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. Reserved

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.

RISK FACTOR SUMMARY

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

- We have not generated material revenue, have incurred significant losses since our inception and anticipate that we will continue to incur significant losses for the foreseeable future.
- Our limited operating history may make it difficult for you to evaluate the success of our business to date and to assess our future viability.
- We will require substantial additional funding to commercialize and scale KidneyIntelX, which may not be available to us on acceptable terms, or at all, and, if not so available, may require us to delay, limit, curtail or discontinue our operations.
- If we cannot continue to execute on our strategy to partner with healthcare systems to incorporate KidneyIntelX into their treatment regime and integrate their EHR systems with our technology, our revenue prospects could be significantly reduced.
- We are highly reliant on our partnership with Mount Sinai, and our failure to maintain that relationship could negatively impact our business, reputation and strategic goals.
- We may underestimate the timing and complexity of successfully integrating KidneyIntelX into the clinical guidelines of new healthcare systems with which we partner.
- Our ability to be profitable in the future will depend on our ability to successfully commercialize KidneyIntelX, and any other products we may develop in the future, to scale nationally in the United States.

- KidneyIntelX is based on novel artificial intelligence technologies that are rapidly evolving. Our artificial intelligence-enabled algorithms and other technologies depend on our ability to continue to build a substantial repository of kidney disease-related data and validate additional product designs.
- 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.
- Due to our limited resources and access to capital, our strategic decisions with respect to the development of certain diagnostic products may affect the development or timing of our business prospects.
- Our commercial success could be compromised if we do not obtain and maintain coverage and adequate reimbursement from third-party payors—Medicare, specifically—for KidneyIntelX.
- Payors from whom we may receive reimbursement are able to withdraw or decrease the amount of reimbursement provided for our products at any time in the future.
- If we are unable to compete successfully with respect to our current or future products, we may be unable to increase or sustain our revenues or achieve profitability.
- Our business could be adversely affected by the effects of health epidemics, including the current COVID-19 pandemic, in regions where we or third parties on which we rely have significant manufacturing facilities, concentrations of validation study sites or other business operations.
- Holders of our American Depository Shares, or ADSs, have fewer rights than our shareholders and must act through the depositary to exercise their rights.
- We qualify as a foreign private issuer and, as a result, we will not be subject to U.S. proxy rules and will be 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.
- The rights of our shareholders may differ from the rights typically offered to shareholders of a U.S. corporation.

Risks related to our financial condition and capital requirements

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

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

We have incurred losses in each year since our inception. Our net losses attributable to ordinary shareholders for the fiscal years ended June 30, 2022, 2021 and 2020 were $45.3 million, $35.3 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 continue 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 have filed a submission with the Food and Drug Administration, or FDA, seeking 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 as of June 30, 2022 will enable us to fund our operating expenses and capital expenditure requirements 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 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.

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

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

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

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

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

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

Risks related to our business and strategy

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

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

Our ability to execute on this strategy could suffer if:

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

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

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

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

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

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

- the behavioral dynamics of the patients and clinicians, including across specialties;
- the clinical workflow and norms of each clinical specialty;
- the way in which new solutions like KidneyIntelX are communicated, recommended or mandated within the healthcare system;

- the quality and depth of the healthcare system's EHR system;
- the health system partner's IT resources and expertise and time available to ensure a smooth and robust integration with the KidneyIntelX platform; and
- other factors such as specific institutional clinical protocols and practices.

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

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

Our ability to be profitable in the future will depend on our ability to commercially scale KidneyIntelX and any other products we may develop in the future in the United States. 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 are initially providing 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.

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., who represents the Icahn School of Medicine at Mount Sinai 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 through at least 2024. We are currently undergoing a Medicare coverage determination process and have begun receiving payments under an individual claims review, or ICR, process. Our success is highly dependent

on ultimately receiving a positive local or national Medicare coverage determination. If we do not receive a positive Medicare coverage determination, we could experience negative consequences including:

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

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

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

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

In the United States, the principal decisions about reimbursement for new medical products are typically made by the Centers for Medicare & Medicaid Services, or 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. presidential executive orders. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug and medical device pricing, reduce the cost under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies. For example, based on a recent executive order, the Biden administration expressed its intent to pursue certain policy initiatives to reduce drug prices. We expect to experience pricing pressures in connection with the sale of any of our products due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

