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

FORM 20-F

(Mark One)

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

OR

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

For the fiscal year ended June 30, 2022

OR

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

OR

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

Date of event requiring this shell company report

Commission File Number 001-39387

RENALYTIX PLC

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

ENGLAND AND WALES
(Jurisdiction of incorporation or organization)

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

James McCullough
Chief Executive Officer
Renalytix plc
Finsgate
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Securities registered or to be registered pursuant to Section 12(b) of the Act:

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

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

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

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

Indicate the number of outstanding shares of each of the issuer's classes of capital or common stock as of the close of the period covered by the annual report. **Ordinary Shares: 74,760,432 outstanding as of June 30, 2022**

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

If this report is an annual or transition report, indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934. ☐ Yes ☒ No

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

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

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

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

If an emerging growth company that prepares its financial statements in accordance with U.S. GAAP, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards† provided pursuant to Section 13(a) of the Exchange Act. ☐

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

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

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

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

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

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

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INTRODUCTION

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

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

PRESENTATION OF FINANCIAL INFORMATION

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

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

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

INDUSTRY AND MARKET DATA

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

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

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

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

- the timing and plans for commercialization of KidneyIntelx;
- the timing and plans for regulatory filings and decisions;
- our plans to obtain and maintain regulatory approvals of KidneyIntelX;
- the potential benefits of KidneyIntelX;
- the market opportunities for KidneyIntelX and our ability to maximize those opportunities;
- our business strategies and goals;
- our ability and plans to establish and maintain partnerships and projections related to future test volume as part of those partnerships;
- our ability and plans to drive adoption of KidneyIntelX and integrate KidneyIntelX into clinical workflow;
- estimates of our sales, revenue, expenses, capital requirements and need for additional financing;
- third-party payor reimbursement and coverage decisions;
- the performance of our third-party suppliers and manufacturers,
- our expectations regarding our ability to obtain and maintain intellectual property protection for our diagnostic products and our ability to operate our business without infringing on the intellectual property rights of others;
- our expectations regarding regulatory classification of KidneyIntelX, as well as the regulatory response to the marketing and promotion of KidneyIntelX;
- our expectations regarding developments relating to our competitors;
- our ability to identify, recruit and retain key personnel;
- our plans and timing with respect to Kantaro;
- the potential impact of the current COVID-19 pandemic on our business or operations; and
- the sufficiency of our existing cash, cash equivalents and short-term investments to fund our operations and capital expenditure requirements.

You should refer to the section of this annual report titled "Risk factors" for a discussion of important factors that may cause our actual results to differ materially from those expressed or implied by our forward-looking statements. As a result of these factors, we cannot assure you that the forward-looking statements in this annual report will prove to be accurate. Furthermore, if our forward-looking statements prove to be inaccurate, the inaccuracy may be material. In light of the significant uncertainties in these forward-looking statements, you should not regard these statements as a representation or warranty by us or any other person that we will achieve our objectives and plans in any specified time frame, or at all. We undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law, applicable regulations or the rules of any stock exchange to which we are subject.

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

PART I

Item 1. Identity of Directors, Senior Management and Advisers

Not applicable.

Item 2. Offer Statistics and Expected Timetable

Not applicable.

Item 3. Key Information

A. 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

foreign exchange rates not only between the pound sterling and the U.S. dollar, but also the currencies of other countries, which may have a significant impact on our results of operations and cash flows from period to period. Currently, we do not have any exchange rate hedging arrangements in place.

Item 4. Information on the Company

A. History and Development of the Company

We were incorporated as a public limited company under the laws of England and Wales on March 15, 2018, with company number 11257655. Our principal executive offices in the United States are located at 1460 Broadway, New York, New York 10036 and our telephone number is +1 646 397 3970. Our registered office in the United Kingdom is located at Finsgate, 5-7 Cranwood Street, London, EC1V 9EE, United Kingdom, and the telephone number of our registered office is +44 20 3139 2910. Our agent for service of process in the United States is Renalytix AI, Inc., located at 1460 Broadway, New York, New York 10036. In June 2021, we changed our name from Renalytix AI plc to Renalytix plc and our registered address from Avon House 19 Stanwell Road Penarth Cardiff CF64 2EZ to Finsgate 5-7 Cranwood Street London EC1V 9EE.

Renalytix AI, Inc., a Delaware corporation, and Renalytix AI Limited, an Irish corporation, are our wholly owned subsidiaries.

In 2022, we established a third laboratory in St. Petersburg, Florida. The laboratory facility in Florida is approximately 1,200 square feet and has been established to be compliant with the FDA's quality system regulation. This site will be used in addition to our laboratories in New York City, New York and Salt Lake City, Utah which were established for research, development and clinical testing. In 2022, 2021 and 2020 we spent $0.6 million, $0.9 million and $0.9 million respectively on Property, Plant & Equipment related to our sites. Additionally, in 2022 we spent $0.1 million in software and development costs related to software designed for use in our labs.

The SEC maintains an Internet site that contains reports, proxy information statements and other information regarding issuers that file electronically with the SEC. The address of that site is http://www.sec.gov. Our website address is www.renalytix.com. The reference to our website is an inactive textual reference only and information contained in, or that can be accessed through, our website or any other website cited in this annual report is not part of this annual report.

B. Business Overview

Renalytix is focused on optimizing clinical management of kidney disease to drive improved patient outcomes and lower healthcare costs. KidneyIntelX, our first-in-class *in vitro* diagnostic platform, employs a proprietary algorithm that combines diverse data inputs, including validated blood-based biomarkers, inherited genetics and personalized patient data from electronic health record, or EHR, systems, to generate a unique patient risk score. This patient risk score enables prediction of progressive kidney function decline in chronic kidney disease, or CKD, allowing physicians and healthcare systems to optimize the allocation of treatments and clinical resources to patients at highest risk. CKD affects approximately 37 million individuals in the United States, significantly impacting their quality of life and, according to the United States Renal Data System's Annual Data Report, resulting in Medicare spending of over $120 billion per year. In response to this substantial kidney disease burden, a U.S. Presidential Executive Order on Advancing American Kidney Health was issued in July 2019 to support change in kidney disease care. We believe we are well-positioned to help meet this urgent medical need with KidneyIntelX, a laboratory developed test, or LDT, initially indicated for adult patients with type 2 diabetes and existing CKD, which is referred to as diabetic kidney disease, or DKD. KidneyIntelX has already been granted a common procedural terminology, or CPT, code, national Medicare pricing, a testing contract with the U.S. Federal Government, contracts with 35 state Medicaid programs and positive coverage determinations from 22 regional and local health insurance payors. Further, it has been granted breakthrough device designation from the U.S. Food and Drug Administration, or the FDA. Building on these significant reimbursement and regulatory milestones, we believe our population health-based business model, which includes partnerships with healthcare systems, such as Mount Sinai Health System, and commercial launch within the Veterans Health Administration System will help facilitate commercial adoption of KidneyIntelX in the United States. Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The National Kidney Foundation, or the NKF, estimates that one-third of adults in the United States are at risk of developing kidney disease. Advanced kidney disease is generally not reversible and, once the disease progresses to kidney failure, the only available treatments are long-term dialysis and kidney transplant. In 2019, more than 809,000 patients had end-stage kidney disease, or ESKD, with more than 566,000 requiring dialysis at least three times a week. More than 131,000 patients begin

dialysis each year to treat ESKD. Once on dialysis, patients typically experience a five-year mortality rate of up to 65%, about the equivalent rate for brain cancer. Furthermore, transplants are expensive and uncertain. As of 2022, about 92,000 Americans were on the waiting list to receive a kidney transplant and six patients die in the United States while waiting for a kidney transplant every day.

Moreover, the kidney disease crisis is continuing to grow along with the increased prevalence of contributing risk factors. One of the most significant risk factors for developing CKD is diabetes. It is estimated that there are approximately 12.6 million adults with DKD in the United States, and DKD is the most common cause of ESKD in most developed countries. Obesity is believed to account for 80% to 85% of the risk of developing type 2 diabetes. The worldwide prevalence of obesity nearly tripled between 1975 and 2016. Further, according to a 2019 study from the Harvard T.H. Chan School of Public Health, by 2030, it is estimated that about half of the U.S. adult population will be classified as obese and about a quarter as severely obese. This significant projected increase in the prevalence of obesity is expected to continue to drive an increase in diabetes, CKD, DKD and ESKD.

Managing a CKD population of this scale and the associated healthcare spending presents a unique healthcare system challenge, requiring a solution that provides a clearer understanding of clinical risk tied to specific guideline-driven clinical recommendations. The ability to predict which patients will experience progressive kidney function decline, which includes rapid kidney function decline, or RKFD, sustained significant decline in kidney function, kidney failure, initiation of long-term dialysis or kidney transplant, is critical to changing patient outcomes and health economics. Current methods for risk stratification of patients with CKD lack sufficient precision in predicting progressive kidney function decline, especially at earlier stages of the disease. This can exacerbate the occurrence of unexpected and expensive clinical events. In fact, up to 38% of patients with CKD initiate dialysis with little or no prior clinical specialist consultation, and up to 63% of patients with CKD initiate dialysis in an unplanned fashion with a central venous catheter and/or during emergency hospitalization, which we refer to as “dialysis crash.” This highlights the need for a mechanism to identify potential instances of rapidly progressing CKD before it becomes critical to the patient’s health and costly to healthcare providers.

We believe that the KidneyIntelX platform will be central to managing CKD, helping to identify which patients could benefit from clinical interventions at earlier stages of CKD before significant and irreversible kidney damage has taken place. For patients with CKD as a result of diabetes, obesity or other factors, early intervention can lower the risk of progressing to life-altering advanced disease, kidney failure, dialysis and diminished quality of life. For primary care physicians and specialists, KidneyIntelX provides an easy-to-understand, reportable patient risk score integrated with specific guideline-driven clinical recommendations designed to maximize patient treatment and compliance outcomes. For insurance payors, KidneyIntelX can help drive health economics gains over time. For population health and clinical medicine departments, KidneyIntelX provides a powerful prognostic tool to stratify CKD populations into low-, intermediate- and high-risk categories applied to a continuous scale, enabling physicians to optimize the choice of treatment and allocation of clinical resources to benefit patient outcomes and health economics.

We believe that the utilization of KidneyIntelX across large patient populations will have a significant impact on overall healthcare costs. Health economic benefits are projected to be derived from three key areas of benefit: (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. By deploying our proprietary algorithm in a clinically validated, *in vitro* diagnostic test, KidneyIntelX is able to help predict which patients will experience progressive kidney function decline within a five-year timeframe, equipping physicians with the information they need to properly assess risk and stratify patients, more efficiently allocate treatments and clinical resources for high-risk patients, and intensify or pivot treatment over time as a patient’s risk evolves. An independent review that we commissioned was conducted by Boston Healthcare Associates, or BHA, to develop a health economic model analyzing the cost and care pathway for patients with DKD at all stages of the disease and the potential cost savings of implementing and utilizing KidneyIntelX. According to the BHA study, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in 12-24 months and deliver a cost savings of up to $1.1 billion over five years per 100,000 patients with DKD.

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

payors to drive commercial adoption. We have already achieved a number of reimbursement and regulatory milestones critical to these goals, including:

- the grant of a government-wide contract in April 2021 by the U.S. General Services Administration for KidneyIntelX testing services at $950 per reportable result, which applies to more than 140 U.S. government departments, agencies and affiliates, including the U.S. Veterans Administration, Department of Defense military branches (Army, Navy, Air Force and Marines) and Indian Health Services;
- initiation of coverage determination processes with Medicare contractors
- becoming an accepted provider in 35 Medicaid state programs, with additional applications pending;
- receiving a KidneyIntelX positive coverage determination by one of New York State's largest not-for-profit health insurance companies with over 1.5 million members;
- receiving a CPT code for KidneyIntelX, which can be used to report the use of KidneyIntelX to private and public payors throughout the United States for reimbursement;
- the Centers for Medicare & Medicaid Services, or CMS, including KidneyIntelX on the Final 2020 Clinical Laboratory Fee Schedule, or CLFS, and setting the national price for KidneyIntelX at $950 per reportable test;
- positive coverage determinations from 20 regional and local private insurance payors including Capital District Physicians' Health Plan, Inc. and Blue Cross Blue Shield;
- secured Medicare Provider Transaction Access Number, or PTAN, from both National Government Services (NGS) and Noridian Healthcare Solutions, the regional Medicare Administrative Contractors with responsibility for overseeing laboratory facilities and providers located in the northeastern and western United States, respectively, which qualifies us as a provider and allows us to bill for services provided to patients with Medicare and Medicaid health insurance coverage in the United States from both our New York City and Salt Lake City laboratories;
- the FDA granting breakthrough device designation for KidneyIntelX;
- receiving a Clinical Laboratory Improvement Amendments, or CLIA, Certificate of Registration for our commercial laboratory operation in Salt Lake City, Utah, which we believe will support scale-up test volumes, optimize processing costs and accelerate payor coverage determinations;
- receiving clinical laboratory permits required to provide commercial testing of KidneyIntelX in all 50 U.S. states from our laboratories in Utah and New York, and;
- submitting filing to FDA seeking De Novo marketing authorization for KidneyIntelX.

We plan to deploy KidneyIntelX to patient populations with DKD on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients and nationally through the Veterans Health System under our GSA contract. We are building integrated partnerships with healthcare systems and engaging their clinical leadership teams to initiate and deploy our solution. Integration of the KidneyIntelX software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting.

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

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

Recent developments

In September 2020, we announced the launch of the KidneyIntelX clinical test reporting platform within the Mount Sinai Health System (Mount Sinai) in New York City under a real-world assessment study. KidneyIntelX risk assessment of progressive decline in kidney function or kidney failure, including education support for treating clinicians, is now commercially available for patients with early stage DKD. In addition to patient testing and risk assessment, a central component of this introduction milestone was the physician education and support program developed in close collaboration with leadership of the Mount Sinai Departments of Medicine and Population Health Science and Policy, with input from patient advocacy groups and the broader clinical community. This expert experience is reflected in the design of the KidneyIntelX test report and the newly launched product website, www.kidneyintelx.com. We believe this education and support program will be an important resource to help improve care for early stage DKD patients at Mount Sinai and support future deployments of KidneyIntelX. To date, we have provided over 4,600 reportable patient results across 232 providers in the Mount Sinai Health System.

In May 2021, we entered into a partnership with Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine to implement an advanced clinical care model to improve kidney health and reduce kidney disease progression and kidney failure. Through these partnerships, KidneyIntelX access will be enabled to primary care physicians, endocrinologists, nephrologists and care teams in 37 hospitals and more than 1,350 care locations across the Carolinas and Georgia. To date, we have provided over 500 reportable patient results in the Atrium Wake Forest system across 78 providers.

We announced a partnership with Singing River Health System in January 2022 to deploy KidneyIntelX informed care management to improve kidney health in individuals across the Mississippi Gulf Coast with type 2 diabetes and early-stage chronic kidney disease. We expect to commence integrated testing with Singing River in November of 2022.

The American Diabetes Association (ADA) and Renalytix announced in January 2022 a joint program to improve overall kidney health in patients with type 2 diabetes in the United States. This adds to our education program previously announced with the National Kidney Foundation.

Clinical Evidence Publications and Presentations

During fiscal year 2022 and in the post-period, several publications and presentations supporting KidneyIntelX were disseminated, including:

- published data in the American Journal of Nephrology demonstrating KidneyIntelX successfully monitored patient response to new drug therapy in 1,325 multinational clinical trial cohort patients;
- KidneyIntelX showed ability to assess risk of heart failure hospitalization and death in large international diabetic kidney disease patient cohort (published in Kidney360);
- peer-reviewed publication in Journal of Medical Economics supporting payer coverage for early-stage risk assessment and care management in the primary care office; projecting significant savings from KidneyIntelX testing at primary care level;
- data results published in American Journal of Managed Care demonstrate adoption and clinical utility of KidneyIntelX™; 98% of 401 primary care physicians confirmed KidneyIntelX has value as a risk decision tool (post-period);
- multiple data presentations at the American Diabetes Association (ADA) 82nd Scientific Sessions® meeting, including one that demonstrated KidneyIntelX testing in 1,112 adult diabetic kidney disease (DKD) patients at Mount Sinai Health System showed utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients;
- World Congress of Nephrology data showing KidneyIntelX predicts the future rate of decline in kidney function compared with current standard diagnostics in patients with early-stage chronic kidney disease and type 2 diabetes; and
- ongoing clinical studies at Wake Forest / Atrium Health and Mount Sinai Health System substantiating clinical utility of KidneyIntelX.

Submission to FDA seeking clearance of KidneyIntelX

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

We continue to work closely and constructively with the FDA on our De Novo Breakthrough Device authorization submission. Notably, we have provided additional comprehensive data which further confirms the performance of KidneyIntelX in risk discrimination for patients with diabetic kidney disease. We now believe we are approaching the completion of the De Novo regulatory process and while there is no guarantee of success until FDA has made its final determination, we are optimistic based on the analytic and clinical evidence provided.

Our strategy

Our goal is to lower healthcare costs and improve patient quality of life by transforming the paradigm for kidney disease risk assessment and clinical management through our KidneyIntelX platform. To achieve this goal, we plan to:

- ***Continue to Build Integrated Partnerships with Healthcare Systems on a Population Health Basis.*** We are focused on building partnerships with healthcare systems and the engagement and support of their clinical leadership teams, which will enable us to efficiently initiate and deploy our solution to patient populations with DKD. A key aspect of this is technical integration of the KidneyIntelX software platform with healthcare systems' EHR systems and clinical workflow. In September 2020, we announced the initiation of patient testing with Mount Sinai Health System. Integrated partnerships such as this are designed to allow KidneyIntelX to be deployed directly to patient populations and their treating clinicians in a cost- efficient and timely manner. We are engaging with multiple healthcare institutions and national payors regarding additional partnership opportunities.
- ***Actively Market KidneyIntelX in Veterans Health Administration.*** Following our 10-year government-wide contract provided in April 2021 by the U.S. General Services Administration for KidneyIntelX testing services at $950 per reportable result, we are now staffing sales and support teams and establishing enabling infrastructure to deploy KidneyIntelX at Veterans Health Administration. The Veterans Health Administration is America's largest integrated health care system, providing care at 1,293 health care facilities, including 171 medical centers and 1,112 outpatient sites, serving nine million enrolled veterans each year. The veteran population has an approximately one-third higher chronic kidney disease and DKD prevalence than the general population, which has been attributed to the significant multi-morbidity and higher mean age in this group. The economic costs for providing healthcare for Veterans with kidney disease are high and are increasing at a rapid rate. Excluding costs associated with dialysis, $17.9 billion was spent on care for Veterans with CKD in 2014. New VHA Directive 1053, distributed on March 17, 2020, established policy to improve prevention, early recognition, and management of CKD in VA medical facilities. An update to the VA/DoD Clinical Practice Guideline for the Management of CKD released in 2019 identified the need for accurate risk assessment in patients with early-stage kidney disease.
- ***Further Expand Insurance Payor Coverage.*** We are building pathways for payment for KidneyIntelX across a range of insurance payors in multiple states including from Blue Cross Blue Shield, Medicaid, Medicare, Medicare Advantage and private insurance concerns. We believe KidneyIntelX is reaching critical scale of coverage in several key markets including in Illinois, New York and North Carolina.
- ***Continue to Pursue Medicare Coverage.*** We achieved our first payments from a major Medicare Administrative Contractor, or MAC, in October 2022. We are pursuing additional coverage from other MACs in different territories and also believe the potential exists to achieve a national coverage determination from Medicare should we receive De Novo marketing authorization from the FDA. We

estimate that Medicare currently provides insurance coverage for approximately 14 million patients with CKD, an estimated 40% of which have DKD.

- ***Obtain FDA Clearance of KidneyIntelX to Further Drive Commercial Adoption in the United States.*** While not required for commercialization as an LDT, we are seeking marketing authorization from the FDA through the De Novo pathway as part of our strategy to produce a product capable of becoming the new, long-term standard of care for patients with CKD. We have designed KidneyIntelX under a quality-controlled product development process to support our FDA clearance application, and to take advantage of the dynamic capability of machine learning applied to large datasets through regulated, versioned product releases. KidneyIntelX was granted breakthrough device designation from the FDA in May 2019. In addition, we believe that preparing for and potentially obtaining FDA clearance could support our eventual efforts to obtain regulatory approvals of KidneyIntelX in the United Kingdom, European Union, China and other major global market territories, provide support for the adoption of KidneyIntelX across clinical disciplines and assist with the establishment of private third-party and government-based reimbursement.
- ***Build Substantial Repository of Kidney Disease-Related Data.*** We are building a repository of kidney disease-related data for the development of progressive KidneyIntelX product versions and additional artificial intelligence-powered clinical applications. We are designing applications to examine disease patterns in large patient populations and to optimize clinical care navigation and management effectiveness. These developments are underpinned by the goals of driving patient and physician behavior changes and ultimately improving patient outcomes. Access to current and historical patient data, combined with the ability to analytically and clinically validate study results in a quality-controlled framework, provides us with a powerful product development platform. Moreover, the depth, specificity and quality of data is of paramount importance to developing solutions with demonstrated clinical utility across a range of practice specialties and patient demographics, and securing access to this data is central to our strategy of demonstrating both short- and long-term impact on patient outcomes and health economics.
- ***Expand Our Product Portfolio.*** We believe there are significant opportunities to expand our technology platform through incremental version releases of KidneyIntelX as well as through extending the KidneyIntelX platform into new applications into additional populations of CKD patients beyond those with diabetes, including repeat testing to monitor changes in risk and therapeutic response and other CKD subtypes, including patients of African ancestry with the *APOL1* high-risk genotype. We also intend to develop solutions for use in other large chronic disease patient populations, like CKD associated cardiovascular disease. KidneyIntelX has been designed within a regulated, manufacturing-quality environment to allow us to take advantage of the dynamic nature of machine learning to improve product performance through a sequence of controlled version releases. We believe that our product development approach, which is based on a quality systems framework following FDA's Quality System Regulations and the ISO guidelines applicable to medical devices, will enable our KidneyIntelX platform to rapidly generate exponential data growth and new clinical use cases, with a clearer path to achieving the regulated and reimbursed introduction and subsequent product improvements of an artificial intelligence-powered *in vitro* diagnostic.
- ***Real World Evidence Program.*** Through our growing number of health system partnerships, pharmaceutical collaborations and payor models, we are now publishing on scaled real-world evidence (RWE) and data generation. The primary objective of demonstrating the clinical and economic impact of KidneyIntelX informed care management in large populations and we expect to expand the scale of this program with extensive publication and dissemination of the results.

  Importantly, we are actively pursuing opportunities to leverage the KidneyIntelX platform and this unique RWE program focused on chronic condition management at primary care to other indications, most notably kidney disease associated cardiovascular disease, heart failure and liver disease.
- ***Launch in Major International Markets.*** We plan to pursue the launch of KidneyIntelX in major medical markets outside of the United States, including in the United Kingdom, European Union and China, which have large and growing populations of CKD patients and are facing cost and clinical management challenges similar to the United States. According to a recent report published by NHS Kidney Care, in the United Kingdom, treatment for CKD costs more than breast, lung, colon and skin cancer combined. We plan to pursue foreign regulatory approval pathways, continue data accumulation and study development with ex-U.S. clinical investigators and seek integrated medical

center opportunities for addressing CKD patient populations outside of the United States, subject to obtaining the required marketing authorizations.

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

Our competitive strengths

The KidneyIntelX platform has the following key strengths:

- ***Novel Bioprognostic™ Platform Incorporating Biomarkers and Health Record Features Analyzed with a Machine Learning Algorithm to Assess the Risk for Kidney Disease Progression***. KidneyIntelX is the first machine learning enabled *in vitro* diagnostic with the ability to identify patients at risk of progressive kidney function decline while in the earlier stages of DKD, when costs and outcomes can be better controlled.
- ***Large and Growing Addressable Market***. CKD affects over 850 million people worldwide, including approximately 37 million people in the United States. The NKF estimates that one third of adults in the United States are at risk of developing kidney disease. Type 2 diabetes is one of the most significant risk factors for developing CKD and obesity is believed to account for 80% to 85% of the risk of developing type 2 diabetes. It is estimated that there are approximately over 12.6 million adults with DKD in the United States. Published data suggests that the DKD population will continue to grow along with the anticipated increase in the occurrence of type 2 diabetes and obesity. One study estimates that by 2060, the number of adults in the United States diagnosed with diabetes will reach 60 million. Further, according to a 2019 study from the Harvard T.H. Chan School of Public Health, by 2030, about half of the adult U.S. population will be obese and about a quarter will be severely obese.
- ***Achievements in Reimbursement and Coverage***. KidneyIntelX has received Medicare payment, Medicare pricing and multiple private insurance coverage determinations to date. We believe these positive outcomes are the result of several factors: (1) our rigorous approach to a product development and the market access process, (2) significant changes in U.S. reimbursement law with the full implementation of the Protecting Access to Medicare Act, and (3) global improvements in kidney disease policy management, including the U.S. Presidential Executive Order on Advancing American Kidney Health issued in July 2019.
- ***Economic Health Benefits***. We have designed KidneyIntelX to provide accurate, real-time, actionable results for patients and physicians while reducing costs and promoting improved health economics for patients, physicians, healthcare systems and payors. Health economic benefits are projected to be derived from three key areas: (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. By deploying our proprietary artificial intelligence-enabled algorithm in a clinically validated, *in vitro* diagnostic test, KidneyIntelX is able to help predict which patients will experience progressive kidney function decline within a five-year timeframe, equipping physicians with the information they need to properly risk stratify patients, more efficiently allocate treatments and allocate clinical resources for high-risk patients, and intensify or pivot treatment over time as a patient's risk evolves. According to a study conducted by BHA, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in 12-24 months and deliver a cost savings of up to $1.3 billion over five years per 100,000 patients with DKD.
- ***Partnered Business Model at Population Health Level***. We have begun to deploy KidneyIntelX to patient populations with DKD on a regional basis through partnerships with healthcare systems (including Mount Sinai, University of Utah, Atrium Health, Wake Forest Baptist Health and Wake Forest School of Medicine) and insurance payors that provide coverage to certain healthcare systems' patients. KidneyIntelX has had the support of clinical and population health leadership, with the primary focus of quickly and efficiently deploying an effective prognostic solution to their DKD patients. As a result, we believe KidneyIntelX will be able to reach and potentially benefit significant patient populations without employing a large, traditional sales force on a provider-level basis at those health systems. In addition, integration of the KidneyIntelX software platform with healthcare providers' EHR systems enables seamless electronic test ordering and score reporting.
- ***Regulatory-compliant Versioning Approach***. KidneyIntelX is designed as a scalable platform that can be optimized and deployed into clinical use on a validated-version by validated-version basis. Because we are operating as the Manufacturer of Record, KidneyIntelX is designed and manufactured under an *in vitro* diagnostics, quality-controlled process following FDA requirements and ISO guidelines. As a result, and with support from recent FDA policy initiatives, KidneyIntelX may conduct a version-controlled process to optimize algorithmic performance and expand clinical indications on an iterative basis. We believe this regulatory framework could potentially provide KidneyIntelX with the following competitive advantages: (1) more rapid machine-learning algorithm optimization as

additional biomarker and patient EHR data are aggregated at a logarithmic rate, (2) a simplified pathway to expanded indications for use, including therapeutic drug response monitoring, and (3) more personalized patient diagnostic information as the heterogeneity of data density is better analyzed.

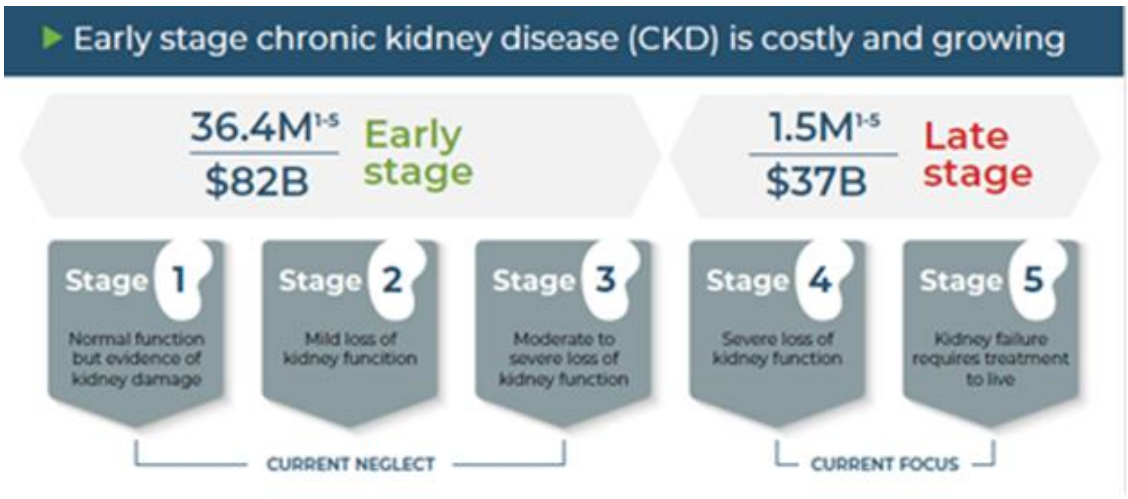
- ***Kidney Disease Data Repository***. As a result of our partnered business model at a population health level, we anticipate that we will have the opportunity to build the most comprehensive de-identified kidney disease data repository geared toward early identification of high-risk patients and optimization of care pathways. Further, our partnerships with relevant insurance payors increases the visibility and the potential cost/benefit economics of KidneyIntelX. As we expand coverage, we believe that the velocity of data aggregation will continue to increase, leading to greater KidneyIntelX fidelity and therefore greater competitive barriers to entry.

Industry background

Chronic kidney disease

Kidney disease is a worldwide public health crisis, resulting in more deaths per year than breast or prostate cancer. The International Society of Nephrology estimates that kidney disease affects over 850 million people worldwide. According to the Centers for Disease Control and Prevention, or CDC, CKD affects approximately 37 million people in the United States alone, and the NKF estimates that one third of adults in the United States are at risk of developing kidney disease.

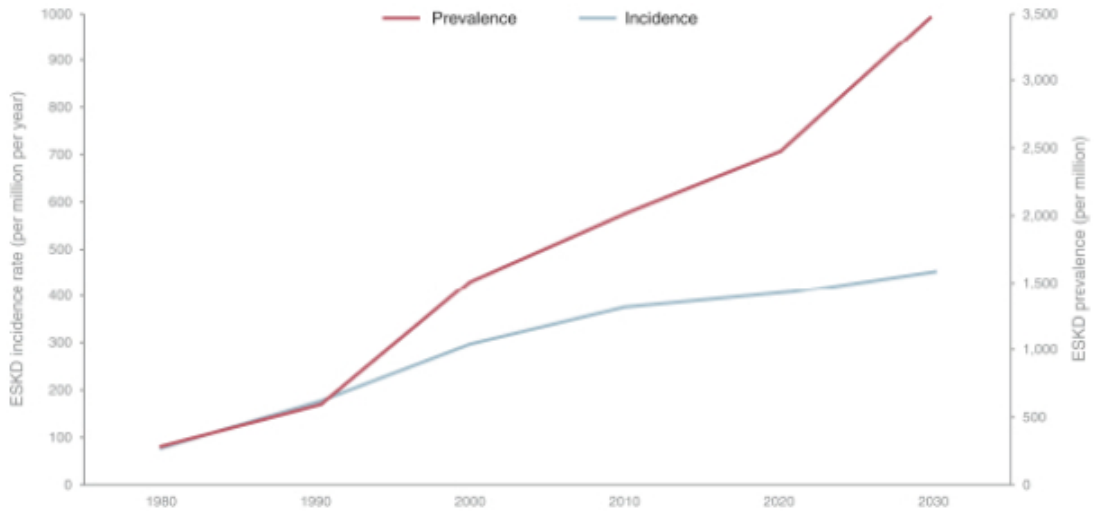
CKD, also called chronic kidney failure, is the loss of kidney function over time. Advanced kidney disease is generally not reversible. There are five stages of CKD, from mild kidney damage in Stage 1 to complete kidney failure in Stage 5. The stages of kidney disease are based on how well the kidneys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



Commonly referred to as a "silent disease," CKD is often asymptomatic until approximately 70% to 80% of kidney function has been lost. According to the CDC, in the United States, nine out of ten adults with CKD are not aware they have the disease. In fact, up to 38% of patients with CKD initiate dialysis with little or no prior clinical specialist consultation, and up to 63% of patients with CKD initiate dialysis in an unplanned fashion with a central venous catheter and/or during emergency hospitalization, which we refer to as "dialysis crash." This highlights the

need for an early mechanism to identify potential instances of rapidly progressing CKD before it becomes critical to the patient's health and costly to healthcare providers.

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



Once on dialysis, patients typically experience a five-year mortality rate of up to 70%, about the equivalent rate for brain cancer. According to the NKF, over two million people worldwide currently receive treatment with dialysis or a kidney transplant to stay alive, yet this number may only represent 10% of people who actually need treatment to live. As of July 2019, nearly 100,000 Americans were on the waiting list to receive a kidney transplant and 13 patients die in the United States while waiting for a kidney transplant every day.

Studies have shown that ethnicity is a determining factor for kidney disease risk. According to the CDC, Americans of African ancestry are three times more likely to develop kidney disease than Caucasians. Since approximately 13% of the U.S. population is of African ancestry, this is a crucial population group that can benefit from advanced and ongoing risk assessment of kidney health. Genetic studies have identified the *APOL1* genotype that is responsible for much of the increased risk for CKD and ESKD in individuals of African ancestry. The *APOL1* high-risk genotypes (two copies of the *APOL1* kidney disease risk variants; G1/G1; G2/G2 or G1/G2) have been shown to be associated with increased ESKD risk, CKD progression, eGFR decline and CKD incidence.

Chronic kidney disease, obesity and diabetes

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

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

projected increase in the prevalence of obesity and severe obesity is expected to continue to drive an increase in diabetes, CKD, DKD and ESKD.

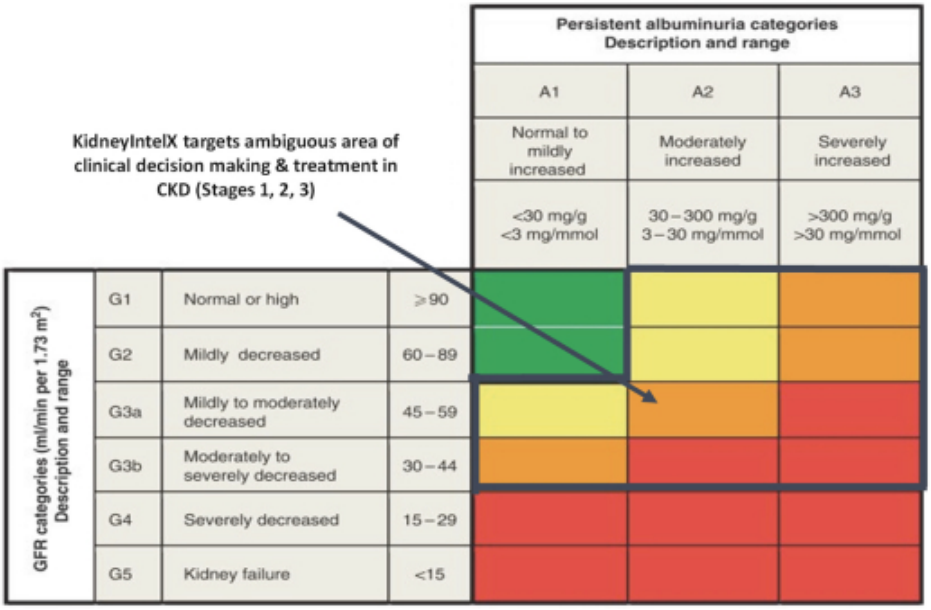
Significant healthcare system costs associated with CKD

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

Current risk classification paradigm and limitations

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

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



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

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

Second, there are biologic differences within the KDIGO classification system that are not recognized, and there are dichotomies created that are not biologically or prognostically heterogeneous. For example, eGFR of 46 versus 44 crosses G3a to G3b and places someone in a different KDIGO risk category, as does a UACR of 29 vs. 32 mg/mmol. In other words, the KDIGO classification system imposes cutoffs of risk strata despite the fact that the underlying biologic variables are continuous. As a result, the KDIGO classification system has been shown in practice to lack sufficient precision to predict who will experience RKFD, especially in earlier stages of DKD (Stages 1 through 3). In our clinical validation studies in patients with DKD, we observed that the KDIGO classification system only identified approximately 20% of patients that experienced an adverse kidney outcome as very high-risk patients with the recommendation of referral to a nephrologist, while KidneyIntelX identified nearly half of such patients.

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

Further, lack of ability to accurately predict which patients are at high risk of RKFD has led to strained clinician resources, inadequate referrals to clinical specialists and suboptimal treatment of DKD resulting in significant patient suffering and diminished quality of life. Because kidney disease is so common and the current standard of care does not adequately risk stratify patients, primary care physicians or endocrinologists typically are caring for most people with non-dialysis dependent CKD and many high-risk patients are not referred to clinical specialists in a timely manner. The high burden and lack of available time for each patient do not allow these physicians to fully assess the vast amount of data from the EHR to enable proper risk stratification and treatment. For example, only around half of all eligible patients with DKD are on antagonists of the renin angiotensin aldosterone system, medications which are the standard of care, and less than 10% are on sodium-glucose transport protein 2, or SGLT2, inhibitors, newer medications that have been shown to substantially slow kidney disease progression. In addition, there is a lack of appropriate patient counseling on the progressive nature of the patient's disease, leading to lack of compliance with treatment protocol and decreased awareness of kidney disease.

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

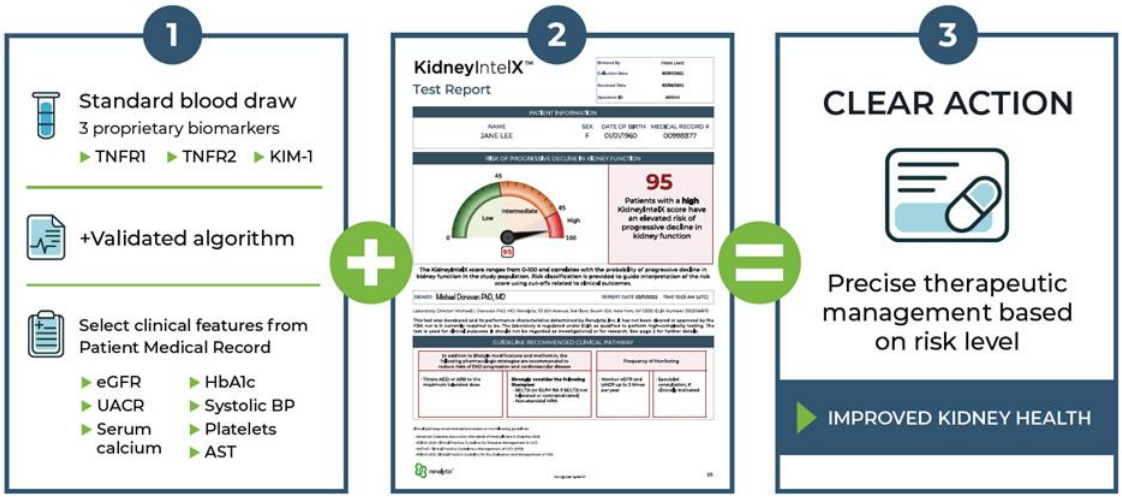
Market opportunity

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

Our technology platform solution

Overview

We have designed KidneyIntelX, our first-in-class diagnostic platform, to enable risk prediction of progressive kidney function decline in patients with CKD. KidneyIntelX employs an artificial intelligence-enabled algorithm that is capable of using diverse data inputs, including validated blood-based biomarkers from a patient blood draw, inherited genetics and personalized patient data from EHR systems, to generate a unique patient risk score.



The unique patient risk score is then reported to the treating clinician through an interface that provides the reportable risk score, categories of risk classification and specific guideline-driven clinical actions, as depicted in the graphic below.

Potential benefits of KidneyIntelX

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

- **For patients**, with CKD as a result of diabetes, obesity or other factors, early intervention can lower the risk of progressing to life-altering advanced disease, kidney failure, dialysis, suffering and diminished quality of life. Patients that are designated to be low- or intermediate-risk, requiring lower intensity of treatments, can continue care with their existing primary care physician or endocrinologist.

For example, healthcare providers may be able to use a wider range of preventative and therapeutic measures such as dietary advice (optimizing intake of salt, proteins, fluids and supplements), lifestyle changes (weight management and smoking cessation) and medication. High-risk patients are able to receive appropriate referral to a specialist, increased monitoring intervals, improved awareness of kidney health, referral to dieticians, reinforcement of usage of antagonists of the renin angiotensin aldosterone system, and increased motivation to start recently approved medications, including SGLT2 inhibitors to slow disease progression. All of these factors can result in the delay or prevention of ESKD and may reduce the occurrence of dialysis crashes. In addition, earlier engagement with clinical specialists may also allow for more time to advise and educate patients about home-based dialysis and pre-emptive or early kidney transplant.

