately 10% of the company's then issued share capital, such authorities (unless previously renewed, revoked or varied) to expire at the conclusion of the annual general meeting of the company to be held in 2020.

On July 13, 2020, our shareholders authorized our board of directors to allot ordinary shares up to an aggregate nominal value of £51,989.115 in connection with the global offering.

In certain circumstances, our shareholders may have statutory preemptive rights under the Companies Act in respect of the allotment of new shares as described in "—Preemptive Rights" and "—Differences in Corporate Law—Preemptive Rights" in this annual report.

Transfer of shares

Any shareholder holding shares in certificated form may transfer all or any of his shares by an instrument of transfer in any usual or common form or in any other manner which is permitted by the Companies Act and approved by the board. Any written instrument of transfer shall be signed by or on behalf of the transferor and (in the case of a share which is not fully paid up) the transferee.

All transfers of uncertificated shares shall be made in accordance with and subject to the provisions of the Uncertificated Securities Regulations 2001 and the facilities and requirements of its relevant system. The Uncertificated Securities Regulations 2001 permit shares to be issued and held in uncertificated form and transferred by means of a computer-based system.

The board of directors may decline to register any transfer of any share in certificated form:

- which is not a fully paid share, provided that such discretion may not be exercised in a way in which the London Stock Exchange regards as preventing dealing in shares from taking place on an open and proper basis;
- where the company has a lien over such share;
- unless any written instrument of transfer, duly stamped or duly certificated or otherwise shown to the satisfaction of the board of directors to be exempt from stamp duty (if this is required), is lodged with us at our registered office or such other place as the board may from time to time determine, accompanied by the certificate for the shares to which it relates;
- unless there is provided such evidence as the board may reasonably require to show the right of the transferor to make the transfer and if the instrument of transfer is executed by some other person on his behalf, the authority of that person to do so;
- where the transfer is in respect of more than one class of share; and
- in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred exceeds four.

The board of directors may decline to register a transfer of uncertificated shares in any circumstances that are allowed or required by the Uncertificated Securities Regulations 2001 and the requirements of its relevant system.

If the board of directors declines to register a transfer it shall, as soon as practicable and in any event within two months after the date on which the transfer is lodged or the instructions to the relevant system received, send to the transferee notice of the refusal, together with reasons for the refusal or, in the case of uncertified shares, notify such persons as may be required by the Uncertified Securities Regulations 2001 and the requirements of the relevant system concerned.

CREST

To be traded on AIM, securities must be able to be transferred and settled through the CREST system. CREST is a computerized paperless share transfer and settlement system which allows securities to be transferred by electronic means, without the need for a written instrument of transfer. Our articles of association are consistent with CREST membership and, amongst other things, allow for the holding and transfer of shares in uncertificated form.

Annual general meetings

In accordance with the Companies Act, we are required in each year to hold an annual general meeting in addition to any other general meetings in that year and to specify the meeting as such in the notice convening it. The annual general meeting shall be convened whenever and wherever the board sees fit, subject to the requirements of the Companies Act, as described in "—Differences in Corporate Law—Annual General Meeting" and "—Differences in Corporate Law—Notice of General Meetings" in this annual report.

Notice of general meetings

The arrangements for the calling of general meetings are described in "—Differences in Corporate Law—Notice of General Meetings" in this annual report.

Quorum of general meetings

No business shall be transacted at any general meeting unless a quorum is present. At least two shareholders present in person or by proxy and entitled to vote shall be a quorum for all purposes.

Class meetings

The provisions in our articles of association relating to general meetings apply to every separate general meeting of the holders of a class of shares except that:

- the quorum for such class meeting shall be two holders in person or by proxy representing not less than one-third in nominal value of the issued shares of the class (excluding any shares held in treasury); and
- if at any adjourned meeting of such holders a quorum is not present at the meeting, one holder of shares of the class present in person or by proxy at an adjourned meeting constitutes a quorum.

Number of directors

We may not have less than two directors or more than fifteen directors on the board of directors. We may, by ordinary resolution of the shareholders, vary the minimum and/or maximum number of directors from time to time.

Appointment of directors

Subject to the provisions of our articles of association, we may, by ordinary resolution of the shareholders, appoint any person to be a director, either to fill a casual vacancy or as an addition to the existing board. However, any person that is not a director retiring from the existing board must be recommended by the board of directors, or be proposed by a shareholder not less than seven and not more than 42 days before the date appointed for the meeting, in order to be eligible for appointment.

Without prejudice to the power to appoint any person to be a director by shareholder resolution, the board has power to appoint any person to be a director, either to fill a casual vacancy or as an addition to the existing board but so that the total number of directors does not exceed the maximum number fixed by or in accordance with our articles of association.

Any director appointed by the board will hold office only until the following annual general meeting. Such a director is eligible for re-appointment at that meeting.

Rotation of directors

At every annual general meeting, any director who has been appointed by the board of directors since the last annual general meeting, or who shall have been a director at each of the preceding two annual general meetings and who did not retire at either such meeting, or any director who has held office (other than in an executive position) for a continuous period of nine years or more shall retire and may offer himself for re-appointment by the shareholders. A retiring director shall be eligible for re-appointment. A director retiring at a meeting shall, if he is not re-appointed at such meeting, retain office until the meeting appoints someone in his place, or if it does not do so, until the conclusion of such meeting.

Directors' interests

The directors may authorize, to the fullest extent permitted by law, any matter or situation proposed to them which would otherwise result in a director infringing his duty to avoid a situation in which he has, or can have, a direct or indirect interest that conflicts, or possibly may conflict, with our interests. A director shall not, save as otherwise agreed by him, be accountable to us for any remuneration, profit or other benefit which he derives from any matter authorized by the directors and any contract, transaction or arrangement relating thereto shall not be liable to be avoided on the grounds of any such remuneration, profit or other benefit.

Subject to the requirements under sections 175, 177 and 182 of the Companies Act, a director who is any way, whether directly or indirectly, interested in a proposed or existing transaction or arrangement with us shall declare the nature of his interest at a meeting of the directors.

A director shall not vote in respect of any transaction or arrangement with the company in which he has an interest and which may reasonably be regarded as likely to give rise to a conflict of interest. A director shall not be counted in the quorum at a meeting in relation to any resolution on which he is debarred from voting.

A director shall be entitled to vote (and be counted in the quorum) in respect of any resolution concerning any of the following matters:

- the giving of any guarantee, security or indemnity in respect of money lent or obligations incurred by him or by any other person at the request of or for the benefit of our company or any of our subsidiary undertakings;
- the giving of any guarantee, security or indemnity in respect of a debt or obligation of our company or any of our subsidiary undertakings for which he himself has assumed responsibility in whole or in part under a guarantee or indemnity or by the giving of security;
- any proposal concerning an offer of securities of or by our company or any of our subsidiary undertakings in which offer he is or may be entitled to participate as a holder of securities or in the underwriting or sub-underwriting of which he is to participate;
- any contract, arrangement or transaction concerning any other body corporate in which he or any person connected with him (within the meaning of sections 252-5 of the Companies Act) is interested, directly or indirectly and whether as an officer or shareholder or otherwise howsoever, provided that he and any persons so connected with him do not to his knowledge hold an interest (within the meaning of sections 820 to 825 of the Companies Act) in one per cent. or more of any class of the equity share capital of such body corporate or of the voting rights available to members of the relevant body corporate;
- any contract, arrangement or transaction for the benefit of employees of our company or any of our subsidiary undertakings which does not accord to him any privilege or advantage not generally accorded to the employees to whom the scheme relates;

- any contract, arrangement or transaction concerning any insurance which our company is to purchase and/or maintain for, or for the benefit of, any directors or persons including directors;
- the giving of an indemnity in relation to another director; and
- the provision of funds to any director to meet, or the doing of anything to enable a director to avoid incurring, expenditure of the nature described in section 205(1) or 206 of the Companies Act.

If a question arises at a meeting of the board or of a committee of the board as to the right of a director to vote or be counted in the quorum, and such question is not resolved by his voluntarily agreeing to abstain from voting or not to be counted in the quorum, the question shall be determined by the chairman and his ruling in relation to any director other than himself shall be final and conclusive except in a case where the nature or extent of the interest of the director concerned has not been fairly disclosed.

Directors' fees and remuneration

Each of the directors shall be paid a fee at such rate as may from time to time be determined by the board (or for the avoidance of doubt any duly authorized committee of the board) provided that the aggregate of all such fees so paid to directors shall not exceed £2,000,000 per annum, or such higher amount as may from time to time be determined by ordinary resolution of shareholders.

Each director may be paid his reasonable traveling, hotel and other expenses of attending and returning from meetings of the board or committees of the board or general meetings or separate meetings of the holders of any class of shares or of debentures and shall be paid all expenses properly incurred by him in the conduct of the company's business.

Any director who is appointed to any executive office or who serves on any committee or who devotes special attention to the business of our company, or who otherwise performs services which in the opinion of the directors are outside the scope of the ordinary duties of a director, may be paid such extra remuneration by way of salary, commission, participation in profits or otherwise as the directors may determine.

Borrowing powers

The board of directors may exercise all the powers to borrow money, which shall not, without the previous sanction of an ordinary resolution of the shareholders, exceed an amount equal to £100,000,000, provide and indemnity or guarantee, and to mortgage or charge our undertaking, property and assets (present or future) and uncalled capital or any part thereof and to issue debentures and other securities and give security, whether outright or as collateral security for any debt, liability or obligation of us or of any third party.

Indemnity

Every director or other officer of our group may be indemnified against all costs, charges, expenses, losses and liabilities incurred by them in connection with that director's or officer's duties or powers in relation to the company or other members of our group.

Exclusive jurisdiction

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 federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Save in respect of any cause of action arising under the Securities Act, by subscribing for or acquiring shares, a shareholder submits all disputes between him or herself and us or our directors to the exclusive jurisdiction of the English courts.

Other English law considerations

Notification of voting rights

A shareholder in a public company incorporated in the United Kingdom whose shares are admitted to trading on AIM is required pursuant to Rule 5 of the Disclosure Guidance and Transparency Rules of the U.K. Financial Conduct Authority to notify us of the percentage of his or her voting rights if the percentage of voting rights which he or she holds as a shareholder or through his or her direct or indirect holding of financial instruments (or a combination of such holdings) reaches, exceeds or falls below 3%, 4%, 5%, and each 1% threshold thereafter up to 100% as a result of an acquisition or disposal of shares or financial instruments.

Mandatory purchases and acquisitions

Pursuant to Sections 979 to 991 of the Companies Act, where a takeover offer has been made for us and the offeror has acquired or unconditionally contracted to acquire not less than 90% in value of the shares to which the offer relates and not less than 90% of the voting rights carried by those shares, the offeror may give notice to the holder of any shares to which the offer relates which the offeror has not acquired or unconditionally contracted to acquire that he wishes to acquire, and is entitled to so acquire, those shares on the same terms as the general offer. The offeror would do so by sending a notice to the outstanding minority shareholders telling them that it will compulsorily acquire their shares.

Such notice must be sent within three months of the last day on which the offer can be accepted in the prescribed manner. The squeeze-out of the minority shareholders can be completed at the end of six weeks from the date the notice has been given, subject to the minority shareholders failing to successfully lodge an application to the court to prevent such squeeze-out any time prior to the end of those six weeks following which the offeror can execute a transfer of the outstanding shares in its favor and pay the consideration to us, which would hold the consideration on trust for the outstanding minority shareholders. The consideration offered to the outstanding minority shareholders whose shares are compulsorily acquired under the Companies Act must, in general, be the same as the consideration that was available under the takeover offer.

Sell out

The Companies Act also gives our minority shareholders a right to be bought out in certain circumstances by an offeror who has made a takeover offer for all of our shares. The holder of shares to which the offer relates, and who has not otherwise accepted the offer, may require the offeror to acquire his shares if, prior to the expiry of the acceptance period for such offer, (1) the offeror has acquired or unconditionally agreed to acquire not less than 90% in value of the voting shares, and (2) not less than 90% of the voting rights carried by those shares. The offeror may impose a time limit on the rights of minority shareholders to be bought out that is not less than three months after the end of the acceptance period. If a shareholder exercises his rights to be bought out, the offeror is required to acquire those shares on the terms of this offer or on such other terms as may be agreed.

Disclosure of interest in shares

Pursuant to Part 22 of the Companies Act and our articles of association, we are empowered by notice in writing to any person whom we know or have reasonable cause to believe to be interested in our shares, or at any time during the three years immediately preceding the date on which the notice is issued has been so interested, within a reasonable time to disclose to us particulars of that person's interest and (so far as is within his knowledge) particulars of any other interest that subsists or subsisted in those shares.

Under our articles of association, if a person defaults in supplying us with the required particulars in relation to the shares in question, or default shares, within the prescribed period, the directors may by notice direct that:

- in respect of the default shares, the relevant shareholder shall not be entitled to vote (either in person or by representative or proxy) at any general meeting or to exercise any other right conferred by a shareholding in relation to general meetings; and

- where the default shares represent at least 0.25% in nominal value of the issued shares of their class, (a) any dividend or other money payable in respect of the default shares shall be retained by us without liability to pay interest and/or (b) no transfers by the relevant shareholder of any default shares may be registered (unless the shareholder himself is not in default and the shareholder provides a certificate, in a form satisfactory to the directors, to the effect that after due and careful enquiry the shareholder is satisfied that none of the shares to be transferred are default shares).

Purchase of own shares

Under the laws of England and Wales, a limited company may only purchase its own shares out of the distributable profits of the company or the proceeds of a fresh issue of shares made for the purpose of financing the purchase, provided that they are not restricted from doing so by their articles of association. A limited company may not purchase its own shares if, as a result of the purchase, there would no longer be any issued shares of the company other than redeemable shares or shares held as treasury shares. Shares must be fully paid in order to be repurchased.

Subject to the above, we may purchase our own shares in the manner prescribed below. We may make an "on-market" purchase of our own fully paid shares pursuant to an ordinary resolution of shareholders. The resolution authorizing the purchase must:

- specify the maximum number of shares authorized to be acquired;
- determine the maximum and minimum prices that may be paid for the shares; and
- specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

We may purchase our own fully paid shares in an "off-market" purchase otherwise than on a recognized investment exchange pursuant to a purchase contract authorized by resolution of shareholders before the purchase takes place. Any authority will not be effective if any shareholder from whom we propose to purchase shares votes on the resolution and the resolution would not have been passed if he had not done so. The resolution authorizing the purchase must specify a date, not being later than five years after the passing of the resolution, on which the authority to purchase is to expire.