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

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

Further, even if we obtain written agreements regarding coverage and reimbursement with certain payors, these agreements are not guarantees of indefinite coverage in an adequate amount. For example, these agreements are typically terminable without cause by either party and are typically renewable annually, and the applicable payor could opt against renewal upon expiration. In addition, the terms of certain of our written arrangements may require us to seek pre-approval from the payor or put in place other controls and procedures prior to conducting a test for a customer. To the extent we fail to follow these requirements, we may fail to receive some or all of the reimbursement payments to which we are otherwise entitled. These payors must also conclude that our claim satisfies the applicable contractual criteria. In addition, our written agreements regarding reimbursement with payors may not guarantee us the receipt of reimbursement payments at what we believe to be the applicable contracted rate for each reimbursement claim that we submit to such payors. If payors withdraw coverage for our products, once commercialized, or reduce the reimbursement amounts for such products, our ability to generate revenue could be limited, which may have a material adverse effect on our financial condition, results of operations and cash flow. 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 commercialized products;
- compliance with complex federal and state regulations related to billing government healthcare programs, including Medicare and Medicaid;
- risk of government and commercial audits related to billing;
- disputes among payors as to which party is responsible for payment;
- differences in coverage and information and billing requirements among payors, including the need for prior authorization and/or advanced notification;
- the effect of patient co-payments or co-insurance and our ability to collect such payments from patients;
- changes to billing codes used for our products;
- changes to requirements related to our current or future clinical trials, including our registry studies, which can affect eligibility for payment;
- ongoing monitoring provisions of local coverage decisions for our products, which can affect the circumstances under which a claim would be considered medically necessary;
- incorrect or missing billing information; and
- the resources required to manage the billing and claims appeals process.

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

Additionally, our billing activities will require us to implement compliance procedures and oversight, train and monitor our employees, and undertake internal audits to evaluate compliance with applicable laws and regulations as well as internal compliance policies and procedures. If a payor denies a claim we may submit, we may challenge the reason, low payment amount or payment denials. Payors also conduct external audits to evaluate payments, which

add further complexity to the billing process. If the payor makes an overpayment determination, there is a risk that we may be required to return all or some portion of prior payments we have received.

Additionally, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, 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 of Compliance for our Utah and New York laboratories and CLIA Certificate of Registration for our Florida laboratory To renew our CLIA certificates, we are subject to survey and inspection every two years to assess compliance with program standards. We also may be subject to additional unannounced inspections. Laboratories performing high complexity testing are required to meet more stringent requirements than laboratories performing less complex tests. In addition, a laboratory that is certified as “high complexity” under CLIA may develop, manufacture, validate and use LDTs. CLIA requires analytical validation including accuracy, precision, specificity, sensitivity and establishment of a reference range for any LDT used in clinical testing. The regulatory and compliance standards applicable to the testing we perform may change over time, and any such changes could have a material effect on our business.

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

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

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

- 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 and their respective business associates that perform services for them that involve the use, or disclosure of, individually identifiable health information relating to the privacy, security and transmission of individually identifiable health information as well as their covered subcontractors. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;
- federal false claims and civil monetary penalties laws, including the 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), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals, and certain ownership and investment interests held by physicians and their immediate family members;
- the Eliminating Kickbacks in Recovery Act of 2018, or EKRA, prohibits knowingly and willfully soliciting or receiving any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, in return for referring a patient or patronage to a laboratory; or paying or offering any remuneration (including any kickback, bribe or rebate) directly or indirectly, overtly or covertly, in cash or in kind, to induce a referral of an individual to a laboratory or in exchange for an individual using the services of that laboratory. EKRA was enacted to help reduce opioid-related fraud and abuse. However, EKRA defines the term "laboratory" broadly and without reference to any connection to substance use disorder treatment. EKRA applies to all payors including commercial payors and government payors. Violations of EKRA are subject to significant fines and/or up to ten years in jail, separate and apart from existing AKS regulations and penalties. The law includes a limited number of exceptions, some of which closely align with corresponding AKS exceptions and safe harbors, and others that materially differ. Currently, there is no regulation interpreting or implementing EKRA, nor any guidance released by a federal agency regarding the scope of EKRA;
- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- state law equivalents of each of the above federal laws, such as anti-kickback, false claims and self-referred laws, which may apply to items or services reimbursed by any third-party payor, including commercial insurers, state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources, and state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to physicians and

other healthcare providers, marketing expenditures or product pricing; state and local laws that require the registration of medical device sales representatives.