- **For primary care physicians and specialists**, KidneyIntelX provides an easy-to-understand, reportable patient risk score integrated with specific guideline-driven clinical recommendations designed to maximize patient treatment and compliance outcomes. Primary care physicians are empowered to continue to treat low-risk patients with actionable guidelines, and high-risk patients are appropriately referred to specialist care.
- **For insurance payors**, KidneyIntelX can help drive health economics gains over time by (1) slowing progression to the next stage of CKD, (2) delaying or preventing progression to ESKD and the need for dialysis or kidney transplant and (3) avoiding dialysis crashes. According to the BHA study, based on the Medicare price of $950 per reportable test, KidneyIntelX would generate a positive return for health insurers in 12-24 months and deliver cost savings of up to $1.1 billion over five years per 100,000 DKD patients.
- **For population health and clinical medicine departments**, KidneyIntelX provides a powerful diagnostic tool to stratify kidney disease populations into low-, intermediate- and high-risk categories applied to a continuous scale, enabling physicians to optimize the choice of treatment and allocation of clinical resources to benefit patient outcomes and health economics.

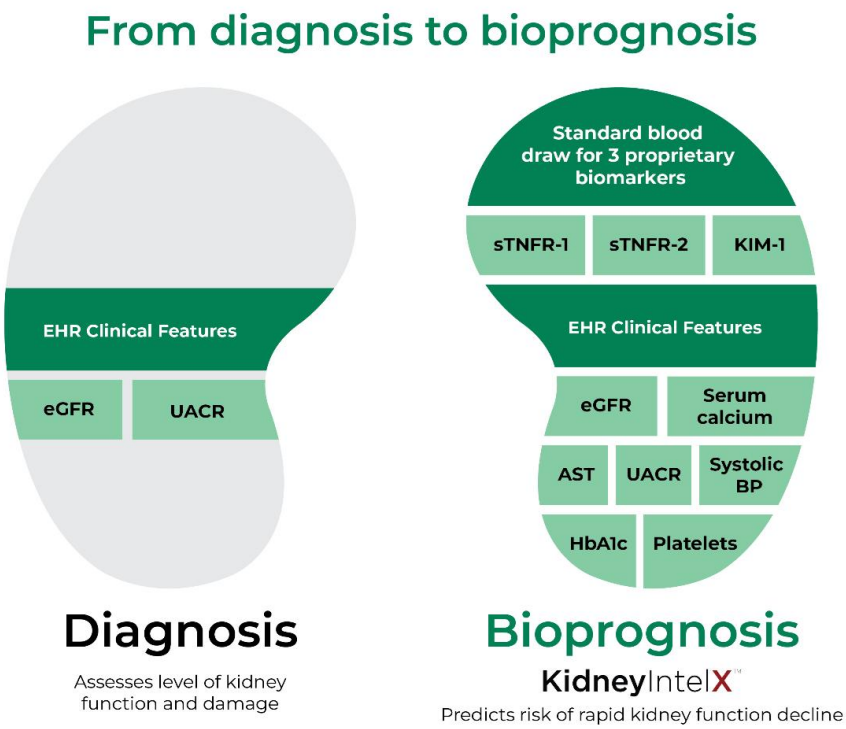
These benefits are primarily driven by the following:

- *Improved Patient Risk Stratification in Earlier Stage CKD.* The machine learning-enabled patient risk score generated by KidneyIntelX, unlike static CKD risk classification systems, is able to take into account the continuous values of key inputs, including eGFR and uACR (the two measures utilized by the KDIGO classification system), other kidney-related laboratory values (such as serum sodium, potassium, calcium, bicarbonate, urea nitrogen, phosphate and hemoglobin), physiologic variables (such as age, weight and blood pressure), and combine them with predictive blood-based biomarkers. In clinical studies, KidneyIntelX was able to more accurately identify potentially fast- progressing CKD in individuals with type 2 diabetes and those of African ancestry over current clinical practice. In addition to the individual features themselves, combinations and interactions of these features, called meta-features, can add to the predictive performance of the model and can be deployed in clinical practice for the first time.
- *Advanced Data Analytics for Earlier Stage CKD*. The deployment of KidneyIntelX in the partnership model setting with healthcare systems and insurance payors presents an opportunity to improve outcomes. Specifically, we believe the partnership model can highlight how early CKD risk stratification integrates into health system clinical workflows to slow or prevent disease progression and kidney failure and improve efficiency of care delivery. To maximize insight, we are bringing together a multi-disciplinary team that includes data science, health economics, behavioral economics and clinical specialists for initial deployments. This team consists of both our internal employee base and third-party groups that have experience examining large quantities of population-based data.

The KidneyIntelX model

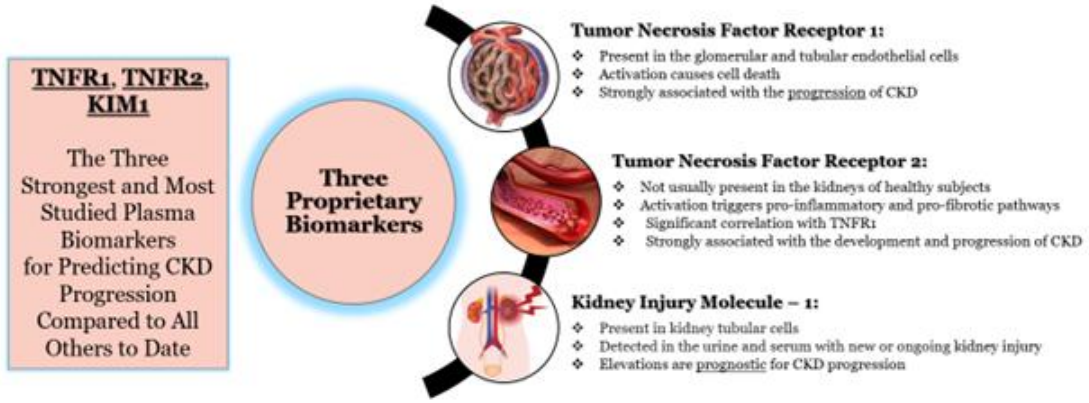
At the core of our approach is an artificial intelligence-enabled algorithm capable of synthesizing a set of current and diverse data inputs, such as biomarkers, EHR data, genomics, patient-generated digital data, environmental information, clinical utility, and actuarial and clinical compliance information.

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



Validated proprietary blood-based biomarkers

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



Electronic health records data harmonization, adjudication and machine learning

The use of EHRs has been adopted broadly by hospital systems in the United States, the United Kingdom, the European Union and other developed countries. EHR data are generally collected during routine clinical encounters and contain detailed information on disease and treatment patterns. When assessed in the aggregate, EHR data can provide insights into disease progression and clinical management strategies across diverse populations. EHR factors may include items such as current or past therapeutic regimes, diagnostic results, weight, age, geographic location, physician visiting habits and physician annotations. Additional data factors can be added to the KidneyIntelX algorithm to address different target populations. For example, the next generation test is being developed to address the increased incidence in kidney disorders amongst individuals of African ancestry by incorporating genotyping for *APOL1*.

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

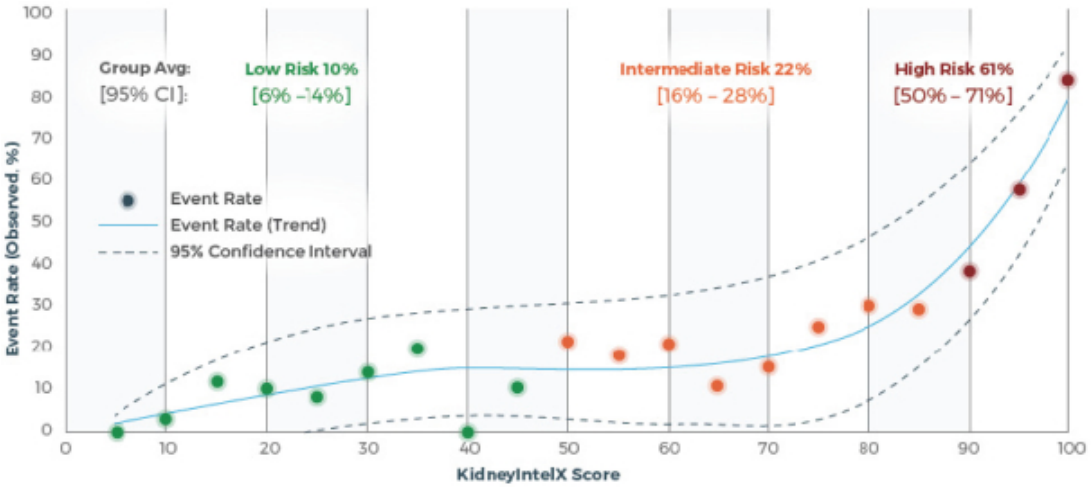
Through experience with our clinical study work, we have developed a proprietary data processing methods that enables us to analyze patient data collected during clinical encounters by a diverse set of physicians in different clinical environments and still ensure that the data used by the KidneyIntelX platform to support product development and clinical testing is consistent and falls within specific quality control metrics. We have tested this capability in our clinical validation studies involving stored specimens from over 1,500 patients with DKD from the Mount Sinai Health System and University of Pennsylvania Health System biobanks.

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

Patient-specific continuous risk score

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

The graph below shows the probability of the composite kidney endpoint by quantile of the KidneyIntelX risk score in our multi-center validation study discussed below. The event rate of the composite kidney endpoint, which represents the five-year progression of disease, includes three categories of progressive kidney function decline: (1) RKFD, which is defined as eGFR decline of at least 5 ml/min/1.73m^2/year, (2) sustained 40% decline in eGFR and (3) one of the following: (a) kidney failure, defined as a sustained eGFR < 15 ml/min/1.73m^2, (b) long-term dialysis or (c) kidney transplant.

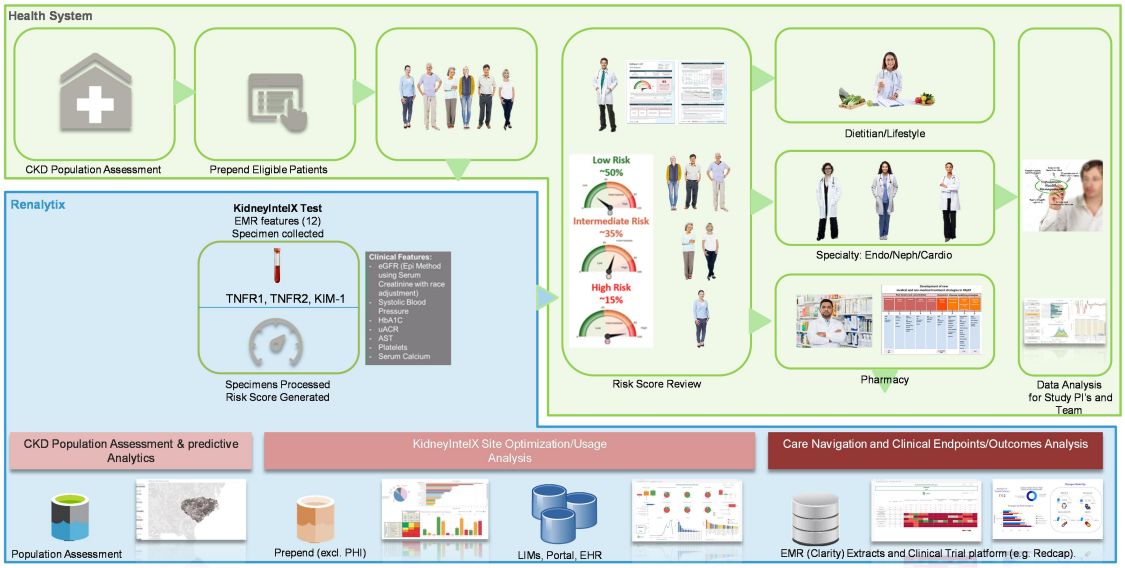


PPV: positive predictive value

NPV: negative predictive value

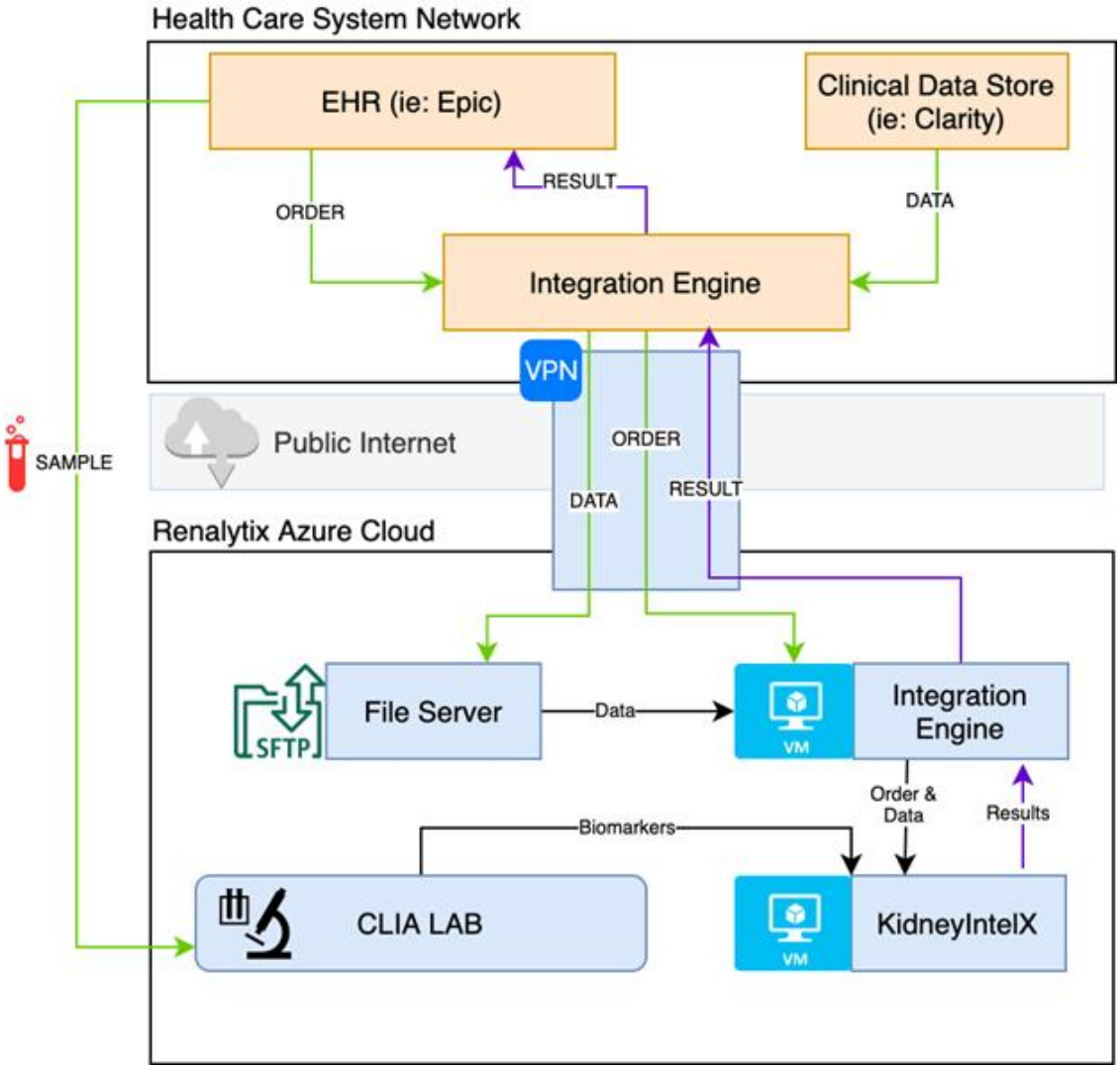
This novel capability of using machine learning to generate a continuous risk score enables the timely and accurate prediction of risk of disease progression in the earlier stages of DKD (Stages 1 through 3), where active intervention has the most potential to delay or prevent progression to ESKD and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

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



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

KidneyIntelX is designed to extract from the EHR system the information required for each ordered test, which is then combined with biomarker data to generate the risk score and test report. We anticipate that future versions of KidneyIntelX will enable periodically updated patient risk scores through repeat testing, and integration of the risk score back into the EHR as part of the permanent medical record of the patient. The treating physician can have all of the relevant information pertinent to the patient's care delivered to them at the time of the clinical encounter and can trigger care pathways directly from the EHR interface, with the goal of driving a virtuous cycle in which patients and clinicians have increased visibility on the effects of changes in care management and patient behavior on kidney health.



We anticipate that the kidney disease risk score will be provided to the clinician at the point-of-care through standard approaches for reporting, mobile device and/or the Renalytix provider portal. In addition, we plan to be able to provide the kidney disease risk score directly to patients via access to the Renalytix patient portal and patient-facing mobile device applications.

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

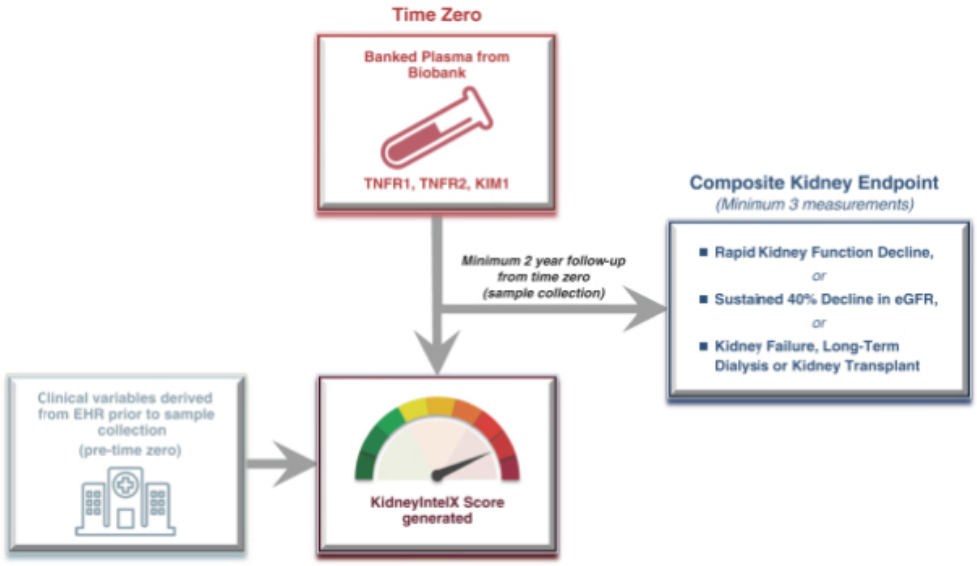
We have been working with Persistent Systems Limited, or Persistent Systems, to develop secure, cloud-based data integration software architecture and secure, high-performance algorithms for our platform. Persistent Systems is a leader in software development and has long-standing relationships with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

Clinical validation studies

We have completed three clinical validation studies using blood biobank facilities with integrated patient EHR data over a multi-year period from Mount Sinai Health System and University of Pennsylvania Health System. We also evaluated KidneyIntelX in the CANVAS trial, a completed large, randomized control trial for a novel treatment (canagliflozin) for DKD.

Completed clinical validation studies

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



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

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

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

Validation Study 1—Mount Sinai Health System

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

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

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

* Prior to time zero (sample collection).

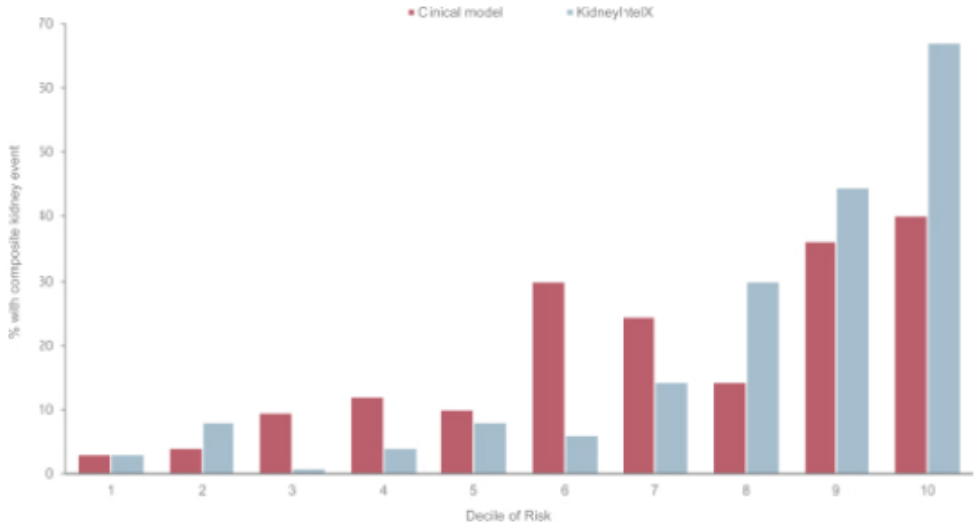
The observations in this study showed that, in patients with type 2 diabetes or patients of African ancestry with the high-risk *APOL1* genotype, KidneyIntelX significantly improved prediction of eGFR decline or kidney failure over standard clinical models.

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

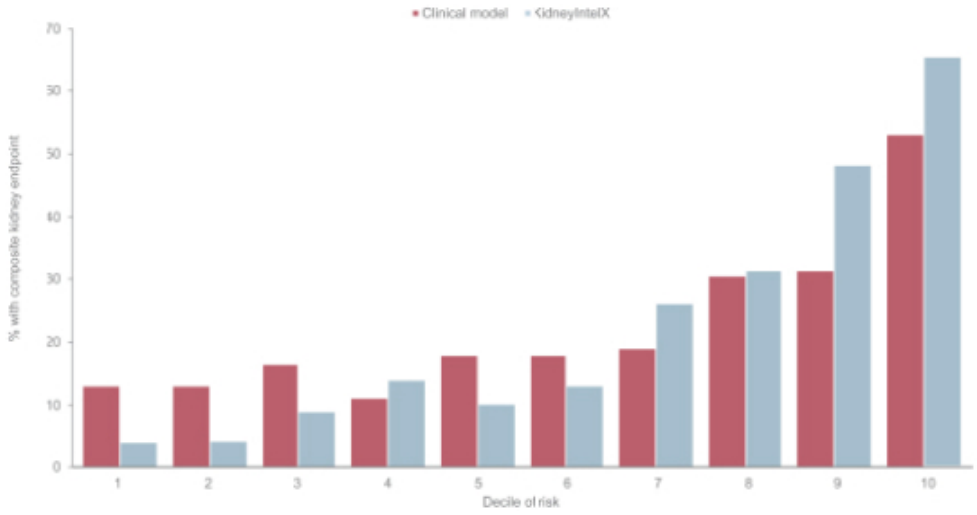
For the patients with *APOL1* high risk genotype, the AUC for KidneyIntelX in the training set (80%, n=398) was 0.86 (95% CI: 0.84 -0.87) and 0.80 (95% CI: 0.77 -0.83) in the test set (20%, n=99). The clinical model had an AUC of 0.72 (95% CI: 0.71 -0.73) in the *APOL1*-HR cohort (n=498).

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

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



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



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

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

	Risk Cutoff	Sensitivity	Specificity	PPV	NPV
Type 2 Diabetes KidneyIntelX					
Bottom 50%	0.192	0.82	0.59	0.38	0.92
Top 20%	0.444	0.5	0.89	0.58	0.86
Top 15%	0.555	0.4	0.93	0.62	0.84
Top 10%	0.707	0.29	0.96	0.68	0.82
Type 2 Diabetes Clinical Model					
Bottom 50%	0.148	0.58	0.55	0.31	0.85
Top 20%	0.24	0.38	0.85	0.43	0.82
Top 15%	0.278	0.3	0.89	0.46	0.81
Top 10%	0.338	0.23	0.94	0.54	0.8
***APOL 1*-HR KidneyIntelX**					
Bottom 50%	0.209	0.88	0.58	0.32	0.96
Top 20%	0.438	0.6	0.89	0.56	0.91
Top 15%	0.489	0.52	0.93	0.62	0.9
Top 10%	0.546	0.36	0.96	0.66	0.87
***APOL 1*-HR Clinical Model**					
Bottom 50%	0.151	0.79	0.57	0.29	0.93
Top 20%	0.322	0.42	0.85	0.38	0.87
Top 15%	0.387	0.32	0.87	0.39	0.85
Top 10%	0.448	0.22	0.93	0.4	0.84

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

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

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

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

	Patients with DKD (n=1,146)
Median baseline estimated eGFR	54 ml/min/1.73m2
Median uACR	61 mg/g
Median follow-up (years)	4.3

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

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

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

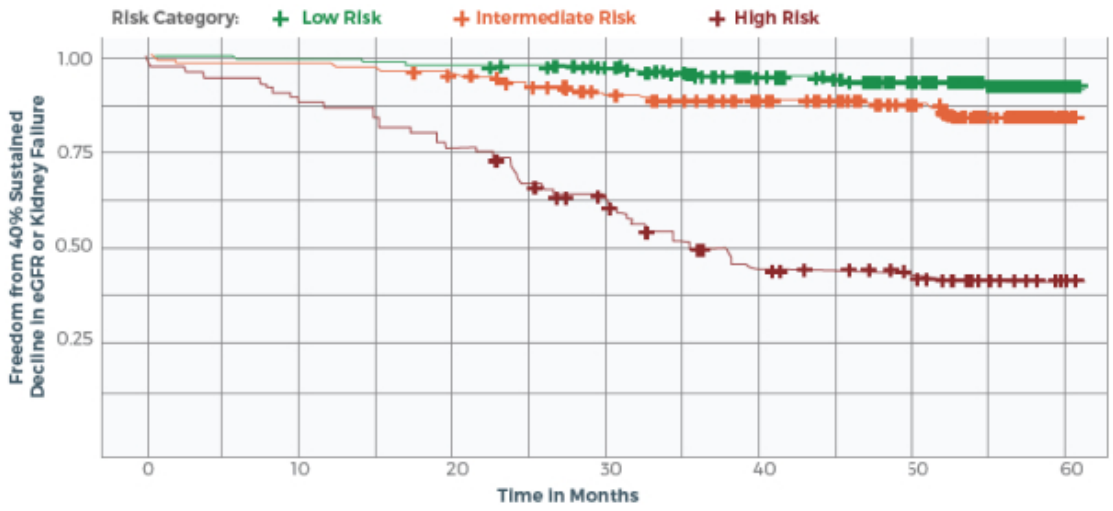
We also compared KidneyIntelX to KDIGO risk strata:

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

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

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

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



Validation Study 3— Evaluation of KidneyIntelX in the Multinational CANVAS trial

We evaluated the performance of KidneyIntelX in 3,500 patients with type 2 diabetes from the CANagliflozin cardiovascular Assessment Study (CANVAS) in collaboration with University Medical Center Groningen, Netherlands. KidneyIntelX risk scores were calculated (blinded to outcome) on the 1325 participants in both the placebo and canagliflozin arms of CANVAS with DKD at the time of randomization. Blood samples for plasma TNFR1, TNFR2 and KIM-1 assays were obtained at baseline, 52, 156, and 312 weeks after randomization and measured on the high-performance electrochemiluminescence immunoassay on the Mesoscale Sector s600 instrument in the Renalytix laboratory in New York, NY, USA.

The collaborative study involves multiple components, including: (1) how effectively KidneyIntelX predicts which patients experience progressive decline in kidney function in both placebo and treatment arms; (2) whether KidneyIntelX can predict at baseline those most likely to benefit from treatment and (3) the effect of treatment on changes on the KidneyIntelX risk score over time.

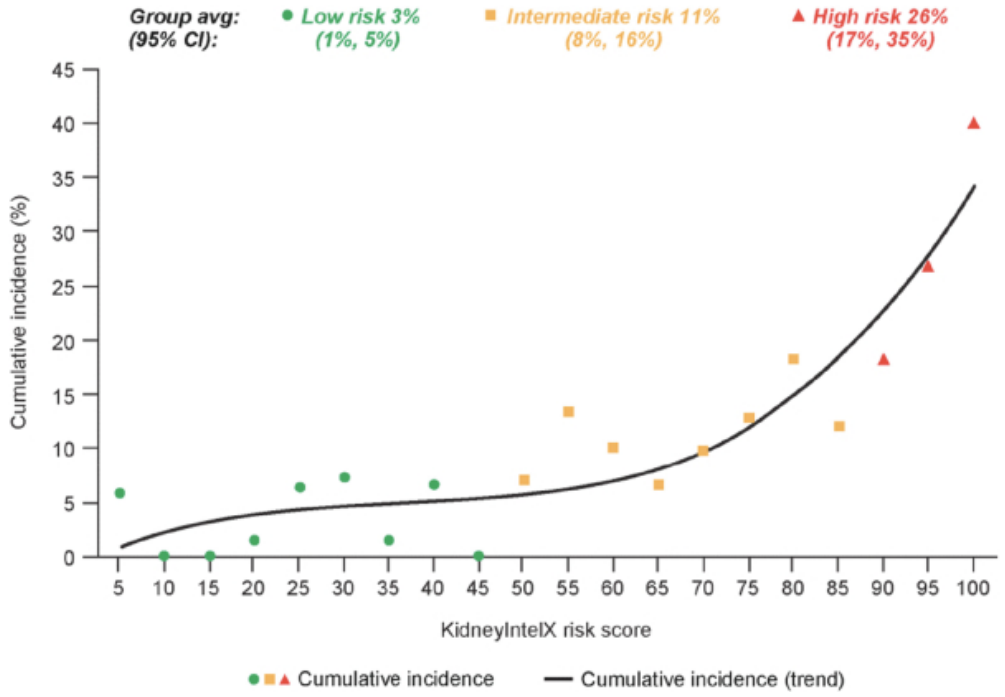
Study population

Of the 1396 participants in the CANVAS trial with prevalent DKD, 1325 had available blood samples at baseline and 1019 had samples available at baseline and at 1 year. The mean age of the full study population was 64 years, 32% were female, mean eGFR was 65 mL/min/1.73 m^2, and median UACR was 56 mg/g.

Association between baseline KidneyIntelX risk score with the composite kidney outcome

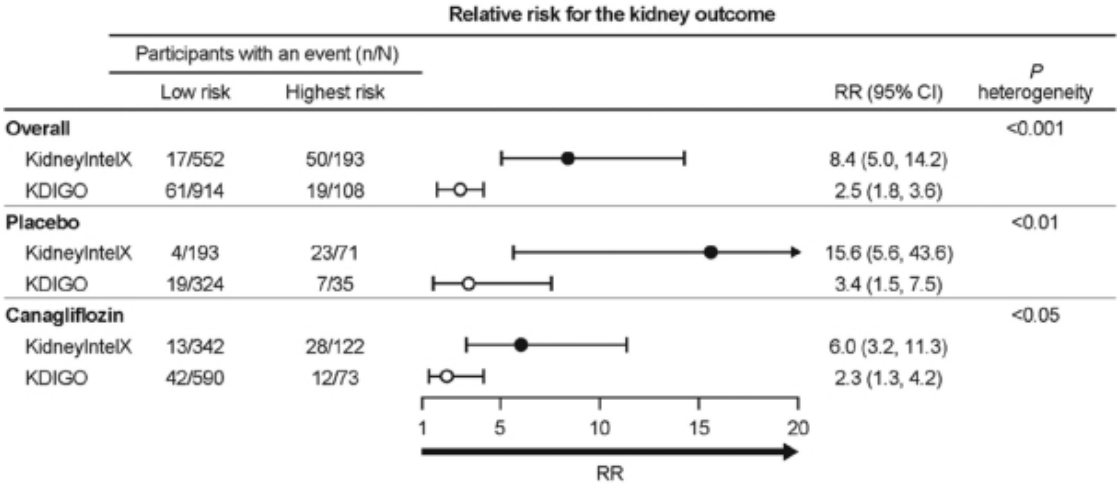
During a mean follow-up of 6.2 (5.8-7.3) years, 131 (9.9%) of the 1325 with baseline DKD experienced the composite kidney outcome. Using risk cutoffs from prior validation studies, the cumulative incidence of the composite kidney outcomes increased as KidneyIntelX risk scores increased (shown in **Fig. 1**). In terms of the KidneyIntelX risk strata, 41.7% of participants were classified as low risk, 43.8% were classified as intermediate risk, and 14.6% were classified as high risk. The corresponding incidence of the composite outcome was 3.1%, 10.9%, and 26.4% for low, intermediate, and high risk, respectively, with an overall risk ratio of 8.4 (95% CI: 5.0, 14.2) for the high-risk versus low-risk groups. In the canagliflozin arm, the corresponding incidence was 3.6%, 9.5%, and 23.0%, respectively, yielding a risk ratio of 6.0 (95% CI: 3.2, 11.3) for the high-risk versus low-risk groups. In the placebo arm, the corresponding incidence was 2.1%, 13.3%, and 32.4%, yielding a risk ratio of 15.6 (95% CI: 5.6, 43.6; shown in **Fig. 2**). By way of illustration for how KidneyIntelX can be incorporated into clinical practice, we compared the risk categorization to the KDIGO categorization based on eGFR and UACR, which stratified 69%, 23%, and 8% of the DKD population into “moderately increased risk,” “high risk,” and “very high risk,” with event rates of 7%, 17%, and 18% (relative risk [RR] of 2.5 [95% CI: 1.8, 3.6] overall for “very high risk” vs “moderately increased risk”; 2.3 [95% CI: 1.3, 4.2] in the canagliflozin arm; and 3.4 [95% CI: 1.5-7.5] in the placebo arm). The net reclassification index (continuous) for KidneyIntelX risk strata versus KDIGO risk strata was 0.342 overall, 0.227 for those who developed the composite outcome, and 0.115 in those who did not experience the composite outcome.

Figure 1. Cumulative incidence of the composite kidney outcome by continuous KidneyIntelX risk scores.



CI, confidence interval.

Fig. 2. Absolute and relative risk for kidney outcomes by KidneyIntelX vs. KDIGO.



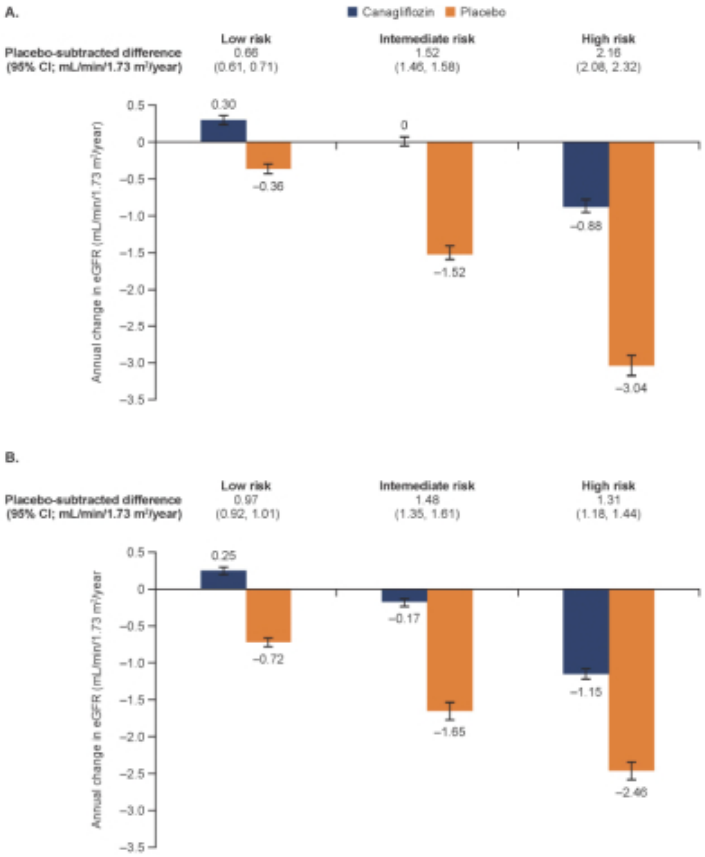
RR, relative risk; CI, confidence interval.

P value test for heterogeneity between the relative risk for KidneyIntelX vs. KDIGO by the overall population and placebo and canagliflozin arms individually.

Effect of canagliflozin on eGFR slope by baseline KidneyIntelX risk strata

We examined the effect of canagliflozin versus placebo on chronic eGFR slopes by KidneyIntelX strata (shown in **Fig. 3**). The difference in eGFR slope for canagliflozin versus placebo by KidneyIntelX risk strata, was 0.66 mL/min/1.73 m^2 in low risk, 1.52 mL/min/1.73 m^2 in intermediate risk, and 2.16 mL/min/1.73 m^2 in high risk; p for interaction=0.15). The difference in eGFR slope for canagliflozin versus placebo in the high-risk KidneyIntelX stratum (2.16 mL/min/1.73 m^2) was of greater magnitude when compared to the effect of canagliflozin versus placebo in the highest risk KDIGO stratum (1.31 mL/min/1.73 m^2; p<0.001; shown in **Fig. 3**).

Fig. 3. Absolute effect of canagliflozin versus placebo on eGFR slope by KidneyIntelX (A) and KDIGO risk strata (B).

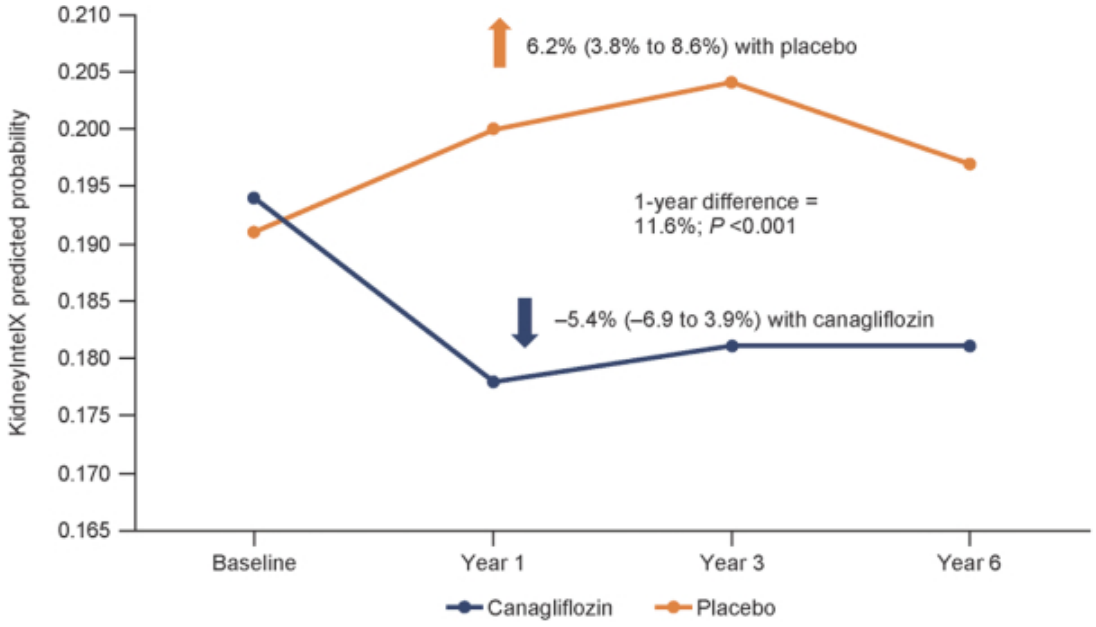


eGFR, estimated glomerular filtration rate; CI, confidence interval. P value for interaction by KidneyIntelX Risk Strata = 0.15.

Effect of canagliflozin on KidneyIntelX risk scores over time

Among the 1013 participants with baseline and year 1 samples available, the continuous KidneyIntelX risk score increased from baseline to year 1 in the placebo group by 6.2% (95% CI: 3.8, 8.6) and decreased by 5.4% (95% CI: –6.9, –3.9) in those randomized to canagliflozin (p<0.001). This effect of canagliflozin on the KidneyIntelX risk score persisted over time until the end of follow-up (shown in **Fig. 4**).

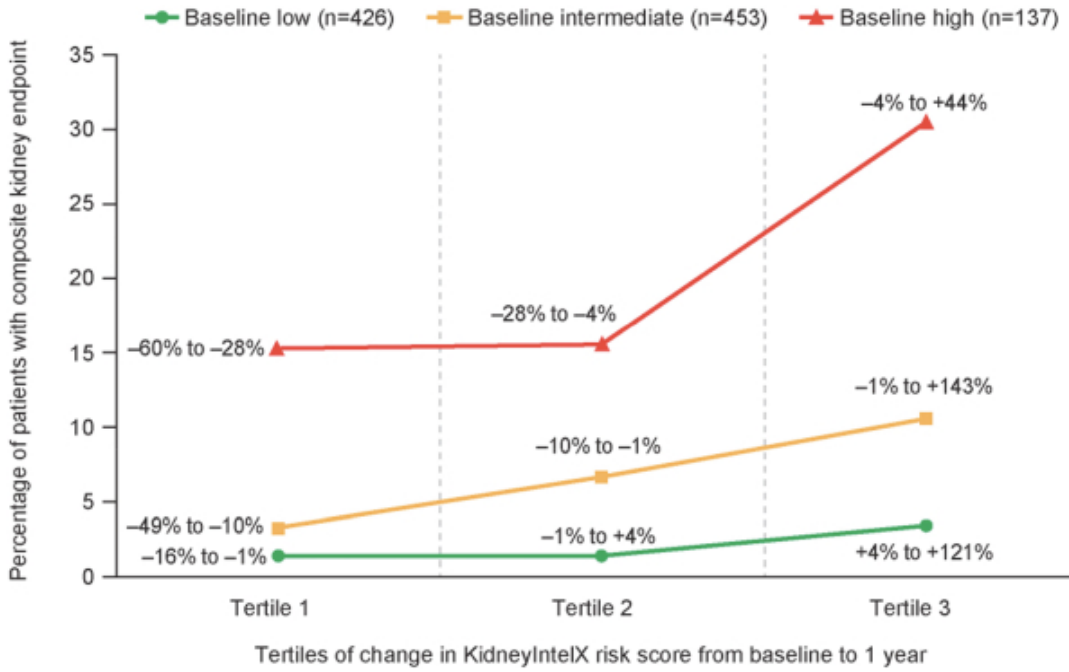
Fig. 4. Changes in KidneyIntelX over time in canagliflozin versus placebo-treated participants.