For these purposes, on-market purchases can only be made on AIM. Any purchase of our ADSs through the Nasdaq Global Market would be an off-market purchase.

Distributions and dividends

Under the Companies Act, before a company can lawfully make a distribution or dividend, it must ensure that it has sufficient distributable reserves (on a non-consolidated basis). The basic rule is that a company's profits available for the purpose of making a distribution are its accumulated, realized profits, so far as not previously utilized by distribution or capitalization, less its accumulated, realized losses, so far as not previously written off in a reduction or reorganization of capital duly made. The requirement to have sufficient distributable reserves before a distribution or dividend can be paid applies to us and to each of our subsidiaries that has been incorporated under the laws of England and Wales.

It is not sufficient that we, as a public company, have made a distributable profit for the purpose of making a distribution. An additional capital maintenance requirement is imposed on us to ensure that the net worth of the company is at least equal to the amount of its capital. A public company can only make a distribution:

- if, at the time that the distribution is made, the amount of its net assets (that is, the total excess of assets over liabilities) is not less than the total of its called up share capital and undistributable reserves; and

- if, and to the extent that, the distribution itself, at the time that it is made, does not reduce the amount of the net assets to less than that total.

City Code on Takeovers and Mergers

As a public company incorporated in England and Wales with our registered office in England and Wales which has shares admitted to AIM, we are subject to the U.K. City Code on Takeovers and Mergers, or the City Code, which is issued and administered by the U.K. Panel on Takeovers and Mergers, or the Panel. The City Code provides a framework within which takeovers of companies subject to it are conducted. In particular, the City Code contains certain rules in respect of mandatory offers. Under Rule 9 of the City Code, if a person:

- acquires an interest in our shares which, when taken together with shares in which he or persons acting in concert with him are interested, carries 30% or more of the voting rights of our shares; or
- who, together with persons acting in concert with him, is interested in shares that in the aggregate carry not less than 30% and not more than 50% of the voting rights of our shares, and such persons, or any person acting in concert with him, acquires additional interests in shares that increase the percentage of shares carrying voting rights in which that person is interested,

the acquirer and depending on the circumstances, its concert parties, would be required (except with the consent of the Panel) to make a cash offer for our outstanding shares at a price not less than the highest price paid for any interests in the shares by the acquirer or its concert parties during the previous twelve months.

Under the City Code, a "concert party" arises where persons acting together pursuant to an agreement or understanding (whether formal or informal and whether or not in writing) cooperate, through the acquisition by them of an interest in shares in a company, to obtain or consolidate control of the company. "Control" means holding, or aggregate holdings, of an interest in shares carrying 30% or more of the voting rights of the company, irrespective of whether the holding or holdings give de facto control.

When our ordinary shares were admitted to trading on AIM in November 2018, the Panel confirmed that three distinct concert parties existed and that the three distinct concert parties were not considered to be acting in concert as between each other. As at July 9, 2020 each concert party had an aggregate shareholding representing less than 29.99% in the share capital of the Company. The concert parties are the EKF Concert Party (consisting of EKF Diagnostics Holdings plc, Christopher Mills, Julian Baines, Richard Evans, Adam Reynolds, Carl Dominic Contadini and Salim Hamir), which as of July 9, 2020 held, in aggregate 13,813,939 ordinary shares and 80,724 options to subscribe for ordinary shares, the Mount Sinai Concert Party (consisting of the Icahn School of Medicine at Mount Sinai, Barbara Murphy, MD, Steven Coca, MD, Girish Nadkarni, MD, and Michael Donovan, MD), which as at July 9, 2020 held, in aggregate 9,004,226 ordinary shares and 850,295 options to subscribe for ordinary shares, and the Renwick Concert Party (consisting of Renwick Capital LLC, James McCullough and O. James Sterling), which as at July 9, 2020 held, in aggregate 4,772,750 ordinary shares.

Exchange controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash, cash equivalents and short-term investments for use by us, or that may affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs representing our ordinary shares, other than withholding tax requirements. There is no limitation imposed by the laws of England and Wales or in the articles of association on the right of non-residents to hold or vote shares.

Corporate governance code

The AIM Rules for Companies published by the London Stock Exchange require us to include on our website details of a recognized corporate governance code that our board of directors has decided to apply, how we

comply with that code and, where we depart from our chosen corporate governance code, an explanation of the reasons for doing so.

The company recognizes the value of good corporate governance in every part of its business. Our board of directors has adopted the principles of the Quoted Companies Alliance's Corporate Governance Code (2018 edition), or the QCA Code. Our board of directors views this as an appropriate corporate governance framework for our company and consideration has been given to each of the ten principles set out in the code. We provide a statement of compliance with the QCA Code on our website which we update annually on the website and in our annual report.

Differences in corporate law

The applicable provisions of the Companies Act differ from laws applicable to U.S. corporations and their shareholders. Set forth below is a summary of certain differences between the provisions of the Companies Act applicable to us and the General Corporation Law of the State of Delaware relating to shareholders' rights and protections. This summary is not intended to be a complete discussion of the respective rights and it is qualified in its entirety by reference to Delaware law and the laws of England and Wales.

	England and Wales	**Delaware**
Number of Directors	Under the Companies Act, a public limited company must have at least two directors and the number of directors may be fixed by or in the manner provided in a company's articles of association.	Under Delaware law, a corporation must have at least one director and the number of directors shall be fixed by or in the manner provided in the bylaws.
Removal of Directors	Under the Companies Act, shareholders may remove a director without cause by an ordinary resolution (which is passed by a simple majority of those voting in person or by proxy at a general meeting) irrespective of any provisions of any service contract the director has with the company, provided 28 clear days' notice of the resolution has been given to the company and its shareholders. On receipt of notice of an intended resolution to remove a director, the company must forthwith send a copy of the notice to the director concerned. Certain other procedural requirements under the. Companies Act must also be followed such as allowing the director to make representations against his or her removal either at the meeting or in writing.	Under Delaware law, any director or the entire board of directors may be removed, with or without cause, by the holders of a majority of the shares then entitled to vote at an election of directors, except (a) unless the certificate of incorporation provides otherwise, in the case of a corporation whose board of directors is classified, shareholders may effect such removal only for cause, or (b) in the case of a corporation having cumulative voting, if less than the entire board of directors is to be removed, no director may be removed without cause if the votes cast against his removal would be sufficient to elect him if then cumulatively voted at an election of the entire board of directors, or, if there are classes of directors, at an election of the class of directors of which he is a part.
Vacancies on the Board of Directors	Under the laws of England and Wales, the procedure by which	Under Delaware law, vacancies and newly created directorships

	England and Wales	Delaware
	directors, other than a company's initial directors, are appointed is generally set out in a company's articles of association, provided that where two or more persons are appointed as directors of a public limited company by resolution of the shareholders, resolutions appointing each director must be voted on individually.	may be filled by a majority of the directors then in office (even though less than a quorum) or by a sole remaining director unless (a) otherwise provided in the certificate of incorporation or by-laws of the corporation or (b) the certificate of incorporation directs that a particular class of stock is to elect such director, in which case a majority of the other directors elected by such class, or a sole remaining director elected by such class, will fill such vacancy.
Annual General Meeting	Under the Companies Act, a public limited company must hold an annual general meeting in each six-month period following its annual accounting reference date.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the Companies Act, a general meeting of the shareholders of a public limited company may be called by the directors. Shareholders holding at least 5% of the paid-up capital of the company carrying voting rights at general meetings (excluding any paid up capital held as treasury shares) can require the directors to call a general meeting and, if the directors fail to do so within a certain period, may themselves convene a general meeting.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	Subject to a company's articles of association providing for a longer period, under the Companies Act, 21 clear days' notice must be given for an annual general meeting and any resolutions to be proposed at the meeting. Subject to a company's articles of association providing for a longer	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and

	England and Wales	Delaware
	period, at least 14 clear days' notice is required for any other general meeting. In addition, certain matters, such as the removal of directors or auditors, require special notice, which is 28 clear days' notice. The shareholders of a company may in all cases consent to a shorter notice period, the proportion of shareholders' consent required being 100% of those entitled to attend and vote in the case of an annual general meeting and, in the case of any other general meeting, a majority in number of the members having a right to attend and vote at the meeting, being a majority who together hold not less than 95% in nominal value of the shares giving a right to attend and vote at the meeting.	shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	Under the Companies Act, at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.
Preemptive Rights	Under the Companies Act, "equity securities," being (1) shares in the company other than shares that, with respect to dividends and capital, carry a right to participate only up to a specified amount in a distribution, referred to as "ordinary shares," or (2) rights to subscribe for, or to convert securities into, ordinary shares, proposed to be allotted for cash must be offered first to the existing equity shareholders in the company in proportion to the respective nominal value of their	Under Delaware law, shareholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.

	England and Wales	Delaware
	holdings, unless an exception applies or a special resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act.	
Authority to Allot	Under the Companies Act, the directors of a company must not allot shares or grant of rights to subscribe for or to convert any security into shares unless an exception applies or an ordinary resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act.	Under Delaware law, if the corporation's charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.
Liability of Directors and Officers	Under the Companies Act, any provision, whether contained in a company's articles of association or any contract or otherwise, that purports to exempt a director of a company, to any extent, from any liability that would otherwise attach to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. Any provision by which a company directly or indirectly provides an indemnity, to any extent, for a director of the company or of an associated company against any liability attaching to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he is a director is also void except as permitted by the Companies	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful

	England and Wales	Delaware
	Act, which provides exceptions for the company to (a) purchase and maintain insurance against such liability; (b) provide a "qualifying third party indemnity" (being an indemnity against liability incurred by the director to a person other than the company or an associated company or criminal proceedings in which he is convicted); and (c) provide a "qualifying pension scheme indemnity" (being an indemnity against liability incurred in connection with our activities as trustee of an occupational pension plan).	dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.
Voting Rights	Under the laws of England and Wales, unless a poll is demanded by the shareholders of a company or is required by the chairman of the meeting or our articles of association, shareholders shall vote on all resolutions on a show of hands. Under the Companies Act, a poll may be demanded by (a) not fewer than five shareholders having the right to vote on the resolution; (b) any shareholder(s) representing not less than 10% of the total voting rights of all the shareholders having the right to vote on the resolution (excluding any voting rights attaching to treasury shares); or (c) any shareholder(s) holding shares in the company conferring a right to vote on the resolution (excluding any voting rights attaching to treasury shares) being shares on which an aggregate sum has been paid up equal to not less than 10% of the total sum paid up on all the shares conferring that right. A company's articles of association may provide more extensive rights for shareholders to call a poll.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

	England and Wales	Delaware
	Under the laws of England and Wales, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present, in person or by proxy, who, being entitled to vote, vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present, in person or by proxy, at the meeting. If a poll is demanded, a special resolution is passed if it is approved by holders representing not less than 75% of the total voting rights of shareholders in person or by proxy who, being entitled to vote, vote on the resolution.	
Shareholder Vote on Certain Transactions	The Companies Act provides for schemes of arrangement, which are arrangements or compromises between a company and any class of shareholders or creditors and used in certain types of reconstructions, amalgamations, capital reorganizations, or takeovers. These arrangements require: • the approval at a shareholders' or creditors' meeting convened by order of the court, of a majority in number of shareholders or creditors representing 75% in value of the capital held by, or debt owed to, the class of shareholders or creditors, or class thereof present and voting, either in person or by proxy; and	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

	England and Wales	Delaware
	• the approval of the court.	
Standard of Conduct for Directors	Under the laws of England and Wales, a director owes various statutory and fiduciary duties to the company, including: • to act in the way he considers, in good faith, would be most likely to promote the success of the company for the benefit of its members as a whole; • to avoid a situation in which he has, or can have, a direct or indirect interest that conflicts, or possibly conflicts, with the interests of the company; • to act in accordance with our constitution and only exercise his powers for the purposes for which they are conferred; • to exercise independent judgment; • to exercise reasonable care, skill, and diligence; • not to accept benefits from a third party conferred by reason of his being a director or doing, or not doing, anything as a director; and • a duty to declare any interest that he has, whether directly or indirectly, in a proposed or existing transaction or arrangement with the company.	Delaware law does not contain specific provisions setting forth the standard of conduct of a director. The scope of the fiduciary duties of directors is generally determined by the courts of the State of Delaware. In general, directors have a duty to act without self-interest, on a well-informed basis and in a manner they reasonably believe to be in the best interest of the stockholders. Directors of a Delaware corporation owe fiduciary duties of care and loyalty to the corporation and to its shareholders. The duty of care generally requires that a director act in good faith, with the care that an ordinarily prudent person would exercise under similar circumstances. Under this duty, a director must inform himself of all material information reasonably available regarding a significant transaction. The duty of loyalty requires that a director act in a manner he reasonably believes to be in the best interests of the corporation. He must not use his corporate position for personal gain or advantage. In general, but subject to certain exceptions, actions of a director are presumed to have been made on an informed basis, in good faith and in the honest belief that the action taken was in the best interests of the corporation. However, this presumption may be rebutted by evidence of a breach of one of the fiduciary duties. Delaware courts have also imposed a heightened standard of conduct upon directors of a Delaware corporation who take any action designed to defeat

	England and Wales	Delaware
		a threatened change in control of the corporation. In addition, under Delaware law, when the board of directors of a Delaware corporation approves the sale or break-up of a corporation, the board of directors may, in certain circumstances, have a duty to obtain the highest value reasonably available to the shareholders.
Stockholder Suits	Under the laws of England and Wales, generally, the company, rather than its shareholders, is the proper claimant in an action in respect of a wrong done to the company or where there is an irregularity in the company's internal management. Notwithstanding this general position, the Companies Act provides that (1) a court may allow a shareholder to bring a derivative claim (that is, an action in respect of and on behalf of the company) in respect of a cause of action arising from a director's negligence, default, breach of duty or breach of trust and (2) a shareholder may bring a claim for a court order where our affairs have been or are being conducted in a manner that is unfairly prejudicial to some of its shareholders.	Under Delaware law, a stockholder may initiate a derivative action to enforce a right of a corporation if the corporation fails to enforce the right itself. The complaint must: • state that the plaintiff was a stockholder at the time of the transaction of which the plaintiff complains or that the plaintiffs shares thereafter devolved on the plaintiff by operation of law; and • allege with particularity the efforts made by the plaintiff to obtain the action the plaintiff desires from the directors and the reasons for the plaintiff's failure to obtain the action; or • state the reasons for not making the effort. Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Stock exchange listing

Our ADSs are listed on the Nasdaq Global Market under the symbol "RNLX." Our ordinary shares are traded on AIM, a market operated by the London Stock Exchange, under the ticker symbol "RENX."