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

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

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

The ACA substantially changed the way health care is financed by both governmental and private insurers. Among other things, the ACA required each certain medical device manufacturer to pay an excise tax equal to 2.3%, 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 have been executive, judicial and Congressional challenges to certain aspects of the ACA. For example, President Trump signed executive orders and other directives designed to delay, circumvent, or loosen certain requirements mandated by the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA.

While Congress has not passed repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties effective January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance and eliminating the implementation of certain ACA-mandated fees. On June 17, 2021, the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. However, it is possible that the ACA will be subject to

additional judicial or Congressional challenges in the future. In addition, the ACA has been subject to various health reform measures. For example, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, or IRA, into law, which among other things, extends enhanced subsidies for individuals purchasing health insurance coverage in ACA marketplaces through plan year 2025. It is unclear how any additional healthcare reform measures of the Biden administration will impact the ACA. Other legislative changes have been proposed and adopted since the ACA was enacted. 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 until 2031 unless additional congressional action is taken. These Medicare sequester reductions were suspended from May 1, 2020 through March 31, 2022 due to the COVID-19 pandemic. Following the resumption of the sequester, under current legislation, the actual reduction in Medicare payments will vary from 1% in 2022 to up to 4% in the final fiscal year of this sequester. 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, once commercialized, could often exceed the amount actually received from the patient.

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

Our business activities may be subject to the 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 as well as their covered subcontractors. 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 data; many of these requirements may impose significant, divergent and conflicting compliance obligations. For example, the General Data Protection Regulation of the European Union, or the GDPR, applies to processing operations carried out in the context of the activities of an establishment in the European Economic Area, or EEA, and any processing relating to the offering of goods or services to individuals in the EEA and/or the monitoring of their behavior in the EEA (including as may occur in the conduct of clinical trials in the EEA). Also, notwithstanding the U.K.'s withdrawal from the EU, by operation of the so-called U.K. GDPR, the GDPR continues to apply in substantially equivalent form to processing operations carried out in the context of the activities of an establishment in the U.K., and any processing relating to the offering of goods or services to individuals in the U.K. and/or monitoring of their behavior in the U.K. (including in the conduct of clinical trials in the U.K.). Accordingly, references in this section to the GDPR are also deemed to be references to the U.K. GDPR in the context of the U.K., unless the context requires otherwise. The GDPR also

provides that EEA Member States and the U.K. may make their own further laws and regulations to introduce supplementary requirements related to the processing of “special categories of personal data” (including health data and genetic information processed in the course of clinical trials); as well as personal data related to criminal offences or convictions. Such country-specific regulations, as well as differing and/or conflicting interpretations of the GDPR across the EEA and U.K., may lead to divergence in the application of the laws that govern our processing of personal data across the EEA and/or U.K., endeavoring to comply with each of which may increase our costs and could increase our overall compliance risk. Such country-specific regulations could also limit our ability to collect, use and share data in the context of our EEA and/or U.K. operations, and/or could cause our compliance costs to increase, ultimately having an adverse impact on our business and harming our business and financial condition.

The GDPR and the country-specific regulations noted above impose stringent data privacy and security requirements on both processors and controllers of personal data, including health data and genetic information processed in the course of clinical trials (even when that personal data is processed only in pseudonymized or key-coded form). In particular, the GDPR imposes several requirements relating to ensuring there is a lawful basis for processing personal data and, where relevant, a valid condition to processing special categories of 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, , creates mandatory data breach notification requirements in certain circumstances, and establishes onerous obligations on service providers who process personal data on behalf of others.

In particular, the GDPR and many other European data protection laws generally prohibit the transfer of personal data to the United States and other countries in respect of which the European Commission or other relevant regulatory body has not issued a so-called ‘adequacy decision’, unless the parties to the transfer have implemented specific safeguards to protect the transferred personal data. This is an area of evolving complexity and achieving effective compliance with ever-changing requirements and guidance in relation to data transfers from Europe is highly challenging. If we are unable to implement sufficient safeguards to ensure that our transfers of personal data from Europe are lawful, we may face increased exposure to regulatory action(s), substantial fines and injunctions against processing personal data from Europe. Loss of our ability to lawfully transfer personal data out of Europe to the United States or any other jurisdictions may (1) restrict our activities in Europe, (2) limit our ability to conduct clinical trials in Europe and/or to work with partners, service providers, contractors and other companies subject to European data protection laws, and/or (3) require us to increase our data processing capabilities in Europe at significant expense or otherwise cause us to change the geographical location or segregation of our relevant systems and operations — any or all of which could adversely affect our financial results. Additionally, other countries outside of the EEA, UK and Switzerland have passed or are considering passing similar cross-border data transfer restrictions and laws requiring local data residency, which could increase the cost and complexity of operating our business.