Associations between changes in KidneyIntelX and outcomes

We examined the association of the change in KidneyIntelX from baseline to year 1 with the composite kidney outcome among the 1013 participants with available samples and no event prior to year 1. Overall, stratified by baseline KidneyIntelX score and adjusted for treatment arm, each 10% reduction in KidneyIntelX risk was associated with a 20% lower risk of experiencing the composite kidney outcome (adjusted odds ratio per 10% reduction of 0.80 [95% CI: 0.77, 0.83]; p<0.001). Although the median changes in KidneyIntelX varied markedly by baseline risk strata (shown in **Fig. 5**), there was no evidence of interaction on the association between the change in KidneyIntelX and the risk for the outcomes (each 10% reduction in KidneyIntelX was associated with an 18%, 21%, and 18% reduction in the risk for the outcome by low, intermediate, and high baseline KidneyIntelX risk strata, respectively). In addition, there was no effect modification on the association between changes and outcomes by treatment arm ($p_{interaction}$=0.59).

Fig. 5. Change in KidneyIntelX and risk for composite kidney outcome.



Tertiles of changes in KidneyIntelX risk scores from baseline to follow-up, stratified by baseline KidneyIntelX risk stratum. Range of percent changes are shown for each stratum in each tertile

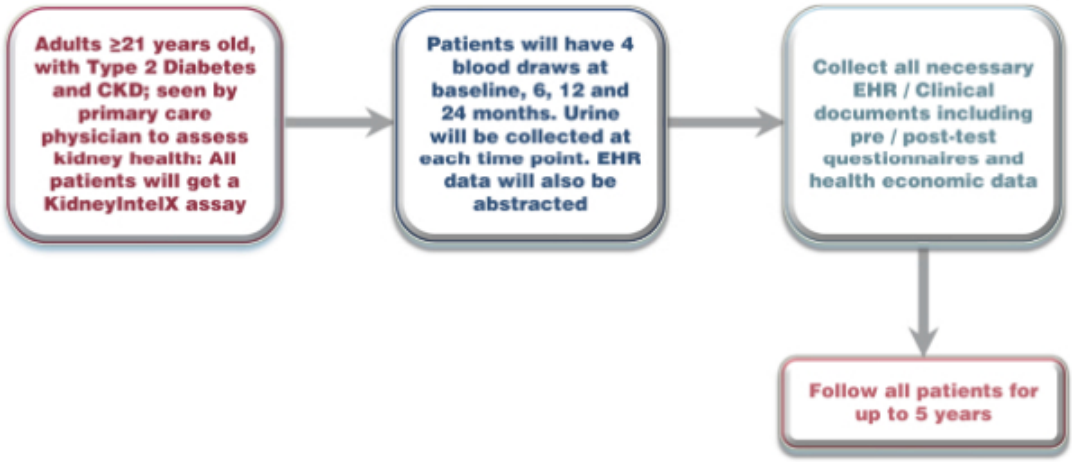
In conclusion, we observed that KidneyIntelX successfully risk stratified a large multinational external cohort for risk of progression of DKD, with larger differences in eGFR slope for canagliflozin versus placebo in those with higher versus lower baseline KidneyIntelX scores, as well as compared to KDIGO risk strata. Canagliflozin treatment reduced KidneyIntelX risk scores over time, and changes in the KidneyIntelX score from baseline to 1 year predicted future risk of DKD progression. Based on these results, we believe repeat testing of KidneyIntelX has prognostic and likely clinical utility.

The results from this study were presented at the World Congress of Nephrology sponsored by the International Society of Nephrology in April 2021 and the Scientific Sessions of the American Diabetes Association in 2021 The results presented above were compiled in a composite manuscript and accepted for peer-reviewed publication in the American Journal of Nephrology in October 2021.

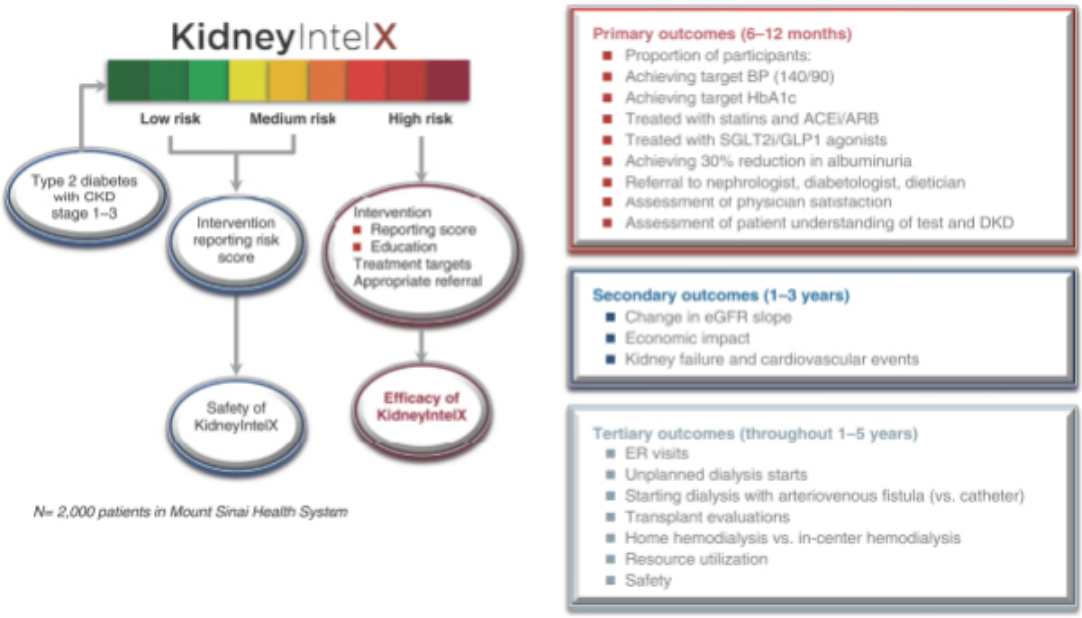
Planned clinical utility study program

As part of a comprehensive, multi-center clinical utility program, clinical utility studies were initiated at Mount Sinai Health System in Q4 2021, and at Wake Forest Atrium/Baptist Health in Q4 2021. These studies were designed to evaluate how the results of KidneyIntelX impact the clinical management of patients with type 2 diabetes identified as having increased risk of progressive kidney function decline within a five-year timeframe, as well as cardiovascular events and health economics. Specific clinical decisions such as referral to a nephrologist, or initiating treatment (e.g. SGLT2 inhibitors, angiotensin-converting enzyme inhibitors, or ACEi, angiotensin II receptor blockers, or ARBs, statins) will be tracked along with measurable clinical endpoints such as lowering of blood pressure and reduction in levels of Hb1Ac. Urine will also be collected as part of these studies given the well-established importance of urine as the source of a biological signal for kidney health.

These studies are prospective, interrupted time series, shared decision-impact and health-economic assessment studies. The design of the clinical utility study at Mount Sinai is depicted below.



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



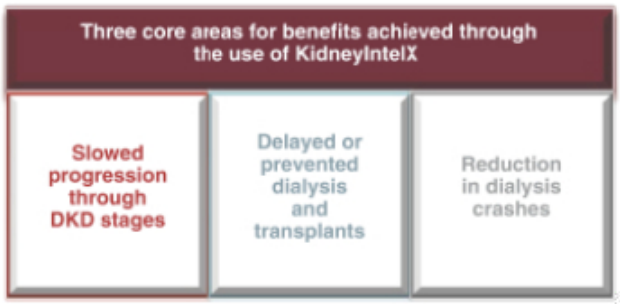
Health economics

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

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

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

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



The model compared differences in the following treatment costs between KidneyIntelX and standard of care patients: (1) costs of preventative measures (treatments and office visits) in KidneyIntelX high-risk patients (DKD Stages 1 through 3); (2) costs of each DKD stage; (3) costs of dialysis, transplants (including post- transplant care), and dialysis crashes; and (4) costs of KidneyIntelX test ($1,050, including $950 per reportable test and $100 administration cost). Peer-reviewed published data was used to estimate annual costs associated with each stage of DKD, annual incremental costs to standard of care associated with the actionable results of the KidneyIntelX test, cost of preventative measures for the KidneyIntelX group, and cost of dialysis, transplants, and dialysis crashes. All costs were based on published U.S. estimates and inflation-adjusted to 2019 dollars.

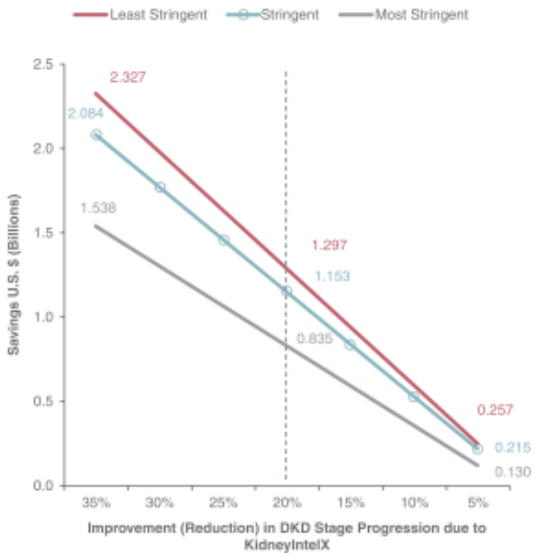
Of the 100,000 patients in the cohort, 16% were assumed to have a high-risk patient score and receive additional medical management and preventative measures. Patients undergoing risk assessment with KidneyIntelX using KidneyIntelX were assumed to have a 20% slowed progression rate through DKD stages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

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

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

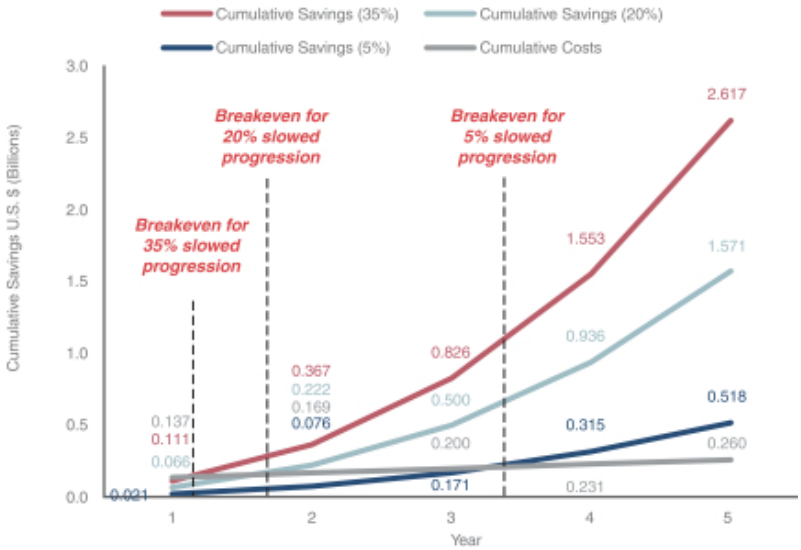
As shown in the graph below, the net present value of five-year payor savings associated with KidneyIntelX adoption for the 100,000 patient cohort was estimated to range between $835 million and $1.1 billion over a five-year time horizon for the most stringent and least stringent definitions of progression, respectively. The estimated savings realized for the stringent definition of progression (or base-case) was $1.15 billion.

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



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

Cumulative (undiscounted) savings vs cost of KidneyIntelX implementation



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

- accurately predicting which patients with earlier stage DKD (Stages 1 through 3) are at high-risk (top 16%) of experiencing progressive kidney function decline within a five-year timeframe;

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

Recent and upcoming studies, presentations or publications

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

- Late-breaking data presented at American Diabetes Association Scientific Sessions® in June of 2022 demonstrated increased adherence to care guidelines for physicians using KidneyIntelX risk assessment testing in 1,112 adult diabetic kidney disease (DKD) patients at Mount Sinai Health System demonstrated utility in driving guideline appropriate use of therapies, including SGLT-2 inhibitors and RAAS inhibitor use, and timely consultation to specialists in high-risk patients. In the study, more than half of KidneyIntelX prognostic tests were ordered by primary care physicians, followed by endocrinologists. Application of guideline-based care, including therapeutics and appropriate specialist consultation, increased in proportion to reported risk of rapid progressive decline in kidney function (e.g., low, intermediate, or high risk). The breakdown of risk in the real-world evidence (RWE) population was similar to what was observed in peer-reviewed, published KidneyIntelX clinical validation cohorts: High risk 13% vs. 17%; intermediate 40% vs. 37%; and low risk 46% vs 46%. In the 1,112 patients tested, KidneyIntelX re-stratified patient's risk from standard kidney function metrics (eGFR and UACR) and identified high risk adult patients with type 2 diabetes that were in stages 1, 2, and 3 of chronic kidney disease (CKD). Most importantly, the KidneyIntelX test helped physicians overcome the inertia seen with novel therapeutics proven to slow CKD progression and reduce associated patient cardiovascular event risk. As compared to patients who scored low risk, there were increases in use of anti-hypertensives, a 6-fold increase in the initiation of guideline-recommended treatments (SGLT-2 inhibitors or GLP-1 receptor agonists), and a nearly 3-fold increase in referrals to nephrologists, endocrinologists or dietitians. In the high-risk patient category, 20% of patients were referred to a specialist.
- In an oral presentation on June 3rd at the American Diabetes Association 82nd Scientific Sessions® in New Orleans. The study was conducted using a subgroup analysis of KidneyIntelX in the multi-national CANagliflozin cardioVascular Assessment Study (CANVAS). The results have also been published in Kidney360 online. In the CANVAS study, application of KidneyIntelX to this population showed that those with high-risk KidneyIntelX scores were at a three-fold higher risk for hospitalization for heart failure, severe kidney disease progression or death. Moreover, those individuals who scored as high-risk in this study were most likely to benefit from treatment with canagliflozin vs. placebo. These data were peer-reviewed and published in Kidney360

- In a recent publication of a clinical utility study in The American Journal of Managed Care, it was demonstrated that Primary Care Physicians (PCPs) understand the value of KidneyIntelX™ in determining appropriate guideline-recommended treatment decisions in their adult patients with type 2 diabetes (T2D) and early chronic kidney disease stages 1-3 (diabetic kidney disease). The study of 401 geographically diverse clinicians was conducted by Boston Healthcare Associates, a third party specialized in medical device evaluation, clinical development, and data management. The results support growing awareness among PCPs in terms of the recognized value of KidneyIntelX in clinical decision making as per the following findings: 1) The KidneyIntelX test had a greater relative importance than the standard of care (eGFR and UACR) for PCPs in prescribing guideline-recommended therapies and deciding when to consult with a specialist; 2) 98% of PCPs responded they were somewhat, very, or extremely likely to use KidneyIntelX to predict which of their patients will experience rapid progressive kidney function decline; 3) A behavioral shift among PCPs was examined after the introduction of KidneyIntelX. Approximately 80 percent of PCPs in the study noted risk assessment would support the decision to take more aggressive, guideline recommended clinical actions in high-risk, early stage (stage 1 through 3b) diabetic kidney disease patients.

Our key agreements

Mount Sinai Health System

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

We paid Mount Sinai $10.0 million as an up-front payment upon entering into the Mount Sinai Agreement. Under the terms of the Mount Sinai Agreement, we are obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. We are also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, we are obligated to pay Mount Sinai between 15% and 25% of any consideration received by us from a sublicensee. The two provisional patent applications covering the KidneyIntelX diagnostic in-licensed under the Mount Sinai Agreement were filed in February 2020 and April 2020, respectively. If issued, these patents will expire in February 2041 and April 2041, respectively. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

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

Joslin Diabetes Center

In July 2017, EKF Diagnostics Holding Plc, or EKF, entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or Joslin. In October 2018, EKF assigned to us all of its rights, title, interest and benefit in the Joslin Agreement.

Pursuant to the Joslin Agreement and the related assignment from EKF, we obtained a worldwide, royalty- bearing, exclusive license under any patents and any related know-how of Joslin related to the patent application filed with respect to the use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD, or the Joslin IP, to make, have made, use, offer for sale and sell licensed products covered by claims in the Joslin IP, and to perform, practice offer for sale and sell certain licensed processes related to the Joslin IP. We are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products and licensed processes, including in accordance with a development plan.

Under the terms of the Joslin Agreement, we are obligated to pay Joslin certain milestone payments of up to $1.3 million in the aggregate based on specified commercial milestones as follows: $300,000 upon the achievement of total net sales of $2.0 million for any licensed products or licensed processes and $1.0 million upon the achievement of total net sales of $10.0 million for any licensed products or licensed processes. We are also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, we are obligated to pay Joslin 25% of any consideration received by us from a sublicensee.

The Joslin Agreement initially expires on July 31, 2025, and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that we cease developing or commercializing licensed products or processes, if we fail to maintain certain required insurance policies, and if we fail to pay patent expenses related to the licensed patents.

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

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into the Advisory Agreement, pursuant to which we have agreed to provide certain advisory services to Kantaro.

Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to us in respect of the services to be rendered by us under the Advisory Agreement. A portion of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to us).

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

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

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

AstraZeneca

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

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

Commercialization

We plan to deploy KidneyIntelX to patient populations with DKD on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients. We believe that our core partnership with Mount Sinai Health System, a large integrated disease network in the New York metropolitan area, will demonstrate the value of our partnership model.

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

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

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

Reimbursement and regulatory developments

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

- ***CPT Code 0105U Effective.*** In October 2019, a distinct CPT code 0105U became effective for KidneyIntelX, which can be used to report the use of KidneyIntelX to private and public payors throughout the United States for reimbursement.
- ***Medicare National Pricing Set.*** CMS included KidneyIntelX on the Final 2020 CLFS, setting the national price for KidneyIntelX at $950 per reportable test result, effective for a three-year term as of January 1, 2020, and repriced thereafter based on the weighted-average private insurance market reimbursed rate.
- ***FDA Breakthrough Device Designation Received.*** In May 2019, the FDA granted breakthrough device designation for KidneyIntelX.
- ***Utah CLIA Certificate of Registration Received.*** In January 2020, we announced that our newly established commercial laboratory operation in Salt Lake City, Utah received a CLIA Certificate of Registration. We believe our Utah facility will support our ability to scale-up test volumes, optimize processing costs and accelerate payor coverage determinations.
- ***New York State Clinical Laboratory Permit Received.*** In June 2020, we announced that our commercial laboratory in New York City received a clinical laboratory permit from the New York State Department of Health to provide commercial testing of KidneyIntelX. With licensed CLIA commercial laboratories in Utah and New York, we can now provide KidneyIntelX testing services in all 50 states.

- ***California Clinical Laboratory Permit Received.*** In September 2020, we received a Clinical Laboratory License from the California Department of Health for our clinical laboratory in Salt Lake City, Utah.
- ***Submission to FDA seeking clearance of KidneyIntelX.*** We filed a submission seeking clearance of KidneyIntelX with the FDA in August 2020.
- ***ISO Compliance.*** In March 2020, we successfully passed the ISO-13485:2016 inspection. We have been recommended for certification by the notified body.

Coverage and reimbursement

Current environment

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

In order to secure coverage and reimbursement for any medical product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost- effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, products may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor. Further, due to the COVID-19 pandemic, millions of individuals have lost, or will be losing, employer-based insurance coverage, which may adversely affect our ability to commercialize our products.

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

These measures, and future state and federal healthcare reform measures that may be adopted in the future, may result in additional reductions in Medicare and other healthcare funding and otherwise affect the price of KidneyIntelX and any diagnostic product for which we may obtain regulatory approval or the frequency with which any such products are prescribed or used.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges, as the pricing of biological products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular technology to currently available products or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Efforts to control prices and utilization of biological products will likely continue as countries attempt to manage healthcare expenditures.

Current coverage and reimbursement status

We intend to generate revenue from several sources, including government and third-party payors, and self- paying individuals.

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

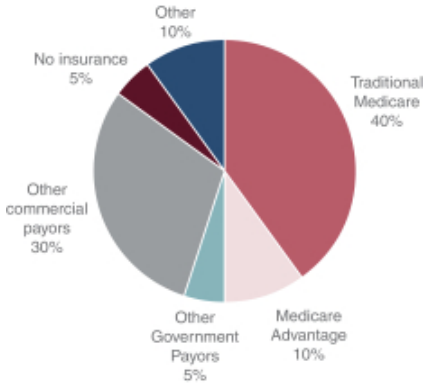
Under Medicare, payment for laboratory tests generally is made under the CLFS, with payment amounts assigned to specific procedure billing codes. Having both a unique test code and an established Medicare price often accelerates reimbursement timelines and facilitates coverage determinations and success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

Our coverage and reimbursement strategy

We are actively engaged in efforts to achieve broad commercial coverage and reimbursement for KidneyIntelX and to contract with third-party payors. Achieving positive coverage determinations eliminates the need for appeals and reduces failures to collect from the patient's third-party payor. Implementing our strategy includes our managed care and medical affairs teams educating third-party payors regarding our strong health economic and clinical validation data, and in the future clinical utility and outcomes data, which we believe validates the value of our products and provides evidence for third-party payors to establish value-based reimbursement.

We believe our reimbursement strategy is aligned with our commercialization strategy. The KidneyIntelX test is a single site, *in vitro*, artificial intelligence-enabled diagnostic test, and we are both the manufacturer and the service provider for the test. In all cases, we will bill payors and patients for the test.

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



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

In 2019, we achieved a significant milestone toward obtaining Medicare coverage, with CMS including KidneyIntelX on the Final 2020 CLFS and setting the national price for KidneyIntelX at $950 per reportable test result, effective for a three-year term as of January 1, 2020. This price will be re-evaluated at the end of this three-year period using an average of accepted payment from private health insurance plans. In March 2020, we announced that our application for a Medicare PTAN was approved by Noridian Healthcare Solutions, the regional Medicare Administrative Contractor with responsibility for overseeing facilities and providers located in the western United States, and we were granted a Medicare provider number for our Salt Lake City, Utah clinical laboratory. As a result, we are now qualified as a provider and can bill for services provided to patients with Medicare health insurance coverage in the United States.

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

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

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

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

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

Competition

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

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

Principal competitive factors in our market include:

- quality and strength of clinical and analytical validation data;
- proprietary access to extensively validated biomarkers for CKD;

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

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

Manufacturing, supply and operations

KidneyIntelX is an artificial intelligence-enabled *in vitro* prognostic testing solution that has been developed to be commercialized as a single-site *in vitro* diagnostic. As such, we expect to achieve FDA regulatory clearance of KidneyIntelX and operate under ISO 13485 certification. We are both the Manufacturer of Record and the service provider for the testing solution.

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

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

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

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

Intellectual property

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

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

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

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

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our current and future diagnostic products and the methods used to develop and manufacture them, as well as successfully defending these patents against third-party challenges and operating without infringing on the proprietary rights of others. Our ability to stop third parties from making, using, selling, offering to sell or importing our diagnostic products depends on the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities. We cannot be sure that patents will be granted with respect to any of our pending patent applications or with respect to any patent applications filed by us in the future, nor can we be sure that any of our existing patents or any patents that may be granted to us in the future will be commercially useful in protecting our diagnostic products, discovery programs and processes. For this and more comprehensive risks related to our intellectual property, see "Risk factors—Risks related to our intellectual property."

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

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

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

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

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

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

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

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

In-licensed intellectual property

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

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

Government regulation and product approval

Clinical laboratory framework

Clinical Laboratory Improvement Amendments of 1988

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

We maintain a CLIA Certificate of Compliance for our Utah laboratory that allows us to perform non-waived (moderate and/or high complexity) testing at that site. In 2021, the laboratory was inspected by the Utah Department of Health and found to be in full compliance with CLIA regulations. Following the successful inspection, CMS issued a Certificate of Compliance for our Utah laboratory. Additionally, in 2021 we opened a lab in Florida and have received a CLIA Certificate of Registration from the Florida Department of Health which will allow us to begin testing. We have an on-site CLIA survey schedule in November 2022. CMS will issue a CLIA Certificate of Compliance if we successfully complete the survey. In June 2020, we received CLIA certification for our New York laboratory through the New York State Department of Health.

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

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

State laboratory licensing

In addition to federal certification requirements of laboratories under CLIA, CLIA provides that states may adopt laboratory regulations and licensure requirements that are more stringent than those under federal law. A number of states have implemented their own more stringent laboratory regulatory requirements. Such laws, among other things, establish standards for the day-to-day operation of a clinical laboratory, including the training and skills required of personnel and quality control. Five states require a separate out-of-state license before we can provide testing services for their residents: California, Maryland, New York, Pennsylvania and Rhode Island. We have received all five out-of-state licenses for both our New York and Utah laboratories.

Federal oversight of laboratory developed tests

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

Although the FDA has statutory authority to assure that medical devices are safe and effective for their intended uses, the FDA has generally exercised its enforcement discretion and not enforced applicable regulations with respect to *in vitro* diagnostics that are designed, manufactured, and used within a single laboratory for use only in that laboratory (i.e., LDTs). We believe KidneyIntelX qualifies as an LDT and, thus, is currently subject to the FDA's enforcement discretion and not subject to the FDA's active oversight.

Legislative and administrative proposals proposing to amend FDA's oversight of LDTs have been introduced in recent years and we expect that new legislative and administrative proposals will continue to be introduced from time to time. It is possible that legislation could be enacted into law or regulations or guidance could be issued by the FDA which may result in new or increased regulatory requirements for us to continue to offer LDTs or to develop and introduce new tests as LDTs. For example, FDA has stated its intention to modify its enforcement discretion policy with respect to LDTs. Specifically, in July 2014, the FDA notified the U.S. Congress of its intent to modify, in a risk-based manner, its policy of enforcement discretion with respect to LDTs. In October 2014, the FDA issued two draft guidance documents titled "Framework for Regulatory Oversight of Laboratory Developed Tests (LDTs)," or the Framework Guidance, and "FDA Notification and Medical Device Reporting for Laboratory Developed Tests (LDTs)," or the Reporting Guidance. The Framework Guidance stated that FDA intends to modify its policy of enforcement discretion with respect to LDTs in a risk-based manner consistent with the classification of medical devices generally in Classes I through III. The Reporting Guidance would have further enabled FDA to collect information regarding the LDTs currently being offered for clinical use through a notification process, as well as to enforce its regulations for reporting safety issues and collecting information on any known or suspected adverse events related to the use of an LDT.

Although the FDA halted finalization of these guidance documents in November 2016 to allow for further public discussion on an appropriate oversight approach to LDTs and to give congressional authorizing committees the opportunity to develop a legislative solution, and the FDA issued a discussion paper on possible approaches to LDT regulation in January 2017, the FDA could ultimately modify its current approach to LDTs in a way that would subject LDTs to additional regulatory requirements. Legislative measures could likewise result in a change to the approach to FDA's regulation over LDTs, including a requirement for premarket review of LDTs, among other things. For example, on March 5, 2020, Congress introduced legislation entitled the Verifying Accurate, Leading-edge IVCT Development Act, or VALID Act, which would create a new test product category, *in vitro* clinical tests, or IVCTs, including LDTs and test kits, and would give FDA authority to review and approve such IVCTs. Currently it is unclear whether or in what form such legislation will be enacted.

Medical device regulatory framework

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

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

Device classification

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

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

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

Class III devices include devices deemed by the FDA to pose the greatest risk, such as life-supporting, life- sustaining devices, or implantable devices, in addition to those deemed novel and not substantially equivalent following the 510(k) process. The safety and effectiveness of Class III devices cannot be reasonably assured solely by the General Controls and Special Controls described above. Therefore, these devices are subject to the PMA application process, which is generally more costly and time-consuming than the 510(k) process. Through the PMA application process, the applicant must submit data and information demonstrating reasonable assurance of the safety and effectiveness of the device for its intended use to the FDA's satisfaction. Accordingly, a PMA typically includes, but is not limited to, extensive technical information regarding device design and development, preclinical and clinical trial data, manufacturing information, labeling and financial disclosure information for the clinical investigators in device studies. The PMA application must provide valid scientific evidence that demonstrates to the FDA's satisfaction a reasonable assurance of the safety and effectiveness of the device for its intended use.

The 510(k) clearance process

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

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

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

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

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

The PMA approval process

Following receipt of a PMA application, the FDA conducts an administrative review to determine whether the application is sufficiently complete to permit a substantive review. If it is not, the agency will refuse to file the PMA. If it is, the FDA will accept the application for filing and begin the review. The FDA has 180 days to review a filed PMA application, although the review of an application more often occurs over a significantly 107 longer period of time. During this review period, the FDA may request additional information or clarification of information already provided, and the FDA may issue a major deficiency letter to the applicant, requesting the applicant's response to deficiencies communicated by the FDA.

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

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

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

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

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

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

The investigational device process

In the United States, absent certain limited exceptions, human clinical trials intended to support medical device clearance or approval require an investigational device exemption, or IDE, application. Some types of studies deemed to present "non-significant risk" are deemed to have an approved IDE —without affirmative submission of an IDE application to the FDA—once certain requirements are addressed and Institutional Review Board, or IRB, approval is obtained. If the device presents a "significant risk" to human health, as defined by the FDA, the sponsor must submit an IDE application to the FDA and obtain IDE approval prior to commencing the human clinical trials. The IDE application must be supported by appropriate data, such as animal and laboratory testing results, showing that it is safe to test the device in humans and that the testing protocol is scientifically sound. Generally, clinical trials for a significant risk device may begin once the IDE application is approved by the FDA and the study protocol and informed consent are approved by appropriate IRBs at the clinical trial sites. Submission of an IDE will not necessarily result in the ability to commence clinical trials, and although the FDA's approval of an IDE allows clinical testing to go forward for a specified number of subjects, it does not bind the FDA to accept the results of the trial as sufficient to prove the product's safety and efficacy, even if the trial meets its intended success criteria.

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

Post-market regulation

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

- establishment registration and device listing with the FDA;
- QSR requirements, which require manufacturers, including third-party manufacturers, to follow stringent design, testing, control, documentation and other quality assurance procedures during all aspects of the design and manufacturing process;
- labeling regulations and FDA prohibitions against the promotion of investigational products, or the promotion of ''off-label'' uses of cleared or approved products;
- requirements related to promotional activities;

- clearance or approval of product modifications to 510(k)-cleared devices that could significantly affect safety or effectiveness or that would constitute a major change in intended use of one of our cleared devices, or approval of certain modifications to PMA-approved devices;
- Medical Device Reporting regulations, which require that a manufacturer report to the FDA if a device it markets may have caused or contributed to a death or serious injury, or has malfunctioned and the device or a similar device that it markets would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur;
- correction, removal and recall reporting regulations, which require that manufacturers report to the FDA field corrections and product recalls or removals if undertaken to reduce a risk to health posed by the device or to remedy a violation of the FDCA that may present a risk to health;
- the FDA's recall authority, whereby the agency can order device manufacturers to recall from the market a product that is in violation of governing laws and regulations; and
- post-market surveillance activities and regulations, which apply when deemed by the FDA to be necessary to protect the public health or to provide additional safety and effectiveness data for the device.

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

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

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

U.S. federal and state health care laws

Federal and state physician self-referral prohibitions

We are subject to the federal physician self-referral prohibitions, commonly known as the Stark Law, and to comparable state laws. Together these restrictions generally prohibit us from billing a patient or governmental or private payor for certain designated health services, including clinical laboratory services, when the physician ordering the service, or a member of such physician's immediate family, has a financial relationship, such as an ownership or investment interest in or compensation arrangement with us, unless the relationship meets an applicable exception to the prohibition. Several Stark Law exceptions are relevant to many common financial relationships involving clinical laboratories and referring physicians, including: (1) fair market value compensation for the provision of items or services; (2) payments by physicians to a laboratory for clinical laboratory services; (3) space and equipment rental arrangements that satisfy certain requirements, and (4) personal services arrangements

that satisfy certain requirements. The laboratory cannot submit claims to the Medicare Part B program for services furnished in violation of the Stark Law, and Medicaid reimbursements may be at risk as well.

Sanctions for a Stark Law violation include the following:

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

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

Federal and state anti-kickback laws

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

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

Federal and state law enforcement authorities scrutinize arrangements between healthcare providers and potential referral sources to ensure that the arrangements are not designed as a mechanism to induce patient care referrals or induce the purchase or prescribing of particular products or services. Generally, courts have taken a broad interpretation of the scope of the AKS, holding that the statute may be violated if merely one purpose of a payment arrangement is to induce referrals or purchases.

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

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

Corporate practice of medicine; fee splitting

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

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

Other federal and state healthcare laws

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

The FCA prohibits, among other things, a person from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment or approval and from, making, using, or causing to be made or used, a false record or statement material to a false or fraudulent claim in order to secure payment or retaining an overpayment by the federal government. In addition to actions initiated by the government itself, the statute authorizes actions to be brought on behalf of the federal government by a private party having knowledge of the alleged fraud through whistleblower or qui tam actions. Because the complaint is initially filed under seal, the action may be pending for some time before the defendant is even aware of the action. If the government intervenes and is ultimately successful in obtaining redress in the matter or if the plaintiff succeeds in obtaining redress without the government's involvement, then the plaintiff will receive a percentage of the recovery. In addition, the improper retention of an overpayment for 60 days or more is also a basis for a FCA action, even if the claim was originally submitted appropriately. Penalties for FCA violations include fines for each false claim, plus up to three times the amount of damages sustained by the federal government. A FCA violation may provide the basis for exclusion from the federally funded healthcare programs. In addition, some states have adopted similar fraud, whistleblower and false claims provisions. The Social Security Act includes its own provisions that prohibit the filing of false claims or submitting false statements in order to obtain payment. The Social Security Act also includes civil monetary penalty provisions that impose penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal health program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent. In addition, a person who offers or provides to a Medicare or Medicaid beneficiary any remuneration, including waivers of co-payments and deductible amounts (or any part thereof), that the person knows or should know is likely to influence the beneficiary's selection of a particular provider, practitioner or supplier of Medicare or Medicaid payable items or services may be liable under the civil monetary penalties statute. Moreover, in certain cases, providers who routinely waive copayments and deductibles for Medicare and Medicaid beneficiaries, for example, in connection with patient assistance programs, can also be held liable under the AKS and FCA. One of the statutory exceptions to the prohibition is non-routine, unadvertised waivers of copayments or deductible amounts based on individualized determinations of financial need or exhaustion of reasonable collection efforts. The OIG, emphasizes, however, that this exception should only be used occasionally to address special financial needs of a particular patient. Although this prohibition applies only to federal healthcare program beneficiaries, applicable state laws related to, among other things, unlawful schemes to defraud, excessive fees for services, tortious interference with patient contracts and statutory or common law fraud, may also be implicated for similar practices offered to patients covered by private third-party payors.

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

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

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

The Physician Payments Sunshine Act, enacted as part of the ACA, and its implementing regulations, also imposed annual reporting requirements on manufacturers of certain devices, drugs and biologics for payments available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) and other transfers of value to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain other healthcare professionals (such as physician assistants and nurse practitioners), and teaching hospitals; as well as ownership and investment interests held by physicians and their immediate family members. Any failure to comply with these reporting requirements could result in significant fines and penalties. Because our service offerings are currently limited to LDTs solely for use by or within our own laboratory, we believe that we are exempt from these reporting requirements. We cannot guarantee, however, that the government will agree with our determination, and a determination that we have violated these laws and regulations, or a public announcement that we are being investigated for possible violations, could adversely affect our business, prospects, results of operations or financial condition. If KidneyIntelX receives marketing clearance from the FDA and we receive reimbursement from Medicare, Medicaid or the Children's Health Insurance Program for the product, then we will likely be subject to the reporting requirements under the Physician Payments Sunshine Act.

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 broadly regulate marketplace activities and activities that potentially harm consumers.

Finally, there are analogous state and foreign laws and regulations, such as state and foreign laws that require medical device companies to comply with the medical device industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require device manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or product pricing; state and local laws that require the registration of medical device sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

International regulations

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

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

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

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

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

Privacy and security laws

Health Insurance Portability And Accountability Act

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, impose, among other things, requirements relating to the privacy, security and transmission of protected health information, or PHI, on covered entities including certain healthcare providers, health plans, and health clearinghouses and their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information as well as their covered subcontractors. HIPAA also regulates standardization of data content, codes and formats used in certain healthcare transactions and standardization of identifiers for health plans and providers.

HITECH created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions. HIPAA also authorizes state attorneys general to file suit on behalf of their residents for violations. Courts are able to award damages, costs and attorneys' fees related to violations of HIPAA in such cases. While HIPAA does not create a private right of action allowing individuals to file suit against us in civil court for violations of HIPAA, its standards have been used as the basis for duty of care cases in state civil suits such as those for negligence or recklessness in the misuse or breach of PHI. In addition, HIPAA mandates

that the Secretary of the Department of Health and Human Services, or HHS, conduct periodic compliance audits of HIPAA covered entities, such as us, and their business associates for compliance with the HIPAA privacy and security standards. It also tasks HHS with establishing a methodology whereby harmed individuals who were the victims of breaches of unsecured PHI may receive a percentage of the civil monetary penalty paid by the violator.

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

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

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

We are committed to information technology and data security. Given the AI-derived algorithm that incorporates features from a patient's EHR, we have access to patient data that requires high standards for data integrity. Therefore, we are undergoing compliance activities to submit ISO/IEC 27001:2013 certification, which specifies the

requirements for establishing, implementing, maintaining and continually improving an information security management system within the context of the organization. It also includes requirements for the assessment and treatment of information security risks tailored to the needs of the organization. We achieved ISO 27000 certification in 2021.

Healthcare reform

In March 2010, the Patient Protection and Affordable Care Act of 2010, as amended by the Healthcare and Education Reconciliation Act of 2010, collectively the ACA, was enacted in the United States. The ACA made a number of substantial changes to the way healthcare is financed both by governmental and private insurers. For example, the ACA also contains a number of provisions, including provisions governing enrollment in federal and state healthcare programs, reimbursement matters and fraud and abuse, which we expect will impact our industry and our operations in ways that we cannot currently predict. There have been executive, judicial and Congressional challenges to certain provisions of the ACA. For example, President Trump signed Executive Orders and other directives designed to delay the implementation of certain provisions of the ACA. Concurrently, Congress considered legislation that would repeal or repeal and replace all or part of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, eliminating the implementation of certain ACA-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D.

On June 17, 2021 the U.S. Supreme Court dismissed a challenge on procedural grounds that argued the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress. However, it is possible that the ACA will be subject to additional judicial or Congressional challenges in the future. In addition, the ACA has been subject to various health reform measures. For example, prior to the U.S. Supreme Court ruling, on January 28, 2021, President Biden issued an executive order that initiated a special enrollment period for purposes of obtaining health insurance coverage through the ACA marketplace, which began on February 15, 2021 and remained open through August 15, 2021. The executive order also instructed certain governmental agencies to review and reconsider their existing policies and rules that limit access to healthcare, including among others, reexamining Medicaid demonstration projects and waiver programs that include work requirements, and policies that create unnecessary barriers to obtaining access to health insurance coverage through Medicaid or the ACA. On August 16, 2022, President Biden signed the Inflation Reduction Act of 2022, 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 in the United States since the ACA was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2031 unless additional Congressional action is taken. These Medicare sequester reductions have been 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. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. As part of the 2020 federal spending package, the ACA-required medical device manufacturer 2.3% sales tax has been eliminated, effective January 1, 2020.

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

C. Organizational structure

The following is a list of our subsidiaries as of September 30, 2022:

Name of Subsidiary	Country of Incorporation	Proportion of Ownership Interest
Renalytix AI, Inc.	United States	100%
Renalytix AI Limited	Ireland	100%

D. Property, plants and equipment

We lease laboratory and office space in New York City, New York on short-term leases that automatically renew. The laboratory is use for KidneyIntelX testing and the office is used for corporate. Combined our New York locations are approximately 1,000 square feet. In addition, we lease laboratory space in Salt Lake City, Utah, which lease expires in October 2024 and laboratory space in St. Petersburg, Florida, which lease expires in January 2024. The Utah lab is approximately 4,000 square feet and used for KidneyIntelX testing as well and research activities. The Florida lab is approximately 1,200 square feet and was established to be used for KidneyIntelX testing as well as research activities.

Item 4A. Unresolved Staff Comments

Not applicable.