Registrar of shares, depositary for ADSs

Our share register is maintained by Link Asset Services Limited. The share register reflects only registered holders of our ordinary shares. Holders of ADSs representing our ordinary shares are not treated as our shareholders and their names will therefore not be entered in our share register. Citibank, N.A., or Citibank, acts as the depositary for the ADSs representing our ordinary shares and the custodian for ordinary shares represented by ADSs is Citibank, N.A., London Branch.

C. Material Contracts

Mount Sinai Health System

In May 2018, we entered into a license agreement, or the Mount Sinai Agreement, with the Icahn School of Medicine at Mount Sinai, or 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 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 entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or 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 use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD, or 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.

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into an Advisory Agreement pursuant to which we have 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 us as the sole consideration for the services to be rendered by us under the Advisory Agreement. A portion of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum 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 us).
The term of the Advisory Agreement will continue until the fifth anniversary of the execution thereof, unless earlier terminated. The Advisory Agreement may be terminated by either party upon an uncured material breach of the Advisory Agreement by the other party or in the event the other party is unable to perform under the Advisory Agreement for a specified period of time due to a force majeure event. Kantaro may also terminate the Advisory Agreement by notice to us if we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. See “Item 5—Our key agreements—Kantaro Biosciences LLC” for additional information.

D. Exchange Controls

There are no governmental laws, decrees, regulations or other legislation in the United Kingdom that may affect the import or export of capital, including the availability of cash and cash equivalents for use by us, or that may

affect the remittance of dividends, interest, or other payments by us to non-resident holders of our ordinary shares or ADSs, other than withholding tax requirements. There is no limitation imposed by English law or our articles of association on the right of non-residents to hold or vote shares.

E. Taxation

Material U.S. federal income tax considerations for U.S. Holders

The following is a description of the material U.S. federal income tax consequences to the U.S. Holders described below of owning and disposing of our ordinary shares or ADSs. It is not a comprehensive description of all tax considerations that may be relevant to a particular person's decision to acquire securities. This discussion applies only to a U.S. Holder that holds our ordinary shares or ADSs as a capital asset for tax purposes (generally, property held for investment). In addition, it does not describe all of the tax consequences that may be relevant in light of a U.S. Holder's particular circumstances, including state and local tax consequences, estate tax consequences, alternative minimum tax consequences, the potential application of the Medicare contribution tax, and tax consequences applicable to U.S. Holders subject to special rules, such as:

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, "straddle," wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose "functional currency" for U.S. federal income tax purposes is not the U.S. dollar;
- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

If an entity that is classified as a partnership for U.S. federal income tax purposes holds ordinary shares or ADSs, the U.S. federal income tax treatment of a partner will generally depend on the status of the partner and the activities of the partnership. Partnerships holding ordinary shares or ADSs and partners in such partnerships are encouraged to consult their tax advisors as to the particular U.S. federal income tax consequences of holding and disposing of ordinary shares or ADSs.

The discussion is based on the Code, administrative pronouncements, judicial decisions, final, temporary and proposed Treasury Regulations, and the income tax treaty between the United Kingdom and the United States (the "Treaty"), all as of the date hereof, changes to any of which may affect the tax consequences described herein — possibly with retroactive effect.

A "U.S. Holder" is a holder who, for U.S. federal income tax purposes, is a beneficial owner of ordinary shares or ADSs who is eligible for the benefits of the Treaty and is:

(1) a citizen or individual of the United States;

(2) a corporation, or other entity taxable as a corporation for U.S. federal income tax purposes, created or organized in or under the laws of the United States, any state therein or the District of Columbia;

(3) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or

(4) a trust if (1) a U.S. court is able to exercise primary supervision over the administration of the trust and one or more U.S. persons have authority to control all substantial decisions of the trust or (2) the trust has a valid election to be treated as a U.S. person under applicable U.S. Treasury Regulations.

U.S. Holders are encouraged to consult their tax advisors concerning the U.S. federal, state, local and non-U.S. tax consequences of owning and disposing of ordinary shares or ADSs in their particular circumstances.

The discussion below assumes that the representations contained in the deposit agreement are true and that the obligations in the deposit agreement and any related agreement will be complied with in accordance with their terms. Generally, a holder of an ADS should be treated for U.S. federal income tax purposes as holding the ordinary shares represented by the ADS. Accordingly, no gain or loss will be recognized upon an exchange of ADSs for ordinary shares.

Passive Foreign Investment Company rules

A non-U.S. corporation will be classified as a PFIC for any taxable year in which, after applying certain look-through rules, either:

- at least 75% of its gross income is passive income (such as interest income); or
- at least 50% of its gross assets (determined on the basis of a quarterly average) is attributable to assets that produce passive income or are held for the production of passive income (including cash).

For purposes of this test, a non-U.S. corporation will be treated as owning its proportionate share of the assets and earning its proportionate share of the income of any other corporation, the equity of which such non-U.S. corporation owns, directly or indirectly, 25% or more (by value).

Based on our current estimates of the composition of our income and valuation of our assets, including goodwill, we believe that we may be treated as a PFIC for our taxable year ending June 30, 2020. Based on our operating history and the projected composition of our income and valuation of our assets, including goodwill, we may also be treated as a PFIC for our taxable year ending June 30, 2021. In addition, the U.S. tax treatment of the FractalDx spin-off is complex. The FractalDX spin-off may cause us to incur additional passive income (based in part on the fair market value of the Verici Dx shares distributed to our shareholders) which could make it more likely that we are treated as a PFIC. U.S. Holders should consult with their tax advisors regarding the implications of owning stock in a PFIC. A separate determination must be made after the close of each taxable year as to whether we are a PFIC for that year. As a result, our PFIC status may change. In particular, the total value of our assets for purposes of the asset test generally will be calculated using the market price of the ordinary shares or ADSs, which may fluctuate considerably. Fluctuations in the market price of the ordinary shares or ADSs may result in our being a PFIC for any taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. 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 classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless we cease to be a PFIC and the U.S. Holder has made a “deemed sale” election under the PFIC rules. If such a deemed sale election is made, a U.S. Holder will be deemed to have sold the ordinary shares or ADSs

the U.S. Holder holds at their fair market value and any gain from such deemed sale would be subject to the rules described below. After the deemed sale election, so long as we do not become a PFIC in a subsequent taxable year, the U.S. Holder's ordinary shares or ADSs with respect to which such election was made will not be treated as shares in a PFIC and the U.S. Holder will not be subject to the rules described below with respect to any "excess distribution" the U.S. Holder receives from us or any gain from an actual sale or other disposition of the ordinary shares or ADSs. U.S. Holders should consult their tax advisors as to the possibility and consequences of making a deemed sale election if we cease to be a PFIC and such election becomes available.

For each taxable year we are treated as a PFIC with respect to U.S. Holders, U.S. Holders will be subject to special tax rules with respect to any "excess distribution" such U.S. Holder receives and any gain such U.S. Holder recognizes from a sale or other disposition (including a pledge) of ordinary shares or ADSs, unless (i) such U.S. Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC, or (ii) our ordinary shares or ADSs constitute "marketable stock" and such U.S. Holder makes a mark-to-market election (as discussed below). Distributions a U.S. Holder receives in a taxable year that are greater than 125% of the average annual distributions a U.S. Holder received during the shorter of the three preceding taxable years or the U.S. Holder's holding period for the ordinary shares or ADSs will be treated as an excess distribution. Under these special tax rules:

- the excess distribution or gain will be allocated ratably over a U.S. Holder's holding period for the ordinary shares or ADSs;
- the amount allocated to the current taxable year, and any taxable year prior to the first taxable year in which we became a PFIC, will be treated as ordinary income; and
- the amount allocated to each other year will be subject to the highest tax rate in effect for that year and the interest charge generally applicable to underpayments of tax will be imposed on the resulting tax attributable to each such year.

The tax liability for amounts allocated to years prior to the year of disposition or "excess distribution" cannot be offset by any net operating losses for such years, and gains (but not losses) realized on the sale of the ordinary shares or ADSs cannot be treated as capital, even if a U.S. Holder holds the ordinary shares or ADSs as capital assets.

If we are a PFIC, a U.S. Holder will generally be subject to similar rules with respect to distributions we receive from, and our dispositions of the stock of, any of our direct or indirect subsidiaries that also are PFICs, as if such distributions were indirectly received by, and/or dispositions were indirectly carried out by, such U.S. Holder. U.S. Holders should consult their tax advisors regarding the application of the PFIC rules to our subsidiaries.

If a U.S. Holder makes an effective QEF Election, the U.S. Holder will be required to include in gross income each year, whether or not we make distributions, as capital gains, such U.S. Holder's pro rata share of our net capital gains and, as ordinary income, such U.S. Holder's pro rata share of our earnings in excess of our net capital gains. However, a U.S. Holder can only make a QEF election with respect to ordinary shares or ADSs in a PFIC if such company agrees to furnish such U.S. Holder with certain tax information annually. An electing U.S. Holder's basis in ordinary shares or ADSs will be increased to reflect the amount of any taxed but undistributed income. Distributions of income that had previously been taxed will result in a corresponding reduction of basis in the ordinary shares or ADSs and may not be taxed again as distributions to the U.S. Holder.

A QEF election made with respect to the company will not apply to any non-U.S. subsidiary that is a PFIC; a QEF election must be made separately for each such subsidiary (in which case the treatment described above would apply to such subsidiary). If a U.S. Holder makes a timely QEF election with respect to a subsidiary PFIC, it would be required in each taxable year to include in gross income its pro rata share of the ordinary earnings and net capital gain of such subsidiary PFIC.

If the company determines that it, and any non-U.S. subsidiary in which the company owns, directly or indirectly, more than 50% of such subsidiary's total aggregate voting power, is a PFIC in any taxable year, the

company intends to make available to U.S. Holders, upon request and in accordance with applicable procedures and confidentiality requirements, a "PFIC Annual Information Statement" with respect to the company and any such subsidiary for such taxable year. The "PFIC Annual Information Statement" may be used by U.S. Holders for purposes of complying with the reporting requirements applicable to a QEF election with respect to the company and any subsidiary PFIC.

U.S. Holders should note that if they make QEF elections with respect to us (and any subsidiary PFICs), they may be required to pay U.S. federal income tax with respect to their ordinary shares or ADSs for any taxable year significantly in excess of any cash distributions (which are expected to be zero) received on the ordinary shares or ADSs for such taxable year. U.S. Holders should consult their tax advisors regarding PFIC investments and making QEF elections based on their particular circumstances.

U.S. Holders can avoid the interest charge on excess distributions or gain relating to the ordinary shares or ADSs by making a mark-to-market election with respect to the ordinary shares or ADSs, provided that the ordinary shares or ADSs are "marketable stock." Ordinary shares or ADSs will be marketable stock if they are "regularly traded" on certain U.S. stock exchanges or on a non-U.S. stock exchange that meets certain conditions. For these purposes, the ordinary shares or ADSs will be considered regularly traded during any calendar year during which they are traded, other than in de minimis quantities, on at least 15 days during each calendar quarter. Any trades that have as their principal purpose meeting this requirement will be disregarded. Our ADSs will be listed on the Nasdaq, which is a qualified exchange for these purposes. Consequently, if our ADSs remain listed on the Nasdaq and are regularly traded, and you are a holder of ADSs, we expect the mark-to-market election would be available to U.S. Holders if we are a PFIC. Each U.S. Holder should consult its tax advisor as to the whether a mark-to-market election is available or advisable with respect to the ordinary shares or ADSs.

A U.S. Holder that makes a mark-to-market election must include in ordinary income for each year an amount equal to the excess, if any, of the fair market value of the ordinary shares or ADSs at the close of the taxable year over the U.S. Holder's adjusted tax basis in the ordinary shares or ADSs. An electing holder may also claim an ordinary loss deduction for the excess, if any, of the U.S. Holder's adjusted basis in the ordinary shares or ADSs over the fair market value of the ordinary shares or ADSs at the close of the taxable year, but this deduction is allowable only to the extent of any net mark-to-market gains for prior years. Gains from an actual sale or other disposition of the ordinary shares or ADSs will be treated as ordinary income, and any losses incurred on a sale or other disposition of the shares will be treated as an ordinary loss to the extent of any net mark-to-market gains for prior years. Once made, the election cannot be revoked without the consent of the IRS unless the ordinary shares or ADSs cease to be marketable stock.

However, a mark-to-market election generally cannot be made for equity interests in any lower-tier PFICs that we own, unless shares of such lower-tier PFIC are themselves "marketable stock." As a result, even if a U.S. Holder validly makes a mark-to-market election with respect to our ordinary shares or ADSs, the U.S. Holder may continue to be subject to the PFIC rules (described above) with respect to its indirect interest in any of our investments that are treated as an equity interest in a PFIC for U.S. federal income tax purposes. U.S. Holders should consult their tax advisors as to the availability and desirability of a mark-to-market election, as well as the impact of such election on interests in any lower-tier PFICs.

Unless otherwise provided by the U.S. Treasury, each U.S. shareholder of a PFIC is required to file an annual report containing such information as the U.S. Treasury may require. A U.S. Holder's failure to file the annual report will cause the statute of limitations for such U.S. Holder's U.S. federal income tax return to remain open with regard to the items required to be included in such report until three years after the U.S. Holder files the annual report, and, unless such failure is due to reasonable cause and not willful neglect, the statute of limitations for the U.S. Holder's entire U.S. federal income tax return will remain open during such period. U.S. Holders should consult their tax advisors regarding the requirements of filing such information returns under these rules.