Companies that violate the GDPR, whether acting as a controller or a processor, can face robust regulatory enforcement and significant penalties for noncompliance, including fines of up to the greater of €20 million or 4% of their worldwide annual revenue for the preceding financial year. In addition to administrative fines, a wide variety of other potential enforcement powers are available to competent supervisory 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. 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. Additionally, as noted above, the U.K. has transposed the GDPR into the laws of the U.K. by way of the U.K. GDPR, which could expose us to two parallel regimes, each of which potentially authorizes similar fines, with the U.K. GDPR permitting fines of up to the higher of £17.5 million or 4% of global annual revenue of any noncompliant organizations for the preceding financial year; as well as other potentially divergent enforcement actions for certain violations.

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

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

We also license intellectual property from Mount Sinai. In May 2018, we entered into the Mount Sinai Agreement pursuant to which we obtained a worldwide, royalty-bearing, exclusive license under certain patents and a worldwide, royalty-bearing, non-exclusive license under certain know-how of Mount Sinai to develop and commercialize licensed products in connection with the application of artificial intelligence for the diagnosis of kidney disease. Pursuant to the terms of the Mount Sinai Agreement, we are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products, including in accordance with specified diligence milestones. If we fail to meet our obligations under the Mount Sinai Agreement or if the Mount Sinai Agreement is terminated for any reason, it could negatively impact our business and strategic goals.

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

We have also entered into partnerships with health systems such as Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement KidneyIntelX testing as part of their clinical care models. If we do

not continue to enter into partnerships with health systems at the rate and on the scale that we anticipate, or if these existing partnerships are terminated or do not result in the rate and quantity of KidneyIntelX testing that we anticipate, our business could be harmed.

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

We have sourced and will continue to source components of our technology, including instruments and reagents and other laboratory materials, from third parties. The assay reagents and materials for the KidneyIntelX test are sourced from Meso Scale Diagnostics, LLC, 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, Utah and Florida. These facilities are not fully redundant. Our facilities and equipment could be harmed or rendered inoperable by natural or man-made disasters, including war, fire, earthquake, power loss, communications or Internet failure or interruption, terrorism, or pandemic which may render it difficult or impossible for us to provide these services for some period of time. The inability to provide

these services or to reduce the backlog of analyses that could develop if one or more of our laboratories become inoperable, for even a short period of time, may result in the loss of customers or harm to our reputation, and we may be unable to regain those customers or repair our reputation in the future. Furthermore, our facilities and the equipment we use to perform our research and development work could be unavailable or costly and time- consuming to repair or replace. It would be difficult, time-consuming, and expensive to rebuild any of our facilities or license or transfer our proprietary technology to a third party, particularly in light of the licensure and accreditation requirements for commercial laboratories like ours. We may be unable to negotiate commercially reasonable terms with such third parties. Adverse consequences resulting from an interruption of our overall laboratory operations could harm relationships with our customers and regulatory authorities, and our reputation, and could affect our ability to generate revenue.

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

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

Risks related to our business operations and industry

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

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

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

Principal competitive factors in our market include:

- quality and strength of clinical and analytical validation data;
- proprietary access to extensively validated biomarkers for CKD;
- partnerships with healthcare systems;
- confidence in diagnostic or prognostic performance;
- technical performance and innovation to deliver products that provide clinically actionable results;
- reputation among health systems, physicians and payors as a provider of high-value diagnostic products;
- third-party reimbursement achievements;

- regulatory achievements;
- inclusion in practice guidelines;
- economic health benefits; and
- ease of use and willingness of physicians to include products as part of their routine care for patients with kidney disease.