Item 5. Operating and Financial Review and Prospects

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

We plan to deploy KidneyIntelX to patient populations with DKD on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients. Following the receipt of national Medicare pricing at $950 per reportable test for KidneyIntelX in January 2020, we are actively pursuing Medicare coverage and a determination under the MolDX Program. In March 2020, we announced that our

application for a Medicare PTAN was approved by Noridian Healthcare Solutions, the regional Medicare Administrative Contractor with responsibility for overseeing facilities and providers located in the western United States, and, as a result, we are now qualified as a provider and can bill for services provided to patients with Medicare and Medicaid health insurance coverage in the United States. In addition, in October 2019, Capital District Physicians' Health Plan, Inc., a physician-led health insurance payor in New York, adopted coverage determination policies that provide insurance for certain patients with DKD who are tested with KidneyIntelX. We are working with additional private insurance payors and healthcare providers to expand insurance coverage for KidneyIntelX nationwide, which we believe will be accelerated by our recent achievement of a CPT code and national Medicare pricing.

Since our inception in March 2018, we have focused primarily on organizing and staffing our company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting our intellectual property portfolio and commercial laboratory operations, pursuing regulatory approval and developing our reimbursement strategy. To date, we have not generated any revenue from the sales of KidneyIntelX tests. We have funded our operations primarily through equity financings. In November 2018, we sold 18.4 million of our ordinary shares in our initial public offering, or IPO, and our ordinary shares were admitted to trading on AIM, a market operated by the London Stock Exchange, resulting in gross proceeds of approximately $29.1 million. Prior to our IPO on the London Stock Exchange, EKF Diagnostics Holding Plc, or EKF, provided debt financing, referred to as our related-party note payable. All borrowings with EKF were repaid in their entirety upon completion of the equity offering in November 2018.

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

In April 2022, we entered into an A&R Bond Agreement with CVI Investments, Inc. for $21.2 million in amortizing senior convertible bonds due in 2027 (the "Bonds"). On April 7, 2022, we issued the Bonds to CVI with a maturity date of April 7, 2027 comprising of total net proceeds of $18.0 million. The Bonds accrue interest at an annual rate of 5.5%, payable quarterly in equal instalments. The Notes contain various conversion and redemption features.

In April 2022, we also entered into a private placement agreement to sell, an aggregate of 2,428,688 ordinary shares (including in the form of ADSs) (the "PIPE Shares"), for a purchase price of $3.625 per ordinary share ($7.25 per ADS) and an aggregate purchase price of $8.8 million.

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

Our Key Agreements

Mount Sinai Health System

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

We paid Mount Sinai $10.0 million as an up-front payment upon entering into the Mount Sinai Agreement. Under the terms of the Mount Sinai Agreement, we are obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. We are also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, we are obligated to pay Mount Sinai between 15% and 25% of any consideration received by us from a sublicensee. The two provisional patent applications covering the KidneyIntelX diagnostic in-licensed under the Mount Sinai Agreement were filed in February 2020 and April 2020, respectively. If issued, these patents will expire in February 2041 and April 2041, respectively. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

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

Joslin Diabetes Center

In July 2017, EKF entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or Joslin. In October 2018, we purchased all of EKF's rights, title, interest and benefit in the Joslin Agreement in exchange for the issuance of 15.4 million of our ordinary shares.

Pursuant to the Joslin Agreement and the related assignment from EKF, we obtained a worldwide, royalty- bearing, exclusive license under any patents and any related know-how of Joslin related to the patent application filed with respect to the use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD, or the Joslin IP, to make, have made, use, offer for sale and sell licensed products covered by claims in the Joslin IP, and to perform, practice offer for sale and sell certain licensed processes related to the Joslin IP. We are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products and licensed processes, including in accordance with a development plan.

Under the terms of the Joslin Agreement, we are obligated to pay Joslin aggregate commercial milestone payments of $0.3 million and $1.0 million in commercial milestone payments upon achieving worldwide net sales of licensed products and processes of $2.0 million and $10.0 million, respectively. We are also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, we are obligated to pay Joslin 25% of any consideration received by us from a sublicensee.

The Joslin Agreement initially expires on July 31, 2025, and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that we cease developing or commercializing licensed products or processes, if we fail to maintain certain required insurance policies, and if we fail to pay patent expenses related to the licensed patents.

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro Biosciences LLC, or Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into an Advisory Agreement pursuant to which we have agreed to provide certain advisory services to Kantaro.

Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to us as the sole consideration for the services to be rendered by us under the Advisory Agreement. A portion

of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to us). Through June 30, 2022 we funded $250,000 of our financing contract and incurred $253,000 in losses.

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

Financial operations overview

Revenues

During the fiscal year ended June 30, 2022, we continued to deploy KidneyIntelX to patient populations with DKD, on a regional basis through partnerships with healthcare systems and insurance payors that provide coverage to those healthcare systems' patients. If these strategic partners fail to meet their key contractual obligations or to purchase KidneyIntelX tests, that will likely have an adverse effect on us and our ability to achieve our commercial objectives, potentially including the attainment of sales volumes leading to profitability.

Additionally, during the fiscal year ended June 30, 2022, we recognized services revenue related to our contract with AstraZeneca. We plan to pursue further collaborations with pharmaceutical companies and make 'Pharmaceutical Services Revenue' a core part of our business going forward with the goal of improving guideline-based standard-of-care for optimal utilization of existing and novel therapeutics using the KidneyIntelX testing platform and care management software.

Cost of Revenue

During the fiscal years ended June 30, 2022 and June 30, 2021, cost of revenue consists of costs directly attributable to the services rendered, including labor costs directly related to revenue generating activities. There was no cost of revenue for the year ended June 30, 2020.

Acquired in-process research and development expenses

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

Research and development expenses

Research and development costs consist primarily of costs incurred in connection with the development of KidneyIntelX. We are currently continuing to conduct clinical utility and other studies for KidneyIntelX to determine clinical value and performance in different CKD populations. We expense research and development costs as incurred. Because we have limited resources and access to capital to fund our operations, we must decide which diagnostic product to pursue and the amount of resources to allocate to each. As such, we have been focused primarily on the development of KidneyIntelX.

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

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

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

- the uncertainty of the scope, progress, costs and results of clinical validation studies and other research and development activities;
- the cost of manufacturing clinical supply of KidneyIntelX;
- the efficacy and potential advantages of KidneyIntelX compared to alternative solutions, including any standard of care, and our ability to achieve market acceptance for KidneyIntelX;

- continuing to expand study data for KidneyIntelX, including data demonstrating the clinical utility over the short, intermediate and long term use of KidneyIntelX in different clinical settings;
- ability to achieve FDA clearance under our current Breakthrough Device designation process;
- raising necessary additional funds to continue operations; and
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining, enforcing and protecting our intellectual property rights and defending against any intellectual property-related claims.

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

General and administrative expenses

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

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

Equity losses in affiliate

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

Foreign currency gain (loss), net

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

Other income (expense)

Other income primarily relates to income realized on the reduction of the Kantaro liability for future services to be performed for the joint venture as well as interest income earned on our cash deposits.

Consolidated results of operations

(in thousands, except share data)	Twelve Months Ended June 30, 2022	Twelve Months Ended June 30, 2021	Twelve Months Ended June 30, 2020
Revenue	$ 2,970	$ 1,491	$ —
Cost of revenue	2,096	858	—
Gross profit	874	633	—
Operating expenses:			
Research and development	14,648	10,040	4,565
General and administrative	39,524	23,479	5,750
Performance of contract liability to affiliate	(115)	(970)	—
Total operating expenses	54,057	32,549	10,315
Loss from operations	(53,183)	(31,916)	(10,315)
Equity in net (losses) earnings of affiliate	9	(2,112)	(63)
Foreign currency gain (loss), net	9,694	(8,772)	245
Fair value adjustment to VericiDx investment	(5,900)	6,483	—
Fair value adjustment to convertible notes	3,998	—	—
Other income, net	131	981	289
Net loss before income taxes	(45,251)	(35,336)	(9,844)
Income tax expense	(25)	—	—
Net loss	(45,276)	(35,336)	(9,844)
Net loss attributable to noncontrolling interest	—	(611)	—
Net loss attributable to ordinary shareholders	(45,276)	(34,725)	(9,844)
Net loss per ordinary share—basic	$ (0.62)	$ (0.49)	$ (0.17)
Net loss per ordinary share—diluted	$ (0.67)	$ (0.49)	$ (0.17)
Weighted average ordinary shares—basic	72,861,448	71,484,934	59,079,522
Weighted average ordinary shares—diluted	73,837,496	71,484,934	59,079,522
Other comprehensive income (loss):			
Changes in the fair value of the convertible notes	536	—	—
Foreign exchange translation adjustment	(9,727)	9,501	(378)
Comprehensive loss	(54,467)	(25,835)	(10,222)
Comprehensive loss attributable to noncontrolling interest	—	(72)	—
Comprehensive loss attributable to Renalytix	$ (54,467)	$ (25,763)	$ (10,222)

Comparison of years ended June 30, 2022 and 2021

Revenue

During the year ended June 30, 2022, we recognized $2.7 million of revenue related to KidneyIntelX and $0.2 million of revenue related to services performed for AstraZeneca. During the year ended June 30, 2021, we recognized $0.4 million revenue related to KidneyIntelX, $0.5 million of revenue of pharmaceutical services revenue related to services performed for Astra Zeneca and $0.6 million of services revenue related to work performed for Mount Sinai and $0.4 million of KidneyIntelX testing revenue.

Cost of Revenue

During the year ended June 30, 2022, we recognized cost of revenue of $2.1 million primarily attributable to KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. We recognized $0.9 million of cost of revenue for the year ended June 30, 2021.

Research and development expenses

Research and development expenses increased by $4.6 million from $10.0 million for the year ended June 30, 2021 to $14.6 million for year ended June 30, 2022. The increase was attributable to an increase of $3.6 million increase related to external R&D project and studies at Mont Sinai, Wake Forest and the University of Utah, $0.8 million in compensation and related benefits, including share-based payments, due to increased headcount, $0.4 million increase in lab supplies purchases partially offset by a $0.2 million decrease in other miscellaneous expenses.

General and administrative expenses

General and administrative expenses increased $16.0 million from $23.5 million for the year ended June 30, 2021 to $39.5 million for the year ended June 30, 2022. The increase was due to an increase of $9.5 million in compensation and related benefits, including share-based payments, due to increased headcount, $3.8 million increase in consulting and professional fees, including accounting and legal, $1.0 million increase in marketing and public relations, $1.2 million increase in IT Costs, $0.1 million increase in rent and $0.4 million increase in other operating expenses.

Foreign currency gain (loss)

During the year ended June 30, 2022, we recognized a foreign currency gain of $9.8 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the year ended June 30, 2021, we recognized foreign currency losses of $8.8 million.

Fair value adjustments to VericiDx Investment

The Company accounts for the investment in VericiDx equity securities at fair value, with changes in fair value recognized in the income statement. During the year ended June 30, 2022, we recorded a loss of $5.9 million to adjust the VericiDx investment to fair value. During the year ended June 30, 2021, we recorded a gain of $6.5 million to adjust the VericiDx investment to fair value.

Fair value adjustment on convertible notes

We elected to account for the bonds at fair value with qualifying changes in fair value recognized through the statements of operations until the notes are settled. This excludes fair value adjustments related to instrument-specific credit risk, which are recognized in OCI. For the year ended June 30, 2022, we recorded a gain of $4.0 million to adjust the bonds to fair value. There was no fair value adjustment for the year ended June 30, 2021 as we had not issued convertible debt at that time.

Other income (expense)

During the year ended June 30, 2022, we realized $0.1 million of income on the reduction of the Kantaro liability for future services to be performed for the joint venture as well as $0.01 million interest income earned on our cash deposits. During the year ended June 30, 2021, we received $0.2 million of interest income as a result of interest earned on cash deposits and we received notification that the full amount of the $0.3 million Paycheck Protection Program (the “PPP”) loan was forgiven. We also decreased the liability to perform services to Kantaro based on updated forecasts and projections which resulted in a $0.5 million increase to other income.

Comparison of years ended June 30, 2021 and 2020

Revenue

During the year ended June 30, 2021, we recognized $0.4 million revenue related to KidneyIntelX, $0.5 million of revenue of pharmaceutical services revenue related to services performed for Astra Zeneca and $0.6 million of services revenue related to work performed for Mount Sinai and $0.4 million of KidneyIntelX testing revenue. We did not recognize revenue during the year ended June 30, 2020.

Cost of Revenue

During the year ended June 30, 2022, we recognized cost of revenue of $0.9 million primarily attributable to KidneyIntelX testing, including labor and materials costs directly related to revenue generating activities. We did not recognized cost of revenue for the year ended June 30, 2020.

Research and development expenses

Research and development expenses increased by $5.4 million from $4.6 million for the year ended June 30, 2020 to $10.0 million for year ended June 30, 2021. The increase was attributable to an increase of $2.7 million in compensation and related benefits, including share-based payments, due to increased headcount, $2.5 million increase in consulting and professional fees, $0.2 million increase in lab supplies purchases, $0.1 million increase due to depreciation in lab equipment, offset by $0.1 million decrease in rent due to the deconsolidation of VericiDx.

General and administrative expenses

General and administrative expenses increased $17.7 million from $5.6 million for the year ended June 30, 2020 to $23.5 million for the year ended June 30, 2021. The increase was due to an increase of $6.6 million in compensation and related benefits, including share-based payments, due to increased headcount, $4.5 million related to director and officer insurance policies, $4.4 million increase in consulting and professional fees, including accounting and legal which were driven by increased compliance and reporting associated with being listed on the Nasdaq, $1.0 million increase in recruiting related expenses, $0.7 million increase in marketing and public relations, $0.3 million increase in IT Costs and $0.2 million increase in other operating expenses as we expand operations.

Equity losses in affiliate

During the year ended June 30, 2021, we recognized $2.1 million in losses which represents $0.2 million of our proportionate share of losses in Kantaro, $1.7 million impairment of our equity method investment in Kantaro as well as a $0.2 million expense related to the write down of the Kantaro receivable.

Foreign currency loss

During the year ended June 30, 2021, we recognized foreign currency losses of $8.8 million due to exchange rate fluctuations on transactions denominated in a currency other than our functional currency. During the year ended June 30, 2020, we recognized a foreign currency gain of $0.2 million.

Fair value adjustments to VericiDx Investment

In prior year, we accounted for our investment in VericiDx using the equity method of accounting and have elected to use the fair value option to value the investment. During the year ended June 30, 2021, we recorded a gain of $6.5 million to adjust the VericiDx investment to fair value. There was no fair value adjustment for the year ended June 30, 2020 as we did not have an investment in VericiDx at that time.

Other income (expense)

We received $0.2 million of interest income during the year ended June 30, 2021 as a result of interest earned on cash deposits. We also decreased the liability to perform services to Kantaro based on updated forecasts and projections which resulted in a $0.5 million increase to other income. During the year ended June 30, 2020, we received $0.1 million of interest income as a result of interest earned on cash deposits and realized gains of $0.1 million on the sale of U.S. Treasury securities. We also recognized unrealized foreign exchange gains of $0.2 million and other income of $0.1 million related to the sale of excess supplies during the year ended June 30, 2020. Lastly, during the year ended June 30, 2021, we received notification that the full amount of the $0.3 million Paycheck Protection Program (the "PPP") loan was forgiven. We did not record a gain on loan extinguishment for the year ended June 30, 2020.

B. Liquidity and capital resources

Since our inception, we have incurred net losses. We incurred net losses attributable to ordinary shareholders of $45.3 million, $35.3 million and $9.8 million for the years ended June 30, 2022, 2021 and 2020, respectively. As of June 30, 2022, we had an accumulated deficit of $132.7 million.

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

- the cost, progress and results of our ongoing and planned validation studies and health economic studies;

- the cost, timing and outcome of entering into and maintaining partnership agreements with healthcare systems for the commercial sale of KidneyIntelX;
- the cost of manufacturing clinical and commercial supply of KidneyIntelX;
- the cost, timing and outcome of regulatory review of KidneyIntelX, including any post-marketing studies that could be required by regulatory authorities;
- the cost, timing and outcome of identified and potential future commercialization activities, including manufacturing, marketing, sales and distribution, for KidneyIntelX;
- the costs and timing of preparing, filing and prosecuting patent applications, maintaining and enforcing our intellectual property rights and defending any intellectual property-related claims, including any claims by third parties that we are infringing upon their intellectual property rights;
- the timing and amount of future revenue, if any, received from commercial sales of KidneyIntelX;
- the sales price and availability of adequate third-party coverage and reimbursement for KidneyIntelX;
- the effect of competing technological and market developments; and
- the extent to which we acquire or invest in businesses, products and technologies, such as Kantaro, although we currently have no other commitments or agreements to complete any such transactions.

To date, we have primarily financed our operations through equity and debt financings. As of June 30, 2022, we had cash of $41.3 million. We believe that our existing cash will enable us to fund our current operating plan for at least the next 12 months. Such expectation is based, in part, on the achievement of certain assumed revenue; however, there is no guarantee we will achieve this amount of revenue during the time period we assume. Management assesses that various operating cost mitigation options are available to the Company if needed. We have based this estimate on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect.

Until such time, if ever, as we can generate substantial revenue from sales of KidneyIntelX tests, we expect to finance our cash needs through a combination of securities offerings, debt financings, collaborations, strategic alliances and marketing, distribution or licensing arrangements with third parties. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our shareholders. EKF provided short-term debt financing that was repaid in November 2018 and we received a loan in an aggregate principal amount of $255,000 pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. Additionally, on April 5, 2022, the Company entered into an A&R Bond Agreement with CVI Investments, Inc. for $21.2 million in amortizing senior convertible bonds due in 2027 (the "Bonds"). On April 7, 2022, the Company issued the Bonds to CVI with a maturity date of April 7, 2027 comprising of total net proceeds of $18.0 million. The Bonds accrue interest at an annual rate of 5.5%, payable quarterly in equal instalments, payable in ordinary shares, although we retain the right to make any of the quarterly instalment payments in cash. The Notes contain various conversion and redemption features. Debt financing and preferred equity financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise funds through collaborations, strategic alliances or marketing, distribution or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or diagnostic products or grant licenses on terms that may not be favorable to us. Additional capital may not be available when needed, on reasonable terms, or at all, and our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to and volatility in the credit and financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic. If we are unable to raise additional funds through equity or debt financings or other arrangements when needed, we may be required to delay, curtail or discontinue our product development or future commercialization efforts, or grant rights to develop and market products that we would otherwise prefer to develop and market ourselves.

Cash flows

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

	Year ended June 30,		
(in thousands, except share and per share amounts)	**2022**	**2021**	**2020**
Net cash used in operating activities	$ (45,924)	$ (28,399)	$ (9,522)
Net cash used in investing activities	(662)	(751)	(1,174)
Net cash provided by financial activities	25,630	77,240	15,938
Effect of exchange rate changes on cash	(2,839)	3,745	(150)

Net cash used in operating activities

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

During the year ended June 30, 2021, net cash used in operating activities was $28.4 million and was primarily attributable to our $35.4 million net loss which were offset by $3.1 million net change in our operating assets and liabilities and $3.8 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to $4.4 million increase in our accrued expenses and other current liabilities due to the timing of payment to our vendors, offset by a $1.3 million increase in accounts receivables, prepaids and other current assets. Noncash charges were primarily related to $5.5 million in unrealized foreign exchange losses, $2.6 million in share-based compensation expense, and $2.1 million in equity losses of affiliate which were offset by $6.5 million unrealized gain on the company's equity method investment in VericiDx.

During the year ended June 30, 2020, net cash used in operating activities was $9.5 million and was primarily attributable to our $9.8 million net loss and $0.7 million in the net change in our operating assets and liabilities that was offset by $1.0 million in noncash charges. The change in our operating assets and liabilities was primarily attributable to $0.5 million decrease in our accrued expenses and other current liabilities due to the timing of payment to our vendors. Noncash charges were primarily related to share-based compensation expense of $1.2 million.

Net cash provided by and used in investing activities

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

During the year ended June 30, 2021 net cash used in investing activities was $0.8 million and primarily attributable to $0.9 million for the purchase of lab and office equipment and $0.6 million of software development costs and $0.2 million related to loans to Kantaro. Cash outflows due to investing activities were offset by $1.0 million in proceeds of short-term investments.

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

Net cash provided by financing activities

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

$0.2 million in proceeds from the exercise of stock options and $0.2 million in proceeds from the issuance of ordinary shares under employee share purchases.

During the year ended June 30, 2021, net cash provided by financing activities was $77.2 million and was primarily attributable to $79.2 million of proceeds from our IPO on the Nasdaq Global Market which was partially offset by offering costs of $2.3 million associated with the IPO that were paid in the period. Additionally, the company received $0.2 million in proceeds from the exercise of stock options and $0.1 million in proceeds from the issuance of ordinary shares under employee share purchases.

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

Off-balance sheet arrangements

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

Recent accounting pronouncements

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

Qualitative and quantitative disclosures about market risk

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

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

We are exposed to market risk related to changes in interest rates. As of June 30, 2022, we had cash of $41.3 million consisting of bank deposits. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities.

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

JOBS Act transition period

In April 2012, the JOBS Act was enacted. Section 107 of the JOBS Act provides that an "emerging growth company" can take advantage of the extended transition period provided in Section 7(a)(2)(B) of the Securities Act of 1933, as amended, for complying with new or revised accounting standards. An emerging growth company can

delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to take advantage of the extended transition period for complying with new or revised accounting standards and, as a result, our financial statements may not be comparable to companies that comply with new or revised accounting pronouncements as of public company effective dates.

We have evaluated the benefits of relying on other exemptions and reduced reporting requirements under the JOBS Act. Subject to certain conditions, as an emerging growth company, we have chosen to rely on certain of these exemptions, including without limitation exemptions to the requirements for (1) providing an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404(b) of the Sarbanes-Oxley Act and (2) complying with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements, known as the auditor discussion and analysis. We will remain an emerging growth company until the earlier to occur of (a) the last day of the fiscal year (1) following the fifth anniversary of the completion of our U.S. IPO, (2) in which we have total annual gross revenues of at least $1.235 billion or (3) in which we are deemed to be a "large accelerated filer" under the rules of the SEC, which means the market value of our ordinary shares and ADSs that are held by non-affiliates exceeds $700.0 million as of the prior December 31, or (b) the date on which we have issued more than $1.0 billion in non-convertible debt during the prior three-year period.

C. Research and Development, Patents and Licenses, etc.

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

D. Trend Information

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

E. Critical Accounting Estimates

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

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

Research and development expenses

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

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

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

Share-based compensation

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

We classify share-based compensation expense in our consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Convertible Notes

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

F. Safe Harbor

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

Item 6. Directors, Senior Management and Employees

A. Directors and Senior Management

The following table sets forth information regarding our executive officers and directors, including their ages as of September 30, 2022.

Name	Age	Position(s)
Executive Officers:		
James McCullough	54	Chief Executive Officer and Director
Fergus Fleming	55	Chief Technical Officer and Director
Thomas McLain	64	President
O. James Sterling	52	Chief Financial Officer
Michael J. Donovan, Ph.D., M.D.	68	Chief Medical Officer
Non-Executive Directors:		
Daniel J. Levangie	72	Non-Executive Director
Erik Lium, Ph.D	54	Non-Executive Director
Christopher Mills.	70	Non-Executive Director
Chirag R. Parikh, Ph.D., M.D	49	Non-Executive Director
Timothy Scannell.	58	Non-Executive Director

Executive officers

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

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

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

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

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

Non-executive directors

Daniel J. Levangie has served as a member of our board of directors since August 2021. Mr. Levangie has served as co-founder and manager of ATON Partners, a private investment firm, since 2013 and as president and CEO of CereVasc, LLC, a medical device company, since September 2018. He has served on the board of directors of Exact Sciences Corporation (NASDAQ: EXAS) since 2010. From 2013 through January 2017, Mr. Levangie served as president of Insulet Drug Delivery Systems and served as a lead director of Insulet Corporation. From 2011 through 2013, Mr. Levangie was chief executive officer of Dune Medical Devices, Inc., and co-founder and managing partner of Constitution Medical Investors, Inc., a Boston-based private investment and product development firm acquired by Roche Diagnostics Corporation in 2013. Previously, Mr. Levangie held executive management positions with Cytyc Corporation including executive vice president and chief operating officer, chief executive officer and president until the acquisition of Cytyc by Hologic, in 2007. He served on the board of Hologic from 2007 to 2009. Mr. Levangie received a B.S. in Pharmacy from Northeastern University.

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

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

Chirag R. Parikh, Ph.D., M.D. has served as a member of our board of directors since October 2019. Since July 2018, Dr. Parikh has served as a Professor of Medicine and the Division Director of Nephrology at Johns Hopkins University. Dr. Parikh also served a faculty member at Yale University where he directed the Program of Applied Translational Research. Dr. Parikh's research focuses on the translation and validation of novel biomarkers for the diagnosis and prognosis of kidney diseases. He has assembled multicenter longitudinal prospective cohorts for translational research studies across several clinical settings of acute kidney injury and chronic kidney disease for the efficient translation of novel biomarkers. Dr. Parikh received his medical degree from Seth G.S. Medical College and KEM Hospital in Mumbai, India and subsequently completed his Nephrology fellowship and a Ph.D. in Clinical Investigation at the University of Colorado Health Sciences Center.

Timothy J. Scannell was appointed to the Company's board of directors in March 2022. Since October 2021, Mr. Scannell has served as an Executive Advisor at Stryker, one of the world's leading medical technology companies. His career at Stryker spans 30+ years, during which he has held several leadership roles, including serving as President and Chief Operating Officer from August 2018 to October 2021, and as Group President of MedSurg & Neurotechnology from January 2019 to July 2018. Mr. Scannell also serves as Chair of Insulet Corporation's board of directors and serves on the board of directors for Novocure and Collagen Matrix. Mr. Scannell brings extensive strategic, sales and marketing, and operational skills and experience, with a track record for delivering top tier results. Mr. Scannell earned Bachelor of Business Administration and Master of Business Administration degrees from the University of Notre Dame.

Family Arrangements and Selection Arrangements

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

B. Compensation

Director Compensation

The remuneration of our non-executive directors is proposed by the remuneration committee and determined by our board of directors as a whole, based on a review of current practices in other companies. The remuneration paid to our non-executive directors during the year ended June 30, 2022 is set forth in the table below.

Name	Salary and Fees (in thousands)	
Mount Sinai (1)	$	27
Christopher Mills		27
Chirag R. Parikh, Ph.D., M.D.		61
Ann Berman (2)		20
Daniel J. Levangie		16
Timothy Scannell (3)		-

(1) Dr. Lium sits on our board as a representative of the Icahn School of Medicine at Mount Sinai. This fee is invoiced annually by Mount Sinai.
(2) Ann Berman resigned from the board effective September 20, 2022
(3) Timothy Scannell joined the board effective February, 22, 2022.

The table below sets out, for each element of pay, a summary of how remuneration of non-executive directors is structured and how it supports the Company's strategy.

	Chair and Non-Executive Directors		
Purpose and Link to Strategy	**Operation**	**Maximum Opportunity**	**Performance Metrics**
Cash fees and Benefits			
Set at a level that is sufficient to attract and retain high calibre non-executives who contribute to the business.	The Chair and the Non- Executive Directors receive fees paid in cash. Fees are paid and reviewed annually. Non-Executive Directors ordinarily do not participate in any pension, bonus or performance-based share incentive plans. Travel, accommodation and other business-related expenses incurred in carrying out the role as well as fees for tax advice associated with completion of international tax returns will be paid by the Company including, if relevant, any gross-up for tax. Tax equalisation and/or relocation benefits may be provided to Non-Executive Directors who are required to relocate or become tax resident in a new jurisdiction.	When reviewing fee levels and benefits, account is taken of market movements in the fees and benefits of Non-Executive Directors, Board Committee responsibilities and ongoing time commitments. Actual fee levels are disclosed in the annual Directors' Remuneration Report for the relevant financial year.	Not performance related.
Equity-based awards			
To facilitate share ownership and provide alignment with shareholders.	Non-Executive Directors may receive equity awards under any equity incentive plan operated by the Company from time to time which permits their participation with careful consideration being given to ensuring their independence. Non-Executive Directors may receive an initial equity award upon appointment or election. Initial equity awards will normally vest over a specified period of time, subject generally to continued service. Vesting of equity awards may be accelerated in part or in full in connection with certain corporate events such as a change of control. In addition, Non-Executive Directors may be granted an equity award each year which may vest in full upon grant or over time subject to continued service. If a new Non-Executive Director joins the Board following the date of grant of this annual grant in any calendar year, such Non- Executive Director may be granted a pro rata portion of the next annual grant to reflect his or her service during the relevant part of the relevant year.	There is no maximum number of equity incentive awards that may be awarded to individuals each year. However, when reviewing award levels, account is taken of market movements in equity incentive awards, Board committee responsibilities, ongoing time commitments and the general economic environment.	Non-executive directors do not participate in performance based equity incentives.

The following table sets forth our non-executive directors' interests in our shares as of June 30, 2022.

			Options			
	Total shares owned outright plus vested options	Shares owned outright	Percentage of issued share capital	Vested but not exercised	Unvested but subject to performance	Unvested and not subject to performance (1)
Mount Sinai (2)	204,501	—	—	204,501	—	—
Christopher Mills (3)	9,726,125	9,726,125	13.0%	—	—	—
Chirag R. Parikh, Ph.D., M.D.	107,394	—	—	107,394	—	8,330
Daniel J. Levangie	—	—	—	—	—	40,000
Timothy Scannell	68,967	68,967	0.1%	—	—	40,000

(1) Options unvested and not subject to performance exclude those options that will only vest if a floor condition is met.
(2) Dr. Lium sits on our board as a representative of the Icahn School of Medicine at Mount Sinai. Mount Sinai receives all fees payable in respect of Erik Lium's service as a non-executive director, and Mount Sinai has been granted an option under our Share Option Plan in relation to such service.
(3) Christopher Mills is partner and Chief Investment Officer of Harwood Capital LLP. Harwood Capital LLP is Investment Manager to North Atlantic Smaller Companies Investment Trust plc and investment adviser to Oryx International Growth Fund Limited. Christopher's shareholding is made up of 6,145,001 ordinary shares held by North Atlantic Smaller Companies Investment Trust PLC, 2,780,000 ordinary shares are held by Oryx International Growth Fund Limited and 801,124 ordinary shares are held by Harwood Capital LLP.

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

Non-executive director agreements

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

Executive Officer Compensation

Executive Officer Remuneration Policy

The table below sets out, for each element of pay, a summary of how remuneration of executive directors is structured and how it supports the Company's strategy.

Executive Directors			
Purpose and Link to Strategy	**Operation**	**Maximum Opportunity**	**Performance Metrics**
Base Salary			
To attract, retain and motivate executive directors of the highest calibre who are capable of delivering the Company's strategic objectives, reflecting the individual's experience and role within the Company. Base salary is designed to provide an appropriate level of fixed income to avoid an over-reliance on variable pay elements that could encourage excessive risk taking.	Salaries are normally reviewed annually, and changes are generally effective from 1 July- The annual salary review of the Executive Directors takes into consideration a number of factors, including: • scope of the individual's responsibilities; • abilities, experience and performance of the individual; • business performance; • salary increases awarded to the overall employee population; • market competitiveness and US and UK market practice; and • the underlying rate of inflation.	Executive Director level salaries are determined considering industry benchmarking data. There is no prescribed maximum annual salary or salary increase. Base salary increases are awarded at the discretion of the Committee; however, the Committee is guided by the general increase for the broader employee population but may decide to award a lower increase for Executive Directors or exceed this to recognise, for example, an increase in the scale, scope or responsibility of the role and/or take account relevant market movements. salary increases will normally Executive Director level salaries are approved by the Board in line with corporate performance and are consistent with positions held.	No formal metrics, although any increases take account of Company performance and the individual performance of the Executive Director.
Benefits			
Benefits in kind offered to Executive Directors are provided on a market- competitive basis, to assist with their recruitment and retention.	The Company aims to offer benefits that are in line with the Executive Directors' local market and those offered to the wider workforce.	There is no defined maximum value for benefits, but the Committee will consider the aggregate value of any such benefits when determining what should be offered.	Not performance related.
Pension			

The Company aims to provide a contribution towards life in retirement.	Depending on their location and comparable benefits offered to local employees, Executive Directors may be eligible to receive employer contributions to a defined contribution pension scheme or a cash supplement in lieu of such contributions, or a mixture of both.	The maximum employer pension contribution or cash in lieu amount will be a percentage of annual base salary aligned with that provided to other senior executives in the Executive Director's location.	Not performance related.
Annual Bonus			
An annual bonus rewards the achievement of objectives that support the Company's corporate goals and delivery of the business strategy	Bonuses are determined based on objectives that are agreed with the Committee, and the Board, at the start of each [financial] year although the Committee retains the discretion to amend objectives during the year if it considers that objectives are no longer appropriate. Different performance measures and weightings may be used each year, as agreed with the Committee, to take into account changes in the business strategy. Bonuses are normally paid in cash (but may be paid in the form of an equity award, at the discretion of the Committee).	Executive Director level bonuses are approved by the Board in line with corporate performance and are consistent with positions held.	Performance measures are determined by the Committee each year and may vary to ensure that they promote the Company's business strategy and shareholder value. The annual bonus will be based on corporate measures, including, but not limited to, financial and/or strategic measures. Bonus measures are reviewed at least annually and the Committee has the discretion to change the measures or to introduce new measures when it deems appropriate.
Equity Incentive Plan ('EIP')			

To attract, motivate, retain and reward for long-term, sustainable performance linked to corporate strategy and provide alignment with shareholders' interests.	Equity awards granted to Executive Directors may take the form of options, restricted shares, performance share units, restricted share units, or other forms of awards granted in accordance with the discretionary EIP that may be in place from time to time. The Executive Directors received a grant under the EIP's predecessor plan upon listing on AIM and it is intended that top-up awards shall be issued under the EIP from time to time in the discretion of the Committee.	There is no maximum opportunity for equity incentives. However, the Committee will generally assess the position at similar sized comparator companies prior to making any award to ensure that any awards are aligned to the market.	Vesting of equity awards is generally subject to continued employment and may also be subject to the achievement of performance conditions aligned with the Company's strategic plan. Measures, their weightings and the period over which performance is tested will be determined by the Committee. The Committee will select the most appropriate form of EIP for awards each year and/or each individual grant. Vesting of equity awards may be accelerated in part or in full in connection with certain corporate events such as a change of control.
All employee equity plans			
Encourages employee share ownership and therefore increases alignment of interests with shareholders.	The Company may, from time to time, operate tax- advantaged share plans for which Executive Directors would be eligible on the same basis as all other eligible employees.	Within the limits of the relevant legislation.	Not performance related.

The following table shows the remuneration of our executive directors for the year ended June 30, 2022.

(in thousands)	Basic salary (1)	Benefits (2)	Bonus (3)	Pension (4)	Total remuneration
James McCullough	$ 601	$ 34	$ -	$ 13	$ 648
Fergus Fleming	$ 0	$ 449	$ -	$ 0	$ 449

(1) This is the amount earned in respect of the financial period.
(2) This is the taxable value of benefits paid or payable in respect of the financial period.
(3) This is the total bonus earned under the annual bonus scheme in respect of the financial year (despite being paid in the following financial year, following determination of final outcomes).
(4) The amount shown relates to Company contributions to the defined contribution scheme, plus any cash in lieu.

Executive officer employment agreements

Employment agreement of James McCullough

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

Pursuant to the terms of the employment agreement, Mr. McCullough is entitled to annual base salary, initially $350,000, which is subject to annual review by our remuneration committee and to a minimum annual increase of 3%. Our remuneration committee approved an increase to Mr. McCullough's annual base salary to $601,000. Under the terms of the employment agreement, Mr. McCullough is also: (1) eligible for an annual cash bonus in the sole discretion of the remuneration committee; (2) entitled to participate on the same basis as similarly situated employees in our benefit plans in effect from time to time during his employment; and (3) entitled to five weeks' holiday per annum.

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

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

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

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

Employment agreement of Fergus Fleming

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

Pursuant to the terms of the employment agreement, Mr. Fleming is entitled to an annual base salary, initially €200,000, which is subject to annual review by our remuneration committee. Our remuneration committee approved an increase to Mr. Fleming's annual base salary to €336,000. Under the terms of the employment agreement, Mr. Fleming is also: (1) eligible to join any pension scheme we operate from time to time and, should he so join, we will make contributions to such pension scheme at a rate of 5% of Mr. Fleming's annual base salary each year; (2) entitled to a car allowance of €5,000 per year, for so long as he holds a driving license; (3) entitled to participate, at our expense, in our private medical expenses insurance scheme; and (4) entitled to 25 days' holiday per annum, plus holiday pay during the period between Christmas and New Year each year.

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

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

Limitations on Liability and Indemnification Matters

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

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

Equity Incentive Plans

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

2020 Equity Incentive Plan

In July 2020, our board of directors adopted and our shareholders approved our 2020 Equity Incentive Plan, or EIP.

As of June 30, 2022, there were options to purchase 4,554,901 ordinary shares outstanding with a weighted average exercise price of $5.31 per ordinary share. The options generally lapse after ten years from the date of the grant.

Eligibility and administration

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

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

Shares available for awards

The maximum number of ordinary shares that may be issued under our 2020 EIP is 15,716,928 ordinary shares. No more than 25,500,000 ordinary shares may be issued under the 2020 EIP upon the exercise of incentive share options. In addition, the number of ordinary shares reserved for issuance under our 2020 EIP will automatically increase on January 1 of each year, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to 5% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year. Our board may act prior to January 1 of a given year to provide that there will be no increase for such year or that the increase for such year will be a lesser number of ordinary shares, ordinary shares issued under the 2020 EIP may be new shares, shares purchased on the open market or treasury shares.

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

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

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

Awards

The 2020 EIP provides for the grant of market value options, market value share appreciation rights, or SARs, restricted shares, restricted share units, or RSUs, performance restricted share units, or PSUs, and other share- based

awards. All awards under the 2020 EIP will be set forth in award agreements, which will detail the terms and conditions of awards, including any applicable vesting and payment terms, change of control provisions and post-termination exercise limitations. A brief description of each award type follows.

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

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

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

Performance criteria

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

Certain transactions

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

Plan amendment and termination

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

Transferability and participant payments

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

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

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

2020 Non-Employee sub-plan

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

2020 Employee Share Purchase Plan

In July 2020, our board of directors adopted and our shareholders approved our 2020 Employee Share Purchase Plan, or 2020 ESPP.

Purpose

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

Administration

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

Ordinary Shares Subject to the 2020 ESPP

Subject to adjustment for certain changes in our capitalization, the maximum number of ordinary shares that may be issued under the 2020 ESPP is 2,242,000 ordinary shares. In addition, the number of ordinary shares reserved for issuance under our 2020 ESPP will automatically increase on January 1 of each year, commencing on January 1, 2021 and ending on (and including) January 1, 2030, in an amount equal to the lesser of 1% of the total number of ordinary shares outstanding on December 31 of the preceding calendar year, and 2,000,000 ordinary shares. If any rights granted under the 2020 ESPP terminate without being exercised in full, the ordinary shares not purchased

under such rights again become available for issuance under the 2020 ESPP. The ordinary shares issuable under the 2020 ESPP will be new shares. As of June 30, 2022, we have issued 33,734 ordinary shares pursuant to offerings under our ESPP.

Offerings

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

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

Eligibility

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

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

Participation in the 2020 ESPP

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

Purchase Price

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

Payment of Purchase Price; Payroll Deductions

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

Purchase Limits

In connection with each offering made under the 2020 ESPP, the Plan Administrator may specify (i) a maximum number of ordinary shares that may be purchased by any participant pursuant to such offering, (ii) a maximum number of ordinary shares that may be purchased by any participant on any purchase date pursuant to such offering, (iii) a maximum aggregate number of ordinary shares that may be purchased by all participants pursuant to such offering, and/or (iv) a maximum aggregate number of ordinary shares that may be purchased by all participants on any purchase date pursuant to such offering. If the aggregate purchase ordinary shares issuable upon exercise of purchase rights granted under such offering would exceed any such maximum aggregate number, then the Plan Administrator will make a pro rata allocation of available shares in a uniform and equitable manner.

Withdrawal

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

Termination of Employment

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

Restrictions on Transfer

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

Changes in Capitalization

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

Effect of Certain Corporate Transactions

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

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

Non-US Participants

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

Duration, Amendment and Termination

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

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

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

Federal Income Tax Information

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

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

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

If the shares are sold or otherwise disposed of more than two years after the beginning of the offering period and more than one year after the shares are transferred to the participant, then the lesser of the following will be treated as ordinary income: (i) the excess of the fair market value of the shares at the time of such sale or disposition over the purchase price; or (ii) the excess of the fair market value of the shares as of the beginning of the offering period

over the purchase price (determined as of the beginning of the offering period). Any further gain or any loss will be taxed as a long-term capital gain or loss.

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

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

New Plan Benefits

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

Share option plan

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

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

Eligibility, awards and administration

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

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

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

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

General terms of options

Options may be granted within 42 days immediately following the end of a closed period, which has the same meaning as in Regulation (EU) No 596/2014 of the European Parliament and of the Council of 16 April 2014 on

market abuse, and within any other period that our remuneration committee has decided options should be granted as exceptional circumstances exist.