Taxation of distributions

Subject to the discussion above under "Passive Foreign Investment Company Rules," distributions paid on ordinary shares or ADSs, other than certain *pro rata* distributions of ordinary shares or ADSs, will generally be treated as dividends to the extent paid out of our current or accumulated earnings and profits (as determined under U.S. federal income tax principles). Because we may not calculate our earnings and profits under U.S. federal income tax principles, we expect that distributions generally will be reported to U.S. Holders as dividends. Subject to applicable limitations, dividends paid to certain non-corporate U.S. Holders may be taxable at preferential rates applicable to "qualified dividend income." However, the qualified dividend income treatment may not apply if we are treated as a PFIC with respect to the U.S. Holder. The amount of the dividend will be treated as foreign-source dividend income to U.S. Holders and will not be eligible for the dividends-received deduction generally available to U.S. corporations under the Code. Dividends will generally be included in a U.S. Holder's income on the date of the U.S. Holder's receipt of the dividend. The amount of any dividend income paid in foreign currency will be the U.S. dollar amount calculated by reference to the exchange rate in effect on the date of actual or constructive receipt, regardless of whether the payment is in fact converted into U.S. dollars. If the dividend is converted into U.S. dollars on the date of receipt, a U.S. Holder should not be required to recognize foreign currency gain or loss in respect of the dividend income. A U.S. Holder may have foreign currency gain or loss if the dividend is converted into U.S. dollars after the date of receipt. Such gain or loss would generally be treated as U.S.-source ordinary income or loss. The amount of any distribution of property other than cash (and other than certain pro rata distributions of ordinary shares or ADSs or rights to acquire ordinary shares or ADSs) will be the fair market value of such property on the date of distribution. For foreign tax credit purposes, our dividends will generally be treated as passive category income.

Sale or other taxable disposition of ordinary shares and ADSs

Subject to the discussion above under "Passive Foreign Investment Company Rules," gain or loss realized on the sale or other taxable disposition of ordinary shares or ADSs will be capital gain or loss, and will be long-term capital gain or loss if the U.S. Holder held the ordinary shares or ADSs for more than one year. The amount of the gain or loss will equal the difference between the U.S. Holder's tax basis in the ordinary shares or ADSs disposed of and the amount realized on the disposition, in each case as determined in U.S. dollars. This gain or loss will generally be U.S.-source gain or loss for foreign tax credit purposes. The deductibility of capital losses is subject to limitations.

If the consideration received by a U.S. Holder is not paid in U.S. dollars, the amount realized will be the U.S. dollar value of the payment received determined by reference to the spot rate of exchange on the date of the sale or other disposition. However, if the ordinary shares or ADSs are treated as traded on an "established securities market" and you are either a cash basis taxpayer or an accrual basis taxpayer that has made a special election (which must be applied consistently from year to year and cannot be changed without the consent of the IRS), you will determine the U.S. dollar value of the amount realized in a non-U.S. dollar currency by translating the amount received at the spot rate of exchange on the settlement date of the sale. If you are an accrual basis taxpayer that is not eligible to or does not elect to determine the amount realized using the spot rate on the settlement date, you will recognize foreign currency gain or loss to the extent of any difference between the U.S. dollar amount realized on the date of sale or disposition and the U.S. dollar value of the currency received at the spot rate on the settlement date.

WE STRONGLY URGE YOU TO CONSULT YOUR TAX ADVISOR REGARDING THE IMPACT OF OUR PFIC STATUS ON YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs AS WELL AS THE APPLICATION OF THE PFIC RULES TO YOUR INVESTMENT IN THE ORDINARY SHARES OR ADSs.

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup

withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

Backup withholding is not an additional tax. The amount of any backup withholding from a payment to a U.S. Holder will be allowed as a credit against the holder's U.S. federal income tax liability and may entitle it to a refund, provided that the required information is timely furnished to the IRS.

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions). U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

United Kingdom taxation

The following is intended as a general guide to current U.K. tax law and HM Revenue & Customs, or HMRC, published practice applying as at the date of this annual report (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding of ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all U.K. tax considerations relating to the holding of ADSs, or all of the circumstances in which holders of ADSs may benefit from an exemption or relief from U.K. taxation. It is written on the basis that the company does not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from U.K. land, and that the company is and remains solely resident in the U.K. for tax purposes and will therefore be subject to the U.K. tax regime and not the U.S. tax regime save as set out in the above under "Material U.S. Federal Income Tax Considerations for U.S. Holders".

Except to the extent that the position of non-U.K. resident persons is expressly referred to, this guide relates only to persons who are resident (and, in the case of individuals, domiciled or deemed domiciled) for tax purposes solely in the United Kingdom and do not have a permanent establishment or fixed base in any other jurisdiction with which the holding of the ADSs is connected, or U.K. Holders, who are absolute beneficial owners of the ADSs (where the ADSs are not held through an Individual Savings Account or a Self-Invested Personal Pension) and who hold the ADSs as investments.

This guide may not relate to certain classes of U.K. Holders, such as (but not limited to):

- persons who are connected with the company;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities;
- persons who have (or are deemed to have) acquired their ADSs by virtue of an office or employment or who are or have been officers or employees of the company or any of its affiliates; and
- individuals who are subject to U.K. taxation on a remittance basis.

The decision of the First-tier Tribunal (Tax Chamber) in HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial

owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for U.K. purposes as that person's own income) for U.K. direct tax purposes.

THESE PARAGRAPHS ARE A SUMMARY OF CERTAIN U.K. TAX CONSIDERATIONS AND ARE INTENDED AS A GENERAL GUIDE ONLY. IT IS RECOMMENDED THAT ALL HOLDERS OF ADSs OBTAIN ADVICE AS TO THE CONSEQUENCES OF THE ACQUISITION, OWNERSHIP AND DISPOSAL OF THE ADSs IN THEIR OWN SPECIFIC CIRCUMSTANCES FROM THEIR TAX ADVISORS. IN PARTICULAR, NON-U.K. RESIDENT OR DOMICILED PERSONS ARE ADVISED TO CONSIDER THE POTENTIAL IMPACT OF ANY RELEVANT DOUBLE TAXATION AGREEMENTS.

U.K. taxation of dividends

Withholding tax

Dividends paid by the company will not be subject to any withholding or deduction for or on account of U.K. tax.

Income tax

An individual U.K. Holder may, depending on his or her particular circumstances, be subject to U.K. income tax on dividends received from the company. An individual holder of ADSs who is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. income tax on dividends received from the company unless he or she carries on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency to which the ADSs are attributable. There are certain exceptions for trading in the United Kingdom through independent agents, such as some brokers and investment managers.

All dividends received by an individual U.K. Holder from us or from other sources will form part of that U.K. Holder's total income for income tax purposes and will constitute the top slice of that income. For the tax year 2020/2021, a nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the individual U.K. Holder. Income within the nil rate band will be taken into account in determining whether income in excess of the £2,000 tax-free allowance falls within the basic rate, higher rate or additional rate tax bands. Dividend income in excess of the tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 7.5% to the extent that the excess amount falls within the basic rate tax band, 32.5% to the extent that the excess amount falls within the higher rate tax band and 38.1% to the extent that the excess amount falls within the additional rate tax band.

Corporation tax

A corporate holder of ADSs that is not resident for tax purposes in the United Kingdom should not be chargeable to U.K. corporation tax on dividends received from the company unless it carries on (whether solely or in partnership) a trade in the United Kingdom through a permanent establishment to which the ADSs are attributable.

Corporate U.K. Holders should not be subject to U.K. corporation tax on any dividend received from the company so long as the dividend qualifies for an exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, while of wide application, are not comprehensive and are subject to anti-avoidance rules in relation to a dividend. If the conditions for the exemption are not satisfied or anti-avoidance provisions apply, or such U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the rate of 19% for the tax year 2020/2021).

U.K. taxation of disposals

A disposal or deemed disposal of ADSs by a U.K. Holder may, depending on the U.K. Holder's circumstances and subject to any available exemptions or reliefs (such as the annual exemption), give rise to a chargeable gain or an allowable loss for the purposes of U.K. capital gains tax and corporation tax on chargeable gains.

If an individual U.K. Holder who is subject to U.K. income tax at either the higher or the additional rate is liable to U.K. capital gains tax on the disposal of ADSs, the applicable rate will be 20% (for the tax year 2020/2021). For an individual U.K. Holder who is subject to U.K. income tax at the basic rate and liable to U.K. capital gains tax on such disposal, the applicable rate would be 10% (for the tax year 2020/2021), save to the extent that any capital gains when aggregated with the U.K. Holder's other taxable income and gains in the relevant tax year exceed the unused basic rate tax band. In that case, the rate applicable to the excess would be 20% (for the tax year 2020/2021). In each case above, the amount of capital gains tax payable will be subject to the availability of any exemptions, reliefs and/or allowable losses to such U.K. holder.

If a corporate U.K. Holder becomes liable to U.K. corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of U.K. corporation tax (at the rate of 19% for the tax year 2020/2021) would apply, subject to any exemptions, reliefs and/or allowable losses.

A holder of ADSs which is not resident for tax purposes in the United Kingdom should not normally be liable to U.K. capital gains tax or corporation tax on chargeable gains on a disposal (or deemed disposal) of ADSs unless the person is carrying on (whether solely or in partnership) a trade, profession or vocation in the United Kingdom through a branch or agency (or, in the case of a corporate holder of ADSs, through a permanent establishment) to which the ADSs are attributable. However, an individual holder of ADSs who has ceased to be resident for tax purposes in the United Kingdom or is treated as resident outside the United Kingdom for the purposes of a double taxation treaty for a period of less than five years and who disposes of ADSs during that period of temporary non-residence may be liable on his or her return to the United Kingdom (or upon ceasing to be regarded as resident outside the United Kingdom for the purpose of double taxation relief) to U.K. tax on any capital gain realized (subject to any available exemption or relief).

U.K. stamp duty and stamp duty reserve tax

The discussion below relates to the holders of our ordinary shares or ADSs wherever resident, however it should be noted that special rules may apply to certain persons such as market makers, brokers, dealers or intermediaries.

Issue of ordinary shares

No U.K. stamp duty or stamp duty reserve tax, or SDRT, is payable on the issue of the underlying ordinary shares in the company.

Transfers of ordinary shares

Neither U.K. stamp duty nor SDRT should arise on transfers of the underlying ordinary shares (including instruments transferring ordinary shares and agreements to transfer ordinary shares on the basis that the ordinary shares are admitted to trading on AIM, provided the following requirements are (and continue to be) met:

- the ordinary shares are admitted to trading on AIM, but are not listed on any recognized stock exchange (with the term "listed" being construed in accordance with section 99A of the Finance Act 1986), and this has been certified to Euroclear; and
- AIM continues to be accepted as a "recognised growth market" (as construed in accordance with section 99A of the Finance Act 1986).

In the event that either of the above requirements is not met, stamp duty or SDRT will generally apply to transfers of, or agreements to transfer, ordinary shares. Where applicable, the purchaser normally pays the stamp duty or SDRT.

For the avoidance of doubt, listing of our ADSs on the Nasdaq Global Market should not preclude the above exemption from applying.

Issue or transfers of ADRs

No U.K. stamp duty or SDRT should be payable on the issue or transfer of (including an agreement to transfer) ADRs in the Company.

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

We are subject to the information reporting requirements of the Exchange Act applicable to foreign private issuers and under those requirements will file reports with the SEC. Those reports may be inspected without charge at the locations described below. As a foreign private issuer, we are exempt from the rules under the Exchange Act related to the furnishing and content of proxy statements, and our officers, directors and principal shareholders are exempt from the reporting and short-swing profit recovery provisions contained in Section 16 of the Exchange Act. In addition, we are not required under the Exchange Act to file periodic reports and financial statements with the SEC as frequently or as promptly as United States companies whose securities are registered under the Exchange Act. Nevertheless, we will file with the SEC an Annual Report on Form 20-F containing financial statements that have been examined and reported on, with and opinion expressed by an independent registered public accounting firm.

We maintain a corporate website at *www.renalytixai.com*. We intend to post our annual report on our website promptly following it being filed with the SEC. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report. We have included our website address in this annual report solely as an inactive textual reference.

The Securities and Exchange Commission maintains a website (*www.sec.gov*) that contains reports, proxy and information statements and other information regarding registrants, such as Renalytix AI plc, that file electronically with the SEC.

With respect to references made in this annual report to any contract or other document of our company, such references are not necessarily complete and you should refer to the exhibits attached or incorporated by reference to this annual report for copies of the actual contract or document.

I. Subsidiary Information

Not required.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

We report our consolidated financial results in U.S. dollars. Renalytix AI plc’s and Renalytix AI, Inc.’s function currency is their local currency. The functional currency of Renalytix Al plc is the pound sterling which is

translated into the U.S. dollar for assets and liabilities at the exchange rate at the balance sheet dates and revenue and expenses are translated at the weighted-average exchange rates during the reporting period. Translation adjustments are not included in determining net income (loss) but are included in foreign exchange adjustment to accumulated other comprehensive income (loss), a component of shareholders' equity.

We do not currently engage in currency hedging activities in order to reduce our currency exposure, but we may begin to do so in the future. Instruments that may be used to hedge future risks may include foreign currency forward and swap contracts. These instruments may be used to selectively manage risks, but there can be no assurance that we will be fully protected against material foreign currency fluctuations.

We are exposed to market risk related to changes in interest rates. As of June 30, 2020, we had cash, cash equivalents and short-term investments of $14.3 million consisting of bank deposits and U.S. Treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities.

Our available-for-sale securities are subject to interest rate risk and will fall in value if market interest rates increase.

Due to the short-term duration of our investment portfolio and the low risk profile of our investments, an immediate 10% change in interest rates would not have a material effect on the fair market value of our portfolio. We have the ability to hold our available-sale-securities until maturity, and therefore, we would not expect our operating results or cash flows to be affected to any significant degree by the effect of a change in market interest rates on our investments. We do not currently have any auction rate securities.

Item 12. Description of Securities Other Than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

Citibank N.A., or Citibank, acts as the depositary for the ADSs representing our ordinary shares. Citibank's depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A. (London), located at Citigroup Centre, Canary Wharf, London, E14 5LB, United Kingdom.

We have appointed Citibank as depositary pursuant to a deposit agreement. The form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website (*www.sec.gov*). Please refer to registration number 333-239729 when retrieving such copy.