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

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

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

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

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

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

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

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

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

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

Future sales of our products will be dependent on purchasing decisions of and reimbursement from government health administration authorities, distributors and other organizations. As a result of adverse conditions affecting the global economy and credit and financial markets, including disruptions due to political instability, global pandemics and diseases 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, 2022, we had U.S. federal net operating loss carryforwards of approximately $79.9 million and U.S. state and local net operating loss carryforwards of approximately $120.1 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 net operating loss and tax credit carryforwards and certain built-in losses to reduce future tax payments or benefit from favorable U.K. tax legislation.

As a U.K. resident trading entity, we are subject to U.K. corporate taxation. Due to the nature of our business, we have generated losses since inception. As of June 30, 2022, we had cumulative carryforward tax losses of approximately $13.5 million in the UK. Subject to any relevant utilization criteria and restrictions (including those that limit the percentage of profits that can be reduced by carried forward losses and those that can restrict the use of carried forward losses where there is a change of ownership of more than half the ordinary shares of the company and a major change in the nature, conduct or scale of the trade), we expect these to be eligible for carry forward and utilization against future operating profits.

As a company that carries out extensive research and development activities, we seek to benefit from the U.K. research and development tax relief programs, being the Small and Medium-sized Enterprises R&D tax relief program, or SME Program, and, to the extent that our projects are grant funded or relate to work subcontracted to the company by third parties, the Research and Development Expenditure Credit program, or RDEC Program. Under the SME Program, we may be 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 majority of our research and development activities are eligible for inclusion within these tax credit cash rebate claims. 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. The U.K. Finance Act 2021 introduced a cap on payable credit claims under the SME Program in excess of £20,000 with effect from April 2021 by reference to, broadly, three times the total PAYE and NICs liability of the company, subject to an exception which prevents the cap from applying. That exception requires the company to be creating, taking steps to create or managing intellectual property, as well as having qualifying research and development expenditure in respect of connected parties which does not exceed 15% of the total claimed. If such exception does not apply, this could restrict the amount of payable credit that we claim. Additionally, the U.K. Government has announced its intention to introduce further restrictions to the U.K. research and development relief programs, refocusing such programs towards innovation in the U.K. On July 21, 2022, draft legislation was published setting out, among other things, details of such proposed restrictions which (if enacted) would, in particular, limit our ability (except in limited circumstances) to make claims under the existing relief programs in respect of accounting periods beginning on or after April 1, 2023 for: (i) research and development subcontracted to a third party (and, in the case of the RDEC Program, in respect of contributions made to a qualifying body) where such third party (or qualifying body) performs the work outside of the U.K., and (ii) expenditure incurred on externally provided workers that are not paid through UK payroll. These and other potential future changes to the U.K. research and development tax relief programs may mean we no longer qualify or may impact on the extent to which we can make claims.

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

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

The tax treatment of the company is, and our ADSs and ordinary shares are, subject to changes in tax laws, regulations and treaties, or the interpretation thereof, tax policy initiatives and reforms under consideration and the practices of tax authorities in jurisdictions in which we operate, as well as tax policy initiatives and reforms related to the Organization for Economic Co-Operation and Development’s 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, or the stamp duty or stamp duty reserve tax treatment of our ADSs or ordinary shares. We are unable to predict what tax reform may be proposed or enacted in the future or what effect such changes would have on our business, but such changes, to the extent they are brought into tax legislation, regulations, policies or practices, could affect our financial position and overall or effective tax rates in the future in countries where we have operations, reduce post-tax returns to our shareholders, and increase the complexity, burden and cost of tax compliance.

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

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

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

Risks related to our intellectual property

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

Our success depends in large part on our ability to obtain and maintain patent protection in the United States and other countries with respect to our proprietary products. If we do not adequately protect our intellectual property, competitors may be able to erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. To protect our proprietary position, we file patent applications in the United States and abroad related to our novel products that are important to our business. The patent application and approval process is expensive and time-consuming. We may not be able to file and prosecute all necessary or desirable patent applications at a reasonable cost or in a timely manner.