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

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

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

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

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

Vesting and exercise

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

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

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

Limitations on awards

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

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

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

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

Leavers

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

Certain transactions

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

Changes to capital structure

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

Amendment and termination

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

Non-Employee Sub-Plan

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

U.S. Sub-Plan

The U.S. Sub-Plan permits the grant of options to eligible participants under the Share Option Plan and the Non-Employee Sub-Plan who are U.S. residents and U.S. taxpayers, including potentially tax efficient incentive stock options. The exercise price of options granted under the U.S. Sub- Plan shall not be less than 100% of the fair market value of an ordinary share on the date of grant, determined in accordance with Section 409A of the Code.

C. Board Practices

Composition of our board of directors

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

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

Committees of our board of directors

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

Audit committee

Our audit committee consists of Erik Lium, Ph.D. and Daniel J. Levangie and assists the board of directors in overseeing our accounting and financial reporting processes and the audits of our financial statements. The audit committee consists exclusively of members of our board who are financially literate, and Mr. Levangie is considered an "audit committee financial expert" as defined by applicable SEC rules and has the requisite financial sophistication as defined under the applicable Nasdaq rules and regulations. Our board has determined that all of the members of the audit committee satisfy the "independence" requirements set forth in Rule 10A-3 under the Exchange Act. The audit committee is governed by a charter that complies with Nasdaq rules. Ann Berman resigned from the Company board of directors effective September 20, 2022. We intend to replace Ms. Berman on our board with someone who would also be an appropriate addition to the audit committee, thereby bringing the number of members on the committee back to three upon such appointment.

The audit committee's responsibilities include:

- monitoring the integrity of our financial and narrative reporting;
- reviewing accounting policies and key estimates and judgments;
- reviewing the appropriateness and completeness of the internal controls;
- recommending the appointment, re-appointment or removal of the independent auditor to the annual general meeting of shareholders;
- the appointment, compensation, retention and oversight of any accounting firm engaged for the purpose of preparing or issuing an audit report or performing other audit services;
- pre-approving the audit services and non-audit services to be provided by our independent auditor before the auditor is engaged to render such services;
- evaluating the independent auditor's qualifications, performance and independence, and presenting its conclusions to the full board of directors on at least an annual basis;
- reviewing and discussing with the executive officers, the board of directors and the independent auditor our financial statements and our financial reporting process; and
- reviewing procedures for detection of fraud, whistleblowing and prevention of bribery, and reports on systems for internal financial control, financial reporting and risk management.

Remuneration committee

Our remuneration committee consists of Daniel L. Levangie, and Erik Lium, Ph.D. and assists the board of directors in determining executive officer compensation. Mr. Levangie serves as chairman of the remuneration committee.

The remuneration committee's responsibilities include:

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

Nomination committee

Our nomination committee consists of Chirag Parikh, Ph.D., M.D., and assists our board of directors in identifying individuals qualified to become members of our board and executive officers consistent with criteria established by our board and in developing our corporate governance principles. Dr. Parikh serves as chairperson of the nomination committee. Ann Berman resigned from the Company board of directors effective September 20, 2022. We intend to replace Ms. Berman on our board with someone who would also be an appropriate addition to the nomination committee, thereby bringing the number of members on the committee back to two upon such appointment.

The nomination committee's responsibilities include:

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

Code of business conduct and ethics

We have adopted a Code of Business Conduct and Ethics, or Code of Ethics, applicable to our and our subsidiaries' employees, independent contractors, executive officers and directors, including our principal executive officer, principal financial officer, principal accounting officer or controller, or persons performing similar functions. A current copy of the Code of Ethics is posted on our website, which is located at www.renalytixai.com. Information contained on, or that can be accessed through, our website does not constitute a part of this annual report and is not incorporated by reference herein.

D. Employees

As of June 30, 2022, we had 102 employees, including 91 employed by our U.S. subsidiary, Renalytix AI, Inc., 6 full-time employees employed by Renalytix AI, Ltd. and 5 employees employed directly by Renalytix plc. None of our employees are represented by labor unions or covered by collective bargaining agreements. We consider our relationship with our employees to be good.

E. Share Ownership

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

Item 7. Major Shareholders and Related Party Transactions

A. Major Shareholders

The following table sets forth information with respect to the beneficial ownership of our ordinary shares as of September 30, 2022 for:

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

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to those securities and include ordinary shares issuable upon the exercise of options that are immediately exercisable or exercisable within 60 days of September 30, 2022. Percentage ownership calculations are based on 74,891,844 ordinary shares outstanding as of September 30, 2022.

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

Except as otherwise indicated in the table below, addresses of the directors, executive officers and named beneficial owners are care of Renalytix plc, Finsgate, 5-7 Cranwood Street, London, EC1V 9EE, United Kingdom.

Name of Beneficial Owner	Number of Ordinary Shares Beneficially Held	Percentage of Ordinary Shares Beneficially Held
5% or Greater Shareholders (other than Executive Officers and Directors):		
Icahn School of Medicine at Mount Sinai (1)	12,058,875	16.1 %
Executive Officers and Directors:		
James McCullough (2)	2,746,386	3.7
Fergus Fleming (3)	1,107,642	1.5
Thomas McLain (4)	1,105,647	1.5
O. James Sterling (5)	1,805,236	2.4
Michael J. Donovan, Ph.D., M.D. (6)	269,081	*
Christopher Mills (7)	9726125	13
Erik Lium, Ph.D.	—	—
Chirag R. Parikh, Ph.D., M.D. (8)	115,724	*
Daniel J. Levangie	12,500	*
Timothy Scannell	68,967	*
All current executive officers and directors as a group (10 persons) (9)	16,957,308	22.1

* Less than 1%

(1) Consists of 204,501 shares issuable upon exercise of options vested as of November 30, 2022. The address of Mount Sinai is 1 Gustave L. Levy Place, New York, New York, 10029.
(2) Includes shares held by The McCullough 2020 Irrevocable Trust, of which Mr. McCullough is trustee.
(3) Consists of (i) 569,481 shares and (ii) 538,161 shares issuable upon exercise of options vested as of November 30, 2022.
(4) Consists of (i) 59,150 shares and (ii) 1,046,497 shares issuable upon exercise of options vested as of November 30, 2022.
(5) Consists of 1,805,236 shares held by Mr. Sterling.
(6) Consists of 269,081 shares issuable upon exercise of options vested as of November 30, 2022.

(7) Consists of (i) 6,145,001 shares held by North Atlantic Smaller Companies Investment Trust plc ("NASCIT"), of which Harwood Capital LLP is investment manager, (ii) 2,780,000 shares held by Oryx International Growth Fund Limited ("Oryx"), of which Harwood Capital LLP is an investment advisor and (iii) 801,124 shares held by Harwood Capital Nominees Limited ("Harwood"). Mr. Mills is partner and chief investment officer of Harwood Capital LLP. The address of Harwood, NASCIT and Oryx is 6 Stratton St, Mayfair, London W1J 8LD, United Kingdom.
(8) Consists of 115,724 shares issuable upon exercise of options vested as of November 30, 2022.
(9) Consists of (i) 14,975,345 shares and (ii) 1,981,963 shares issuable upon exercise of options vested as of November 30, 2022.

Significant Changes in Percentage Ownership

The significant changes in the percentage ownership held by our principal shareholders since January 1, 2019 are as a result of dilution from our global offering in July 2020 in which we issued and sold 12,583,500 ordinary shares in our U.S. IPO, which converted into 6,291,750 ADSs, and 30,000 ordinary shares in a concurrent private placement in Europe as well as the April 2022 offering in which we issued and sold 2,428,688 ordinary shares, (including in the form of ADSs).

Shareholders in the United States

As of September 30, 2022, to the best of our knowledge, 37,722,486 of our outstanding ordinary shares (including ordinary shares represented by ADSs) were held by 17 shareholders of record in the United States. The actual number of holders is greater than these numbers of record holders, and includes beneficial owners whose ordinary shares or ADSs are held in street name by brokers and other nominees. This number of holders of record also does not include holders whose shares may be held in trust by other entities.

B. Related Party Transactions

Icahn School of Medicine at Mount Sinai

Mount Sinai Agreement

In May 2018, we entered into the Mount Sinai Agreement. See "Item 5—Our key agreements—Mount Sinai Health System." As part of the collaboration, Mount Sinai became a shareholder in the Company and has subsequently made equity investments both in our IPO on AIM in November 2018, the subsequent sale of ordinary shares in July 2019 and our IPO on Nasdaq in July 2020. As of June 30, 2022, amounts due to Mount Sinai totaled $1.1 million. During the year ended June 30, 2022, we incurred expenses of $2.2 million related to the Mount Sinai Agreement.

Kantaro

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into the Advisory Agreement, pursuant to which we have agreed to provide certain services to Kantaro. For the year ended June 30, 2022, the Company recognized $0.1 million in the statement of operations related to services performed under the Advisory Agreement. For the year ended June 30, 2022, $0.05 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $0.07 million was included within general and administrative expense, respectively. See "Item 5— Our key agreements—Kantaro Biosciences LLC" for additional information.

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

Participation in our Global Offering

In our global offering in July 2020, Mount Sinai purchased 948,750 ADSs. This purchase was made through the underwriters at the initial public offering price of $13.50 per ADS.

Participation in Private Placement

In April 2022, Mount Sinai participated in our private placement and purchased 551,724 ADSs. This purchase was made through the underwriters at the offering price of $7.25 per ADS.

Additionally, the directors of the Company (the "Directors") and certain of its persons discharging managerial responsibility (“PDMRs”) as defined under Regulation (596/2014/EU) as it forms part of domestic law in the United Kingdom pursuant to the European Union (Withdrawal) Act 2018, as amended, including certain senior managers, have subscribed for a total of 703,446 ordinary shares raising an aggregated total amount of $2.55 million at the Reference ADS Price pursuant to the Equity Fundraise.

Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 551,724 new ordinary shares at $3.625 per ordinary share. Following completion of the purchase, Christopher Mills and his related parties are interested in 9,726,125 ordinary shares representing 13.0% of the Company's issued share capital at the time of private placement.

Timothy Scannell, Non-Executive Director, subscribed for a total of 68,964 new ordinary shares at $3.625 per ordinary share. Following completion of the purchase, Timothy Scannell is interested in 68,964 Ordinary Shares representing 0.09% of the Company's issued share capital at the time of private placement.

Thomas McLain, President, subscribed for a total of 55,172 new ordinary shares at $3.625 per ordinary share. Following completion of the purchase, Thomas McLain is interested in 59,150 ordinary shares representing 0.08% of the Company's issued share capital at the time of private placement.

Agreements with our executive officers and directors

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

Indemnification agreements

In July 2020, we entered into deeds of indemnity with each of our directors and executive officers in connection with the listing of our ADSs on Nasdaq. The deeds of indemnity and our articles of association require us to indemnify our directors and executive officers to the fullest extent permitted by law.

Related person transaction policy

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

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

C. Interests of Experts and Counsel

Not applicable.

Item 8. Financial Information

A. Consolidated Statements and Other Financial Information

Consolidated Financial Statements

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

Dividend Distribution Policy

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

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

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

Legal Proceedings

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

B. Significant Changes

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

Item 9. The Offer and Listing

A. Offer and Listing Details

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

B. Plan of Distribution

Not applicable.

C. Markets

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

D. Selling Stockholders

Not applicable.

E. Dilution

Not applicable.

F. Expenses of the Issue

Not applicable.

Item 10. Additional Information

A. Share Capital

Not applicable.

B. Memorandum and Articles of Association

General

We were incorporated as a public limited company under the laws of England and Wales on March 15, 2018, with the name Renalytix plc and company number 11257655. On June 23, 2021, we changed our name to Renalytix plc. Our principal executive offices in the United States are located at 1460 Broadway, New York, New York 10036 and our telephone number is +1 646 397 3970. Our registered office in the United Kingdom is located at Finsgate, 5-7 Cranwood Street, London, EC1V 9EE, United Kingdom, and the telephone number of our registered office is +44 20 3139 2910.

Since November 6, 2018, our ordinary shares have been traded on AIM under the symbol "RENX". Our website address is www.renalytixai.com. The information contained on, or that can be accessed from, our website does not form part of this annual report. Our agent for service of process in the United States is Renalytix AI, Inc., located at 1460 Broadway, New York, New York 10036.

As of June 30, 2022, we had 74,760,432 ordinary shares outstanding, with a nominal value of £0.0025 per ordinary share. Each issued ordinary share is fully paid.

Ordinary shares

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

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

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

Options

As of June 30, 2022, there were options to purchase 4,554,901 ordinary shares outstanding with a weighted average exercise price of $5.31 per ordinary share. The options generally lapse after ten years from the date of the grant.

Share register

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

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

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

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

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

Preemptive rights

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

At our annual general meeting held on December 17, 2021, our shareholders approved the disapplication of preemptive rights for the period up to the earlier of the conclusion of our next annual general meeting or the close of business on March 17, 2023, which disapplication allows for the issue of ordinary shares in an offering made on a preemptive basis or otherwise up to a maximum aggregate nominal amount of £27,115.85, and that will need to be renewed upon expiration to remain effective.

Articles of association

Shares and rights attaching to them

Objects

The objects of the company are unrestricted.

Share rights

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

Voting rights

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

- any resolution put to the vote of a general meeting must be decided exclusively on a poll;

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

Restrictions on voting

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

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

Dividends

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

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

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

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

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

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

Change of control

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

Distributions on winding up

On a winding up, the liquidator may, with the sanction of a special resolution of shareholders and any other sanction required by law, divide amongst the shareholders in specie the whole or any part of the assets of the company and may, for that purpose, value any assets and determine how the division shall be carried out as between the

shareholders or different classes of shareholders. The liquidator may, with the like sanction, vest the whole or any part of the assets in trustees upon such trusts for the benefit of the shareholders as he may with the like sanction determine, but no shareholder shall be compelled to accept any assets upon which there is a liability.

Variation of rights

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

Alteration to share capital

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

Allotment of shares and preemption rights

In accordance with the Companies Act, the board of directors may be generally and unconditionally authorized to exercise all the powers of the company to allot shares up to an aggregate nominal amount equal to the amount stated in the relevant ordinary resolution authorizing such allotment.

At our annual general meeting held on December 17, 2021, our shareholders granted our directors authority to (a) allot shares and grant rights to subscribe for, or convert any security into, shares in the company up to an aggregate nominal amount of £59,654.87 and (b) allot further equity securities (as defined in the Companies Act) in connection with a rights issue up to an aggregate nominal amount of £59,654.87. These authorities apply for period to the conclusion of our next annual general meeting or, if earlier, the close of business on March 15, 2023.

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

Transfer of shares

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

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

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

- which is not a fully paid share, provided that such discretion may not be exercised in a way in which the London Stock Exchange regards as preventing dealing in shares from taking place on an open and proper basis;
- where the company has a lien over such share;

- unless any written instrument of transfer, duly stamped or duly certificated or otherwise shown to the satisfaction of the board of directors to be exempt from stamp duty (if this is required), is lodged with us at our registered office or such other place as the board may from time to time determine, accompanied by the certificate for the shares to which it relates;
- unless there is provided such evidence as the board may reasonably require to show the right of the transferor to make the transfer and if the instrument of transfer is executed by some other person on his behalf, the authority of that person to do so;
- where the transfer is in respect of more than one class of share; and
- in the case of a transfer to joint holders, the number of joint holders to whom the share is to be transferred exceeds four.

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

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

CREST

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

Annual general meetings

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

Notice of general meetings

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

Quorum of general meetings

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

Class meetings

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

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

Number of directors

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

Appointment of directors

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

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

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

Rotation of directors

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

Directors' interests

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

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

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

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

- the giving of any guarantee, security or indemnity in respect of money lent or obligations incurred by him or by any other person at the request of or for the benefit of our company or any of our subsidiary undertakings;
- the giving of any guarantee, security or indemnity in respect of a debt or obligation of our company or any of our subsidiary undertakings for which he himself has assumed responsibility in whole or in part under a guarantee or indemnity or by the giving of security;

- any proposal concerning an offer of securities of or by our company or any of our subsidiary undertakings in which offer he is or may be entitled to participate as a holder of securities or in the underwriting or sub-underwriting of which he is to participate;
- any contract, arrangement or transaction concerning any other body corporate in which he or any person connected with him (within the meaning of sections 252-5 of the Companies Act) is interested, directly or indirectly and whether as an officer or shareholder or otherwise howsoever, provided that he and any persons so connected with him do not to his knowledge hold an interest (within the meaning of sections 820 to 825 of the Companies Act) in one per cent. or more of any class of the equity share capital of such body corporate or of the voting rights available to members of the relevant body corporate;
- any contract, arrangement or transaction for the benefit of employees of our company or any of our subsidiary undertakings which does not accord to him any privilege or advantage not generally accorded to the employees to whom the scheme relates;
- any contract, arrangement or transaction concerning any insurance which our company is to purchase and/or maintain for, or for the benefit of, any directors or persons including directors;
- the giving of an indemnity in relation to another director; and
- the provision of funds to any director to meet, or the doing of anything to enable a director to avoid incurring, expenditure of the nature described in section 205(1) or 206 of the Companies Act.

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

Directors' fees and remuneration

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

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

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

Borrowing powers

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

Indemnity

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

Exclusive jurisdiction

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

Other English law considerations

Notification of voting rights

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

Mandatory purchases and acquisitions

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

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

Sell out

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

Disclosure of interest in shares

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

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

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

Purchase of own shares

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

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

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

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

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

At our annual general meeting held on December 7, 2021, our shareholders authorized the company to make "on-market" purchases of ordinary shares on AIM up to a maximum aggregate number of 7,230,893 ordinary shares subject to certain minimum and maximum price thresholds.

Distributions and dividends

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

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

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

City Code on Takeovers and Mergers

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

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

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

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

When our ordinary shares were admitted to trading on AIM in November 2018, the Panel confirmed that three distinct concert parties existed and that the three distinct concert parties were not considered to be acting in concert as between each other. As at June 30, 2022 each concert party had an aggregate shareholding representing less than 29.99% in the share capital of the Company.

Exchange controls

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

Corporate governance code

The AIM Rules for Companies published by the London Stock Exchange require us to include on our website details of a recognized corporate governance code that our board of directors has decided to apply, how we comply with that code and, where we depart from our chosen corporate governance code, an explanation of the reasons for doing so.

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

Differences in corporate law

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

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

Annual General Meeting	Under the Companies Act, a public limited company must hold an annual general meeting in each six-month period following its annual accounting reference date.	Under Delaware law, the annual meeting of stockholders shall be held at such place, on such date and at such time as may be designated from time to time by the board of directors or as provided in the certificate of incorporation or by the bylaws.
General Meeting	Under the Companies Act, a general meeting of the shareholders of a public limited company may be called by the directors. Shareholders holding at least 5% of the paid-up capital of the company carrying voting rights at general meetings (excluding any paid up capital held as treasury shares) can require the directors to call a general meeting and, if the directors fail to do so within a certain period, may themselves convene a general meeting.	Under Delaware law, special meetings of the stockholders may be called by the board of directors or by such person or persons as may be authorized by the certificate of incorporation or by the bylaws.
Notice of General Meetings	Subject to a company's articles of association providing for a longer period, under the Companies Act, 21 clear days' notice must be given for an annual general meeting and any resolutions to be proposed at the meeting. Subject to a company's articles of association providing for a longer period, at least 14 clear days' notice is required for any other general meeting. In addition, certain matters, such as the removal of directors or auditors, require special notice, which is 28 clear days' notice. The shareholders of a company may in all cases consent to a shorter notice period, the proportion of shareholders' consent required being 100% of those entitled to attend and vote in the case of an annual general meeting and, in the case of any other general meeting, a majority in number of the members having a right to attend and vote at the meeting, being a majority who together hold not less than 95% in nominal value of the shares giving a right to attend and vote at the meeting.	Under Delaware law, unless otherwise provided in the certificate of incorporation or bylaws, written notice of any meeting of the stockholders must be given to each stockholder entitled to vote at the meeting not less than 10 nor more than 60 days before the date of the meeting and shall specify the place, date, hour, and purpose or purposes of the meeting.
Proxy	Under the Companies Act, at any meeting of shareholders, a shareholder may designate another person to attend, speak and vote at the meeting on their behalf by proxy.	Under Delaware law, at any meeting of stockholders, a stockholder may designate another person to act for such stockholder by proxy, but no such proxy shall be voted or acted upon after three years from its date, unless the proxy provides for a longer period. A director of a Delaware corporation may not issue a proxy representing the director's voting rights as a director.

Preemptive Rights	Under the Companies Act, "equity securities," being (1) shares in the company other than shares that, with respect to dividends and capital, carry a right to participate only up to a specified amount in a distribution, referred to as "ordinary shares," or (2) rights to subscribe for, or to convert securities into, ordinary shares, proposed to be allotted for cash must be offered first to the existing equity shareholders in the company in proportion to the respective nominal value of their holdings, unless an exception applies or a special resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act.	Under Delaware law, shareholders have no preemptive rights to subscribe to additional issues of stock or to any security convertible into such stock unless, and except to the extent that, such rights are expressly provided for in the certificate of incorporation.
Authority to Allot	Under the Companies Act, the directors of a company must not allot shares or grant of rights to subscribe for or to convert any security into shares unless an exception applies or an ordinary resolution to the contrary has been passed by shareholders in a general meeting or the articles of association provide otherwise in each case in accordance with the provisions of the Companies Act.	Under Delaware law, if the corporation's charter or certificate of incorporation so provides, the board of directors has the power to authorize the issuance of stock. It may authorize capital stock to be issued for consideration consisting of cash, any tangible or intangible property or any benefit to the corporation or any combination thereof. It may determine the amount of such consideration by approving a formula. In the absence of actual fraud in the transaction, the judgment of the directors as to the value of such consideration is conclusive.

Liability of Directors and Officers	Under the Companies Act, any provision, whether contained in a company's articles of association or any contract or otherwise, that purports to exempt a director of a company, to any extent, from any liability that would otherwise attach to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company is void. Any provision by which a company directly or indirectly provides an indemnity, to any extent, for a director of the company or of an associated company against any liability attaching to him in connection with any negligence, default, breach of duty or breach of trust in relation to the company of which he is a director is also void except as permitted by the Companies Act, which provides exceptions for the company to (a) purchase and maintain insurance against such liability; (b) provide a "qualifying third party indemnity" (being an indemnity against liability incurred by the director to a person other than the company or an associated company or criminal proceedings in which he is convicted); and (c) provide a "qualifying pension scheme indemnity" (being an indemnity against liability incurred in connection with our activities as trustee of an occupational pension plan).	Under Delaware law, a corporation's certificate of incorporation may include a provision eliminating or limiting the personal liability of a director to the corporation and its stockholders for damages arising from a breach of fiduciary duty as a director. However, no provision can limit the liability of a director for: • any breach of the director's duty of loyalty to the corporation or its stockholders; • acts or omissions not in good faith or that involve intentional misconduct or a knowing violation of law; • intentional or negligent payment of unlawful dividends or stock purchases or redemptions; or • any transaction from which the director derives an improper personal benefit.

Voting Rights	Under the laws of England and Wales, unless a poll is demanded by the shareholders of a company or is required by the chairman of the meeting or our articles of association, shareholders shall vote on all resolutions on a show of hands. Under the Companies Act, a poll may be demanded by (a) not fewer than five shareholders having the right to vote on the resolution; (b) any shareholder(s) representing not less than 10% of the total voting rights of all the shareholders having the right to vote on the resolution (excluding any voting rights attaching to treasury shares); or (c) any shareholder(s) holding shares in the company conferring a right to vote on the resolution (excluding any voting rights attaching to treasury shares) being shares on which an aggregate sum has been paid up equal to not less than 10% of the total sum paid up on all the shares conferring that right. A company's articles of association may provide more extensive rights for shareholders to call a poll. Under the laws of England and Wales, an ordinary resolution is passed on a show of hands if it is approved by a simple majority (more than 50%) of the votes cast by shareholders present (in person or by proxy) and entitled to vote. If a poll is demanded, an ordinary resolution is passed if it is approved by holders representing a simple majority of the total voting rights of shareholders present, in person or by proxy, who, being entitled to vote, vote on the resolution. Special resolutions require the affirmative vote of not less than 75% of the votes cast by shareholders present, in person or by proxy, at the meeting. If a poll is demanded, a special resolution is passed if it is approved by holders representing not less than 75% of the total voting rights of shareholders in person or by proxy who, being entitled to vote, vote on the resolution.	Delaware law provides that, unless otherwise provided in the certificate of incorporation, each stockholder is entitled to one vote for each share of capital stock held by such stockholder.

Shareholder Vote on Certain Transactions	The Companies Act provides for schemes of arrangement, which are arrangements or compromises between a company and any class of shareholders or creditors and used in certain types of reconstructions, amalgamations, capital reorganizations, or takeovers. These arrangements require: • the approval at a shareholders' or creditors' meeting convened by order of the court, of a majority in number of shareholders or creditors representing 75% in value of the capital held by, or debt owed to, the class of shareholders or creditors, or class thereof present and voting, either in person or by proxy; and • the approval of the court.	Generally, under Delaware law, unless the certificate of incorporation provides for the vote of a larger portion of the stock, completion of a merger, consolidation, sale, lease or exchange of all or substantially all of a corporation's assets or dissolution requires: • the approval of the board of directors; and • approval by the vote of the holders of a majority of the outstanding stock or, if the certificate of incorporation provides for more or less than one vote per share, a majority of the votes of the outstanding stock of a corporation entitled to vote on the matter.

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

Stockholder Suits	Under the laws of England and Wales, generally, the company, rather than its shareholders, is the proper claimant in an action in respect of a wrong done to the company or where there is an irregularity in the company's internal management. Notwithstanding this general position, the Companies Act provides that (1) a court may allow a shareholder to bring a derivative claim (that is, an action in respect of and on behalf of the company) in respect of a cause of action arising from a director's negligence, default, breach of duty or breach of trust and (2) a shareholder may bring a claim for a court order where our affairs have been or are being conducted in a manner that is unfairly prejudicial to some of its shareholders.	Additionally, the plaintiff must remain a stockholder through the duration of the derivative suit. The action will not be dismissed or compromised without the approval of the Delaware Court of Chancery.

Stock exchange listing

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

Registrar of shares, depositary for ADSs

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

C. Material Contracts

Underwriting Agreement

We entered into an underwriting agreement with J.P. Morgan Securities LLC and Stifel, Nicolaus & Company, Incorporated as representatives of the underwriters, on July 16, 2020, with respect to the ADSs and ordinary shares sold in our global offering. We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act, and to contribute to payments the underwriters may be required to make in respect of such liabilities.

Mount Sinai Health System

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

We paid Mount Sinai $10.0 million as an up-front payment upon entering into the Mount Sinai Agreement. Under the terms of the Mount Sinai Agreement, we are obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. We are also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of

such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, we are obligated to pay Mount Sinai between 15% and 25% of any consideration received by us from a sublicensee. The two provisional patent applications covering the KidneyIntelX diagnostic in-licensed under the Mount Sinai Agreement were filed in February 2020 and April 2020, respectively. If issued, these patents will expire in February 2041 and April 2041, respectively. Furthermore, we agreed to carry out and fund a clinical utility study for KidneyIntelX at a cost to be determined upon approval of the study protocol by the IRB.

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

Joslin Diabetes Center

In July 2017, EKF entered into a license agreement, or the Joslin Agreement, with the Joslin Diabetes Center, Inc., or Joslin. In October 2018, we purchased all of EKF's rights, title, interest and benefit in the Joslin Agreement in exchange for the issuance of 15.4 million of our ordinary shares.

Pursuant to the Joslin Agreement and the related assignment from EKF, we obtained a worldwide, royalty- bearing, exclusive license under any patents and any related know-how of Joslin related to the patent application filed with respect to the use the TNFR1 and TNFR2 biomarkers for determining whether a patient has an increased risk of developing CKD or ESKD, or the Joslin IP, to make, have made, use, offer for sale and sell licensed products covered by claims in the Joslin IP, and to perform, practice offer for sale and sell certain licensed processes related to the Joslin IP. We are obligated to use commercially reasonable efforts in connection with the development and commercialization of the licensed products and licensed processes, including in accordance with a development plan.

Under the terms of the Joslin Agreement, we are obligated to pay Joslin aggregate commercial milestone payments of $0.3 million and $1.0 million in commercial milestone payments upon achieving worldwide net sales of licensed products and processes of $2.0 million and $10.0 million, respectively. We are also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, we are obligated to pay Joslin 25% of any consideration received by us from a sublicensee.

The Joslin Agreement initially expires on July 31, 2025, and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that we cease developing or commercializing licensed products or processes, if we fail to maintain certain required insurance policies, and if we fail to pay patent expenses related to the licensed patents.

Kantaro Biosciences LLC

In May 2020, we and Mount Sinai entered into the Kantaro Operating Agreement in order to form Kantaro, for the purpose of developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. In connection with the formation of Kantaro, we entered into an Advisory Agreement pursuant to which we have agreed to provide certain advisory services to Kantaro.

Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to us as the sole consideration for the services to be rendered by us under the Advisory Agreement. A portion of our units are subject to forfeiture if, prior to December 31, 2020, Kantaro terminates the Advisory Agreement as a result of our uncured material breach of the Advisory Agreement or in the event we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. We account for our investment in Kantaro using the equity method of accounting as we can exert significant influence over, but do not control, Kantaro.

In addition to the equity granted at formation, we and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $250,000 and an additional $500,000 thereafter. We committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per annum rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to us). The term of the Advisory Agreement will continue until the fifth anniversary of the execution thereof, unless earlier terminated. The Advisory Agreement may be terminated by either party upon an uncured material breach of the Advisory Agreement by the other party or in the event the other party is unable to perform under the Advisory Agreement for a specified period of time due to a force majeure event. Kantaro may also terminate the Advisory Agreement by notice to us if we are acquired by a hospital or health system that serves all or any portion of the service areas served by Mount Sinai. See “Item 5—Our key agreements—Kantaro Biosciences LLC” for additional information.

Convertible Bond Agreement

In April 2022, we issued amortizing senior convertible bonds with a principal amount $21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of $18.0 million and accrue interest at an annual rate of 5.5%, payable quarterly in arrears, in cash or ADSs valued at the ADS Settlement Price at the option of the Company. The Bonds contain various conversion and redemption features. The initial conversion price for the Convertible Bonds of $8.70 has been set at a 20 per cent. premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance and save in limited circumstances, the Bonds have a hard floor in the conversion price of $7.25. Between amortization dates, the Convertible Bond Investor retains the right to advance future amortization payments, provided that (a) there shall be no amortization advancements during the first 12 months, (b) no more than 2 amortization advancements may occur in any 12 month period, and (c) no more than 1 amortization advancement may occur in any 3 month period. The Convertible Bond Investor is also permitted to defer up to two amortization payments to a subsequent amortization date. The Company retains the option to repay any deferred amortization in cash at 100%. of the nominal amount As of June 30, 2022, the entire principal amount was outstanding.

D. Exchange Controls

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

E. Taxation

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

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

- banks, insurance companies, and certain other financial institutions;
- U.S. expatriates and certain former citizens or long-term residents of the United States;
- dealers or traders in securities who use a mark-to-market method of tax accounting;
- persons holding ordinary shares or ADSs as part of a hedging transaction, “straddle,” wash sale, conversion transaction or integrated transaction or persons entering into a constructive sale with respect to ordinary shares or ADSs;
- persons whose “functional currency” for U.S. federal income tax purposes is not the U.S. dollar;

- brokers, dealers or traders in securities, commodities or currencies;
- tax-exempt entities or government organizations;
- S corporations, partnerships, or other entities or arrangements classified as partnerships for U.S. federal income tax purposes (and investors therein);
- regulated investment companies or real estate investment trusts;
- persons who acquired our ordinary shares or ADSs pursuant to the exercise of any employee stock option or otherwise as compensation;
- persons that own or are deemed to own ten percent or more of our shares (by vote or value); and
- persons holding our ordinary shares or ADSs in connection with a trade or business, permanent establishment, or fixed base outside the United States.

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

U.S. Holders that own (directly, indirectly, or constructively through the application of attribution rules) 10% or more of our total combined voting power or value could be subject to adverse U.S. federal income tax consequences pursuant to the controlled foreign corporation rules due to our ownership of a U.S. subsidiary. Such prospective holders should consult with their tax advisors as to the tax consequences of acquiring, owning and disposing of our ADSs.

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

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

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

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

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

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

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

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

Passive Foreign Investment Company rules

If we are classified as a passive foreign investment company, or a PFIC in any taxable year, a U.S. Holder will be subject to special rules generally intended to reduce or eliminate any benefits from the deferral of U.S. federal income tax that a U.S. Holder could derive from investing in a non-U.S. company that does not distribute all of its earnings on a current basis.

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

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

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

Based on our 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. 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. U.S. Holders should consult with their tax advisors regarding the implications of owning stock in a PFIC. As a result, our PFIC status may change. In particular, the total value of our assets for purposes of the asset test generally will be calculated using the market price of the ordinary shares or ADSs, which may fluctuate considerably. Fluctuations in the market price of the ordinary shares or ADSs may result in our being a PFIC for any taxable year. Even if we determine that we are not a PFIC for a taxable year, there can be no assurance that the IRS will agree with our conclusion and that the IRS would not successfully challenge our position. Because of the uncertainties involved in establishing our PFIC status, our U.S. tax counsel expresses no opinion regarding our PFIC status.

If we are classified as a PFIC in any year with respect to which a U.S. Holder owns the ordinary shares or ADSs, we will continue to be treated as a PFIC with respect to such U.S. Holder in all succeeding years during which the U.S. Holder owns the ordinary shares or ADSs, regardless of whether we continue to meet the tests described above unless (i) we cease to be a PFIC and the U.S. Holder has made a "deemed sale" election under the PFIC rules, (ii) we cease to be a PFIC and the U.S. Holder has a valid mark to market election in effect (as described below) or (iii) the U.S. Holder makes a "qualified electing fund" election, or QEF Election, with respect to all taxable years during such U.S. Holder's holding period in which we are a PFIC.

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

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

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

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

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

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

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

Once the PFIC analysis is complete, the company will make a "PFIC Annual Information Statement" available in the future on its website for the 2022 tax year, and intends to make available to U.S. Holders, upon request and in accordance with applicable procedures and confidentiality requirements, a "PFIC Annual Information Statement" with respect to the Company for each future tax year in which it determines it is a PFIC. The "PFIC Annual Information Statement" may be used by U.S. Holders for purposes of complying with the reporting requirements applicable to a QEF election with respect to the company and any subsidiary PFIC.

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

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

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

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

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

Taxation of distributions

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

Sale or other taxable disposition of ordinary shares and ADSs

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

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

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

Information reporting and backup withholding

Payments of dividends and sales proceeds that are made within the United States or through certain U.S.-related financial intermediaries generally are subject to information reporting, and may be subject to backup withholding, unless (i) the U.S. Holder is a corporation or other exempt recipient or (ii) in the case of backup withholding, the U.S. Holder provides a correct taxpayer identification number and certifies that it is not subject to backup withholding.

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

Information with respect to foreign financial assets

Certain U.S. Holders who are individuals (and, under proposed regulations, certain entities) may be required to report information relating to the ordinary shares or ADSs, subject to certain exceptions (including an exception for ordinary shares or ADSs held in accounts maintained by certain U.S. financial institutions). Such U.S. Holders who fail to timely furnish the required information may be subject to a penalty. Additionally, if a U.S. Holder does not file the required information, the statute of limitations with respect to tax returns of the U.S Holder to which the information relates may not close until three years after such information is filed. U.S. Holders should consult their tax advisors regarding their reporting obligations with respect to their ownership and disposition of the ordinary shares or ADSs.

United Kingdom taxation

The following is intended as a general guide to current U.K. tax law and HM Revenue & Customs, or HMRC, practice applying as at the date of this annual report (both of which are subject to change at any time, possibly with retrospective effect) relating to the holding of ADSs. It does not constitute legal or tax advice and does not purport to be a complete analysis of all U.K. tax considerations relating to the holding of ADSs, or all of the circumstances in which holders of ADSs may benefit from an exemption or relief from U.K. taxation. It is written on the basis that the company does not (and will not) directly or indirectly derive 75% or more of its qualifying asset value from U.K. land, and that the company is and remains solely resident in the United Kingdom for tax purposes and will therefore be subject to the U.K. tax regime and not the U.S. tax regime save as set out in the above under "Material U.S. federal income tax considerations for U.S. Holders". Except to the extent that the position of non-U.K. resident persons is expressly referred to, this guide relates only to persons who are resident (and, in the case of individuals, domiciled or deemed domiciled and to whom split-year treatment does not apply) for tax purposes solely in the United Kingdom and do not have a permanent establishment, branch, agency (or equivalent) or fixed base in any other jurisdiction with which the holding of the ADSs is connected, or U.K. Holders, who are absolute beneficial owners of the ADSs (where the ADSs are not held through an Individual Savings Account or a Self-Invested Personal Pension) and who hold the ADSs as investments.

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

- persons who are connected with the company;
- financial institutions;
- insurance companies;
- charities or tax-exempt organizations;
- collective investment schemes;
- pension schemes;
- market makers, intermediaries, brokers or dealers in securities;

- persons who have (or are deemed to have) acquired their ADSs by virtue of an office or employment or who are or have been officers or employees of the company or any of its affiliates; and
- individuals who are subject to U.K. taxation on a remittance basis.

The decision of the First-tier Tribunal (Tax Chamber) in HSBC Holdings PLC and The Bank of New York Mellon Corporation v HMRC (2012) cast some doubt on whether a holder of a depositary receipt is the beneficial owner of the underlying shares. However, based on published HMRC guidance we would expect that HMRC will regard a holder of ADSs as holding the beneficial interest in the underlying shares and therefore these paragraphs assume that a holder of ADSs is the beneficial owner of the underlying ordinary shares and any dividends paid in respect of the underlying ordinary shares (where the dividends are regarded for U.K. purposes as that person's own income) for U.K. direct tax purposes.

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

U.K. taxation of dividends

Withholding tax

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

Income tax

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

All dividends received by an individual U.K. Holder from us or from other sources will form part of that U.K. Holder's total income for income tax purposes and will constitute the top slice of that income. A nil rate of income tax will apply to the first £2,000 of taxable dividend income received by the individual U.K. Holder in the current tax year. Income within the nil rate band will be taken into account in determining whether income in excess of the £2,000 tax-free allowance falls within the basic rate, higher rate or additional rate tax bands. Dividend income in excess of the tax-free allowance will (subject to the availability of any income tax personal allowance) be taxed at 8.75% to the extent that the excess amount falls within the basic rate tax band, 33.75% to the extent that the excess amount falls within the higher rate tax band and 39.35% to the extent that the excess amount falls within the additional rate tax band.

Corporation tax

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

Corporate U.K. Holders should not be subject to U.K. corporation tax on any dividend received from the company so long as the dividend qualifies for an exemption, which should be the case, although certain conditions must be met. It should be noted that the exemptions, while of wide application, are not comprehensive and are subject to anti-avoidance rules in relation to a dividend. If the conditions for the exemption are not satisfied or anti-avoidance provisions apply, or such U.K. Holder elects for an otherwise exempt dividend to be taxable, U.K. corporation tax will be chargeable on the amount of any dividends (at the current rate of 19%, but with the main rate; due to an increase to 25% with effect from April 1, 2023).

U.K. taxation of disposals

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

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

If a corporate U.K. Holder becomes liable to U.K. corporation tax on the disposal (or deemed disposal) of ADSs, the main rate of U.K. corporation tax (currently 19%; but due to increase to 25% with effect from April 1, 2023) would apply.

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

U.K. stamp duty and stamp duty reserve tax

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

Issue of ordinary shares

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

Transfers of ordinary shares

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

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

In the event that either of the above requirements is not met, stamp duty or SDRT will generally apply to transfers of, or agreements to transfer, ordinary shares. Where applicable, the purchaser normally pays the stamp duty or SDRT, other than where the transfer is to a clearance service or depositary receipt issuer (where in practice it will generally be paid by the transferors or participants).

Issue or transfers of ADRs

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

F. Dividends and Paying Agents

Not applicable.

G. Statement by Experts

Not applicable.

H. Documents on Display

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

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

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

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

I. Subsidiary Information

Not required.

Item 11. Quantitative and Qualitative Disclosures About Market Risk

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

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

We are exposed to market risk related to changes in interest rates. As of June 30, 2022, we had cash of $41.3 million, consisting of bank deposits and U.S. Treasury securities. Our primary exposure to market risk is interest rate sensitivity, which is affected by changes in the general level of U.S. interest rates, particularly because our investments are in marketable debt securities.

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

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

Item 12. Description of Securities Other Than Equity Securities

A. Debt Securities

Not applicable.

B. Warrants and Rights

Not applicable.

C. Other Securities

Not applicable.

D. American Depositary Shares

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

We have appointed Citibank as depositary pursuant to a deposit agreement. The form of the deposit agreement is on file with the SEC under cover of a registration statement on Form F-6. You may obtain a copy of the deposit agreement from the SEC's website (*www.sec.gov*). Please refer to registration number 333-239729 when retrieving such copy. The portions of this summary description that are italicized describes matters that may be relevant to the ownership of ADSs but that may not be contained in the deposit agreement.