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

Service	Fee
Issuance of ADSs (*e.g.*, an issuance of ADS(s) upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to $0.05 per ADS issued
Cancellation of ADSs (*e.g.*, a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason)	Up to $0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions (*e.g.*, upon a sale of rights and other entitlements)	Up to $0.05 per ADS held
Distribution of ADSs pursuant to (i) share dividends or other distributions, or (ii) exercise of rights to purchase additional ADSs	Up to $0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (*e.g.*, upon a spin-off)	Up to $0.05 per ADS held
ADS services	Up to $0.05 per ADS held on the applicable record date(s) established by the depositary
Registration of ADS transfers (*e.g.*, upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and *vice versa*, or for any other reason)	Up to $0.05 per ADS transferred
Conversion of ADSs of one series for ADSs of another series (*e.g.*, upon conversion of partial entitlement ADSs for full entitlement ADSs, or upon conversion of restricted ADSs into freely transferable ADSs, and *vice versa*)	Up to $0.05 per ADS converted

As an ADS holder, you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary bank and/or service providers (which may be a division, branch or affiliate of the depositary bank) in the conversion of foreign currency;
- the reasonable and customary out-of-pocket expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are

cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees or charges, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees and charges from any distribution to be made to the ADS holder. Certain depositary fees and charges (such as the ADS services fee) may become payable shortly after the closing of the global offering.

Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADSs, by making available a portion of the ADS fees charged in respect of the ADSs or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

Item 14. Material Modifications to the Rights of Security Holders and Use of Proceeds

Global Offering

In July 2020, we completed a global offering of an aggregate of 12,613,500 ordinary shares. The global offering consisted of (i) an initial public offering in the United States of 12,583,500 ordinary shares in the form of ADSs (a total of 6,291,750 ADSs, including 806,750 ADSs issued pursuant to the exercise of the underwriter's option to purchase additional shares) and (ii) 30,000 ordinary shares sold in a concurrent private placement in Europe and other countries outside the United States. The initial public offering price of the ADSs was $13.50 per share and the offering price of the ordinary shares was £5.37 per share, resulting in aggregate gross proceeds of approximately $85.1 million (equivalent to approximately £67.8 million at the exchange rate used in the prospectus for the global offering). Total underwriting discounts and commissions were approximately $6.0 million.

The global offering commenced on July 16, 2020 and did not terminate before all of the securities registered in the registration statement were sold. The effective date of the registration statement, File No. 333-239414, for the global offering was July 16, 2020.

J.P. Morgan Securities LLC and Stifel, Nicolaus & Company, Incorporated acted as joint global coordinators and joint book-running managers for the global offering.

The net proceeds from the global offering have been used, and are expected to continue to be used, as described in the final prospectus for the global offering filed with the U.S. Securities and Exchange Commission 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 15. Controls and Procedures

A. 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, 2020, have concluded that, as of such date, our disclosure controls and procedures were not effective because of the material weakness described further below.

In connection with the preparation of our consolidated financial statements for the years ended June 30, 2020, 2019 and the period from March 15, 2018 (inception) through June 30, 2018, we concluded that there were material

weaknesses in the design of our internal control over financial reporting. 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 segregation of duties as well as our lack of formal processes and procedures and our lack of maintaining a sufficient complement of personnel commensurate with our accounting and reporting requirements. Currently, we have only two designated finance and accounting employees and rely primarily on consultants to provide many accounting, bookkeeping and administrative services. As of June 30, 2020, these material weaknesses remained unremediated. To address these material weaknesses, we will need to add personnel as well as implement new financial processes. We intend to take steps to remediate the material weaknesses described above through hiring additional qualified accounting and financial reporting personnel, and further evolving our accounting processes and policies. We will not be able to fully remediate these material weaknesses until these steps have been completed and have been operating effectively for a sufficient period of time.

B. Management's Annual Report on Internal Control Over Financial Reporting

This annual report does not include a report of management's assessment regarding internal control over financial reporting due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

C. 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 due to a transition period established by rules of the Securities and Exchange Commission for newly public companies.

D. Changes in Internal Control Over Financial Reporting

There has been no change in our internal control over financial reporting during the fiscal year ended June 30, 2020 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 16A. Audit Committee Financial Expert

Our audit committee consists of Erik Lium, Ph.D., Christopher Mills and Barbara Murphy, M.D. The audit committee consists exclusively of members of our board who are financially literate, and Mr. Mills is considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act.

Item 16B. Code of Ethics

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at *www.renalytixai.com*. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our website is not incorporated by reference into this annual report, and you should not consider information on our website to be part of this annual report.

Item 16C. Principal Accountant Fees and Services

Our consolidated financial statements have been prepared in accordance with U.S. GAAP and are audited by Deloitte & Touche LLP, an independent registered public accounting firm registered with the Public Accounting

Oversight Board in the United States. Deloitte & Touche LLP has audited our consolidated financial statements as of June 30, 2018, 2019 and 2020 and for the periods from March 15, 2018 (inception) through June 30, 2018 and the fiscal years ended June 30, 2019 and 2020.

The following table shows the aggregate fees billed to us for professional services for the fiscal years ended June 30, 2019 and 2020:

	Year Ended June 30,	
	2019	2020
	(in thousands)	
Audit Fees	$ 78	$ 456
Audit-Related Fees	—	893
Tax Fees	—	—
Other Fees	—	—
Total	$ —	$ 1,349

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that Deloitte & Touche LLP provides, such as consents and assistance with and review of documents filed with the SEC.

"Audit-Related Fees" are the aggregate fees billed for assurance and related services that are reasonably related to the performance of the audit, including fees related to our public offering, and are not reported under Audit Fees.

"Tax Fees" are the aggregate fees billed for professional services rendered by Deloitte & Touche LLP for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by Deloitte & Touche LLP.

There were no "Tax Fees" or "Other Fees" billed or paid during the fiscal years ended June 30, 2019 or 2020.

Our audit committee reviews and pre-approves the scope and the cost of audit services related to us and permissible non-audit services performed by the independent auditors, other than those for *de minimis* services which are approved by the audit committee prior to the completion of the audit. All of the services related to our company provided by Deloitte & Touche LLP during the last two fiscal years have been approved by the audit committee.

Item 16D. Exemptions from the Listing Standards for Audit Committees

Not applicable.

Item 16E. Purchases of Equity Securities by the Issuer and Affiliated Purchasers

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

Not applicable.

Item 16G. Corporate Governance

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of England and Wales, instead of those otherwise required under The Nasdaq Stock Market,

or Nasdaq, for domestic issuers, we intend to follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

- Exemption from filing quarterly reports on Form 10-Q containing unaudited financial and other specified information or current reports on Form 8-K upon the occurrence of specified significant events;
- Exemption from Section 16 rules requiring insiders to file public reports of their securities ownership and trading activities and providing for liability for insiders who profit from trades in a short period of time;
- Exemption from the Nasdaq rules applicable to domestic issuers requiring disclosure within four business days of any determination to grant a waiver of the code of business conduct and ethics to directors and officers;
- Exemption from the requirement to obtain shareholder approval for certain issuances of securities, including shareholder approval of share option plans;
- Exemption from the requirement that our audit committee have review and oversight responsibilities over all "related party transactions," as defined in Item 7.B of Form 20-F;
- Exemption from the requirement that our board have a compensation committee that is composed entirely of independent directors with a written charter addressing the committee's purpose and responsibilities; and
- Exemption from the requirements that director nominees are selected, or recommended for selection by our board, either by (1) independent directors constituting a majority of our board's independent directors in a vote in which only independent directors participate, or (2) a committee comprised solely of independent directors, and that a formal written charter or board resolution, as applicable, addressing the nominations process is adopted.

Furthermore, Nasdaq Rule 5615(a)(3) provides that a foreign private issuer, such as we, may rely on home country corporate governance practices in lieu of certain of the rules in the Nasdaq Rule 5600 Series and Rule 5250(d), provided that we nevertheless comply with Nasdaq's Notification of Noncompliance requirement (Rule 5625), the Voting Rights requirement (Rule 5640) and that we have an audit committee that satisfies Rule 5605(c)(3), consisting of committee members that meet the independence requirements of Rule 5605(c)(2)(A)(ii). Although we are permitted to follow certain corporate governance rules that conform to U.K. requirements in lieu of many of the Nasdaq corporate governance rules, we intend to comply with the Nasdaq corporate governance rules applicable to foreign private issuers.

Accordingly, our shareholders will not have the same protections afforded to shareholders of companies that are subject to all of the corporate governance requirements of Nasdaq. We may utilize these exemptions for as long as we continue to qualify as a foreign private issuer.

Item 16H. Mine Safety Disclosure

Not applicable.

PART III

Item 17. Financial Statements

We have elected to provide financial statements pursuant to Item 18.

Item 18. Financial Statements

See pages F-1 through F-21 of this annual report.

Item 19. Exhibits

Exhibit	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association	F-1	333-239414	3.1	06/24/2020
4.1	Form of Deposit Agreement	F-1/A	333-239414	4.1	07/13/2020
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-239414	4.1	07/13/2020
4.3*	Description of Securities				
10.1+	Renalytix AI plc Share Option Plan for Employees with Non-Employee Sub-Plan and U.S. Sub-Plan	F-1	333-239414	10.1	06/24/2020
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	06/24/2020
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	06/24/2020
10.4#	Kantaro Biosciences LLC Operating Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of May 4, 2020	F-1	333-239414	10.4	06/24/2020
10.5†#	Advisory Services Agreement, by and between the registrant and Kantaro Biosciences LLC, dated as of May 4, 2020	F-1	333-239414	10.5	06/24/2020
10.6+	2020 Equity Incentive Plan with Non-Employee Sub-Plan and forms of grant notices and agreements thereunder	F-1	333-239414	10.6	06/24/2020
10.7+	2020 Employee Share Purchase Plan	F-1	333-239414	10.7	06/24/2020
10.8+	Form of Amended Deed of Indemnity between registrant and each of its directors	F-1	333-239414	10.8	06/24/2020
10.9+	Form of Deed of Indemnity between registrant and each of its executive officers	F-1	333-239414	10.9	06/24/2020
10.10	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	10.10	06/24/2020

Exhibit	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002				
21.1*	Subsidiaries of the registrant				
101.INS***	XBRL Instance Document				
101.SCH***	XBRL Taxonomy Extension Schema Document				
101.CAL***	XBRL Taxonomy Extension Calculation Linkbase				
101.DEF***	XBRL Taxonomy Extension Definition Linkbase Document				
101.LAB***	XBRL Taxonomy Extension Label Linkbase Document				
101.PRE***	XBRL Taxonomy Extension Presentation Linkbase Document				

* Filed herewith.
** Furnished herewith.
*** To be filed by amendment.
\+ 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.

SIGNATURES

The registrant hereby certifies that it meets all of the requirements for filing on Form 20-F and that it has duly caused and authorized the undersigned to sign this annual report on its behalf.

RENALYTIX AI PLC

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

Date: October 27, 2020

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the Board of Directors of Renalytix AI plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Renalytix AI plc and subsidiaries (the "Company") as of June 30, 2020 and 2019, the related consolidated statements of operations and comprehensive loss, shareholders' (deficit) equity, and cash flows, for each of the two years in the period ended June 30, 2020, and for the period March 15, 2018 (inception) to June 30, 2018, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of June 30, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2020, and for the period March 15, 2018 (inception) to June 30, 2018, in conformity with accounting principles generally accepted in the United States of America.

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 area 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 reasonable basis for our opinion.

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

October 27, 2020

We have served as the Company's auditor since 2020.

RENALYTIX AI PLC

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	June 30, 2020	June 30, 2019	June 30, 2018
Assets			
Current assets:			
Cash and cash equivalents	$ 13,293	$ 8,201	$ 82
Short-term investments	982	994	—
Prepaid expenses and other current assets	551	227	33
Receivable from affiliate	18	—	—
Total current assets	14,844	9,422	115
Property and equipment, net	1,655	278	—
Deferred offering costs	2,364	—	—
Investment in affiliate	1,937	—	—
Note receivable from affiliate	83	—	—
Total assets	$ 20,833	$ 9,700	$ 115
Liabilities and Shareholders' Equity			
Current liabilities:			
Accounts payable	$ 2,218	$ 317	10
Accrued expenses and other current liabilities	683	832	169
Note payable – current	120	—	—
Payable to affiliate - current	271	—	—
Note payable to EKF	—	—	438
Total current liabilities	3,292	1,149	617
Payable to affiliate - non-current	1,544	—	—
Note payable - noncurrent	135	—	—
Total liabilities	4,971	1,149	617
Commitments and contingencies (Note 7)			
Shareholders' equity:			
Ordinary shares, £0.0025 par value per share: 62,444,992 and 56,011,831 shares authorized at June 30, 2020 and June 30, 2019, respectively; 59,416,134, 53,816,134 and 20,000,000 shares issued and outstanding at June 30, 2020, 2019 and 2018, respectively	179	162	66
Additional paid-in capital	69,650	52,084	—
Accumulated other comprehensive loss	(1,200)	(822)	4
Accumulated deficit	(52,717)	(42,873)	(572)
Total shareholders' equity	15,912	8,551	(502)
Total liabilities and shareholders' equity	$ 20,833	$ 9,700	$ 115

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

RENALYTIX AI PLC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share data)	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
Operating expenses:			
Acquired in-process research and development	$ —	$ 35,286	$ —
Research and development	4,565	4,316	193
General and administrative	5,750	2,737	374
Total operating expenses and loss from operations	(10,315)	(42,339)	(567)
Equity in losses of affiliate	(63)	—	—
Other income (expense), net	534	38	(5)
Net loss	9,844	(42,301)	(572)
Other comprehensive income (loss):			
Foreign exchange translation adjustment	(378)	(826)	4
Total comprehensive loss	$ (10,222)	$ (43,127)	(568)
Net loss per ordinary share—basic and diluted	$ (0.17)	$ (0.99)	$ (0.03)
Weighted average ordinary shares—basic and diluted	59,079,522	42,561,600	20,000,000