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

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

Our pending patent applications cannot be enforced against third parties practicing the technology claimed in such applications unless and until patent issues from such applications. Because the issuance of a patent is not conclusive

as to its inventorship, scope, validity or enforceability, our patents or pending patent applications may be challenged in the courts or patent offices in the United States and abroad. For example, we may be subject to a third party preissuance submission of prior art to the U.S. Patent and Trademark Office, 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;
- the volume and timing of sales of KidneyIntelX
- 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 or delays in the regulatory process;
- changes or developments in laws or regulations applicable to our products and commercialization strategy;
- changes to our relationships with health system partners, manufacturers or suppliers;
- announcements concerning our competitors or the diagnostics industry in general;
- actual or anticipated fluctuations in our operating results;
- changes in financial estimates or recommendations by securities analysts;
- potential acquisitions, financing, collaborations or other corporate transactions;
- the 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.

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

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

We had 74,760,432 ordinary shares outstanding as of June 30, 2022. Sales of a substantial number of such ADSs or ordinary shares or the perception that such sales may occur could cause the market price of our ADSs and/or ordinary shares to fall or make it more difficult for purchasers of ADSs to sell their ADSs at a time and price that they deem appropriate.

In addition, we have filed a registration statement on Form S-8 (File No. 333-248741) registering the issuance of an aggregate of 12,378,858 ordinary shares subject to options or other equity awards issued or reserved for future issuance under our equity incentive plans. Shares registered under this registration statement, or any registration statements on Form S-8 that we file in the future, will be available for sale in the public market subject to vesting arrangements and exercise of options and, in the case of our affiliates, the restrictions of Rule 144 under the Securities Act of 1933, as amended, or the Securities Act.

Additionally, we have filed a registration statement on Form F-3 (File No. 333-265280) registering the resale of an aggregate of 11,075,220 ordinary shares and 1,052,197 ADSs pursuant to our obligations under a registration rights agreement with Icahn School of Medicine at Mount Sinai and registration rights of holders of shares purchased in our private placement in April 2022. If these ordinary shares and ADSs are sold, or if it is perceived that they will be sold, in the public market, the trading price of our ADSs and ordinary shares could decline.

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

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

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

We are an "emerging growth company" as defined in the SEC's rules and regulations and we will remain an emerging growth company until the earlier to occur of (a) June 30, 2026, (b) the last day of the fiscal year (1) in which we have total annual gross revenues of at least $1.235 billion or (2) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our ordinary shares and ADSs that are held by non-affiliates exceeds $700.0 million as of the prior December 31, or (c) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes- Oxley Act, 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 December 31 in any given year, which would allow us to take advantage of many of the same exemptions from disclosure requirements, including reduced disclosure obligations regarding executive compensation in our periodic reports and, when required, our proxy statements.

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

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

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

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

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

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 the year ended June 30, 2022, we identified material weaknesses in the design of our internal control over financial reporting impacting accounting for stock-based based compensation. A material weakness is a significant deficiency, or a combination of significant deficiencies, in internal control over financial reporting such that it is reasonably possible that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. The material weaknesses that we identified related to our lack of formal processes and procedures and our lack of maintaining a sufficient complement of personnel commensurate with our accounting and reporting requirements. As of June 30, 2022, these material weaknesses remained unremediated. During the year ended June 30, 2022, we executed a remediation plan by implementing an external stock plan management system and engaging a third-party service provider to administer and manage our employee stock-based compensation plan. The third-party service provider has a proven track record of stock plan management to help companies seamlessly integrate data, manage their stock plan and ensure accurate financial reporting. We have implemented controls to review the service organization control report as well as review dates within the service provider's system to ensure that the stock option data is appropriately recorded in our financial statements. These efforts not only help ensure that our financial records are managed appropriately but also help ensure that the appropriate level of review is performed.

However, implementation of these measures may not fully address the material weaknesses identified in our internal control over financial reporting and we cannot assure that we will be successful in remediating the material weaknesses. Our failure to correct the material weaknesses or our failure to discover and address any other material weaknesses or deficiencies could result in inaccuracies in our financial statements and impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis.

Generally, if we fail to achieve and maintain an effective internal control environment, it could result in material misstatements in our financial statements and could also impair our ability to comply with applicable financial reporting requirements and related regulatory filings on a timely basis. As a result, our businesses, financial condition, results of operations and prospects, as well as the trading price of our ordinary shares and ADSs may be materially and adversely affected. Additionally, ineffective internal control over financial reporting could expose us to increased risk of fraud or misuse of corporate assets and subject us to potential delisting from the stock exchange,

regulatory investigations and civil or criminal sanctions. We may also be required to restate our financial statements from prior periods.