We are providing you with a summary description of the material terms of the ADSs and of your material rights as an owner of ADSs. Please remember that summaries by their nature lack the precision of the information summarized and that the rights and obligations of an owner of ADSs has been determined by reference to the terms of the deposit agreement and not by this summary. We urge you to review the deposit agreement in its entirety.

Each ADS represents the right to receive, and to exercise the beneficial ownership interests in, two ordinary shares that are on deposit with the depositary or custodian. An ADS also represents the right to receive, and to exercise the beneficial interests in, any other property received by the depositary or the custodian on behalf of the owner of the ADS but that has not been distributed to the owners of ADSs because of legal restrictions or practical considerations. We and the depositary may agree to change the ADS-to-share ratio by amending the deposit agreement. This amendment may give rise to, or change, the depositary fees payable by ADS owners.

The custodian, the depositary and their respective nominees will hold all deposited property for the benefit of the holders and beneficial owners of ADSs. The deposited property does not constitute the proprietary assets of the depositary, the custodian or their nominees. Beneficial ownership in the deposited property will under the terms of the deposit agreement be vested in the beneficial owners of the ADSs. The depositary, the custodian and their respective nominees will be the record holders of the deposited property represented by the ADSs for the benefit of the holders and beneficial owners of the corresponding ADSs. A beneficial owner of ADSs may or may not be the holder of ADSs. Beneficial owners of ADSs will be able to receive, and to exercise beneficial ownership interests in, the deposited property only through the registered holders of the ADSs, the registered holders of the ADSs (on behalf of the applicable ADS owners) only through the depositary, and the depositary (on behalf of the owners of the corresponding ADSs) directly, or indirectly, through the custodian or their respective nominees, in each case upon the terms of the deposit agreement.

If you become an owner of ADSs, you will become a party to the deposit agreement and therefore will be bound to its terms and to the terms of any ADR that represents your ADSs. The deposit agreement and the ADR specify our rights and obligations as well as your rights and obligations as an owner of ADSs and those of the depositary. As an ADS holder you appoint the depositary to act on your behalf in certain circumstances. The deposit agreement and the ADRs and ADSs are governed by New York law. However, our obligations to the holders of ordinary shares will continue to be governed by the laws of England and Wales, which may be different from the laws in the United States.

In addition, applicable laws and regulations may require you to satisfy reporting requirements and obtain regulatory approvals in certain circumstances. You are solely responsible for complying with such reporting requirements and obtaining such approvals. None of the depositary, the custodian, us or any of their or our respective agents or affiliates shall be required to take any actions whatsoever on your behalf to satisfy such reporting requirements or obtain such regulatory approvals under applicable laws and regulations. You agree to comply with information requests from us pursuant to applicable laws, stock exchange rules and our articles of association. We may restrict transfers of ADSs and take other actions necessary to comply with any applicable ownership restrictions.

The manner in which you own the ADSs (e.g., in a brokerage account versus as a registered holder, or as a holder of certificated versus uncertificated ADSs) may affect your rights and obligations, and the manner in which, and extent to which, the depositary's services are made available to you.

As an owner of ADSs, we will not treat you as one of our shareholders and you will not have direct shareholder rights. The depositary will hold on your behalf the shareholder rights attached to the ordinary shares underlying your ADSs. As an owner of ADSs, you will be able to exercise the shareholders rights for the ordinary shares represented by your ADSs through the depositary only to the extent contemplated in the deposit agreement. To exercise any shareholder rights not contemplated in the deposit agreement you will, as an ADS owner, need to arrange for the cancellation of your ADSs and become a direct shareholder.

As an owner of ADSs, you may hold your ADSs either by means of an ADR registered in your name, through a brokerage or safekeeping account, or through an account established by the depositary in your name reflecting the registration of uncertificated ADSs directly on the books of the depositary (commonly referred to as the direct registration system or DRS). The direct registration system reflects the uncertificated (book-entry) registration of ownership of ADSs by the depositary. Under the direct registration system, ownership of ADSs is evidenced by periodic statements issued by the depositary to the holders of the ADSs. The direct registration system includes automated transfers between the depositary and The Depository Trust Company, or DTC, the central book-entry clearing and settlement system for equity securities in the United States. If you decide to hold your ADSs through your brokerage or safekeeping account, you must rely on the procedures of your broker or bank to assert your rights as ADS owner. Banks and brokers typically hold securities such as the ADSs through clearing and settlement systems such as DTC. The procedures of such clearing and settlement systems may limit your ability to exercise your rights as an owner of ADSs. Please consult with your broker or bank if you have any questions concerning these limitations and procedures. All ADSs held through DTC will be registered in the name of a nominee of DTC, which nominee will be the only "holder" of such ADSs for purposes of the deposit agreement and any applicable ADR. This summary description assumes you have opted to own the ADSs directly by means of an ADS registered in your name and, as such, we will refer to you as the "holder." When we refer to "you," we assume the reader owns ADSs and will own ADSs at the relevant time.

The registration of the ordinary shares in the name of the depositary or the custodian shall, to the maximum extent permitted by applicable law, vest in the depositary or the custodian the record ownership in the applicable ordinary shares with the beneficial ownership rights and interests in such ordinary shares being at all times vested with the beneficial owners of the ADSs representing the ordinary shares. The depositary or the custodian shall at all times be entitled to exercise the beneficial ownership rights in all deposited property, in each case only on behalf of the holders and beneficial owners of the ADSs representing the deposited property.

Dividends and Other Distributions

As a holder of ADSs, you generally have the right to receive the distributions we make on the securities deposited with the custodian. Your receipt of these distributions may be limited, however, by practical considerations and legal limitations. Holders of ADSs will receive such distributions under the terms of the deposit agreement in proportion to the number of ADSs held as of the specified record date, after deduction the applicable fees, taxes and expenses.

Distributions of Cash

Whenever we make a cash distribution for the securities on deposit with the custodian, we will deposit the funds with the custodian. Upon receipt of confirmation of the deposit of the requisite funds, the depositary will arrange for the funds received in a currency other than U.S. dollars to be converted into U.S. dollars and for the distribution of the U.S. dollars to the holders, subject to the laws and regulations of England and Wales. The conversion into U.S. dollars will take place only if practicable and if the U.S. dollars are transferable to the United States. The depositary will apply the same method for distributing the proceeds of the sale of any property (such as undistributed rights) held by the custodian in respect of securities on deposit.

The distribution of cash will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. The depositary will hold any cash amounts it is unable to distribute in a non-interest bearing account for the benefit of the applicable holders and beneficial owners of ADSs until the distribution can be effected or the funds that the depositary holds must be escheated as unclaimed property in accordance with the laws of the relevant states of the United States.

Distributions of Shares

Whenever we make a free distribution of ordinary shares for the securities on deposit with the custodian, we will deposit the applicable number of ordinary shares with the custodian. Upon receipt of confirmation of such deposit, the depositary will either distribute to holders new ADSs representing the ordinary shares deposited or modify the ADS-to-ordinary shares ratio, in which case each ADS you hold will represent rights and interests in the additional ordinary shares so deposited. Only whole new ADSs will be distributed. Fractional entitlements will be sold, and the proceeds of such sale will be distributed as in the case of a cash distribution.

The distribution of new ADSs or the modification of the ADS-to-ordinary shares ratio upon a distribution of ordinary shares will be made net of the fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes or governmental charges, the depositary may sell all or a portion of the new ordinary shares so distributed.

No such distribution of new ADSs will be made if it would violate a law (e.g., the U.S. securities laws) or if it is not operationally practicable. If the depositary does not distribute new ADSs as described above, it may sell the ordinary shares received upon the terms described in the deposit agreement and will distribute the proceeds of the sale as in the case of a distribution of cash.

Distributions of Rights

Whenever we intend to distribute rights to purchase additional ordinary shares, we will give prior notice to the depositary and we will assist the depositary in determining whether it is lawful and reasonably practicable to distribute rights to purchase additional ADSs to holders.

The depositary will establish procedures to distribute rights to purchase additional ADSs to holders and to enable such holders to exercise such rights we shall have timely requested such rights by made available to shareholders of ADSs, if it is lawful and reasonably practicable to make the rights available to holders of ADSs, and if we provide all of the documentation contemplated in the deposit agreement (such as opinions to address the lawfulness of the transaction). You may have to pay fees, expenses, taxes and other governmental charges to subscribe for the new ADSs upon the exercise of your rights. The depositary is not obligated to establish procedures to facilitate the distribution and exercise by holders of rights to purchase new ordinary shares other represented by ADSs.

The depositary will not distribute the rights to you if:

- we do not timely request that the rights be distributed to you or we request that the rights not be distributed to you;
- we fail to deliver satisfactory documents to the depositary; or
- it is not reasonably practicable to distribute the rights.

The depositary will sell the rights that are not exercised or not distributed if such sale is lawful and reasonably practicable. The proceeds of such sale will be distributed to holders as in the case of a cash distribution. If the depositary is unable to sell the rights, it will allow the rights to lapse.

Elective Distributions

Whenever we intend to distribute a dividend payable at the election of shareholders either in cash or in additional shares, we will give prior notice thereof to the depositary and will indicate whether we wish the elective distribution to be made available to you. In such case, we will assist the depositary in determining whether such distribution is lawful and reasonably practicable.

The depositary will make the election available to you only if it is reasonably practicable and if we have provided all of the documentation contemplated in the deposit agreement. In such case, the depositary will establish procedures to enable you to elect to receive either cash or additional ADSs, in each case as described in the deposit agreement.

If the election is not made available to you, you will receive either cash or additional ADSs, depending on what a shareholder in England and Wales would receive upon failing to make an election, as more fully described in the deposit agreement.

Other Distributions

Whenever we intend to distribute property other than cash, ordinary shares or rights to purchase additional ordinary shares, we will notify the depositary in advance and will indicate whether we wish such distribution to be made to you. If so, we will assist the depositary in determining whether such distribution to holders is lawful and reasonably practicable.

If it is reasonably practicable to distribute such property to you and if we provide all of the documentation contemplated in the deposit agreement, the depositary will distribute the property to the holders in a manner it deems practicable.

The distribution will be made net of fees, expenses, taxes and governmental charges payable by holders under the terms of the deposit agreement. In order to pay such taxes and governmental charges, the depositary may sell all or a portion of the property received.

The depositary will *not* distribute the property to you and will sell the property if:

- we do not request that the property be distributed to you or if we ask that the property not be distributed to you;
- we do not deliver satisfactory documents to the depositary; or
- the depositary determines that all or a portion of the distribution to you is not reasonably practicable.

The proceeds of such a sale will be distributed to holders as in the case of a cash distribution.

Redemption

Whenever we decide to redeem any of the securities on deposit with the custodian, we will notify the depositary in advance. If it is practicable and if we provide all of the documentation contemplated in the deposit agreement, the depositary will provide notice of the redemption to the holders.

The custodian will be instructed to surrender the shares being redeemed against payment of the applicable redemption price. The depositary will convert the redemption funds received into U.S. dollars upon the terms of the deposit agreement and will establish procedures to enable holders to receive the net proceeds from the redemption upon surrender of their ADSs to the depositary. You may have to pay fees, expenses, taxes and other governmental charges upon the redemption of your ADSs. If less than all ADSs are being redeemed, the ADSs to be retired will be selected by lot or on a pro rata basis, as the depositary may determine.

Changes Affecting Ordinary Shares

The ordinary shares held on deposit for your ADSs may change from time to time. For example, there may be a change in nominal value, sub-division, cancellation, consolidation or any other reclassification of such ordinary shares or a recapitalization, reorganization, merger, consolidation or sale of assets of our company.

If any such change were to occur, your ADSs would, to the extent permitted by law and the deposit agreement, represent the right to receive the property received or exchanged in respect of the ordinary shares held on deposit. The depositary may in such circumstances deliver new ADSs to you, amend the deposit agreement, the ADRs and the applicable registration statement(s) on Form F-6, call for the exchange of your existing ADSs for new ADSs and take any other actions that are appropriate to reflect as to the ADSs the change affecting the ordinary shares. If the depositary may not lawfully distribute such property to you, the depositary may sell such property and distribute the net proceeds to you as in the case of a cash distribution.

Issuance of ADSs Upon Deposit of Ordinary Shares

Any ordinary shares being offered pursuant to this prospectus will be deposited by us with the custodian. Upon receipt of confirmation of such deposit, the depositary will issue ADSs pursuant to our instruction.

The depositary may create ADSs on your behalf if you or your broker deposit ordinary shares with the custodian. The depositary will deliver these ADSs to the person you indicate only after you pay any applicable issuance fees and any charges and taxes payable for the transfer of the ordinary shares to the custodian and provide such documentation as may be required pursuant to the deposit agreement. Your ability to deposit ordinary shares and receive ADSs may be limited by the legal considerations under the laws of the United States and England and Wales applicable at the time of deposit.

The issuance of ADSs may be delayed until the depositary or the custodian receives confirmation that all required approvals have been given and that the ordinary shares have been duly transferred to the custodian. The depositary will only issue ADSs in whole numbers.

When you make a deposit of ordinary shares, you will be responsible for transferring good and valid title to the depositary. As such, you will be deemed to represent and warrant that:

- the ordinary shares are duly authorized, validly allotted and issued, fully paid, not subject to any call for the payment of further capital and legally obtained;
- all preemptive (and similar) rights, if any, with respect to such ordinary shares have been validly waived, disapplied or exercised;
- you are duly authorized to deposit the ordinary shares;
- the ordinary shares presented for deposit are free and clear of any lien, encumbrance, security interest, charge, mortgage or adverse claim, and are not, and the ADSs issuable upon such deposit will not be, "restricted securities" (as defined in the deposit agreement);
- the ordinary shares presented for deposit have not been stripped of any rights or entitlements; and
- the deposit of the ordinary shares does not violate any applicable provision of English law.
- If any of the representations or warranties are incorrect in any way, we and the depositary may, at your cost and expense, take any and all actions necessary to correct the consequences of the misrepresentations.

Transfer, Combination and Split Up of ADRs

As an ADR holder, you will be entitled to transfer, combine or split up your ADRs and the ADSs evidenced thereby. For transfers of ADRs, you will have to surrender the ADRs to be transferred to the depositary and also must:

- ensure that the surrendered ADR is properly endorsed or otherwise in proper form for transfer;
- provide such proof of identity and genuineness of signatures, and of such other matters contemplated in the deposit agreement, as the depositary deems appropriate;
- comply with applicable laws and regulations, including regulations imposed by us and the depositary consistent with the deposit agreement, the ADR and applicable law;
- provide any transfer stamps required by the State of New York or the United States; and
- pay all applicable fees, charges, expenses, taxes and other government charges payable by ADR holders pursuant to the terms of the deposit agreement, upon the transfer of ADRs.

To have your ADRs either combined or split up, you must surrender the ADRs in question to the depositary with your request to have them combined or split up, and you must pay all applicable fees, charges and expenses payable by ADR holders, pursuant to the terms of the deposit agreement, upon a combination or split up of ADRs.

Withdrawal of Ordinary Shares Upon Cancellation of ADSs

As a holder of ADSs, you will be entitled to present your ADSs to the depositary for cancellation and then receive the corresponding number of underlying ordinary shares at the custodian's offices. Your ability to withdraw the ordinary shares held in respect of the ADSs may be limited by legal considerations under the laws of the United States and England and Wales applicable at the time of withdrawal. In order to withdraw the ordinary shares represented by your ADSs, you will be required to pay to the depositary the fees for cancellation of ADSs and any charges and taxes payable upon the transfer of the ordinary shares. You assume the risk for delivery of all funds and securities upon withdrawal. Once canceled, the ADSs will not have any rights under the deposit agreement.

If you hold ADSs registered in your name, the depositary may ask you to provide proof of identity and genuineness of any signature and such other documents as the depositary may deem appropriate before it will cancel your ADSs. The withdrawal of the ordinary shares represented by your ADSs may be delayed until the depositary receives satisfactory evidence of compliance with all applicable laws and regulations. Please keep in mind that the depositary will only accept ADSs for cancellation that represent a whole number of securities on deposit.

You will have the right to withdraw the securities represented by your ADSs at any time except as a result of:

- temporary delays that may arise because (i) the transfer books for the ordinary shares or ADSs are closed, or (ii) ordinary shares are immobilized on account of a shareholders' meeting or a payment of dividends;
- obligations to pay fees, taxes and similar charges; or
- restrictions imposed because of laws or regulations applicable to ADSs or the withdrawal of securities on deposit.

The deposit agreement may not be modified to impair your right to withdraw the securities represented by your ADSs except to comply with mandatory provisions of law.

Voting Rights

As a holder, you generally have the right under the deposit agreement to instruct the depositary to exercise the voting rights for the ordinary shares represented by your ADSs. The voting rights of holders of ordinary shares are described in the section titled "Description of Share Capital—Articles of Association" in this prospectus.

At our request, the depositary will distribute to you any notice of shareholders' meeting received from us together with information explaining how to instruct the depositary to exercise the voting rights of the securities represented by ADSs. In lieu of distributing such materials, the depositary bank may distribute to holders of ADSs instructions on how to retrieve such materials upon request.

If the depositary timely receives voting instructions from a holder of ADSs, it will endeavor to vote the securities (in person or by proxy) represented by the holder's ADSs.

Securities for which no voting instructions have been received will not be voted (except as otherwise contemplated herein). If voting is by poll and the depositary does not receive timely voting instructions from a holder of ADSs, such holder shall be deemed to have instructed the depositary to give a discretionary proxy to a person designated by us to vote the deposited securities represented by such ADSs in any manner such person wishes, which may not be in your best interests; provided, however, that no such discretionary proxy shall be given with respect to any matter to be voted upon as to which we inform the depositary that (a) we do not wish such proxy to be given, (b) substantial opposition exists, or (c) the rights of holders of deposited securities may be adversely affected. Please note that the ability of the depositary to carry out voting instructions may be limited by practical and legal limitations and the terms of the securities on deposit. We cannot assure you that you will receive voting materials in time to enable you to return voting instructions to the depositary in a timely manner.

Fees and Charges

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

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

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

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

ADS fees and charges payable upon (i) the issuance of ADSs, and (ii) the cancellation of ADSs are charged to the person to whom the ADSs are issued (in the case of ADS issuances) and to the person whose ADSs are cancelled (in the case of ADS cancellations). In the case of ADSs issued by the depositary into DTC, the ADS issuance and cancellation fees and charges may be deducted from distributions made through DTC, and may be charged to the DTC participant(s) receiving the ADSs being issued or the DTC participant(s) holding the ADSs being cancelled, as the case may be, on behalf of the beneficial owner(s) and will be charged by the DTC participant(s) to the account of

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

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

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

Amendments and Termination

We may agree with the depositary to modify the deposit agreement at any time without your consent. We undertake to give holders of ADSs 30 days' prior notice of any modifications that would materially prejudice any of their substantial rights under the deposit agreement. We will not consider to be materially prejudicial to your substantial rights any modifications or supplements that are reasonably necessary for the ADSs to be registered under the Securities Act or to be eligible for book-entry settlement, in each case without imposing or increasing the fees and charges you are required to pay. In addition, we may not be able to provide you with prior notice of any modifications or supplements that are required to accommodate compliance with applicable provisions of law.

You will be bound by the modifications to the deposit agreement if you continue to hold your ADSs after the modifications to the deposit agreement become effective. The deposit agreement cannot be amended to prevent you from withdrawing the ordinary shares represented by your ADSs (except as permitted by law).

We have the right to direct the depositary to terminate the deposit agreement subject to certain conditions. Similarly, the depositary may in certain circumstances on its own initiative terminate the deposit agreement. In either case, the depositary must give notice to the holders at least 30 days before termination. Until termination, your rights under the deposit agreement will be unaffected.

After termination, the depositary will continue to collect distributions received (but will not distribute any such property until you request the cancellation of your ADSs) and may sell the securities held on deposit. After the sale, the depositary will hold the proceeds from such sale and any other funds then held for the holders of ADSs in a non-interest bearing account. At that point, the depositary will have no further obligations to ADS holders other than to account for the funds then held for the holders of ADSs still outstanding (after deduction of applicable fees, taxes and expenses).

In connection with the termination of the deposit agreement, the depositary may, but shall not be obligated to, independently and without the need for any action by us, make available to holders of ADSs a means to withdraw the ordinary shares and other deposited securities represented by their ADSs and to direct the deposit of such ordinary shares and other deposited securities into an unsponsored American Depositary Shares program established by the depositary, upon such terms and conditions as the depositary may deem reasonably appropriate, subject however, in each case, to satisfaction of the applicable registration requirements by the unsponsored American Depositary Shares program under the Securities Act, and to receipt by the depositary of payment of the applicable fees and charges of, and reimbursement of the applicable expenses incurred by, the depositary.

Books of Depositary

The depositary maintains ADS holder records at its depositary office. You may inspect such records at such office during regular business hours but solely for the purpose of communicating with other holders in the interest of business matters relating to the ADSs and the deposit agreement. The depositary maintains in New York facilities to record and process the issuance, cancellation, combination, split-up and transfer of ADSs. These facilities may be closed from time to time, to the extent not prohibited by law.

Transmission of Notices, Reports and Proxy Soliciting Material

The depositary will make available for your inspection at its office all communications that it receives from us as a holder of deposited securities that we make generally available to holders of deposited securities. Subject to the terms of the deposit agreement, the depositary will send you copies of those communications or otherwise make those communications available to you if we ask it to.

Limitations on Obligations and Liabilities

The deposit agreement limits our obligations and the depositary's obligations to you. Please note the following:

- We and the depositary are obligated only to take the actions specifically stated in the deposit agreement without negligence or bad faith.
- The depositary disclaims any liability for any failure to carry out voting instructions, for any manner in which a vote is cast or for the effect of any vote, provided it acts in good faith and without negligence and in accordance with the terms of the deposit agreement.
- The depositary disclaims any liability for any failure to accurately determine the lawfulness or practicality of any action, for the content of any document forwarded to you on our behalf or for the accuracy of any translation of such a document, for the investment risks associated with investing in ordinary shares, for the validity or worth of the ordinary shares, for any tax consequences that result from the ownership of ADSs or other deposited property, for the credit-worthiness of any third party, for allowing any rights to lapse under the terms of the deposit agreement, for the timeliness of any of our notices or for our failure to give notice or for any act or omission of or information provided by DTC or any DTC participant.
- The depositary shall not be liable for acts or omissions of any successor depositary in connection with any matter arising wholly after the resignation or removal of the depositary.
- We and the depositary will not be obligated to perform any act that is inconsistent with the terms of the deposit agreement.
- We and the depositary disclaim any liability if we or the depositary are prevented or forbidden from or subject to any civil or criminal penalty or restraint on account of, or delayed in, doing or performing any act or thing required by the terms of the deposit agreement, by reason of any provision, present or future of any law or regulation, including regulations of any stock exchange or by reason of present or future provisions of our articles of association, or any provision of or governing the securities on deposit, or by reason of any act of God or war or other circumstances beyond our or the depositary's control.
- We and the depositary disclaim any liability by reason of any exercise of, or failure to exercise, any discretion provided for in the deposit agreement or in our articles of association or in any provisions of or governing the securities on deposit.
- We and the depositary further disclaim any liability for any action or inaction in reliance on the advice or information received from legal counsel, accountants, any person presenting ordinary shares for deposit, any holder of ADSs or authorized representatives thereof, or any other person believed by either of us in good faith to be competent to give such advice or information.
- We and the depositary also disclaim liability for the inability by any ADS holder or beneficiary owner to benefit from any distribution, offering, right or other benefit that is made available to holders of ordinary shares but is not, under the terms of the deposit agreement, made available to you.
- We and the depositary may rely without any liability upon any written notice, request or other document believed to be genuine and to have been signed or presented by the proper parties.

- We and the depositary also disclaim liability for any consequential or punitive damages for any breach of the terms of the deposit agreement.
- We and the depositary disclaim liability arising out of losses, liabilities, taxes, charges or expenses resulting from the manner in which a holder or beneficial owner of ADSs holds ADSs, including resulting from holding ADSs through a brokerage account.
- No disclaimer of any Securities Act liability is intended by any provision of the deposit agreement.

Nothing in the deposit agreement gives rise to a partnership or joint venture, or establishes a fiduciary relationship, among us, the depositary bank and you as ADS holder.

Nothing in the deposit agreement precludes Citibank (or its affiliates) from engaging in transactions in which parties adverse to us or the ADS owners have interests, and nothing in the deposit agreement obligates Citibank to disclose those transactions, or any information obtained in the course of those transactions, to us or to the ADS owners, or to account for any payment received as part of those transactions.

As the above limitations relate to our obligations and the depositary's obligations to you under the deposit agreement, we believe that, as a matter of construction of the clause, such limitations would likely to continue to apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred under the deposit agreement before the cancellation of the ADSs and the withdrawal of the ordinary shares, and such limitations would most likely not apply to ADS holders who withdraw the ordinary shares from the ADS facility with respect to obligations or liabilities incurred after the cancellation of the ADSs and the withdrawal of the ordinary shares and not under the deposit agreement.

In any event, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder. In fact, you cannot waive our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

Taxes

As a Holder or Beneficial Owner of ADSs, you will be responsible for the taxes and other governmental charges payable on the ADSs and the securities represented by the ADSs as provided for in the deposit agreement. We, the depositary and the custodian may deduct from any distribution the taxes and governmental charges payable by Holders and Beneficial Owners (as defined in the deposit agreement) of ADSs and may sell any and all property on deposit to pay the taxes and governmental charges payable by ADS holders. As a Holder or Beneficial Owner of ADSs, you will be liable for any deficiency if the sale proceeds do not cover the taxes that are due.

The depositary may refuse to issue ADSs, to deliver, transfer, split and combine ADRs or to release securities on deposit until all taxes and charges are paid by the applicable Holder or Beneficial Owner (as defined in the deposit agreement) of ADSs. The depositary and the custodian may take reasonable administrative actions to obtain tax refunds and reduced tax withholding for any distributions on your behalf. However, you may be required to provide to the depositary and to the custodian proof of taxpayer status and residence and such other information as the depositary and the custodian may require to fulfill legal obligations. You are required to indemnify us, the depositary and the custodian for any claims with respect to taxes based on any tax benefit obtained for you.

Foreign Currency Conversion

The depositary will arrange for the conversion of all foreign currency received into U.S. dollars if such conversion is practical, and it will distribute the U.S. dollars in accordance with the terms of the deposit agreement. You may have to pay fees and expenses incurred in converting foreign currency, such as fees and expenses incurred in complying with currency exchange controls and other governmental requirements.

If the conversion of foreign currency is not practical or lawful, or if any required approvals are denied or not obtainable at a reasonable cost or within a reasonable period, the depositary may take any of the following actions in its discretion:

- Convert the foreign currency to the extent practical and lawful and distribute the U.S. dollars to the ADS holders for whom the conversion and distribution is lawful and practical.

- Distribute the foreign currency to ADS holders for whom the distribution is lawful and practical.
- Hold the foreign currency (without liability for interest) for the applicable ADS holders.

Governing Law/Waiver of Jury Trial

The deposit agreement and the ADRs and ADSs will be interpreted in accordance with the laws of the State of New York. The rights of holders of ordinary shares (including ordinary shares represented by ADSs) are governed by the laws of England and Wales.

AS A PARTY TO THE DEPOSIT AGREEMENT, YOU WAIVE IRREVOCABLY, TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, YOUR RIGHT TO TRIAL BY JURY IN ANY LEGAL PROCEEDING ARISING OUT OF THE DEPOSIT AGREEMENT OR THE ADSs AGAINST US AND/OR THE DEPOSITARY.

The deposit agreement provides that, to the extent permitted by law, ADS holders waive the right to a jury trial of any claim they may have against us or the depositary arising out of or relating to our ordinary shares, the ADSs or the deposit agreement, including any claim under U.S. federal securities laws. If we or the depositary opposed a jury trial demand based on the waiver, the court would determine whether the waiver was enforceable based on the facts and circumstances of that case in accordance with applicable case law. However, you will not be deemed, by agreeing to the terms of the deposit agreement, to have waived our or the depositary's compliance with U.S. federal securities laws and the rules and regulations promulgated thereunder.

PART II

Item 13. Defaults, Dividend Arrearages and Delinquencies

Not applicable.

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

A. Not applicable.

B. Not applicable.

C. Not applicable.

D. Not applicable.

E. Use of Proceeds

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

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

Item 15. Controls and Procedures

A. Disclosure Controls and Procedures

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

Our principal executive officer and principal financial officer, after evaluating the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Exchange Act) as of June 30, 2022, have concluded that, as of such date, our disclosure controls and procedures were not effective because of the material weaknesses described further below. Notwithstanding the material weaknesses described below, our management has concluded that our consolidated financial statements included in this Annual Report are fairly stated in all material respects in accordance with US GAAP.

Material Weaknesses

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 the 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. To address these material weaknesses, management implemented a remediation plan as described below.

Remediation Plan

During the year ended June 30, 2022, we began 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 also implemented controls to review the service organization control report as well as review information within the service provider's system to ensure that the stock option data is appropriately recorded in our financial statements. These efforts ensure that our financial records are managed appropriately but also help ensure that the appropriate level of review is performed.

While new controls are being designed and implemented, they have not operated for a sufficient period of time to demonstrate that the material weaknesses have been remediated. The material weakness will be considered remediated when management concludes that, through testing, the applicable remediated controls are designed, implemented and operating effectively. We expect the procedures planned for remediation to be completed during the year ended June 30, 2023. The implementation of these measures, however, may not fully address the material weaknesses identified in our internal control over financial reporting, and we may not be able to conclude that it has been fully remedied by that time.

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

Management of the Company is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Exchange Act Rule 13a-15(f). Management assessed the effectiveness of internal control over financial reporting as of June 30, 2022 based on the framework in "Internal Control—Integrated Framework" (2013 framework) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on that assessment, and the material weakness identified, management has concluded that, as June 30, 2022, the Company's internal control over financial reporting was not effective to provide reasonable assurance regarding the reliability of its financial reporting and the preparation of its financial statements for external purposes, in accordance with generally accepted accounting principles. Due to its inherent limitations, internal control over financial reporting may not prevent or detect misstatements and can only provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. Notwihstanding the material weaknesses described above, our management has concluded that our consolidated financial statements included in this Annual Report are fairly stated in all material respects in accordance with US GAAP.

C. Attestation Report of the Registered Public Accounting Firm

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

D. Changes in Internal Control Over Financial Reporting

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 as described in Item 15A above.

Item 16A. Audit Committee Financial Expert

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

Item 16B. Code of Ethics

Our Code of Business Conduct and Ethics is applicable to all of our employees, officers and directors and is available on our website at *www.renalytix.com*. We expect that any amendment to this code, or any waivers of its requirements, will be disclosed on our website. Information contained on, or that can be accessed through, our

website is not incorporated by reference into this annual report, and you should not consider information on our website to be part of this annual report.

Item 16C. Principal Accountant Fees and Services

Our consolidated financial statements have been prepared in accordance with U.S. GAAP and are audited by Ernst & Young LLP, an independent registered public accounting firm registered with the Public Accounting Oversight Board in the United States.

The following table shows the aggregate fees billed to us for professional services for the fiscal years ended June 30, 2022 and 2021:

	Year Ended June 30,	
(in thousands)	2022	2021
Audit Fees.	$ 876	$ 681
Audit-Related Fees.	—	—
Tax Fees.	—	—
Other Fees.	—	—
Total.	$ 876	$ 681

"Audit Fees" are the aggregate fees billed for the audit of our annual financial statements. This category also includes services that the independent registered public accounting firm provides, such as consents and assistance with and review of documents filed with the SEC.

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

"Tax Fees" are the aggregate fees billed for professional services rendered by the independent registered public accounting firm for tax compliance, tax advice and tax planning related services.

"Other Fees" are any additional amounts billed for products and services provided by the independent registered public accounting firm.

There were no "Tax Fees" or "Other Fees" billed or paid during the fiscal years ended June 30, 2022 or 2021.

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

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

The Company's audit committee currently has a vacancy due to Ms. Berman's resignation from our board, effective September 20, 2022. Out board intends to fill such vacancy as soon as it identifies a suitable candidate. In accordance with Nasdaq requirements, the vacancy will be filled by the earlier of the next annual meeting or March 19, 2023.

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

Not applicable.

Item 16F. Change in Registrant's Certifying Accountant

On May 12, 2021, the Company dismissed Deloitte & Touche LLP, or Deloitte, as our independent registered public accounting firm and appointed Ernst & Young LLP, or EY, as successor auditor effective May 12, 2021 and for the fiscal year ended June 30, 2021. The audit report of Deloitte on the financial statements of the Company as of and for the fiscal years ended June 30, 2020 and 2019 did not contain any adverse opinion or disclaimer of opinion, nor was it qualified or modified as to uncertainty, audit scope or accounting principles. The dismissal of Deloitte and the appointment of EY have been considered and approved by the Company's audit committee and board of directors. During the fiscal years ended June 30, 2020 and 2019, and during the period of July 1, 2020 through the date of dismissal, there were no disagreements with Deloitte on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedures that, if not resolved to Deloitte's satisfaction, would have caused Deloitte to make reference in connection with its opinion to the subject matter of the disagreement. No "reportable events", as that term is described in Item 16F(a)(1)(v)(A)-(D) of Form 20-F, occurred within the fiscal years ended June 30, 2020 and 2019 and subsequently up to the date of dismissal.

During the Company's most recent two fiscal years and through the subsequent interim period on or prior to the appointment of the Successor Auditor, Ernst & Young LLP, neither the Company nor anyone on its behalf has consulted with the Successor Auditor on either (a) the application of accounting principles to a specified transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Company's financial statements, or (b) any matter that was the subject of a disagreement, as that term is defined in Item 16F(a)(1)(iv) of Form 20-F (and the related instructions thereto) or a reportable event as set forth in Item 16F(a)(1)(v)(A) through (D) of Form 20-F.

We provided a copy of this disclosure to Deloitte and requested that Deloitte furnish us with a letter addressed to the SEC stating whether it agrees with the above statements, and if not, stating the respects in which it does not agree. A copy of the letter from Deloitte addressed to the SEC, dated June 10, 2021, was filed as Exhibit 16.1 to the Report on Form 6-K filed with the SEC on June 10, 2021.

Item 16G. Corporate Governance

As a "foreign private issuer," as defined by the SEC, although we are permitted to follow certain corporate governance practices of England and Wales, instead of those otherwise required under The Nasdaq Stock Market, or Nasdaq, for domestic issuers, we intend to follow the Nasdaq corporate governance rules applicable to foreign private issuers. While we expect to voluntarily follow most Nasdaq corporate governance rules, we may choose to take advantage of the following limited exemptions:

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

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

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

Item 16H. Mine Safety Disclosure

Not applicable.

Item 16I. Disclosure Regarding Foreign Jurisdiction that Prevent Inspections

Not applicable.

PART III

Item 17. Financial Statements

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

Item 18. Financial Statements

See pages F-1 through F-29 of this annual report.

Item 19. Exhibits

Exhibit	Description	Incorporation by Reference			
		Schedule/ Form	File Number	Exhibit	File Date
3.1	Articles of Association	F-1	333-239414	3.1	06/24/2020
4.1	Form of Deposit Agreement	F-1/A	333-239414	4.1	07/13/2020
4.2	Form of American Depositary Receipt (included in Exhibit 4.1)	F-1/A	333-239414	4.1	7/13/2020
4.3	Description of Securities	20-F	001-39387	4.3	10/28/2020
10.1+	Renalytix plc Share Option Plan for Employees with Non-Employee Sub-Plan and U.S. Sub-Plan	F-1	333-239414	10.1	06/24/2020
10.2†#	Exclusive License and Collaboration Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of May 30, 2018, as amended to date	F-1	333-239414	10.2	06/24/2020
10.3†#	License Agreement, by and between the registrant and Joslin Diabetes Center, Inc., as assigned to the registrant on October 23, 2018, as amended to date	F-1	333-239414	10.3	06/24/2020
10.4#	Kantaro Biosciences LLC Operating Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of May 4, 2020	F-1	333-239414	10.4	06/24/2020
10.5†#	Advisory Services Agreement, by and between the registrant and Kantaro Biosciences LLC, dated as of May 4, 2020	F-1	333-239414	10.5	06/24/2020
10.6+	2020 Equity Incentive Plan with Non-Employee Sub-Plan and forms of grant notices and agreements thereunder	F-1	333-239414	10.6	06/24/2020
10.7+	2020 Employee Share Purchase Plan	F-1	333-239414	10.7	06/24/2020
10.8+	Form of Amended Deed of Indemnity between registrant and each of its directors	F-1	333-239414	10.8	6/24/2020
10.9+	Form of Deed of Indemnity between registrant and each of its executive officers	F-1	333-239414	10.9	06/24/2020
10.10	Registration Rights Agreement, by and between the registrant and Icahn School of Medicine at Mount Sinai, dated as of June 24, 2020	F-1	333-239414	10.10	6/24/2020
10.11*	Amended and Restated Bond Agreement between registrant and CVI Investments, dated as of April 5, 2022				
12.1*	Certification by the Principal Executive Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002				

12.2*	Certification by the Principal Financial Officer pursuant to Securities Exchange Act Rules 13a-14(a) and 15d-14(a) as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
13.1**	Certification by the Principal Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
15.1*	Consent of Ernst & Young LLP, independent registered public accounting firm (PCAOB ID No. 42)
15.2*	Consent of Deloitte & Touche LLP, independent registered public accounting firm (PCAOB ID No. 34)
21.1*	Subsidiaries of the registrant
101.INS	XBRL Instance Document
101.SCH	XBRL Taxonomy Extension Schema Document
101.CAL	XBRL Taxonomy Extension Calculation Linkbase
101.DEF	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	XBRL Taxonomy Extension Label Linkbase Document
101.PRE	XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover page Interactive Data File (formatted as inline XBRL and contained in Exhibit 101)

* Filed herewith.
** Furnished herewith.
+ Indicates a management contract or any compensatory plan, contract or arrangement.
† Certain portions of this exhibit will be omitted because they are not material and would likely cause competitive harm to the registrant if disclosed.
# Certain exhibits and schedules have been omitted pursuant to Item 601(a)(5) of Regulation S-K. The registrant hereby undertakes to furnish supplementally a copy of any omitted exhibit or schedule upon request by the Securities and Exchange Commission.

SIGNATURES

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

RENALYTIX PLC

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

Date: October 31, 2022

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

Report of Independent Registered Public Accounting Firm

To the Shareholders and Board of Directors of Renalytix plc

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Renalytix plc (the Company) as of June 30, 2022 and 2021, the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the two years in the period ended June 30, 2022, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company at June 30, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended June 30, 2022, in conformity with U.S. generally accepted accounting principles.

Basis for Opinion

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

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

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

/s/ Ernst & Young LLP

We have served as the Company's auditor since 2021.
Iselin, New Jersey
October 31, 2022

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Financial Statements

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

Basis for Opinion

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

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

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

/s/ Deloitte & Touche LLP

Parsippany, New Jersey

October 27, 2020

We began serving as the Company's auditor in 2020. In 2021 we became the predecessor auditor.