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

RENALYTIX AI PLC

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' (DEFICIT) EQUITY

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' (deficit) equity
	Shares	Amount				
Balance at March 15, 2018 (inception)	—	—	—	—	—	—
Issuance of ordinary shares upon formation	20,000,000	66	—	—	—	66
Currency translation adjustment	—	—	—	4	—	4
Net loss	—	—	—	—	(572)	(572)
Balance at June 30, 2018	20,000,000	$ 66	$	$ 4	$ (572)	$ (502)
Ordinary shares issued to acquire Joslin license	15,427,704	49	24,237	—	—	24,286
Sale of ordinary shares in initial public offering, net of offering costs of $1,742	18,388,430	47	27,322	—	—	27,369
Share-based compensation expense	—		525	—	—	525
Currency translation adjustments	—		—	(826)	—	(826)
Net loss	—	—	—	—	(42,301)	(42,301)
Balance at June 30, 2019	53,816,134	162	52,084	(822)	(42,873)	8,551
Sale of ordinary shares in secondary offering, net of offering costs of $842	5,600,000	17	16,407	—	—	16,424
Share-based compensation expense	—	—	1,159	—	—	1,159
Currency translation adjustments	—	—	—	(378)	—	(378)
Net loss	—	—	—	—	(9,844)	(9,844)
Balance at June 30, 2020	59,416,134	$ 179	$ 69,650	$ (1,200)	$ (52,717)	$ 15,912

RENALYTIX AI PLC

CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
Cash flows from operating activities:			
Net loss	$ (9,844)	$ (42,301)	$ (572)
Adjustments to reconcile net loss to net cash used in operating activities			
Non-cash in-process research and development charge	—	35,286	—
Depreciation	70	31	—
Share-based compensation	1,159	525	—
Realized gain on short-term investments	(128)	(24)	—
Equity losses in affiliate	63	—	—
Unrealized foreign exchange gain	(213)	—	—
Changes in operating assets and liabilities:			
Prepaid expenses and other current assets	(325)	(197)	(35)
Related party receivable	(18)	—	—
Accounts payable	355	303	10
Accrued expenses and other current liabilities	(456)	221	170
Payable to affiliate.	(185)	—	—
Net cash used in operating activities	(9,522)	(6,156)	(427)
Cash flows from investing activities:			
Note receivable – affiliate	(83)	—	—
Purchases of property and equipment	(804)	(309)	—
Software development costs	(427)	—	—
Purchase of short-term investments	(21,260)	(4,970)	—
Proceeds from short-term investments	21,400	4,000	—
Acquired in-process research and development	—	(11,021)	—
Net cash used in investing activities	(1,174)	(12,300)	—
Cash flows from financing activities:			
Gross proceeds from the issuance of ordinary shares	17,276	29,111	66
Payment of offering costs	(1,593)	(1,292)	—
Proceeds from related-party notes	—	633	442
Proceeds from PPP Loan	255	—	—
Repayment of related-party notes	—	(1,069)	—
Net cash provided by financing activities	15,938	27,383	508
Effect of exchange rate changes on cash	(150)	(808)	1
Net increase in cash and cash equivalents	5,092	8,119	82
Cash and cash equivalents, beginning of year	8,201	82	—
Cash and cash equivalents, end of year	$ 13,293	$ 8,201	$ 82
Supplemental disclosure of cashflow information:			
Cash paid for interest	$ —	$ 21	$ —
Supplemental noncash financing activities:			
Ordinary shares issued to acquire Joslin license	$ —	$ 24,286	$ —
Financing costs in accounts payable and accrued expenses	$ 1,630	$ 450	$ —
Software development costs in accounts payable and accrued expenses	$ 177	$ —	$ —
Purchases of property and equipment in accounts payable.	$ 56	—	—
Fair value of services exchanged for equity method investment of which services are recorded as the payable to affiliate	$ 2,000	$ —	$ —

RENALYTIX AI PLC

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

1. Business and risks

Renalytix AI plc and its wholly-owned subsidiaries, Renalytix AI, Inc. and Verici Dx Limited (collectively, RenalytixAI, or the Company) is an artificial intelligence-enabled *in vitro* diagnostics company, focused on optimizing clinical management of kidney disease to drive improved patient outcomes and significantly lower healthcare costs. KidneyIntelX, the Company's first-in-class diagnostic platform, employs a proprietary artificial intelligence-enabled algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from EHR systems, to generate a unique patient risk score. KidneyIntelX has already been granted a Current Procedural Terminology, or 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 Food and Drug Administration, or FDA.

Since inception in March 2018, the Company has focused primarily on organizing and staffing the Company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting its intellectual property portfolio and commercial laboratory operations, pursuing regulatory clearance and developing a reimbursement strategy. To date, the Company has not generated any revenue from the sales of KidneyIntelX tests. The Company has funded its operations primarily through equity financings.

In April 2020, the Company created a wholly-owned subsidiary, Verici Dx Limited ("Verici Dx"), after evaluating its plans for its FractalDx technology, in-licensed from Mount Sinai in late 2018. In May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to Verici Dx in exchange for $2.0 million, which was satisfied by the issuance of convertible loan notes of Verici Dx to the Company, which notes will be either repaid or converted into equity upon Verici Dx completing an offering and admission of its shares to trading on AIM or another recognized stock exchange. The reduction of capital necessary to implement this transaction was approved by the Company's shareholders at a general meeting held on May 15, 2020 and confirmed by the High Court in England and Wales on June 9, 2020. Prior to completion of a possible admission to AIM or an equivalent financing transaction, and the establishment of an independent Verici board of directors and independent management team, the Company retains control of Verici Dx and as a result of its level of control, Verici Dx continues to be included in the Company's consolidated financial statements and notes thereto.

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

2. Going Concern

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

In July 2019, the Company sold 5.6 million of its ordinary shares to several new and existing investors in exchange for $16.4 million of net cash proceeds. In July 2020, the Company closed an initial public offering (IPO) on Nasdaq Global Market, in which they issued and sold 12.6 million ordinary shares which converted into 6.3 million American depository shares at a public offering price of $13.50 per share. In addition, the Company

completed a concurrent private placement in Europe and other countries outside of the United States of 30,000 ordinary shares at a price of £5.37 per ordinary share (at an exchange rate of GBP:USD 1:1.2563). The Company received net proceeds of approximately $76.1 million as a result of the offering. The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of $52.7 million as of June 30, 2020.

The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of KidneyIntelX or any future products currently in development. Management believes its cash, cash equivalents and short-term investments as of June 30, 2020, and the proceeds from the initial public offering in July 2020, are sufficient to fund the projected operations for at least the next twelve months from the issuance date of these financial statements. Substantial additional capital will be needed by the Company to fund its operations, expand its commercial activities and develop other potential diagnostic related products.

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

3. Basis of presentation and summary of significant accounting policies

The accompanying 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 AI plc and its wholly-owned subsidiaries, Renalytix AI, Inc and Verici Dx Limited. All inter-company balances and transactions have been eliminated in consolidation.

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

Segment information

The Company manages its operations as a single operating segment for the purposes of assessing performance and making operating decisions. The Company's singular focus is to make significant improvements in kidney disease diagnosis and prognosis, clinical care, patient stratification for drug clinical trials, and drug target discovery.

Foreign currency translation

The Company's consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The functional currency of Renalytix AI plc and Verici Dx Limited is GB Pounds. The functional currency Renalytix AI, Inc. is the U.S. dollar. Assets and liabilities of Renaltyix AI plc and Verici Dx Limited are translated at the rate of exchange at year-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss).

Concentrations of credit risk

Financial instruments that potentially subject the Company to concentrations of credit risk consist principally of cash. Periodically, the Company maintains deposits in accredited financial institutions in excess of federally insured limits. The Company deposits its cash in financial institutions that it believes have high credit quality and are not exposed to any unusual credit risk beyond the normal credit risk associated with commercial banking relationships, and has not experienced any losses on such accounts. At June 30, 2020, 2019 and 2018, all of the Company's cash was held at two accredited financial institutions.

Fair value of financial instruments

At June 30, 2020, 2019 and 2018, the Company's financial instruments included prepaid expenses and other current assets, accounts payable and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature.

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of June 30, 2020, the Company had a cash balance of $12.8 million and cash equivalents consisting of $0.5 million held in a money market account. As of June 30, 2019, the Company had a cash balance of $7.2 million and cash equivalents consisting of $1.0 million held in U.S. Treasury Bills.

Short-term investments

Short-term investments consist of debt securities with a maturity date greater than three months when acquired. The Company classifies its short-term investments at the time of purchase as available-for-sale securities. Available-for-sale securities are carried at fair value. Unrealized gains or losses on available-for-sale securities are reported in accumulated other comprehensive income (loss), a component of the shareholders' (deficit) equity, until realized. Short-term investments at June 30, 2020 and 2019 consisted of U.S. Treasury Bills with a fair value of $1.0 million. Unrealized gains (losses) were de minimis as their maturity date was 91 days from original purchase.

Equity method investment

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai (ISMMS or Mount Sinai) entered into an operating agreement ("Kantaro Operating Agreement") to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment.

When the Company can exert significant influence over, but do not control, the investee's operations, through voting rights or representation on the investee's board of directors, the Company accounts for the investment using the equity method of accounting. The Company records its share in the investee'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.

Deferred offering costs

The Company capitalizes certain legal, professional, accounting and other third-party fees that are directly associated with in-process common equity financings as deferred offering costs until such financings are consummated. After consummation of the equity financing, these costs are recorded as a reduction of additional paid-in capital generated as a result of such offering. Should an in-process equity financing be abandoned, the deferred offering costs will be expensed immediately as a charge to operating expenses in the consolidated statements of operations and comprehensive loss. As of June 30, 2020, the company had deferred offering costs of $2.4 million related to the initial public offering (IPO) on the Nasdaq Global Market which was completed in July 2020 (see Note 14).

Property and equipment

Property and equipment are recorded at cost and consist of lab and office equipment. 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.

Impairment of long-lived assets

Long-lived assets are reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated. Impairment charges are recognized at the amount by which the carrying amount of an asset exceeds the fair value of the asset. The Company has not recognized any impairment of long-lived assets for the years ended June 30, 2020 and 2019 and for the period from March 15, 2018 (inception) through June 20, 2018.

Software development costs

The Company follows the provisions of ASC 985, *Software*, which requires software development costs for software to marketed externally to be expensed as incurred until the establishment of technological feasibility, at which time those costs are capitalized until the software is available for general release and amortized over its estimated useful life. Technological feasibility is established upon the completion of a working model that has been validated. As of June 30, 2020, there was $0.6 million of capitalized software development costs which will begin to amortize once development is completed. As of June 30, 2019, and 2018, there were no software development costs capitalized as technological feasibility had not been established.

Acquired in-process research and development expenses

Acquired in-process research and development (IPR&D) expense consists of the initial up-front payments incurred in connection with the acquisition or licensing of products or technologies that do not meet the definition of a business under FASB ASC Topic 805, *Business Combinations*. The Company's acquired IPR&D expense of $35.3 million during the year ended June 30, 2019, reflects the fair value of consideration ascribed to the licenses acquired from Mount Sinai (see Note 9) and the license transfer from EKF (see Note 9).

Research and development expenses

Research and development costs consist primarily of costs incurred in connection with the development of KidneyIntelX and other studies for KidneyIntelX to determine clinical value and performance in different chronic kidney disease populations. Research and development costs are expensed as incurred.

Share-based compensation

The Company measures equity classified share-based awards granted to employees and nonemployees based on the estimated fair value on the date of grant and recognizes compensation expense of those awards over the requisite service period, which is the vesting period of the respective award. The Company accounts for forfeitures as they occur. For share-based awards with service-based vesting conditions, the Company recognizes compensation expense on a straight-line basis over the service period. The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model, which requires inputs based on certain subjective assumptions, including the expected stock price volatility, the expected term of the option, the risk-free interest rate for a period that approximates the expected term of the option, and the Company's expected dividend yield. The Company was a privately-held organization prior to November 2018 and has been a publicly-traded company for a limited period of time and therefore lacks company-specific historical and implied volatility information for its shares. Therefore, it estimates its expected share price volatility based on the historical volatility of publicly-traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is none based on the fact that the Company has never paid cash dividends on ordinary shares and does not expect to pay any cash dividends in the foreseeable future.

The Company classifies share-based compensation expense in its 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' (deficit) equity that result from transactions and economic events other than those with shareholders.

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, 2020 and 2019 have been excluded from the computation of diluted weighted average shares outstanding, as they would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

As of June 30, 2020, and 2019, there were 3,028,858 and 2,195,697 shares issuable upon exercise of outstanding options that were anti-dilutive and excluded from diluted loss per share for the year ended June 20, 2020 and 2019, respectively. There were no potentially dilutive securities outstanding at June 30, 2018.

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 adopted accounting pronouncements

In August 2016, the FASB issued ASU No. 2016-15, *Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments*. ASU No. 2016-15 addresses eight specific cash flow issues with the objective of reducing diversity in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard is effective for fiscal years beginning July 1, 2019, and interim periods within those years. The Company adopted this guidance on July 1, 2019, and it did not have a material impact to its consolidated statement of cash flows.

Recently issued accounting pronouncements

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

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments - Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for

financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2020. The Company is currently evaluating the impact of adopting this guidance to its consolidated financial statements.

4. Fair value

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

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

This hierarchy requires the use of observable market data when available and to minimize the use of unobservable inputs when determining fair value. The Company has classified cash equivalents and short-term investments at June 30, 2020 and 2019, which were comprised of U.S. Treasury Bills and measured at fair value on a recurring basis, as Level 1.

5. Property and equipment

Property and equipment consists of the following at June 30, 2020, 2019 and 2018 (in thousands):

	June 30,		
	2020	2019	2018
Lab equipment	$ 862	$309	$—
Software	744	—	—
Office equipment	31	—	—
Office furniture	10	—	—
Construction in process	113	—	—
Total	1,760	309	—
Less accumulated depreciation	(105)	(31)	—
	$1,655	$278	$—

Depreciation expense was $74,000 and $31,000 for the years ended June 30, 2020 and 2019, respectively. Capitalized software development costs will begin to amortize once development is completed.

6. Accrued expenses and other current liabilities

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

	June 30,		
	2020	2019	2018
Consulting and professional fees	$567	$719	$160
Research and development	80	—	—
Payroll and related benefits	24	28	—
Other	12	85	9
	$683	$832	$169

7. Debt

Paycheck Protection Program

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

At June 30, 2020, the outstanding principal balance of the Loan is $255,000, of which $120,000 is payable in 2021 and $135,000 is payable in 2022. The fair value of the Loan as of June 30, 2020 is $242,000, which is determined based on a discounted cash flow model using an estimated market rate of interest of 4.75%, which is classified as a Level 3 fair value measurement.