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

Our ordinary shares are currently traded on AIM. Investment in equities traded on AIM is sometimes perceived to carry a higher risk than an investment in equities quoted on exchanges with more stringent listing requirements, such as the main market of the London Stock Exchange, New York Stock Exchange or Nasdaq. This is because AIM is less heavily regulated, imposes less stringent corporate governance and ongoing reporting requirements than those other exchanges. In addition, AIM requires only half-yearly, rather than quarterly, financial reporting. You should be aware that the value of our ordinary shares may be influenced by many factors, some of which may be specific to us and some of which may affect AIM companies generally, including the depth and liquidity of the market, our performance, a large or small volume of trading in our ordinary shares, legislative changes and general economic, political or regulatory conditions, and that the prices may be volatile and subject to extensive fluctuations. Therefore, the market price of our ordinary shares, the ADSs, or the ordinary shares underlying the ADSs, may not reflect the underlying value of our company.

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

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

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

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

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

Our management has broad discretion in the application of our cash including the net proceeds from the global offering we completed in July 2020, and 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 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.

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 44.12% of our outstanding ordinary shares, based on the number of ordinary shares outstanding as of June 30, 2022. As a result, depending on the level of attendance at our general meetings of shareholders, these persons, acting together, would be able to significantly influence all matters requiring approval by our shareholders, including the election, re-election and removal of directors, any merger, scheme of arrangement, or sale of all or substantially all of our assets, or other significant corporate transactions, and amendments to our articles of association. In addition, these persons, acting together, may have the ability to control the management and affairs of our company. Accordingly, this concentration of ownership may harm the market price of our ADSs and ordinary shares by:

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

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

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

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

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

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

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

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

If we are a passive foreign investment company, 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 analysis of our income, assets, activities and market capitalization for our taxable year ended June 30, 2022, we believe that we were classified as a PFIC for the taxable year ended June 30, 2022. U.S. Holders should consult with their tax advisors regarding the implications of owning stock in a PFIC. The determination of whether we are a PFIC is a fact-intensive determination made on an annual basis and the applicable law is subject to varying interpretation. In particular, the characterization of our assets as active or passive may depend in part on our current and intended future business plans, which are subject to change. In addition, for our current and future taxable years, the total value of our assets for PFIC testing purposes may be determined in part by reference to the market price of our ordinary shares or ADSs from time to time, which may fluctuate considerably. Under the income test, our status as a PFIC depends on the composition of our income which will depend on the transactions we enter into in the future and our corporate structure. The composition of our income and assets is also affected by how, and how quickly, we spend the cash we raise in any offering. We cannot provide any assurances regarding our PFIC status. Because of the uncertainties involved in establishing our PFIC status, our U.S. tax counsel expresses no opinion regarding our PFIC status.

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

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, 2022, 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, 2023. 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 59,654.87 plus an additional £59,654.87 in connection with a rights offering from December 7, 2021 (being the date of our 2021 annual general meeting) until the conclusion of our 2022 annual general meeting, which authorization will need to be renewed or replaced upon expiration (other than in the case of a preemptive offering).

English law also generally provides shareholders with preemptive rights when new shares are issued for cash. However, it is possible for the articles of association, or for shareholders to pass a special resolution at a general meeting, being a resolution passed by at least 75% of the votes cast, to disapply preemptive rights. Such a disapplication of preemptive rights may be for a maximum period of up to five years from the date of adoption of the articles of association, if the disapplication is contained in the articles of association, or from the date of the shareholder special resolution, if the disapplication is by shareholder special resolution, but not longer than the duration of the authority to allot shares to which the disapplication relates. In either case, this disapplication would need to be renewed by our shareholders upon its expiration (i.e., at least every five years). Typically, English public companies renew the disapplication of preemptive rights on an annual basis at their annual general meeting. We have obtained authority from our shareholders to disapply preemptive rights in respect of shares allotted under the authorization described in the paragraph above up to an aggregate nominal amount of £27,115.85 from December 17, 2021 (being the date of our annual general meeting) until the conclusion of our 2022 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.

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

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

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

Owing to the international scope of our operations, fluctuations in exchange rates, particularly between the pound sterling and the U.S. dollar, may adversely affect us. Since the Brexit referendum in 2016, there has been a significant increase in the volatility of the exchange rate between the pound sterling and the U.S. dollar and an overall weakening of the pound sterling. Our business and the price of our ADSs may be affected by fluctuations in