RENALYTIX PLC

CONSOLIDATED BALANCE SHEETS

(in thousands, except share and per share data)	June 30, 2022	June 30, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 41,333	$ 65,128
Accounts receivable	901	594
Prepaid expenses and other current assets	2,445	993
Note receivable from Kantaro	75	75
Receivable from affiliates	—	1
Total current assets	44,754	66,791
Property and equipment, net	2,558	2,490
Investment in VericiDx	2,744	9,295
Investment in Kantaro	9	—
Total assets	$ 50,065	$ 78,576
Liabilities and Shareholders' Equity		
Current liabilities:		
Accounts payable	$ 1,376	$ 1,403
Accounts payable – related party	1,083	361
Accrued expenses and other current liabilities	3,060	4,602
Accrued expenses – related party	1,496	224
Deferred revenue	46	122
Convertible notes-current	4,660	—
Payable to affiliate – current	55	350
Total current liabilities	11,776	7,062
Convertible notes-noncurrent	7,682	—
Other liabilities	—	53
Total liabilities	19,458	7,115
Commitments and contingencies (Note 8)		
Shareholders' equity:		
Ordinary shares, £0.0025 par value per share: 79,315,333 shares authorized; 74,760,432 and 72,197,286 shares issued and outstanding at June 30, 2022 and June 30, 2021, respectively	228	220
Additional paid-in capital	164,012	150,407
Accumulated other comprehensive income	(915)	8,276
Accumulated deficit	(132,718)	(87,442)
Total shareholders' equity	30,607	71,461
Total liabilities and shareholders' equity	$ 50,065	$ 78,576

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(in thousands, except share data)	Twelve Months Ended June 30, 2022	Twelve Months Ended June 30, 2021	Twelve Months Ended June 30, 2020
Revenue	$ 2,970	$ 1,491	$ —
Cost of revenue	2,096	858	—
Gross profit	874	633	—
Operating expenses:			
Research and development	14,648	10,040	4,565
General and administrative	39,524	23,479	5,750
Performance of contract liability to affiliate	(115)	(970)	—
Total operating expenses	54,057	32,549	10,315
Loss from operations	(53,183)	(31,916)	(10,315)
Equity in net (losses) earnings of affiliate	9	(2,112)	(63)
Foreign currency gain (loss), net	9,694	(8,772)	245
Fair value adjustment to VericiDx investment	(5,900)	6,483	—
Fair value adjustment to convertible notes	3,998	—	—
Other income, net	131	981	289
Net loss before income taxes	(45,251)	(35,336)	(9,844)
Income tax expense	(25)	—	—
Net loss	(45,276)	(35,336)	(9,844)
Net loss attributable to noncontrolling interest	—	(611)	—
Net loss attributable to ordinary shareholders	(45,276)	(34,725)	(9,844)
Net loss per ordinary share—basic	$ (0.62)	$ (0.49)	$ (0.17)
Net loss per ordinary share—diluted	$ (0.67)	$ (0.49)	$ (0.17)
Weighted average ordinary shares—basic	72,861,448	71,484,934	59,079,522
Weighted average ordinary shares—diluted	73,837,496	71,484,934	59,079,522
Other comprehensive income (loss):			
Changes in the fair value of the convertible notes	536	—	—
Foreign exchange translation adjustment	(9,727)	9,501	(378)
Comprehensive loss	(54,467)	(25,835)	(10,222)
Comprehensive loss attributable to noncontrolling interest	—	(72)	—
Comprehensive loss attributable to Renalytix	$ (54,467)	$ (25,763)	$ (10,222)

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

RENALYTIX PLC

CONSOLIDATED STATEMENTS OF SHAREHOLDERS' EQUITY

(in thousands, except share and per share data)	Ordinary shares		Additional paid-in capital	Accumulated other comprehensive income (loss)	Accumulated deficit	Total shareholders' equity attributable to Renalytix	Noncontrolling interest	Total shareholders' equity
	Shares	Amount						
Balance at July 1, 2019	53,816,134	$ 162	$ 52,084	$ (822)	$ (42,873)	$ 8,551	$ —	$ 8,551
Sale of ordinary shares in secondary offering, net of offering costs of $842	5,600,000	17	16,407			16,424	—	16,424
Stock-based compensation expense			1,159			1,159	—	1,159
Currency translation adjustments			—	(378)		(378)	—	(378)
Net loss			—		(9,844)	(9,844)	—	(9,844)
Balance at June 30, 2020	59,416,134	179	69,650	(1,200)	(52,717)	15,912	—	15,912
Sale of ordinary shares in initial public offering on Nasdaq, net of offering costs and underwriting fees of $9,007	12,613,500	40	76,094	—	—	76,134	—	76,134
VericiDx distribution in specie	—	—	1,638	(25)	—	1,613	(1,613)	—
Deconsolidation of Verici	—	—	—	—	—	—	2,296	2,296
Shares issued under the employee share purchase plan	17,652	—	111	—	—	111	—	111
Exercise of stock options	150,000	1	251	—	—	252	—	252
Stock-based compensation expense	—	—	2,663	—	—	2,663	—	2,663
Currency translation adjustments	—	—	—	9,501	—	9,501	(72)	9,429
Net loss	—	—	—	—	(34,725)	(34,725)	(611)	(35,336)
Balance at June 30, 2021	72,197,286	220	150,407	8,276	(87,442)	71,461	—	71,461
Shares issued under the Securities Purchase Agreement	2,428,688	8	8,578	—	—	8,586	—	8,586
Shares issued under the employee share purchase plan	33,734	—	209	—	—	209	—	209
Exercise of stock options	100,724	—	197	—	—	197	—	197
Stock-based compensation expense	—	—	4,621	—	—	4,621	—	4,621
Changes in the fair value of the convertible notes	—	—	—	536	—	536	—	536
Currency translation adjustments	—	—	—	(9,727)	—	(9,727)	—	(9,727)
Net loss	—	—	—	—	(45,276)	(45,276)	—	(45,276)
Balance at June 30, 2022	74,760,432	$ 228	$ 164,012	$ (915)	$ (132,718)	$ 30,607	$ —	$ 30,607

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

RENALYTIX PLC
CONSOLIDATED STATEMENTS OF CASH FLOWS

(in thousands)	Year Ended June 30, 2022	Year Ended June 30, 2021	Year Ended June 30, 2020
Cash flows from operating activities:			
Net loss	$ (45,276)	$ (35,336)	$ (9,844)
Adjustments to reconcile net loss to net cash used in operating activities			
Gain on VericiDx deconsolidation	—	(46)	—
Depreciation and amortization	489	282	70
Stock-based compensation	4,621	2,663	1,159
Gain on loan	—	(255)	—
Realized gain on short-term investments	—	(18)	(128)
Equity in (net earnings) losses of affiliate	(9)	2,112	63
Reduction of Kantaro Liability	(119)	(495)	—
Fair value adjustment to VericiDx investment	5,900	(6,483)	—
Unrealized foreign exchange (gain) loss	(7,340)	5,539	(213)
Fair value adjustment to Convertible Debt	(3,998)	—	—
Changes in operating assets and liabilities:			
Accounts receivable	(307)	(594)	—
Prepaid expenses and other current assets	(1,487)	(710)	(325)
Receivable from affiliates	1	17	(18)
Accounts payable	1,418	782	355
Accounts payable – related party	722	—	—
Accrued expenses and other current liabilities	(1,505)	4,353	(456)
Accrued expenses – related party	1,271	585	—
Deferred revenue	(76)	122	—
Payable to affiliate – current	(176)	(970)	(185)
Other liabilities	(53)	53	—
Net cash used in operating activities	(45,924)	(28,399)	(9,522)
Cash flows from investing activities:			
Purchases of property and equipment	(557)	(773)	(804)
Software development costs	(105)	(749)	(427)
Purchase of short-term investments	—	—	(21,260)
Proceeds from short-term investments	—	1,000	21,400
Note receivable – related party	—	(167)	(83)
Decrease in cash (VericiDx deconsolidation)	—	(62)	—
Net cash used in investing activities	(662)	(751)	(1,174)
Cash flows from financing activities:			
Proceeds from convertible notes	18,020	—	—
Payment of debt issuance costs	(1,382)	—	—
Gross proceeds from the issuance of ordinary shares, net of underwriting fees	—	79,182	—
Gross proceeds from the issuance of ordinary shares	8,804	—	17,276
Payment of offering costs	(218)	(2,305)	(1,593)
Proceeds from the issuance of ordinary shares under employee share purchase plan	209	111	—
Proceeds from exercise of stock options	197	252	—
Proceeds from PPP Loan	—	—	255
Net cash provided by financing activities	25,630	77,240	15,938
Effect of exchange rate changes on cash	(2,839)	3,745	(150)
Net (decrease) increase in cash and cash equivalents	(23,795)	51,835	5,092
Cash and cash equivalents, beginning of period	65,128	13,293	8,201
Cash and cash equivalents, end of period	$ 41,333	$ 65,128	$ 13,293
Supplemental noncash investing and financing activities:			
Financing costs in accounts payable and accrued expenses	$ —	$ —	$ 1,630

Reclassification of note receivable in Kantaro to Investment in Kantaro			$	175	$	—
Deemed distribution of VericiDx ordinary shares	$	—	$	75	$	—
Conversion of distribution of VericiDx note receivable into VericiDx ordinary shares	$	—	$	2,556	$	—
Software development costs in accounts payable and accrued expenses	$	—	$	—	$	177
Purchase of property and equipment in accounts payable and accrued expenses	$	—	$	—	$	56
Fair value of services exchanged for equity method investment of which services are recorded as the payable to affiliate	$	—	$	—	$	2,000

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

1. Business and risks

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

In August 2020, the Company created a wholly-owned subsidiary of Renalytix AI plc, Renalytix AI Limited ("Limited") to facilitate operations in Ireland.

Since inception in March 2018, the Company has focused primarily on organizing and staffing the Company, raising capital, developing the KidneyIntelX platform, conducting clinical validation studies for KidneyIntelX, establishing and protecting its intellectual property portfolio and commercial laboratory operations, pursuing regulatory clearance and developing a reimbursement strategy. The Company has funded its operations primarily through equity and debt financings.

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

2. Liquidity and Going Concern

The Company has incurred recurring losses and negative cash flows from operations since inception and had an accumulated deficit of $132.7 million as of June 30, 2022. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of KidneyIntelX or any future products currently in development. Management believes its cash and cash equivalents of $41.3 million as of June 30, 2022, are sufficient to fund the projected operations for at least the next twelve months from the issuance date of these financial statements. Such expectation is based, in part, on the achievement of a certain volume of assumed revenue; however, there is no guarantee we will achieve this amount of revenue during the time period we assume. Management assessed various additional operating cost reduction options that are available to the Company and would be implemented, if assumed levels of revenue are not achieved and additional funding is not obtained.

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

3. Basis of presentation and summary of significant accounting policies

The accompanying consolidated financial statements have been prepared in conformity with generally accepted accounting principles in the United States ("U.S. GAAP"). Any reference in these notes to applicable guidance is meant to refer to U.S. GAAP as found in the Accounting Standards Codification ("ASC") and Accounting Standards Updates ("ASU") of the Financial Accounting Standards Board ("FASB").

Principles of consolidation

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

Deconsolidation

Upon the occurrence of certain events and on a regular basis, the Company evaluates whether it no longer has a controlling interest in its subsidiaries, including consolidated variable interest entities. If the Company determines it no longer has a controlling interest, the subsidiary is deconsolidated. The Company records a gain or loss on deconsolidation based on the difference on the deconsolidation date between (i) the aggregate of (a) the fair value of any consideration received, (b) the fair value of any retained noncontrolling investment in the former subsidiary and (c) the carrying amount of any noncontrolling interest in the subsidiary being deconsolidated, less (ii) the carrying amount of the former subsidiary's assets and liabilities.

The Company assesses whether a deconsolidation is required to be presented as discontinued operations in its consolidated financial statements on the deconsolidation date. This assessment is based on whether or not the deconsolidation represents a strategic shift that has or will have a major effect on the Company's operations or financial results. If the Company determines that a deconsolidation requires presentation as a discontinued operation on the deconsolidation date, or at any point during the one-year period following such date, it will present the former subsidiary as a discontinued operation in current and comparative period financial statements.

Verici Dx plc

In April 2020, the Company created a wholly-owned subsidiary, Verici Dx plc ("VericiDx"), to hold technology in-licensed from the Icahn School of Medicine at Mount Sinai ("ISMMS" or "Mount Sinai") in late 2018. In May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to VericiDx in exchange for $2.0 million, which was satisfied by the issuance of convertible loan notes of VericiDx to the Company. The reduction of capital necessary to implement this transaction was approved by the Company's shareholders at a general meeting held on May 15, 2020 and confirmed by the High Court in England and Wales on June 9, 2020. The Company's board of directors declared the distribution of shares of VericiDx to the then shareholders of the Company, to effect the FractalDx spin-off, on July 7, 2020, and the distribution occurred on July 10, 2020.

The Company announced on July 8, 2020 that the share capital of VericiDx had been re-designated into 59,416,134 A Shares of £0.001 each and one golden share of £0.001 (the "Golden Share") and that Renalytix would retain the Golden Share and its associated controlling voting rights. Subsequent to that announcement, the Company entered into a declaration of trust whereby Renalytix AI plc had declared that it held the Golden Share as nominee and on trust for certain Directors of Renalytix AI and accordingly, the Company itself had no ongoing beneficial interest in VericiDx shares. This triggered a reconsideration event for ongoing consolidation of VericiDx and since the Company was still the primary funding source for VericiDx, the Company continued to hold a controlling financial interest in VericiDx and continued to consolidate VericiDx. Consequently, the Company recognized noncontrolling interest of $1.6 million to reflect VericiDx's distribution of A Shares and the Golden Share.

As the Company had been the primary funding source for VericiDx since its distribution to the Company's stockholders, the operations and financial position of VericiDx were included in the consolidated financial statements of the Company. Participation of the stockholders in the net assets and losses of VericiDx were reflected in the line items "Noncontrolling interests" in the Company's consolidated balance sheets and "Net loss attributable to the noncontrolling interests" in the Company's consolidated statements of operations and comprehensive loss. Noncontrolling interests adjusts the Company's consolidated results of operations and comprehensive loss to exclude all of the losses of VericiDx as Renalytix AI had no direct equity ownership in VericiDx from the date of the distribution through October 28, 2020. Changes in the underlying net book value of VericiDx due to equity issuances are reflected as equity transaction in the Company's consolidated statements of stockholders' equity.

On November 3, 2020, VericiDx completed an initial public offering on AIM and raised gross proceeds of £14.5 million ("VericiDx IPO") triggering a reconsideration event for ongoing consolidation of VericiDx. The VericiDx IPO resulted in the Company no longer having a controlling financial interest in VericiDx as the Company was no longer VericiDx's primary funding source. VericiDx previously issued the Company an aggregate of $2.5 million in convertible loan notes which reflected the $2.0 million consideration for the FractalDx assets and $0.5 million of additional funding the Company provided VericiDx through October 28, 2020. Prior to the VericiDx IPO, on October 28, 2020, the Company gave notice to convert the aggregate outstanding $2.5 million convertible loan notes into 9,831,681 ordinary shares of VericiDx. As a result of the VericiDx IPO, the Company deconsolidated VericiDx from the consolidated financial statements of the Company as of that date and recognized a gain of $46,000 within other (expense) income in the consolidated statements of operations and comprehensive loss for the year ended June 30, 2021.

Since VericiDx is publicly traded on the AIM market, the Company accounts for its retained interest in VericiDx as an investment at fair value in accordance with ASC 321, *Investments-Equity Securities,* with changes to fair value recorded in earnings. In connection with the deconsolidation of VericiDx, the Company evaluated whether the results of VericiDx should be presented as discontinued operations for the year ended June 30, 2021. The Company concluded that the deconsolidation of VericiDx, as a result of the VericiDx IPO, is not a development that significantly impacts the Company's overall operations and financial results. Research and development expenses incurred related to this program accounted for a minor portion of the Company's overall annual research and development expenses and the Company remains focused on developing the KidneyIntelX platform. Therefore, the Company has not presented the results related to VericiDx as discontinued operations in its consolidated statements of operations and comprehensive loss for the year ended June 30, 2021.

Use of estimates

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

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

Segment information

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

Foreign currency

The Company's consolidated financial statements are presented in U.S. dollars, the reporting currency of the Company. The functional currency of Renalytix plc and Renalytix AI Limited is GB Pounds. The functional currency of Renalytix AI, Inc. is the U.S. dollar. Assets and liabilities of Renalytix plc and Renalytix AI Limited are translated at the rate of exchange at

period-end, while the statements of operations are translated at the weighted average exchange rates in effect during the reporting period. The net effect of these translation adjustments is shown as a component of accumulated other comprehensive income (loss). Transaction gains and losses resulting from exchange rate changes on transactions denominated in currencies other than the functional currency are included in income in the period in which the change occurs and reported in the consolidated statements of operations and comprehensive loss.

Concentrations of credit risk and major customers

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

The Company's accounts receivable are derived from revenue earned from customers located in the U.S. Two customers provided approximately 99% of the Company's revenue, of which one customer made up 91%, for the year ended June 30, 2022. The Company performs initial and ongoing credit reviews on customers, which involve consideration of the customers' financial information, their location, and other factors to assess the customers' ability to pay.

Fair value of financial instruments

At June 30, 2022 and 2021, the Company's financial instruments included accounts receivable, prepaid expenses and other current assets, accounts payable, accrued expenses and other current liabilities. The carrying amounts of these assets and liabilities approximates fair value due to their short-term nature. The convertible notes are recorded at its estimated fair value.

Fair value option

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

Cash and cash equivalents

The Company considers all highly liquid investments purchased with an original maturity of 90 days or less to be cash equivalents. As of June 30, 2022 and 2021, the Company had a cash balance of $41.3 million and $65.1 million, respectively.

Accounts receivable

Accounts receivable are recorded at the invoice amount and are non-interest bearing. The Company considers receivables past due based on the contractual payment terms. The Company reserves specific receivables if collectability is no longer reasonably assured. Estimates for allowances for doubtful accounts are determined based on existing contractual obligations, historical payment patterns, and individual customer circumstances. No reserves have been recorded as of June 30, 2022 and 2021.

Property and equipment

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

Performance of contract liability to affiliate

In May 2020, the Company and the Icahn School of Medicine at Mount Sinai entered into an operating agreement ("Kantaro Operating Agreement") to form a joint venture, Kantaro Biosciences LLC ("Kantaro"), for the purpose of

developing and commercializing laboratory tests for the detection of antibodies against SARS-CoV-2 originally developed by Mount Sinai. Kantaro has a fiscal year ending December 31st. Kantaro has partnered with Bio-Techne Corporation to develop and launch the new test which are designed for use in any authorized clinical testing laboratory without the need for proprietary equipment. During the years ended June 30, 2022 and 2021, the Company recognized $0.1 million and $1.0 million, respectively, related to the performance of the contract liability with Kantaro.

Equity method investments

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

Kantaro Biosciences LLC

As the Company can exert significant influence over, but does not control, Kantaro's operations through voting rights or representation on Kantaro's board of directors, the Company accounts for this investment using the equity method of accounting. The Company records its share in Kantaro's earnings and losses in the consolidated statement of operations. The Company assesses its investment for other-than-temporary impairment when events or changes in circumstances indicate that the carrying amount of the investment might not be recoverable and recognize an impairment loss to adjust the investment to its then-current fair value (see Note 5). The Company owned 25% of the membership equity units in Kantaro at June 30, 2022 and June 30, 2021.

VericiDx plc

In the current year it was determined that the Company no longer can exert significant influence over VericiDx's operations and will now account for its ownership of VericiDx securities at fair value in accordance with ASC 321, *Investments-Equity Securities,* with changes in fair value recorded in earnings as the fair value of VericiDx's ordinary shares is readily determinable via the London Stock Exchange. Based on closing stock price of VericiDx, the fair value of the investment in VericiDx was $2.7 million and $9.3 million at June 30, 2022 and 2021, respectively. During the year ended June 30, 2022 and 2021, the Company recorded a fair value adjustment of $(5.9) million and $6.5 million, respectively, in the consolidated statements of operations and comprehensive loss. The Company owned 5.8% and 6.94% of the ordinary shares of VericiDx at June 30, 2022 and 2021, respectively.

Impairment assessment

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

Software development costs

The Company follows the provisions of ASC 985, *Software*, which requires software development costs for software to marketed externally to be expensed as incurred until the establishment of technological feasibility, at which time those costs are capitalized until the software is available for general release and amortized over its estimated useful life of ten years. For the year ended June 30, 2022, the Company capitalized $0.1 million of research and development expenses related to software development. For the year ended June 30, 2021, the Company capitalized $0.7 million of research and development Expense related to software development. Technological feasibility is established upon the completion of a working model that has been validated.

Revenue recognition

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

The Company only applies the five-step model to contracts when it is probable that it will collect the consideration to which it is entitled in exchange for the goods or services that it transfers to the customer. Once a contract is determined to be within the scope of ASC 606 at contract inception, the Company reviews the contract to determine which performance obligations it must deliver and which of these performance obligations are distinct. Certain contracts have options for the customer to acquire additional services. The Company evaluates these options to determine if a material right exists. If, after that evaluation, it determines a material right does exist, it assigns value to the material right based upon the renewal option approach. The Company recognizes as revenue the amount of the transaction price that is allocated to each performance obligation when that performance obligation is satisfied or as it is satisfied. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer occurs at a point in time. Sales tax and other similar taxes are excluded from revenues.

Cost of revenue

Cost of revenue consists of costs directly attributable to the services rendered, including labor, rent, lab consumables, depreciation, amortization and sample collection costs directly related to revenue generating activities.

Research and development expenses

Research and development costs consist primarily of internal and external labor costs incurred in connection with the development of KidneyIntelX as well as expenses related to studies and clinical trials to further the clinical value, performance and utility of KidneyIntelX. Research and development costs are expensed as incurred.

Share-based compensation

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

The Company classifies share-based compensation expense in its consolidated statement of operations and comprehensive loss in the same manner in which the award recipient's payroll costs are classified or in which the award recipient's service payments are classified.

Income taxes

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

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

Comprehensive loss

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

Net loss per ordinary share

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

The dilutive effect of convertible securities is calculated using the if-converted method. Under the if-converted method, interest charges applicable to the convertible debt as well as nondiscretionary adjustments which include any expenses or charges that are determined based on the income (loss) for the period are added back to net income. The convertible debt is assumed to have been converted at the beginning of the period (or at time of issuance, if later).

For the year ended June 30, 2022, the diluted and basic net loss per share calculation excluded 4,554,901 shares related to stock options, as the exercise price of these options was greater than their market value. Dilutive securities outstanding of 4,265,958 and 3,028,858 as of June 30, 2021 and 2020, respectively, have been excluded from the computation of basic and diluted weighted average shares outstanding as they would be anti-dilutive. Therefore, the weighted average number of shares used to calculate both basic and diluted net loss per share are the same.

Emerging growth company

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

Recently issued accounting pronouncements

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

In June 2016, the FASB issued ASU 2016-13, *Financial Instruments—Credit Losses: Measurement of Credit Losses on Financial Instruments*, which requires measurement and recognition of expected credit losses for financial assets held at the reporting date based on historical experience, current conditions, and reasonable and supportable forecasts. This is different from the current guidance as this will require immediate recognition of estimated credit losses expected to occur over the remaining life of many financial assets. The new guidance will be effective for the Company on July 1, 2023. The Company is currently evaluating the impact of adopting this guidance to its consolidated financial statements.

In January 2020, FASB issued ASU 2020-01, *Investments-Equity Securities (Topic 321), Investments-Equity Method and Joint Ventures (Topic 323), and Derivatives and Hedging (Topic 815)*, which, generally, provides guidance for investments in entities accounted for under the equity method of accounting. ASU 2020-01 is effective for all entities with fiscal years beginning after December 15, 2021, including interim periods therein. The Company is currently evaluating the impact of adopting this guidance to its consolidated financial statements.

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

4. Revenue

Testing services revenue

Testing services revenue is generated from the KidneyIntelX platform, which provides analytical services to customers. Each individual test is a performance obligation that is satisfied at a point in time upon completion of the testing process (when results are reported) which is when control passes to the customer and revenue is recognized. During the years ended June 30, 2022 and 2021, the Company recognized $2.7 million and $0.4 million, respectively, of testing services revenue. Sales tax and other similar taxes are excluded from revenues. There was no testing services revenue recognized in fiscal 2020.

Pharmaceutical services revenue

Pharmaceutical services revenue is generated from the provision of analytical services to customers. Contracts with customers generally include an initial upfront payment and additional payments upon achieving performance milestones. The Company uses present right to payment and customer acceptance as indicators to determine the transfer of control to the customer which may occur at a point in time or over time depending on the individual contract terms. Sales tax and other similar taxes are excluded from revenues.

During the years ended June 30, 2022 and 2021, the Company recognized $0.2 million and $0.5 million, respectively, of pharmaceutical services revenue where performance obligations are satisfied at a point in time. There was no pharmaceutical services revenue recognized in fiscal 2020.

Professional services revenue

Professional services revenue consists of services related to the creation of a branded care navigation portal/pathway for use with KidneyIntelX. Revenue is recognized when control of the promised services is transferred to customers and the performance obligation is fulfilled in an amount that reflects the consideration that the Company expects to be entitled in exchange for those services. During the year ended June 30, 2021 the Company recognized $0.6 million of other services revenue where performance obligations are satisfied at a point in time. There was no professional services revenue recognized in fiscal 2022 and 2020.

Deferred revenue

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

The following table summarizes the changes in deferred revenue:

(in thousands)	June 30, 2022	June 30, 2021	June 30, 2020
Balance, beginning of period	$ 122	$ —	$ —
Deferral of revenue	67	250	—
Revenue recognized	(143)	(128)	—
Balance, end of period	$ 46	$ 122	$ —

5. Fair value measurements and the fair value option

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

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

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

	Fair value measurement at reporting date using		
(in thousands)	(Level 1)	(Level 2)	(Level 3)
June 30, 2022			
Assets:			
Available for sale securities	$ 2,744	$ —	$ —
Liabilities:			
Convertible notes	$ —	$ —	$ 12,342
June 30, 2021			
Assets:			
Equity investment in VericiDx	$ 9,295	$ —	$ —

As further described in Note 9, in April 2022 the Company issued convertible promissory notes (the "Notes") to various investors. The fair value option, as prescribed by ASC 815, *Derivatives and Hedging,* was elected and applied in connection with the preparation of these consolidated financial statements. The fair value of the Notes is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders.

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

(in thousands)	June 30, 2022
Balance at the beginning of the year	$ —
Issuance of convertible promissory notes	16,959
Fair value adjustments	(3,998)
Change in credit risk	(536)
FX Impact	(83)
Balance at June 30, 2022	$ 12,342

Non-financial assets and liabilities

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

During the year ended June 30, 2021, based on sales forecasts, the Company concluded that its equity method investment in Kantaro was impaired due to a shift in focus from COVID antibody testing to promoting vaccination in the United States and European Union. As a result of this shift, demand for COVID antibody testing decreased. The forecasts indicate there is a prolonged period of time that Kantaro's fair value is below the carrying value of the investment and the discounted and undiscounted cash flows are also below the carrying value of the investment. For these reasons, the Company concluded the decline in value is other-than-temporary. As such, during the year ended June 30, 2021, the Company determined the fair value using a discounted cash flow model and concluded that the fair value of the equity method investment in Kantaro was zero. Accordingly, during the year ended June 30, 2021 the Company recorded a $1.9 million impairment charge within equity in losses of affiliate in the consolidated statements of operations.

6. Property and equipment

Property and equipment consists of (in thousands):

(in thousands)	June 30, 2022	June 30, 2021
Lab equipment	$ 1,143	$ 592
Software	1,476	1,534
Office equipment	124	84
Office furniture	35	35
Leasehold improvements	576	576
Construction in progress	—	—
Total	3,354	2,821
Less accumulated depreciation and amortization	(796)	(331)
	$ 2,558	$ 2,490

Depreciation expense was $0.3 million, $0.2 million and $0.1 million for the years ended June 30, 2022, 2021 and 2020, respectively.

As of June 30, 2022 and 2021 there was $1.2 million and $1.3 million, respectively, of unamortized costs of software development and purchased software. Amortization expense related to capitalized software development costs was $0.2 million and $85,000 for the years ended June 30, 2022 and 2021, respectively, and was expensed within cost of revenue in the consolidated statement of operations. There was no amortization expense related to capitalized software development costs for fiscal 2020.

As of June 30, 2022, the expected amortization expense for the next five years and thereafter is as follows:

(in thousands)	
2023	$ 175
2024	175
2025	175
2026	140
2027	120
Thereafter	403
	$ 1,188

7. Accrued expenses and other current liabilities

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

	June 30, 2022	June 30, 2021
Consulting and professional fees	$ 551	$ 954
Research and development	1,060	—
Payroll and related benefits	1,437	3,493
Other	12	155
	$ 3,060	$ 4,602

8. Debt

Paycheck Protection Program

On April 29, 2020, the Company entered into an original loan agreement with Fortis Private Bank as the lender (“Lender”) for a loan in an aggregate principal amount of $255,000 (the “Loan”) pursuant to the Paycheck Protection Program (the “PPP”) under the Coronavirus Aid, Relief, and Economic Security (CARES) Act and implemented by the U.S. Small Business Administration. In June 2020, the Paycheck Protection Program Flexibility Act was enacted which, among other things, extended the deferral period for loan payments to either (1) the date that SBA remits the borrower’s loan forgiveness amount to the lender or (2) if the borrower does not apply for loan forgiveness, ten months after the end of the borrower’s loan forgiveness covered period. The Loan matures in two years and bears interest at a rate of 1% per year, with all payments deferred through August 15, 2021. Principal and interest are payable monthly commencing on August 15, 2021 and may be prepaid by the Company at any time prior to maturity without penalty. The Company may apply for forgiveness of amounts due under the Loan, with the amount of potential loan forgiveness to be calculated in accordance with the requirements of the PPP based on payroll costs, any mortgage interest payments, any covered rent payments and any covered utilities payments during the 8–24 week period after the origination date of the Loan.

On April 28, 2021, the Company received notification that the full amount of the PPP Loan and accrued interest was forgiven. The forgiveness of the PPP Loan was recorded within 'Other (expense) income, net' within the consolidated statements of operations and comprehensive loss.

9. Convertible Notes

In April 2022, the Company issued amortizing senior convertible bonds with a principal amount $21.2 million in amortizing senior convertible bonds due in April 2027 (the "Bonds"). The Bonds were issued at 85% par value with total net proceeds of $18.0 million and accrue interest at an annual rate of 5.5%, payable quarterly in arrears, in cash or ADSs valued at the ADS Settlement Price at the option of the Company. The principal and interest payments are due in equal quarterly installments starting in July 2022. The Bonds contain various conversion and redemption features. The initial conversion price for the Convertible Bonds of $8.70 has been set at a 20 per cent. premium to the Reference ADS Price. The Conversion Price may reset down at 12, 24 and 36 months, depending on share price performance and save in limited circumstances, the Bonds have a hard floor in the conversion price of $7.25. Between amortization dates, the Convertible Bond Investor retains the right to advance future amortization payments, provided that (a) there shall be no amortization advancements during the first 12 months, (b) no more than 2 amortization advancements may occur in any 12 month period, and (c) no more than 1 amortization advancement may occur in any 3 month period.

The Convertible Bond Investor is also permitted to defer up to two amortization payments to a subsequent amortization date. The Company retains the option to repay any deferred amortization in cash at 100 per cent. of the nominal amount As of June 20, 2022, the entire principal amount was outstanding.

On issuance, the Company elected to account for the Bonds at fair value in accordance with ASC 815, *Derivatives and Hedging,* with qualifying changes in fair value being recognized through the statements of operations until the Bonds are settled. Changes in fair value related to instrument-specific credit risk are recognized through comprehensive loss until the Bonds are settled. The fair value of the bonds is determined using a scenario-based analysis that estimates the fair value based on the probability-weighted present value of expected future investment returns, considering each of the possible outcomes available to the noteholders. Significant assumptions used in the fair value analysis include the volatility rate, risk-free rate, dividend yield and risky yield. The fair value of the Bonds was determined to be $16.9 million on issuance, which is the principal amount of the Bonds. On issuance, total debt issuance costs of $1.4 million were immediately expensed as a component of general and administrative expense in consolidated statement of operations during the year end June 30, 2022. The Company recognized a change in fair value of the Notes related to the instrument-specific credit risk of $-0.5 million in the comprehensive loss and a change in fair value related to non-instrument specific credit risk of $4.0 million in the consolidated statement of operations during the year ended June 30, 2022.

10. Commitments and contingencies

Leases

The Company entered into operating lease agreements for office space and laboratory testing facilities with terms ranging from month-to-month to five years. The Company recognized rent expense of $0.7 million, $0.4 million and $0.5 million during the years ended June 30, 2022, 2021 and 2020, respectively, related to all leases.

The future minimum payments for noncancelable leases with terms in excess of one year for each fiscal year are as follows (in thousands):

2023	$	162
2024		153
2025		45
Total	$	360

DaVita Inc.

In January 2021, the Company entered into a Master Care Coordination Services Agreement with DaVita Inc. ("DaVita") whereby DaVita agreed to provide certain care coordination services to covered patients as requested by the Company, with those covered patients identified by the Company's KidneyIntelX diagnostic and subject to insurance coverage. Those covered patients may also be included in connection with various clinical research studies or quality improvement initiatives (each a "Study"). Both parties agreed to establish a joint steering committee to oversee the care coordination services and exchange and evaluate results of each Study. The Company will pay DaVita a monthly fixed fee based on the number of covered patients. The initial term of the agreement is three years with successive one-year renewals upon written mutual agreement of both parties. For the Care Coordination Services furnished by DaVita (or an affiliate of DaVita) under the terms of a statement of work, the Company shall pay DaVita (or such affiliate of DaVita) a monthly payment of (a) $10.00 in respect of Care Coordination Services multiplied by the number of Covered Patients, plus (b) $3.50, in respect of patient engagement services, multiplied by the number of Covered Patients .

Employment agreements

The Company has entered into employment agreements with certain key executives providing for compensation and severance in certain circumstances, as set forth in the agreements.

Retirement plans

The Company maintains a defined contribution 401(k) retirement plan which covers all U.S. employees. Employees are eligible after three months of service. Under the 401(k) plan, participating employees may make contributions in an amount up to the limit set by the Internal Revenue Service on an annual basis. The Company has a safe harbor plan and makes contributions to employee accounts of 5% of compensation (as defined by the plan). The Company paid $0.4 million, $0.2 million and $0.1 million in contributions for the year ended June 30, 2022, 2021, 2020, respectively.

Legal proceedings

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

11. License and services agreements

Mount Sinai license and sponsored research agreements

On May 30, 2018, the Company entered into an exclusive license agreement (the "ISMMS License Agreement") and, on March 7, 2019, a sponsored research agreement (the "ISMMS SRA") with Mount Sinai. Under the terms of the ISMMS License Agreement, ISMMS granted the Company (i) an exclusive, sublicensable license to use certain patent rights covering specific inventions concerning the utilization of biomarkers guided artificial intelligence techniques for detecting kidney functional decline (the "ISMMS Technology"), (ii) a non-exclusive license under unregistered licensed copyrights and licensed know-how and (iii) an exclusive option to obtain licensed technology conceived after May 30, 2018. The Company is obligated to pay Mount Sinai $1.5 million and $7.5 million in commercial milestone payments upon achieving worldwide net sales of KidneyIntelX of $50.0 million and $300.0 million, respectively. The Company is also obligated to pay Mount Sinai a 4% to 5% royalty on net sales of KidneyIntelX, subject to customary reductions. Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. Moreover, the Company is obligated to pay Mount Sinai between 15% and 25% of any consideration received from a sublicensee. Furthermore, the Company agreed to carry out and fund a clinical utility study for KidneyIntelX at an estimated cost of $0.7 million upon approval of the study protocol by the Institutional Review Board.

As part of the ISMMS SRA, the Company has agreed to fund several research projects to further develop the ISMMS Technology. The Company incurred $1.4 million, $0.4 million and $0.2 million related to the ISMMS SRA for the year ended June 30, 2022, 2021 and 2020, respectively.

Mount Sinai license agreement for FractalDx

On December 21, 2018, the Company entered into an exclusive license agreement (the "ISMMS FractalDx License Agreement") with ISMMS. Under the terms of the ISMMS FractalDx License Agreement, ISMMS granted the Company (i) an exclusive license, with sub-license rights, to use certain patent rights covering specific inventions concerning the utilization of biomarkers guided artificial intelligence techniques for detecting kidney functional decline (the ISMMS Technology), (ii) a non-exclusive license under unregistered licensed copyrights and licensed know-how and (iii) an exclusive option to obtain licensed technology conceived after May 30, 2018. The Company is obligated to pay Mount Sinai $0.3 million upon receipt of certain regulatory clearance and approval, $0.3 million upon receipt of U.S. CMS reimbursement code or PAMA reimbursement approval. In addition, the Company is obligated to pay Mount Sinai $1.0 million and $4.0 million in commercial milestone payments upon achieving worldwide net sales of FractalDx of $50.0 million and $250.0 million, respectively. The Company is also obligated to pay Mount Sinai a 6% to 8% royalty on net sales of FractalDx, subject to customary reductions. Moreover, the Company is obligated to pay Mount Sinai between 15% and 70% of any consideration received from a sublicensee.

Royalties are payable on a product-by-product basis from first commercial sale of such product until the later of (1) expiration of the last valid claim of a licensed patent covering such product or (2) on a country-by-country basis, 12 years from first commercial sale of such product in such country. The Company is also subject to an annual license maintenance fee of $25,000 in calendar year 2020 and 2021, $50,000 in calendar year 2022 and 2023, $0.1 million in calendar years 2024 through 2027, and $0.2 million for calendar year 2028 and beyond.

As discussed in Note 3, in May 2020, the Company transferred the in-licensed FractalDx technology and associated assets to VericiDx.

Mount Sinai COVID-19 sponsored research agreement

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

Under the terms of the MASKeD-COVID Study, the Company is obligated to pay for all direct and indirect costs incurred under the sponsored research agreement in an amount totaling $1.1 million. As of June 30, 2022, amounts due to ISMMS under the MASKeD-COVID study totaled $1.1 million and $0.8 million was expensed during the year ended June 30, 2022. As of June 30, 2021, amounts due to ISMMS under the MASKeD-COVID Study totaled $0.3 million and $0.3 million was expensed during the year ended June 30, 2021.

Mount Sinai Clinical Trial agreement

In July 2021, the Company entered into a Clinical Trial Agreement (the "CTA") with ISMMS. Under the CTA, ISMMS will undertake a sponsored clinical trial entitled, “A prospective decision impact trial of KidneyIntelX in patients with Type 2 diabetes and existing chronic kidney disease”. The clinical trial is to be conducted at ISMMS with Renalytix agreeing to pay ISMMS is accordance with the agreed upon budget. The clinical trial is expected to last up to four years with a total estimated budget of $3.2 million. As of June 30, 2022, amounts due to ISMMS under the CTA totaled $0.4 million and $0.6 million was expensed during the year ended June 30, 2022.

Joslin diabetes center agreement

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

Under the terms of the Joslin Agreement, the Company is obligated to pay Joslin aggregate commercial milestone payments of $0.3 million and $1.0 million in commercial milestone payments upon achieving worldwide net sales of licensed products and processes of $2.0 million and $10.0 million, respectively. The Company is also obligated to pay Joslin a 5% royalty on net sales of any licensed products or licensed processes, subject to customary reductions. Moreover, the Company is obligated to pay Joslin 25% of any consideration received from a sublicensee. Royalties recorded for the year ended June 30, 2022 were immaterial.

The Joslin Agreement initially expires on July 31, 2025 and is subject to an automatic five-year extension unless either party notifies the other party of its intent not to extend the agreement at least 180 days prior to initial expiration. Either party may terminate the Joslin Agreement earlier upon an uncured material breach of the agreement by the other party, the insolvency of the other party, or in the event the other party is unable to perform its obligations under the agreement for a specified period. Additionally, Joslin may terminate the agreement in the event that the Company ceases developing or commercializing licensed products or processes, if the Company fails to maintain certain required insurance policies, and if the Company fails to pay patent expenses related to the licensed patents.

12. Shareholders’ equity

Ordinary shares

As of June 30, 2022, the Company had 79,315,333 ordinary shares authorized on a fully diluted basis. Each share entitles the holder to one vote on all matters submitted to a vote of the Company’s shareholders. Ordinary shareholders are entitled to receive dividends as may be declared by the board of directors. From inception through June 30, 2022, no cash dividends have been declared or paid.

PIPE Funding

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

13. Share-based compensation

Equity Incentive Plan

In November 2018, Company established the Renalytix AI plc Share Option Plan (the "Plan") and a U.S. Sub-Plan and Non-Employee Sub-Plan. In July 2020, the Company's board of directors adopted and the Company's shareholders approved the 2020 Equity Incentive Plan (the "EIP"), which superseded the 2018 Share Option Plan. The equity incentive plan provides for the Company to grant options, restricted share awards and other share-based awards to employees, directors and consultants of the Company. As of June 30, 2022, there were 11,162,027 shares available for future issuance under the EIP.

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

With respect to the options granted as of June 30, 2022, 2,984,801 vest equally over twelve quarters following the grant date, 1,070,100 options which vest 25% on the one year anniversary and equally over twelve quarters following the one year anniversary and 500,000 which vest 1/12th immediately and the remainder equally over the remaining eleven quarters. If options remain unexercised after the date one day before the tenth anniversary of grant, the options expire. On termination of employment, any options that remain unexercised are either forfeited immediately or after a delayed expiration period, depending on the circumstances of termination. Upon the exercise of awards, new ordinary shares are issued by the Company.

The Company recorded share-based compensation expense in the following expense categories in the consolidated statements of operations for the years ended June 30, 2022, 2021 and 2020 (in thousands):

	Twelve Months Ended June 30,		
	2022	2021	2020
Research and development	$ 345	$ 683	$ 568
General and administrative	4,276	1,903	591
	$ 4,621	$ 2,586	$ 1,159

The fair value of options is estimated using the Black-Scholes option pricing model, which takes into account inputs such as the exercise price, the value of the underlying ordinary shares at the grant date, expected term, expected volatility, risk-free interest rate and dividend yield. The fair value of each grant of options during the years ended June 30, 2022, 2021, 2020 were determined using the methods and assumptions discussed below.

- The expected term of employee options is determined using the "simplified" method, as prescribed in SEC's Staff Accounting Bulletin No. 107, whereby the expected life equals the arithmetic average of the vesting term and the original contractual term of the option due to the Company's lack of sufficient historical data.
- The expected volatility is based on historical volatility of the publicly-traded common stock of a peer group of companies.
- The risk-free interest rate is based on the interest rate payable on U.S. Treasury securities in effect at the time of grant for a period that is commensurate with the assumed expected term.
- The expected dividend yield is none because the Company has not historically paid and does not expect for the foreseeable future to pay a dividend on its ordinary shares.

For the years ended June 30, 2022, 2021, and 2020, the grant date fair value of all option grants was estimated at the time of grant using the Black-Scholes option-pricing model using the following weighted average assumptions:

	Twelve Months Ended June 30,		
	2022	2021	2020
Expected term (in years)	5.6	5.9	5.7
Expected volatility	61.4%	70.2%	63.7%
Risk-free rate	1.3%	0.8%	1.7%
Dividend yield	—%	—%	—%

The weighted average fair value of the options granted during the years ended June 30, 2022, 2021 and 2020 was $5.64, $6.60 and $2.09 per share, respectively.