8. Commitments and contingencies

Leases

In June 2018, the Company entered into an office lease and, in February 2019, the Company entered into a lease for laboratory testing facilities and offices. Each lease is located in New York City and are month-to-month leasing arrangements. Additionally, in February 2019, the Company entered into a lease for an apartment used by executives for traveling requirements. The apartment was located in New York and expired in October 2019. On October 31, 2019, the Company entered into a lease agreement that established a commercial laboratory operation in Salt Lake City, Utah. The lease has a term of five years and is the first long-term lease entered into by the Company. Rent expense for all leases was $0.5 million and $0.2 million for the years ended June 30, 2020 and 2019, respectively and $9,000 for the period from March 15, 2018 (inception) through June 30, 2018.

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

2021	$205
2022	83
2023	83
2024	83
2025	28
	$482

Employment agreements

The Company has entered into employment agreements with certain key executives providing for compensation and severance in certain circumstances, as set forth 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 $67,000 and $14,000 in contributions for the year ended June 30, 2020 and 2019, respectively. The Company did not make contributions to the plan for the period from March 15, 2018 (inception) through June 30, 2018.

Legal proceedings

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

9. License 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. A license issuance fee of $10.0 million was contingent upon the Company’s completion of an IPO and upon payment, was recorded as acquired in-process research and development expense during the year ended June 30, 2019 on the Company’s consolidated statements of operations and comprehensive loss. The Company accounted for this transaction as an asset acquisition as substantially all of the value acquired by the Company consisted of a single asset with no alternative future use. The Company is obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. The Company is also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, the Company is obligated to pay Mount Sinai between 15% and 25% of any consideration received from a sublicensee. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred approximately $0.2 million and $0.2 million in research and development expenses under the ISMMS SRA for the year ended June 30, 2020 and 2019, respectively.

Mount Sinai license agreement for FractalDx

On December 21, 2018, the Company entered into an exclusive license agreement (the ISMMS FractalDx License Agreement) with ISMMS. Under the terms of the ISMMS FractalDx License Agreement, ISMMS granted the Company (i) an exclusive license, with sub-license rights, to use certain patent rights covering specific inventions concerning the utilization of biomarkers guided artificial intelligence techniques for detecting kidney functional decline (the ISMMS Technology), (ii) a non-exclusive license under unregistered licensed copyrights and licensed know-how and (iii) an exclusive option to obtain licensed technology conceived after May 30, 2018. An up-front license fee of $1.0 million was paid and recorded as acquired in-process research and development expense during the year ended June 30, 2019 on the Company's consolidated statements of operations and comprehensive loss. The Company accounted for this transaction as an asset acquisition as substantially all of the value acquired by the Company consisted of a single asset with no alternative future use. The patent reimbursement fees of approximately $0.3 million were also paid and expensed as general and administrative expenses during the year ended June 30, 2019. The Company is obligated to pay Mount Sinai $0.3 million upon receipt of certain regulatory clearance and approval, $0.3 million upon receipt of U.S. CMS reimbursement code or PAMA reimbursement approval. In addition, the Company is obligated to pay Mount Sinai $1.0 million and $4.0 million in commercial milestone payments upon achieving worldwide net sales of FractalDx of $50.0 million and $250.0 million, respectively. The Company is also obligated to pay Mount Sinai a 6% to 8% royalty on net sales of FractalDx, subject to customary reductions. Moreover, the Company is obligated to pay Mount Sinai between 15% and 70% of any consideration received from a sublicensee.

Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. The Company is also subject to an annual license maintenance fee of $25,000 in calendar year 2020 and 2021, $50,000 in calendar year 2022 and 2023, $0.1 million in calendar years 2024 through 2027, and $0.2 million for calendar year 2028 and beyond.

Joslin diabetes center agreement

In October 2018, the Company purchased a worldwide exclusive license agreement with Joslin (the Joslin Agreement) that was previously entered into with 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). The Company issued 15,427,704 ordinary shares as consideration for total noncash consideration of $24.3 million. Given the timing of the assignment of license to the Company's IPO on AIM, the estimated fair value of the ordinary shares issued was $1.57 per share. The noncash consideration was expensed as acquired in-process research and development expense during the year ended June 30, 2019 on the Company's consolidated statements of operations and comprehensive loss. The Company accounted for this transaction as an asset acquisition as substantially all of the value acquired by the Company consisted of a single asset with no alternative future use.

Under the terms of the Joslin Agreement, the Company is obligated to pay Joslin aggregate commercial milestone payments of $0.3 million and $1.0 million in commercial milestone payments upon achieving worldwide net sales of licensed products and processes of $2.0 million and $10.0 million, respectively. The Company is also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, the Company is obligated to pay Joslin 25% of any consideration received from a sublicensee.

The Joslin Agreement initially expires on July 31, 2025 and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that the Company ceases developing or commercializing licensed products or processes, if the Company fails to maintain certain required insurance policies, and if the Company fails to pay patent expenses related to the licensed patents.

10. Shareholders' (deficit) equity

Ordinary shares

As of June 30, 2020, the Company had 62,444,992 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, 2020, no cash dividends have been declared or paid.

11. Share-based compensation

In November 2018, Company established the Renalytix AI plc Share Option Plan (the Plan) and a U.S. Sub-Plan and Non-Employee Sub-Plan. The Plan provides for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of June 30, 2020, there were 2,352,755 shares available for future issuance under the Plan.

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

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

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

	Year ended June 30,	
	2020	2019
Research and development	$ 568	$322
General and administrative	591	203
	$1,159	$525

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, 2020 and 2019 were determined using the methods and assumptions discussed below.

- The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin (SAB) 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, 2020 and 2019, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Year ended June 30,	
	2020	2019
Expected term (in years)	5.7	5.8
Expected volatility	63.7%	66.9%
Risk-free rate	1.7%	3.1%
Dividend yield	— %	— %

The weighted average fair value of the options granted during the year ended June 30, 2020 and 2019 was $2.09 and $0.97 per share, respectively.

The following table summarizes the stock option granted to employees and nonemployees for the year ended June 30, 2020:

	Number of shares under option plan	Weighted-average exercise price per option	Weighted-average remaining contractual life (in years)
Outstanding at June 30, 2018	—	$ —	
Granted	2,195,697	$ 1.57	
Outstanding at June 30, 2019	2,195,697	$ 1.57	9.4
Granted	833,161	$ 2.95	
Outstanding at June 30, 2020	3,028,858	$ 1.95	8.6
Exercisable at June 30, 2020	1,367,598	$ 1.76	8.5
Vested and expected to vest at June 30, 2020	3,028,858	$ 1.95	8.6

As of June 30, 2020, there was $2.1 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 1.51 years. The aggregate intrinsic value of options outstanding and options exercisable at June 30, 2020 was $10.2 million and $4.8 million, respectively.

12. Income taxes

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

	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
United Kingdom	$ (1,898)	$ (37,803)	$ (118)
United States	(7,946)	(4,498)	(454)
	$ (9,844)	$ (42,301)	$ (572)

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.

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

	Year ended June 30, 2020	Year ended June 30, 2019	From March 15, 2018 (inception) through June 30, 2018
U.K. tax benefit at statutory rate	(19.0)%	(19.0)%	(19.0)%
State taxes, net of federal benefit	(6.6)	(1.2)	(9.1)
Permanent differences	1.6	8.0	0.1
Research and development	0.0	0.0	0.0
Change in valuation allowance	25.0	11.4	29.2
Other	(1.0)	0.7	(1.2)
Effective tax rate	0.0%	0.0%	0.0%

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

	June 30,		
	2020	2019	2018
Deferred tax assets:			
Net operating losses	$ 4,296	$ 1,832	$ 163
Research and development licenses	2,550	2,831	—
Development costs	418	301	—
Share-based compensation	198	88	—
Other	0	6	3
Valuation allowances	(7,331)	(5,000)	(166)
Total deferred tax assets	131	58	—
Deferred tax liabilities:			
Depreciation	(91)	(58)	—
Other	(40)	—	—
Total deferred tax liabilities	(131)	(58)	—
Net deferred tax	$ —	$ —	—

The Company does not have unrecognized tax benefits as of June 30, 2020, 2019 or 2018. 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):

	June 30,		
	2020	2019	2018
United Kingdom	$ 3,640	$1,667	$ 97
U.S. Federal	11,817	4,770	452
U.S. State and Local	21,520	9,540	905

The U.K. and U.S. federal net operating loss carryforwards have no expiration. 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, 2020, June 30, 2019 and June 30, 2018 because of the uncertainty of their realization. The valuation allowance increased by $2.3 million for the year ended June 30, 2020, by $4.8 million for the year ended June 30, 2019, and by $0.2 million for the period from March 15, 2018 (inception) through June 30, 2018.

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 files income tax returns in the United Kingdom, the U.S. federal jurisdiction and various U.S. state jurisdictions. The Company's filed 2019 and 2018 tax returns remain subject to examination.

13. Related-party transactions

EKF Diagnostic Holdings

As discussed in Note 9, in October 2018, the Company purchased a worldwide exclusive license agreement with Joslin, that was previously entered into with EKF in July 2017, in exchange for the issuance of 15,427,704 of the Company's ordinary shares.

EKF provided short-term loans to the Company in the form of notes payable. During the period from March 15, 2018 (inception) through June 30, 2018 and for the year ended June 30, 2019, the Company borrowed $0.4 million and $0.6 million, respectively. The notes bore interest at an annual rate of 5% and the Company recognized $5,000 and $16,000 of interest expense during the period from March 15, 2018 (inception) through June 30, 2018 and for the year ended June 30, 2019. All outstanding principal and accrued interest of $1.0 million and $21,000, respectively, was repaid in November 2018 upon consummation of the Company's IPO. During the years ended June 30, 2020 and 2019, the Company paid fees to employees of EKF who provided services to Renalytix.

Icahn School of Medicine at Mount Sinai

In May 2018, the Company secured its cornerstone license agreement with ISMMS for research and clinical study work and intended commercialization by the Company (see Note 9). As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's IPO in November 2018 and the subsequent sale of ordinary shares in July 2019. Additionally, in December 2018, the Company executed its option with ISMMS for the FractalDx license, which grants rights to technology and patents relating to a series of potential diagnostics and prognostics in the field of kidney transplant and rejection. During the year ended June 30, 2020, the Company incurred approximately $0.2 million of expenses related to research and development activities under the ISMMS SRA and an annual license maintenance fee for FractalDx. In addition, the Company incurred approximately $0.1 million of expenses related to board and consulting fees.

Renwick Capital, LLC

Prior to the Company's IPO on AIM in November 2018, the Company's Chief Executive Officer and Chief Financial Officer provided their respective services through a consulting agreement between the Company and Renwick Capital, LLC. During the year ended June 20, 2019, and for the period from March 15, 2018 (inception) through June 30, 2019 the Company incurred consulting services of $0.2 million and $0.1 million, respectively. Upon consummation of the Company's IPO, the Chief Executive Officer and Chief Financial Officer became employee of the Company and the consulting agreement with Renwick Capital, LLC as terminated.

Kantaro Biosciences LLC

In connection with the formation of Kantaro, the Company entered into a five-year Advisory Services Agreement ("Advisory Agreement") pursuant to which the Company has agreed to provide certain advisory services to Kantaro.

Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to the Company as the sole consideration for the services to be rendered by the Company under the Advisory Agreement. A portion of the Company's units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of an uncured material breach of the Advisory Agreement or in the event the Company is acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. The Company determined the fair value of the services to be provided under the Advisory Agreement was $2.0 million and the fair value of the Class A units received from Kantaro was $2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions which include discount rates and future cash flows, among others. As of June 30, 2020, the total liability associated with the services was $1.8 million of which $0.3 million is classified as a current liability and $1.5 million is classified as a non-current liability.

In addition to the equity granted at formation, the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $0.3 million and an additional $0.5 million thereafter. The Company committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to the Company based on each investor's proportionate ownership). The Company loaned Kantaro $83,333 and had a note receivable for this amount at June 30, 2020. In addition, the Company recognized losses of $63,139 on their investment in Kantaro during the year ended June 30, 2020.

14. Subsequent events

The Company has evaluated subsequent events from the balance sheet date through the date at which the consolidated financial statements were available to be issued, and determined there are no other items requiring disclosure beyond those disclosed below.

In July 2020, the Company closed an initial public offering (IPO) on the Nasdaq Global Market, in which they issued and sold 12,583,500 ordinary shares which converted into 6,291,750 American depository shares at a public offering price of $13.50 per share. In addition, the Company completed a concurrent private placement in Europe and other countries outside of the United States of 30,000 ordinary shares at a price of £5.37 per ordinary share (at an exchange rate of GBP:USD 1:1.2563). The Company received net proceeds of approximately $76.1 million as a result of the offering.

In July 2020 the Company's Board of Directors convened and declared a distribution in specie of shares in Verici to trustees on trust for the Company's shareholders. As a result, Verici's share capital has been re-designated into 59,416,134 A Shares of £0.001 each and 1 golden share of £0.001 (the "Golden Share"). The Golden Share will be the only voting share in the capital of Verici and will be retained by the Company. The Company's shareholders on the register as at close of business on July 9, 2020 will receive one A Share in Verici for every 1 ordinary share held in the Company. As a result of the Company's level of control, Verici will continue to be consolidated in the Company's consolidated financial statements.

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

EXHIBIT 4.3

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934

The following description sets forth certain material terms and provisions of the securities of Renalytix AI plc ("Renalytix," the "Company," "we," "us," and "our") that are registered under Section 12 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). This description also summarizes relevant provisions of English law, including the U.K. Companies Act 2006 (the "Companies Act"). The following summary does not purport to be complete and is subject to, and is qualified in its entirety by reference to, the applicable provisions of English law and our articles of association, a copy of which is incorporated by reference as an exhibit to the Annual Report on 20-F of which this Exhibit is a part. We encourage you to read our articles of association and the applicable provisions of English law for additional information.

General

Our securities include (a) our ordinary shares, nominal value £0.0025 per share, and (b) our American Depositary Shares (the "ADSs"), each representing two ordinary shares, nominal value £0.0025 per share. Our ordinary shares are registered under the Exchange Act not for trading, but only in connection with the listing of the ADSs on The Nasdaq Global Select Market.

Our ADSs are listed on The Nasdaq Global Select Market under the trading symbol "RNLX" and our ordinary shares are traded on AIM under the symbol "RENX."

The following is a description of the rights of (i) the holders of ordinary shares and (ii) ADS holders. Ordinary shares underlying the outstanding ADSs are held by Citibank N.A., as depositary.

Ordinary Shares

In accordance with our articles of association, the following summarizes the rights of holders of our ordinary shares:

Preemptive rights

The laws of England and Wales generally provide shareholders with preemptive rights when new shares are issued for cash; however, it is possible for the articles of association, or shareholders in a general meeting, 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 resolution, if the disapplication is by shareholder resolution. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years).

Share rights

Subject to the Companies Act and any rights attaching to shares already in issue, our shares may be issued with or have attached to them any rights and restrictions as we may by ordinary resolution of the shareholders determine or, in the absence of any such determination, as our board of directors may determine.

Voting rights

Subject to any rights or restrictions attached to any shares from time to time, the general voting rights attaching to shares are as follows:

- any resolution put to the vote of a general meeting must be decided exclusively on a poll;

- on a poll, every shareholder who is present in person or by proxy or corporate representative shall have one vote for each share of which they are the holder. A shareholder, proxy or corporate representative entitled to more than one vote need not, if they vote, use all their votes or cast all the votes in the same way; and
- if two or more persons are joint holders of a share, then in voting on any question the vote of the senior who tenders a vote, whether in person or by proxy, shall be accepted to the exclusion of the votes of the other joint holders. For this purpose, seniority shall be determined by the order in which the names of the holders stand in the share register.

Restrictions on voting

No shareholder shall be entitled to vote at any general meeting or at any separate class meeting in respect of any share held by him unless all calls or other sums payable by him in respect of that share have been paid.

The board may from time to time make calls upon the shareholders in respect of any money unpaid on their shares and each shareholder shall (subject to at least 14 days' notice specifying the time or times and place of payment) pay at the time or times so specified the amount called on their shares.

Dividends

We may by ordinary resolution of shareholders declare dividends out of profits available for distribution in accordance with the respective rights of shareholders, but no such dividend shall exceed the amount recommended by the board of directors.

The board of directors may from time to time pay shareholders such interim dividends as appears to the board to be justified by the profits available for distribution (including any dividends at a fixed rate). If the share capital is divided into different classes, the board of directors may pay interim dividends on shares which confer deferred or non-preferred rights with regard to dividend as well as on shares which confer preferential rights with regard to dividend, but no interim dividend shall be paid on shares carrying deferred or non-preferred rights if, at the time of payment, any preferential dividend is in arrears.

The board of directors may deduct from any dividend or other money payable to any person on or in respect of a share all such sums as may be due from such shareholder to the company on account of calls or otherwise in relation to the shares of the company. Sums so deducted can be used to pay amounts owing to the company in respect of the shares.

Subject to any special rights attaching to or the terms of issue of any share, no dividend or other moneys payable by us on or in respect of any share shall bear interest against us. Any dividend unclaimed after a period of 12 years from the date such dividend became due for payment shall be forfeited and shall revert to us.

Dividends may be declared or paid in any currency and the board may decide the rate of exchange for any currency conversions that may be required, and how any costs involved are to be met.

The board of directors may, by ordinary resolution of the company, direct (or in the case of an interim dividend may without the authority of an ordinary resolution direct) that payment of any dividend declared may be satisfied wholly or partly by the distribution of assets, and in particular of paid up shares or debentures of any other company, or in any one or more of such ways.

Distributions on winding up

On a winding up, the liquidator may, with the sanction of a special resolution of shareholders and any other sanction required by law, divide amongst the shareholders in specie the whole or any part of the assets of the company and may, for that purpose, value any assets and determine how the division shall be carried out as between the shareholders or different classes of shareholders. The liquidator may, with the like sanction, vest the whole or any part of the assets in trustees upon such trusts for the benefit of the shareholders as he may with the like sanction determine, but no shareholder shall be compelled to accept any assets upon which there is a liability.

Variation of rights

All or any of the rights and restrictions attached to any class of shares issued may be varied or abrogated with the consent in writing of the holders of not less than three-fourths in nominal value of the issued shares of that class (excluding any shares held as treasury shares) or by special resolution passed at a separate general meeting of the holders of such shares, subject to the Companies Act and the terms of their issue. The Companies Act provides a right to object to the variation of the share capital by the shareholders who did not vote in favor of the variation. Should an aggregate of 15% of the shareholders of the issued shares in question apply to the court to have the variation cancelled, the variation shall have no effect unless and until it is confirmed by the court.

Transfer of shares

Any shareholder holding shares in certificated form may transfer all or any of his shares by an instrument of transfer in any usual or common form or in any other manner which is permitted by the Companies Act and approved by the board. Any written instrument of transfer shall be signed by or on behalf of the transferor and (in the case of a share which is not fully paid up) the transferee.

All transfers of uncertificated shares shall be made in accordance with and subject to the provisions of the Uncertificated Securities Regulations 2001 and the facilities and requirements of its relevant system. The Uncertificated Securities Regulations 2001 permit shares to be issued and held in uncertificated form and transferred by means of a computer-based system.

The board of directors may decline to register any transfer of any share in certificated form:

- which is not a fully paid share, provided that such discretion may not be exercised in a way in which the London Stock Exchange regards as preventing dealing in shares from taking place on an open and proper basis;
- where the company has a lien over such share;
- unless any written instrument of transfer, duly stamped or duly certificated or otherwise shown to the satisfaction of the board of directors to be exempt from stamp duty (if this is required), is lodged with us at our registered office or such other place as the board may from time to time determine, accompanied by the certificate for the shares to which it relates;
- unless there is provided such evidence as the board may reasonably require to show the right of the transferor to make the transfer and if the instrument of transfer is executed by some other person on his behalf, the authority of that person to do so;
- where the transfer is in respect of more than one class of share; and
- in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred exceeds four.

The board of directors may decline to register a transfer of uncertificated shares in any circumstances that are allowed or required by the Uncertificated Securities Regulations 2001 and the requirements of its relevant system.

If the board of directors declines to register a transfer it shall, as soon as practicable and in any event within two months after the date on which the transfer is lodged or the instructions to the relevant system received, send to the transferee notice of the refusal, together with reasons for the refusal or, in the case of uncertified shares, notify such persons as may be required by the Uncertified Securities Regulations 2001 and the requirements of the relevant system concerned.

CREST

To be traded on AIM, securities must be able to be transferred and settled through the CREST system. CREST is a computerized paperless share transfer and settlement system which allows securities to be transferred by electronic means, without the need for a written instrument of transfer. Our articles of association are consistent with CREST membership and, amongst other things, allow for the holding and transfer of shares in uncertificated form.

Annual general meetings

In accordance with the Companies Act, we are required in each year to hold an annual general meeting in addition to any other general meetings in that year and to specify the meeting as such in the notice convening it. The annual general meeting shall be convened whenever and wherever the board sees fit, subject to the requirements of the Companies Act.

Number of directors

We may not have less than two directors or more than fifteen directors on the board of directors. We may, by ordinary resolution of the shareholders, vary the minimum and/or maximum number of directors from time to time.

Appointment of directors

Subject to the provisions of our articles of association, we may, by ordinary resolution of the shareholders, appoint any person to be a director, either to fill a casual vacancy or as an addition to the existing board. However, any person that is not a director retiring from the existing board must be recommended by the board of directors, or be proposed by a shareholder not less than seven and not more than 42 days before the date appointed for the meeting, in order to be eligible for appointment.

Without prejudice to the power to appoint any person to be a director by shareholder resolution, the board has power to appoint any person to be a director, either to fill a casual vacancy or as an addition to the existing board but so that the total number of directors does not exceed the maximum number fixed by or in accordance with our articles of association.

Any director appointed by the board will hold office only until the following annual general meeting. Such a director is eligible for re-appointment at that meeting.

Rotation of directors

At every annual general meeting, any director who has been appointed by the board of directors since the last annual general meeting, or who shall have been a director at each of the preceding two annual general meetings and who did not retire at either such meeting, or any director who has held office (other than in an executive position) for a continuous period of nine years or more shall retire and may offer himself for re-appointment by the shareholders. A retiring director shall be eligible for re-appointment. A director retiring at a meeting shall, if he is not re-appointed at such meeting, retain office until the meeting appoints someone in his place, or if it does not do so, until the conclusion of such meeting.

Exclusive jurisdiction

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 federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act. Save in respect of any cause of action arising under the Securities Act, by subscribing for or acquiring shares, a shareholder submits all disputes between him or herself and us or our directors to the exclusive jurisdiction of the English courts.

American Depositary Shares

Citibank N.A., or Citibank, acts as the depositary for the ADSs representing our ordinary shares. Citibank’s depositary offices are located at 388 Greenwich Street, New York, New York 10013. ADSs represent ownership interests in securities that are on deposit with the depositary. ADSs may be represented by certificates that are commonly known as American Depositary Receipts, or ADRs. The depositary typically appoints a custodian to safekeep the securities on deposit. In this case, the custodian is Citibank, N.A. (London), located at Citigroup Centre, Canary Wharf, London, E14 5LB, United Kingdom.

We have appointed Citibank as depositary pursuant to a deposit agreement. The form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website (*www.sec.gov*). Please refer to registration number 333-239729 when retrieving such copy.

Fees and Charges

As an ADS holder, you will be required to pay the following fees under the terms of the deposit agreement:

Service	Fee
Issuance of ADSs (*e.g.*, an issuance of ADS(s) upon a deposit of ordinary shares or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason), excluding ADS issuances as a result of distributions of ordinary shares	Up to $0.05 per ADS issued
Cancellation of ADSs (*e.g.*, a cancellation of ADSs for delivery of deposited property or upon a change in the ADS(s)-to-ordinary shares ratio, or for any other reason)	Up to $0.05 per ADS cancelled
Distribution of cash dividends or other cash distributions (*e.g.*, upon a sale of rights and other entitlements)	Up to $0.05 per ADS held
Distribution of ADSs pursuant to (i) share dividends or other distributions, or (ii) exercise of rights to purchase additional ADSs	Up to $0.05 per ADS held
Distribution of securities other than ADSs or rights to purchase additional ADSs (*e.g.*, upon a spin-off)	Up to $0.05 per ADS held
ADS services	Up to $0.05 per ADS held on the applicable record date(s) established by the depositary
Registration of ADS transfers (*e.g.*, upon a registration of the transfer of registered ownership of ADSs, upon a transfer of ADSs into DTC and *vice versa*, or for any other reason)	Up to $0.05 per ADS transferred
Conversion of ADSs of one series for ADSs of another series (*e.g.*, upon conversion of partial entitlement ADSs for full entitlement ADSs, or upon conversion of restricted ADSs into freely transferable ADSs, and *vice versa*)	Up to $0.05 per ADS converted

As an ADS holder, you will also be responsible to pay certain charges such as:

- taxes (including applicable interest and penalties) and other governmental charges;
- the registration fees as may from time to time be in effect for the registration of ordinary shares on the share register and applicable to transfers of ordinary shares to or from the name of the custodian, the depositary or any nominees upon the making of deposits and withdrawals, respectively;
- certain cable, telex and facsimile transmission and delivery expenses;
- the fees, expenses, spreads, taxes and other charges of the depositary bank and/or service providers (which may be a division, branch or affiliate of the depositary bank) in the conversion of foreign currency;

- the reasonable and customary out-of-pocket expenses incurred by the depositary bank in connection with compliance with exchange control regulations and other regulatory requirements applicable to ordinary shares, ADSs and ADRs; and
- the fees, charges, costs and expenses incurred by the depositary bank, the custodian, or any nominee in connection with the ADR program.

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of the applicable beneficial owner(s) in accordance with the procedures and practices of the DTC participants as in effect at the time. ADS fees and charges in respect of distributions and the ADS service fee are charged to the holders as of the applicable ADS record date. In the case of distributions of cash, the amount of the applicable ADS fees and charges is deducted from the funds being distributed. In the case of (i) distributions other than cash and (ii) the ADS service fee, holders as of the ADS record date will be invoiced for the amount of the ADS fees and charges and such ADS fees and charges may be deducted from distributions made to holders of ADSs. For ADSs held through DTC, the ADS fees and charges for distributions other than cash and the ADS service fee may be deducted from distributions made through DTC, and may be charged to the DTC participants in accordance with the procedures and practices prescribed by DTC and the DTC participants in turn charge the amount of such ADS fees and charges to the beneficial owners for whom they hold ADSs. In the case of (i) registration of ADS transfers, the ADS transfer fee will be payable by the ADS holder whose ADSs are being transferred or by the person to whom the ADSs are transferred, and (ii) conversion of ADSs of one series for ADSs of another series, the ADS conversion fee will be payable by the Holder whose ADSs are converted or by the person to whom the converted ADSs are delivered.

In the event of refusal to pay the depositary fees or charges, the depositary may, under the terms of the deposit agreement, refuse the requested service until payment is received or may set off the amount of the depositary fees and charges from any distribution to be made to the ADS holder.

Note that the fees and charges you may be required to pay may vary over time and may be changed by us and by the depositary. You will receive prior notice of such changes. The depositary may reimburse us for certain expenses incurred by us in respect of the ADSs, by making available a portion of the ADS fees charged in respect of the ADSs or otherwise, upon such terms and conditions as we and the depositary agree from time to time.

EXHIBIT 12.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James McCullough, certify that:

1. I have reviewed this annual report on Form 20-F of Renalytix AI 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 company as of, and for, the periods presented in this report;

4. The company's other certifying officer 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)) for the company 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 Company, 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; and

    b. Evaluated the effectiveness of the Company'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

    c. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: October 27, 2020

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

EXHIBIT 12.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, O. James Sterling, certify that:

6. I have reviewed this annual report on Form 20-F of Renalytix AI plc;

7. 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;

8. 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 company as of, and for, the periods presented in this report;

9. The company's other certifying officer 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)) for the company 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 Company, 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; and

    b. Evaluated the effectiveness of the Company'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

    c. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

10. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company'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 company'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 company's internal control over financial reporting.

Date: October 27, 2020

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

EXHIBIT 13.1

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 AI 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 20-F for the year ended June 30, 2020, to which this Certification is attached as Exhibit 13.1 (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: October 27, 2020

/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)

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	Jurisdiction
Renalytix AI, Inc.	United States
Verici Dx Limited	United Kingdom