The following table summarizes the stock option granted to employees and non-employees for the year ended June 30, 2022:

	Number of shares under option plan	Weighted-average exercise price per option	Weighted-average remaining contractual life (in years)
Outstanding at June 30, 2021	4,265,958	$ 4.73	8.2
Granted	555,000	$ 9.59	
Exercised	(100,724)	$ 1.89	
Forfeited	(165,333)	$ 7.34	
Outstanding at June 30, 2022	4,554,901	$ 5.34	8.1
Exercisable at June 30, 2022	3,368,195	$ 3.72	7.0
Vested and expected to vest at June 30, 2022	4,554,901	$ 5.34	8.1

As of June 30, 2022, there was $5.5 million in unrecognized compensation cost related to unvested options that will be recognized as expense over a weighted average period of 8.9 years. The aggregate intrinsic value of options outstanding and options exercisable at June 30, 2022 was nil, respectively.

Employee Share Purchase Plan

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

Under the ESPP, eligible employees can purchase the Company's common stock through accumulated payroll deductions at such times as are established by the board of directors or renumeration committee. Eligible employees may purchase the Company's common stock at 85% of the lower of the fair market value of the Company's common stock on the first day of the offering period or on the purchase date. Eligible employees may contribute up to 15% of their eligible compensation. Under the ESPP, a participant may not purchase more than $25,000 worth of the Company's common stock for each calendar year in which such rights is outstanding. During the years ended June 30, 2022 and 2021, 33,734 and 17,652 shares were purchased under the ESPP, respectively.

In accordance with the guidance in ASC 718-50 – *Compensation – Stock Compensation*, the ability to purchase shares of the Company's common stock at 85% of the lower of the price on the first day of the offering period or the last day of the offering period (i.e. the purchase date) represents an option and, therefore, the ESPP is a compensatory plan under this guidance. Accordingly, share-based compensation expense is determined based on the option's grant-date fair value as estimated by applying the Black Scholes option-pricing model and is recognized over the withholding period. The Company recognized share-based compensation expense of $72,000 and $57,000 in general and administrative expense and $41,000 and $20,000 in research and development expense during the years ended June 30, 2022 and 2021, respectively, related to the ESPP.

14. Income taxes

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

	Twelve Months Ended June 30,		
	2022	2021	2020
United Kingdom	$ (13,061)	$ (6,199)	$ (1,898)
United States	$ (32,194)	(29,137)	(7,946)
	$ (45,255)	$ (35,336)	$ (9,844)

Due to the pretax losses reported in both the United Kingdom and United States for all periods since inception there is no income tax expense or benefit.

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

	Twelve Months Ended June 30,		
	2022	2021	2020
U.K tax benefit at statutory rate	(19.0) %	(19.0) %	(19.0) %
State taxes, net of federal benefit	(3.7)	(12.4)	(6.6)
Permanent differences	1.4	(0.1)	1.6
Research and development	0.0	(0.1)	0.0
Change in valuation allowance	24.1	34.5	25.0
Other	(2.7)	(2.9)	(1.0)
Effective tax rate	0.1 %	0.0 %	0.0 %

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

	Twelve Months Ended June 30,		
	2022	2021	2020
Deferred tax assets:			
Net operating losses	$ 27,201	$ 13,491	$ 4,296
Research and development licenses	3,150	4,133	2,550
Development costs	—	—	418
Share-based compensation	1,025	762	198
Unrealized foreign exchange loss	—	1,739	—
Deferred interest expense	—	2,112	—
Accrued expenses	311	741	—
Other	4	144	—
Valuation allowances	(31,113)	(21,046)	(7,331)
Total deferred tax assets	578	2,076	131
Deferred tax liabilities:			
Depreciation	(473)	(431)	(91)
Mark-to-market securities	(89)	(1,645)	—
Unrealized foreign exchange loss	(16)	—	—
Other	—	—	(40)
Total deferred tax liabilities	(578)	(2,076)	(131)
Net deferred tax	$ —	$ —	$ —

The Company does not have unrecognized tax benefits as of June 30, 2022, 2021, 2020. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense.

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

	Twelve Months Ended June 30,		
	2022	2021	2020
United Kingdom	$ 13,452	$ 9,981	$ 3,640
U.S. Federal	79,896	33,613	11,817
U.S. State and Local	120,146	67,291	21,520

The UK and federal net operating loss carryforwards have no expiration. The amount of UK annual profits that can be relieved by losses carried forward is limited to 50%, in excess of a threshold amount of £5 million of profits. Certain state net operating loss carryforwards begin to expire in 2038. The Company recorded a valuation allowance on the deferred tax assets as of June 30, 2022, 2021, and 2020 because of the uncertainty of their realization. The valuation allowance increased by $10.1 million for the year ended June 30, 2022, $13.7 million for the year ended June 30, 2021 and by $2.3 million for the year ended June 30, 2020.

Utilization of the net operating losses and general business tax credits carryforwards may be subject to a substantial limitation under Sections 382 and 383 of the Internal Revenue Code of 1986 as amended, if changes in ownership of the company have occur previously or occur in the future. Ownership changes may limit the amount of net operating losses and general business tax credits carryforwards that can be utilized annually to offset future taxable income and tax, respectively. In general, an ownership change, as defined by Section 382, results from transactions increasing the ownership of 5-percent shareholders in the stock of a corporation by more than 50 percentage points over a three-year period. If the Company experiences a Section 382 ownership change, the tax benefits related to the NOL carry forwards may be further limited or lost. The Company may also experience ownership changes as a result of shifts in share ownership, some of which are outside its control. Therefore, as a result of ownership changes with respect to ordinary shares, the ability to use current net operating losses and other pre-change tax attributes to offset post-change taxable income or taxes could be subject to limitation.

The Company files income tax returns in the United Kingdom, Ireland the U.S. federal jurisdiction and various state jurisdictions. The Company's 2018 through 2021 tax years remain subject to examine. Carryforward attributes from prior years may be adjusted upon examination by tax authorities if they are used in an open period.

15. Related-party transactions

EKF Diagnostic Holdings

During the years ended June 30, 2022, 2021, 2020, the Company incurred expenses of $0.1 million, $0.2 million and $0.1 million respectively, related to employees of EKF who provided services to Renalytix.

Icahn School of Medicine at Mount Sinai

In May 2018, the Company secured its cornerstone license agreement with ISMMS for research and clinical study work and intended commercialization by the Company (see Note 11). As part of the collaboration, ISMMS became a shareholder in the Company and has subsequently made equity investments both in the Company's IPO on AIM in November 2018, the subsequent sale of ordinary shares in July 2019 and the Company's IPO on Nasdaq in July 2020. As of June 30, 2022 and 2021, amounts due to ISMMS totaled $2.6 million and 0.3 million, respectively. During the years ended June 30, 2022, 2021, 2020, the Company incurred expenses of $3.1 million, $1.3 million and $0.3 million, respectively.

Kantaro Biosciences LLC

In connection with the formation of Kantaro, the Company entered into a five-year Advisory Services Agreement ("Advisory Agreement") pursuant to which the Company has agreed to provide certain advisory services to Kantaro. Pursuant to the Kantaro Operating Agreement, Kantaro issued 750 Class A Units to Mount Sinai in exchange for Mount Sinai granting licenses to Kantaro under certain intellectual property rights of Mount Sinai and 250 Class A Units to the Company as the sole consideration for the services to be rendered by the Company under the Advisory Agreement. The Company determined the fair value of the services to be provided under the Advisory Agreement was $2.0 million and the fair value of the Class A units received from Kantaro was $2.0 million. Fair value was determined using discounted cash flows which is a Level 3 measurement in the fair value hierarchy. The method requires several judgments and assumptions

which include discount rates and future cash flows, among others. As a result of the impairment charge discussed in Note 5, the carrying value of the Kantaro investment was written down to zero.

A contributing factor to the impairment consideration for Kantaro was lower forecasted sales volume and consequently, a lower time commitment from Renalytix employees. Based on these circumstances, the Company adjusted the liability to perform services to Kantaro under the Advisory Agreement. The adjustment for the change in estimate that resulted in a decrease of the liability of $0.5 million is classified within other income, net in the statements of operations and other comprehensive loss. As of June 30, 2022, the total liability associated with the services was $0.1 million, of which the total amount is classified as a current liability. As of June 30, 2021, the total liability associated with the services was $0.8 million, of which the total amount is classified as a current liability.

For the year ended June 30, 2022, the Company recognized $0.1 million in the statement of operations related to services performed under the Advisory Agreement. For the year ended June 30, 2022, $0.05 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $0.07 million was included within general and administrative expense, respectively. For the year ended June 30, 2021, the Company recognized $1.0 million in the statement of operations related to services performed under the Advisory Agreement. For the year ended June 30, 2021, $0.5 million of costs incurred related to the performance of the Advisory Agreement services were included within research and development and $0.2 million was included within general and administrative expense, respectively.

In addition to the equity granted at formation, the Company and Mount Sinai each committed to making a loan to Kantaro. Mount Sinai committed to lend an initial amount of $0.3 million and an additional $0.5 million thereafter. The Company committed to lend an initial amount of $83,333 and an additional $166,667 thereafter. Each loan bears interest at a per year rate equal to 0.25%, compounded monthly, until repaid, and is repayable from the first amounts that would otherwise constitute cash available for distribution to the members of Kantaro (provided that each loan repayment will be made, 75% to Mount Sinai and 25% to the Company based on each investor’s proportionate ownership). The Company loaned Kantaro $250,000 and initially recorded a note receivable. At June 30, 2021, the Company determined that $175,000 was uncollectible and accordingly recorded an impairment charge within equity in losses of affiliate in the consolidated statements of operations. In addition, the Company recognized gains of $0.01 million on their investment in Kantaro during the year ended June 30, 2022. The Company recognized losses of $0.2 million on their investment in Kantaro during the year ended June 30, 2021. The Company elects to recognize the equity investment losses based on the ownership level of each specific investment and will continue to record equity method losses until the amount of the loan receivable is reduced to zero.

VericiDx

During the year ended June 30, 2021 the Company paid the salary of an executive of VericiDx and VericiDx has agreed to reimburse the Company for those amounts. During the year ended June 30, 2022, the Company no longer paid the salary of a VericiDx executive as they were removed from Renalytix Inc.'s payroll. As of June 30, 2022 and 2021, amounts due from VericiDx were de minimis.

Private Placement

In April 2022, the Company also entered into a private placement agreement to sell, an aggregate of 2,428,688 shares of common stock (the "PIPE Shares"), for a purchase price of $3.625 per share and an aggregate purchase price of $8.8 million. Certain related parties, directors of the company and executive officers participated in the private placement.

Mount Sinai subscribed for a total of 1,103,448 new ordinary shares at $3.625 per ordinary share.

EKF Diagnostics Holdings, subscribed for a total of 137,930 new ordinary shares at $3.625 per ordinary share.

Christopher Mills, Non-Executive Chairman, and his related parties subscribed for a total of 551,724 new ordinary shares at $3.625 per ordinary share.

Timothy Scannell, Non-Executive Director, subscribed for a total of 68,964 new ordinary shares at $3.625 per ordinary share.

Thomas McLain, President, subscribed for a total of 55,172 new ordinary shares at $3.625 per ordinary share.

16. Net loss per ordinary share

The following is a reconciliation of basic net loss per share to diluted net loss per share for the fiscal years ended June 30, 2022, 2021 and 2020.

	Year ended June 30,		
	2022	**2021**	**2020**
Basic earnings per share	$ (0.62)	$ (0.49)	$ (0.17)
Average shares outstanding - basic	72,861,448	71,484,934	59,079,522
Convertible debt shares	976,048	—	—
Adjusted average shares outstanding - diluted	73,837,496	71,484,934	59,079,522
Diluted earnings per share	$ (0.67)	$ (0.49)	$ (0.17)

For the fiscal year ended June 30, 2022, the diluted net loss per share calculation included the dilutive effect of convertible debt as well as the impact of the $3.9 million fair value gain related to the convertible debt, which further increase net loss used in the diluted loss per share calculation. For the year ended June 30, 2022, the basic and diluted loss per share calculation excluded 4,554,901 shares related to stock options, as the exercise price of these options was greater than their average market value.

For the fiscal years ended June 30, 2021 and 2020, the basic and diluted loss per share excluded 4,265,958 and 3,028,858 shares related to stock options respectively, as the exercise price of these options was greater than their average market value.

Dated 5 April 2022

Amendment and Restatement Agreement

in respect of the Original Bond Agreement

by

Renalytix plc

with

CVI Investments, Inc.
as Initial Bondholder

White & Case LLP
5 Old Broad Street
London EC2N 1DW

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

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This Agreement is made on 5 April 2022

Between:

(1) **RENALYTIX PLC**, a company incorporated as a public limited company under the laws of England (the "**Company**" or the "**Issuer**"); and

(2) **CVI INVESTMENTS INC.**, a Cayman Islands exempted company (the "**Initial Bondholder**"),

(each a "**Party**" and together the "**Parties**").

Whereas:

(A) The Company and the Initial Bondholder entered into a bond agreement dated 31 March 2022 (the "**Original Bond Agreement**").

(B) The Parties are entering into this Agreement in order to amend and restate the Bond Agreement.

It is agreed as follows:

1. Definitions and Interpretation

1.1 Definitions

In this Agreement, the term:

"**Amended and Restated Bond Agreement**" means the Original Bond Agreement as amended and restated by this Agreement in the form set out in Annex 1 (*Form of Amended and Restated Bond Agreement*).

"**Original Bond Agreement**" has the meaning given to it in Recital (A).

Terms defined in the Amended and Restated Bond Agreement shall have the same meaning herein, unless otherwise defined herein or the context otherwise requires.

1.2 Construction

The principles of construction set out in clause 1.2 (*Construction*) of the Amended and Restated Bond Agreement shall have effect as if set out in this Agreement, *mutatis mutandis*.

2. Amendment and Restatement

With effect at and from the date of this Agreement, each of the Parties hereto consents and agrees that the Original Bond Agreement will be amended and restated in its entirety so that it reads and is construed for all purposes as set out in Annex 1 (*Form of Amended and Restated Bond Agreement*). Save as amended by this Agreement, the provisions of the Original Bond Agreement, the obligations of the parties and all the rights of the Company and the Initial Bondholder thereunder shall continue in full force and effect and this Agreement and the Amended and Restated Bond Agreement shall be read and construed as one instrument.

3. Further Assurance

Each Party shall promptly, at the request of the other Party (acting reasonably) and at its own expense, do all such acts and things necessary or desirable to give effect to the amendments effected or to be effected pursuant to this Agreement.

4. Notices

The provisions of clause 13 (*Notices*) of the Original Bond Agreement shall be incorporated into this Agreement as if set out in full in this Agreement and as if references therein to "this Agreement" were references to this Agreement.

5. Severability

If any provision in or obligation under this Agreement is or becomes invalid, illegal or unenforceable in any respect under the law of any jurisdiction, that will not affect or impair (i) the validity, legality or enforceability under the law of that jurisdiction of any other provision in or obligation under this Agreement, and (ii) the validity, legality or enforceability under the law of any other jurisdiction of that or any other provision in or obligation under this Agreement.

6. Counterparts

This Agreement may be executed in any number of counterparts, and this has the same effect as if the signatures on the counterparts were on a single copy of this Agreement.

7. Contracts (Rights of Third Parties) Act 1999

A Person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement, but this does not affect any right or remedy of a third Party which exists or is available apart from that Act.

8. Governing Law and Jurisdiction

This Agreement and any non-contractual obligations arising out of or in connection with it, shall be governed by, and construed in accordance with, English law. The provisions of clause 21.2 (*Jurisdiction*) of the Original Bond Agreement shall apply to this Agreement as if the same were repeated in full herein, *mutatis mutandis*.

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This Agreement has been entered into on the date stated at the beginning.

RENALYTIX PLC

as ***Company***

By: */s/ James McCullough*

Name: James McCullough

Title: CEO

(Signature Page to the Amendment and Restatement Agreement)

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CVI INVESTMENTS, INC.

as ***Initial Bondholder*** acting by Heights Capital Management, Inc., its authorised agent

By: */s/ Martin Kobinger*
Name: Martin Kobinger
Title: President

(Signature Page to the Amendment and Restatement Agreement)

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ANNEX 1 - Form of Amended and Restated Bond Agreement

[*Begins on the following page*]

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WHITE & CASE

Amended and Restated Bond Agreement

in respect of the commitment to purchase and the issuance of
U.S.$21,200,000 Amortising Senior Convertible Bonds due 2027

by

Renalytix plc

with

CVI Investments, Inc.
as Initial Bondholder

White & Case LLP
5 Old Broad Street
London EC2N 1DW

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This Agreement was made on 31 March 2022 and is amended and restated on 5 April 2022

Between:

(1) **RENALYTIX PLC**, a company incorporated as a public limited company under the laws of England (the "**Company**" or the "**Issuer**"); and

(2) **CVI INVESTMENTS INC.**, a Cayman Islands exempted company (the "**Initial Bondholder**"),

(each a "**Party**" and together the "**Parties**").

Whereas:

(A) The Company has authorised the creation and issue of U.S.$21,200,000 amortising senior convertible bonds due 2027 (the "**Bonds**") to be constituted by this Agreement and subject to the Conditions (as defined below).

(B) Subject to the provisions of the Conditions, the Bonds will be convertible into American Depositary Shares ("**ADSs**") each as at the Closing Date representing two ordinary shares of £0.0025 each in the share capital of the Company (the "**Ordinary Shares**") at an initial conversion price of U.S.$8.70 per ADS (being the sum of a reference price of U.S.$7.25 per ADS plus a 20 per cent. conversion premium), subject to adjustment in accordance with the Conditions.

(C) Prior to or substantially concurrently with the issue of the Bonds, the Company shall offer and sell pursuant to a private sale between the Company and prospective investors: ADSs representing newly issued Ordinary Shares, newly issued Ordinary Shares or a combination of such ADSs and newly issued Ordinary Shares; (the "**Equity Raise Securities**" and which such expression shall include any underlying securities represented by any such ADS), with the issue and placing price of such ADSs being not less than U.S.$6.00 (and the issue and placing price of any such Ordinary Shares (if any) corresponding to the same price) and resulting in no less than U.S.$7,000,000 in gross proceeds for the Company (the "**Equity Raise**").

(D) The Parties hereto wish to record the arrangements agreed between them in relation to the commitment to purchase the Bonds by the Initial Bondholder and the issue of the Bonds by the Company.

It is agreed as follows:

1. Definitions and Interpretation

1.1. Definitions

In this Agreement, the following terms shall have the following meanings (and terms used and not defined in the Recitals above or in this Clause 1.1, and which are defined in the Conditions, shall have the meanings given in the Conditions):

"**ADSs**" has the meaning given to it in Recital (B).

"**affiliate**" has the meaning given to it in Rule 501(b) of Regulation D under the Securities Act.

"**Anti-Bribery and Anti-Corruption Laws**" has the meaning given in Clause 8(u) (*Representations of the Company*).

"**Authorisation**" means an authorisation, consent, approval, resolution, licence, exemption, filing, notarisation or registration.

"**Bond Certificates**" means a Bond certificate in or in substantially the form set out in Schedule 3 (*Form of Bond Certificate*) including any replacement Bond Certificate issued pursuant to Clause 5.6 (*Replacement of Bonds*).

"**Bond Documents**" means this Agreement (including the Conditions), the Calculation Agency Agreement and each Bond Certificate.

"**Bondholder**" means in respect of a Bond, the person in whose name such Bond is for the time being registered in the Register, being, at the Closing Date, the Initial Bondholder.

"**Bonds**" has the meaning given to it in Recital (A).

"**Business Day**" means a day (other than a Saturday or Sunday) on which banks are open for general business in London and New York.

"**Calculation Agency Agreement**" means the calculation agency agreement to be entered into not later than the Closing Date between the Company and the Calculation Agent.

"**Calculation Agent**" means Conv-Ex Advisors Limited.

"**Closing**" means the closing of the issue of the Bonds to the Initial Bondholder.

"**Closing Date**" means the date falling on the fourth Business Day after the occurrence of the Pricing Date, except if the receipt of the monies specified in Clause 4.2(b) (*Closing Procedure*) by the Company shall not occur on such date, in which case it shall be the date falling on the fifth Business Day after the occurrence of the Pricing Date, or such other date as may be agreed in writing between the Parties, in their absolute discretion.

"**Conditions**" means the terms and conditions of the Bonds in Schedule 4 (*Terms and Conditions of the Bonds*) hereto.

"**Confidential Information**" has the meaning given in Clause 14.1 (*Confidentiality*).

"**Conversion Notice**" means a notice (which shall be irrevocable) delivered by (and signed by an authorised signatory of) a Bondholder to the Company, stating the Bondholder is electing to exercise its Conversion Rights (as defined in the Conditions) with respect to certain Bonds, and specifying:

(a) the relevant principal amount of Bonds (and related Bond Certificate number) the subject of such exercise;

(b) confirming the relevant Payment Details (as defined in the Conditions) for the delivery of ADSs and US Dollar bank account details for the payment of cash, in relation to such exercise of Conversion Rights;

(c) confirming the Bonds which are the subject of such notice are free from all liens, charges and encumbrances or any other third party rights; and

(d) confirming any third party nominee to whose account the ADSs are to be delivered, if applicable, have consented to the same.

"**Default**" means an Event of Default or any event or circumstance specified in Condition 10 (*Events of Default*) which would (with the expiry of a grace period, the giving of notice, the making of any determination under the Bond Documents or any combination of any of the foregoing) be an Event of Default.

"**Equity Raise**" has the meaning given to it in Recital (C).

"**Equity Raise Securities**" has the meaning given to it in Recital (C).

"**EUWA**" means the European Union (*Withdrawal*) Act 2018.

"**Exchange Act**" means the United States Securities Exchange Act of 1934, as amended.

"**Existing Holder**" has the meaning given to it in Clause 11.2 (*Permitted Transfers*).

"**FSMA**" means the Financial Services and Markets Act 2000.

"**Governmental Authority**" means the government of any nation, or of any political subdivision thereof, whether state, regional or local, and any agency, authority, branch, department, regulatory body, court, central bank or other entity exercising executive, legislative, judicial, taxing, regulatory or administrative powers or functions of or pertaining to government or any subdivision thereof (including any supra-national bodies).

"**Group**" means the Company and its consolidated Subsidiaries from time to time taken as a whole and references to a member of the Group means any of the Company or any of its consolidated Subsidiaries from time to time.

"**IFRS**" means International Financial Reporting Standards issued by the International Accounting Standards Board (IASB) and interpretations issued by the International Reporting Interpretations Committee of the IASB (as amended, supplemented or re-issued from time to time).

"**Indemnified Person**" has the meaning given to it in Clause 6.1 (*Indemnity*).

"**Initial Bondholder's Solicitors**" means White & Case LLP, a limited liability partnership organised and existing under the laws of England with its registered office at 5 Old Broad Street, London EC2N 1DW, United Kingdom.

"**Intellectual Property Rights**" means, collectively, trademarks, trade names and other rights to inventions, know-how, patents, copyrights, confidential information and other intellectual property.

"**Issue Price**" means, in respect of the Initial Bondholder, [***] of the principal amount of Bonds to be subscribed by such Initial Bondholder.

"**Licences**" has the meaning given to it in Clause 8(l) (*Representations of the Company*).

"**Longstop Time**" means 10:00 a.m. London time on 7 April 2022, or any later date, if so agreed in writing between the Parties, in their absolute discretion.

"**Material Adverse Effect**" means, (a) (solely in respect of the period commencing from the date hereof up to the time of pricing on the Pricing Date) with respect to the Company and
each member of the Group: (i) it is in breach of the terms of, or in default under, any
instrument, agreement or order to which it is a party or by which it or its property is bound
or an event has occurred which with the giving of notice or lapse of time or other condition would constitute a default under any such instrument, agreement or order, except for any

such breach or default which either individually or in the aggregate would not reasonably be expected to be material in the context of the issue and offering of the Bonds; or (ii) it is
engaged (whether as defendant or otherwise) in, or the Company has knowledge of the existence of, or any threat of, any legal, arbitration, administrative, governmental or other proceedings an adverse result of which would reasonably be expected to be material in the context of the issue and offering of the Bonds, or (iii) it has taken any action or any steps have been taken or legal proceedings commenced for the winding up or dissolution of the Company or any member of the Group, or (b) any adverse change or any development or event, in each case when compared to the position which had been publicly disclosed by the Company immediately prior to this Agreement, which could be reasonably expected to, individually or in aggregate, result in a change which is materially adverse to the condition (financial or otherwise), prospects, business, results of operations, or properties of the Group as a whole or (c) any development of which the Company is, or might reasonably be expected to be, aware that could be reasonably expected to materially adversely affect the ability of the Company to perform its obligations under the Bond Documents or the Bonds.

"**Money Laundering Laws**" has the meaning given in Clause 8(w) (*Representations of the Company*).

"**Ordinary Shares**" has the meaning given to it in Recital (B).

"**Pricing Date**" means the date on which the purchase price of the Equity Raise Securities in the Equity Raise is announced by the Company, which shall not occur later than the Longstop Time.

"**Prohibited Payment**" has the meaning given in Clause 8(u) (*Representations of the Company*).

"**Public Statements**" means any information in any press release or announcement by or on behalf of the Company or any member of the Group, whether such information was required to be made public by applicable law and regulation (including, but not limited to, all filings required by the relevant Stock Exchange and/or English law) or otherwise, on or after 30 June 2021.

"**Register**" means the register of Bonds maintained by the Company in or substantially in the form set out in Schedule 6 (*Form of Register*).

"**Regulation S**" means Regulation S under the Securities Act.

"**Related Parties**" has the meaning given to it in Clause 6.1 (*Indemnity*).

"**Sanctions**" means any sanctions administered by the Office of Foreign Assets Control of the U.S. Department of Treasury, the U.S. State Department, any other agency of the U.S. government, the United Nations, the European Union or the United Kingdom.

"**SEC**" means the United States Securities and Exchange Commission.

"**Securities Act**" means the United States Securities Act of 1933, as amended.

"**Stock Exchange**" means, in the case of ADSs in issue or to be issued by the Company, the Nasdaq Global Market, and in the case of Ordinary Shares of the Company, the AIM market operated by the London Stock Exchange plc, in each case as the context may require.

"**Subsidiary**" means a subsidiary undertaking within the meaning of section 1162 of the Companies Act 2006 as if the words "is a member of the undertaking and" had been deleted from subsections 1162(2)(b) and (d).

"**Term Sheet**" means the term sheet in respect of the Bonds dated 27 March 2022 between the Company and the Initial Bondholder.

"**Transfer and Accession Deed**" means a deed substantially in the form set out in Schedule 5 (*Form of Transfer and Accession Deed*) or any other form agreed between the Issuer, the relevant Existing Holder and the New Holder.

"**£**" and "**Sterling**" means the lawful currency of the United Kingdom.

"**U.S. Dollars**" or "**U.S.$**" means the lawful currency of the United States of America.

1.2. **Construction**

(a) Unless a contrary indication appears, any reference in this Agreement to:

(i) the "**Initial Bondholder**", any "**Bondholder**" or any "**Party**" shall be construed so as to include its successors in title, permitted assigns and permitted transferees to, or of, its rights and/or obligations under the Bond Documents;

(ii) "**assets**" includes present and future properties, revenues and rights of every description;

(iii) a "**Bond Document**" or any other agreement or instrument is a reference to that Bond Document or other agreement or instrument as amended, novated, supplemented, extended or restated;

(iv) a "**Person**" includes any individual, firm, company, corporation, government, state or agency of a state or any association, trust, joint venture, consortium, partnership or other entity (whether or not having separate legal personality);

(v) a "**regulation**" includes any regulation, rule, official directive, or official guidance of any governmental, intergovernmental or supranational body, agency, department or of any regulatory, self-regulatory or other Governmental Authority;

(vi) a provision of law is a reference to that provision as amended or re-enacted from time to time; and

(vii) a time of day is a reference to London time.

(b) Time shall be of the essence in this Agreement.

(c) Headings and the table of contents are for ease of reference only and shall not affect the construction of this Agreement.

(d) Any reference in this Agreement to a Clause or a Schedule is, unless otherwise stated, to a Clause or a Schedule hereof. The Schedules form an integral part of this Agreement.

2. The Bonds

2.1. Constitution of the Bonds

On and from the Closing Date, the Company constitutes the Bonds and covenants in favour of each Bondholder that it will duly perform and comply with the obligations expressed to be undertaken by it in this Agreement, in each Bond Certificate and in the Conditions (and for this purpose any reference in the Conditions to any obligation or payment under or in respect of the Bonds shall be construed to include a reference to any obligation or payment under or pursuant to this provision).

2.2. Benefit

This Agreement shall enure to the benefit of each Bondholder and each of their (and any subsequent) successors and assigns, each of which shall be entitled severally to enforce this Agreement against the Company.

3. Issue and Subscription

3.1. Undertaking to Issue

With effect from the date of this Agreement, and subject to:

(a) the occurrence of the Pricing Date; and

(b) the ADSs and Ordinary Shares being issued in accordance with the terms of the Equity Raise (and the relevant subscription monies being received by the Company in connection therewith) prior to or on the Closing Date,

the Company undertakes to the Initial Bondholder that, subject to and in accordance with the terms and conditions of this Agreement, the Company will: (x) issue Bonds in the principal amount specified opposite the Initial Bondholder's name in Schedule 1 (*Subscription Allocation*) on the Closing Date, in accordance with the provisions of this Agreement, and (y) execute the Calculation Agency Agreement, the Bond Certificate in respect of the Initial Bondholder and such other documents necessary for the issuance of the Bonds and the consummation of the transaction contemplated hereby.

3.2. Undertaking to Subscribe

With effect from the date of this Agreement, subject to:

(a) the occurrence of the Pricing Date; and

(b) the ADSs and Ordinary Shares being issued in accordance with the terms of the Equity Raise (and the relevant subscription monies being received by the Company in connection therewith) prior to or on the Closing Date,

the Initial Bondholder undertakes to the Company that, subject to and in accordance with the terms and conditions of this Agreement, it will subscribe for Bonds in the principal amount specified opposite the Initial Bondholder's name in Schedule 1 (*Subscription Allocation*) on the Closing Date at the Issue Price (less the Initial Bondholder's permitted expenses pursuant to the Term Sheet).

4. Completion and Settlement

4.1. Conditions Precedent to Closing

(a) The Initial Bondholder will only be obliged to subscribe for Bonds if:

(i) within a reasonable time prior to the Closing, the Initial Bondholder has received all of the documents and other evidence listed in Schedule 2 (*Conditions Precedent*) in form and substance reasonably satisfactory to it (in its absolute discretion);

(ii) on each of the date hereof and on the Closing Date (A) the representations and warranties of the Company in this Agreement being true, accurate and correct at, and as if made on, such date, (B) the Company having performed all of its obligations under this Agreement to be performed on or before such date and on the Closing Date, and (C) there being no material breach of any of the obligations of the Company under this Agreement;

(iii) on the Closing Date, no Default is continuing or would result from the issue of the Bonds;

(iv) there has been no Material Adverse Effect;

(v) in the Initial Bondholder's good faith opinion, since the date of this Agreement there has been no adverse change in the financial markets in the United Kingdom, the United States, the Cayman Islands, the European Economic Area or the international financial markets, any outbreak of hostilities or escalation thereof, any act of terrorism or war or any declaration of emergency or martial law or other calamity or crisis (including without limitation, a material escalation in any pandemic on or after the date of this Agreement) nor any change or development involving a prospective change in national or international political, financial or economic conditions, currency exchange rates or exchange controls, whether or not foreseeable at the date of this Agreement, which would reasonably be considered material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder;

(vi) prior to the Closing, the Company has received gross proceeds of at least U.S.$7,000,000 in respect of the Equity Raise; and

(vii) on or prior to the Closing, the Initial Bondholder's Solicitors have received the documents listed in Clause 4.2(a)(ii) to be held in escrow pending Closing.

(b) The Initial Bondholder shall notify the Company promptly upon receipt of all of the documents and other evidence listed in Schedule 2 (*Conditions Precedent*) in form and substance satisfactory to it.

(c) The Initial Bondholder may, in its absolute discretion and upon such terms as it thinks fit, waive compliance with the whole or any part of this Clause 4.1 (*Conditions Precedent to Closing*).

(d) If, on the Closing Date, any of the conditions precedent referenced in Clause 4.1(a) have not been satisfied, nor waived as provided in Clause 4.1(c), then the Initial

Bondholder shall, at its election, be relieved of all its obligations under Clause 3.2 (*Undertaking to Subscribe*) to subscribe for the Bonds under this Agreement.

(e) An election by the Initial Bondholder under Clause 4.1(d) above shall not operate as a waiver of any rights the Initial Bondholder may have by reason of such failure or such non-fulfilment.

4.2. **Closing Procedure**

(a) By no later than the Closing Date:

(i) subject to receipt of payment instructions of the Initial Bondholder in accordance with Clause 4.2(b) below, the Company shall make (or shall procure the making of) the appropriate entry in the Register showing the Initial Bondholder as the registered owner of the principal amount of Bonds set out against its name in Schedule 1 (*Subscription Allocation*);

(ii) the Company shall issue and deliver to the Initial Bondholder's Solicitors:

(A) the initial Bond Certificate dated the Closing Date; and

(B) a certified excerpt of the Register updated to reflect the entry referred to in paragraph (i) above,

such documents to be held in escrow to the Company's order until such time as they are deemed to be released pursuant to Clause 4.2(d) below.

(b) At Closing, and subject to Clauses 4.2(c) and 4.2(d), the Company will deliver to the Initial Bondholder the Bonds to be subscribed for by the Initial Bondholder in the form of the documents specified in Clause 4.2(a)(ii) above, against payment by the Initial Bondholder to the Company or its order in immediately available funds of the subscription monies (net of the Initial Bondholder's permitted expenses pursuant to the Term Sheet) to the following account of the Company:

Account Name: Renalytix plc
Sort Code: 40-12-76
Account Number: 83922779
IBAN: GB75HBUK40127683922779
SWIFTBIC: HBUKGB4B

or such account of the Company as the Company designates to the Initial Bondholder in writing at least three Business Days prior to the Closing Date.

(c) On the Closing Date, and following confirmation of receipt from the Initial Bondholder's Solicitors of the documents specified in Clause 4.2(a)(ii), the Initial Bondholder shall pay or procure the payment of its subscription monies (net of the Initial Bondholder's permitted expenses pursuant to the Term Sheet) in accordance with Clause 4.2(b) in immediately available funds and shall notify the Company thereof and provide evidence or a receipt of such payment transfer.

(d) Upon receipt of the net subscription monies specified in Clause 4.2(b), the documents referred to in Clause 4.2(a)(ii) above shall be deemed to be released by the Company to or to the order of the Initial Bondholder. The Company shall promptly on the Closing

Date furnish a written confirmation to the Initial Bondholder of its receipt of the net subscription monies.

5. Register and Title

5.1. Registration of Bonds

(a) The Company shall maintain a Register in respect of the Bonds in accordance with the regulations in Schedule 7 (*Regulations Concerning Transfers and Registration of the Bonds*).

(b) A Bond Certificate will be issued to each Bondholder in respect of its registered holding.

(c) Each Bond Certificate will be numbered serially with an identifying number which will be recorded in the Register by the Company.

5.2. Title

(a) Each Bondholder registered in the Register shall (except as otherwise required by law or as ordered by a court of competent jurisdiction) be treated as the absolute owner of such Bond for all purposes (whether or not it is overdue and regardless of any notice of ownership, trust or any other interest in such Bond, any writing on the Bond Certificate relating to such Bonds (other than a duly executed transfer thereof) or any notice of any previous loss or theft of such Bond Certificate) and no person shall be liable for so treating such Bondholder.

(b) The Company shall promptly on demand by any Bondholder (and in any event by no later than five Business Days after demand) send to such Bondholder a complete and correct copy of the Register.

5.3. Registration and Delivery of Bond Certificates

(a) Promptly following the surrender of a Bond Certificate subject to and in accordance with Clause 11 (*Transfer of Rights and Obligations*), the Company will register the transfer in question and deliver, at the Company's expense (except as provided below), a new Bond Certificate of a like principal amount to the Bonds transferred to each New Holder to the address specified for the purpose by such New Holder and, if applicable, a new Bond Certificate to the Existing Holders in accordance with Clause 11 (*Transfer of Rights and Obligations*).

(b) Promptly following the exercise by any Bondholder of their Conversion Rights and surrender of a Bond Certificate in accordance with Condition 6.10 (*Procedure for exercise of Conversion Rights*), the Company will register such conversion of the Bonds and, solely in the case of a partial conversion of Bonds in accordance with the Conditions, deliver at the Company's expense (except as provided below) a new Bond Certificate to such Bondholder representing the principal amount of Bonds held thereby following such partial conversion.

5.4. Closed Periods

Bondholders may not require transfers to be registered during the period of 5 days ending on the due date for any payment of principal or interest in respect of the Bonds or in respect of which a Conversion Notice has been delivered in accordance with Conditions.

5.5. **Regulations Concerning Transfers and Registration**

All transfers of Bonds, provision of new Bond Certificates (upon transfer) and entries on the Register are subject to the detailed regulations concerning the transfer and registration of Bonds set out in Schedule 7 (*Regulations Concerning Transfers and Registration of the Bonds*).

5.6. **Replacement of Bond Certificates**

Promptly following receipt by the Company of evidence reasonably satisfactory to it of the ownership of and the loss, theft, destruction or mutilation of any Bond Certificate, and:

(a) in the case of loss, theft or destruction, of an indemnity reasonably satisfactory to it; or

(b) in the case of mutilation, upon surrender and cancellation of such Bond Certificate,

the Company shall, at its own expense, execute and deliver, a replacement Bond Certificate.

5.7. **Copies of Bond Certificates**

Whenever in this Agreement or the Conditions there is any requirement to deliver, produce, surrender or possess a Bond Certificate, the delivery, production, surrender or possession of an electronic copy of such Bond Certificate shall be satisfactory, save that in the case of a surrender of a Bond Certificate by electronic means the Bondholder (where not the Company) shall confirm to the Company destruction of any original thereof.

6. Indemnity

6.1. **Indemnity**

(a) The Company agrees to indemnify and hold harmless the Initial Bondholder and each of its affiliates and all their respective officers, directors, general partners, employees, Heights Capital Management, Inc., Heights Capital Ireland, LLC, shareholders and representatives and each of their respective successors (but, for the avoidance of doubt, not including any permitted transferee or assignee of the Initial Bondholder) (each, an "**Indemnified Person**") from and against any and all actions, suits, investigation, inquiry, claims, losses, damages, liabilities, proceedings and documented related out-of-pocket fees and expenses of any kind or nature (a "**Loss**") (subject to the limitations set forth in this Clause 6) which may be incurred by any such Indemnified Person as a result of or arising out of or in connection with or based on:

(i) *Misrepresentation*: any breach or alleged breach of the representations and warranties contained in, or made or deemed to be made by the Company under, this Agreement by reference to the facts and circumstances then subsisting; or

(ii) *Breach*: any breach or alleged breach by the Company of any of its obligations in this Agreement or the Bonds (including, without limitation, the failure by the Company to issue the Bonds on the Closing Date); or

(iii) *Announcements*: any untrue statement contained in any announcement or press release published following the date hereof by or on behalf of the

Company or any member of the Group in connection with the initial offering of and/or initial issue of the Bonds or any omission or alleged omission of a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances in which they are made, not misleading.

(b) The Company shall pay to the relevant Indemnified Person within 10 Business Days of written demand therefor an amount equal to such Loss, provided that no Indemnified Person will be entitled to indemnity hereunder in respect of any Loss to the extent that it is finally judicially determined by a court of competent jurisdiction that such Loss, resulted from the negligence, bad faith or wilful misconduct of such Indemnified Person or its affiliates, officers, directors, partners, trustees, employees, shareholders, agents or controlling persons (all such persons "**Related Parties**").

(c) This Agreement shall not cause any Bondholder to have any duty or obligation, whether as fiduciary or trustee for any Indemnified Person or its Related Parties or otherwise, to recover any such payment or to account to any other person for any amounts paid to it under this Clause 6.

6.2. **Conduct of Claims**

(a) In case any action shall be brought against any Indemnified Person in respect of which recovery may be sought from the Company under this Clause 6, the relevant Indemnified Person shall promptly notify the Company in writing of such fact, but failure to do so will not relieve the Company from any liability under this Agreement and in any event shall not relieve it from any liability which it may have otherwise than on account of the indemnities contained in this Agreement.

(b) Each Indemnified Person shall thereafter, subject to any requirement imposed by an insurer of the Indemnified Person and to the extent permitted by applicable law or regulation:

(i) at reasonable intervals keep the Company informed of the progress of the claim;

(ii) provide the Company with copies of such documentation relating to the claim as it may reasonably request; and

(iii) maintain reasonable consultation with the Company regarding decisions concerning the claim,

subject in each case to the Indemnified Person being indemnified and secured to its reasonable satisfaction against all Losses incurred by it in consequence of its compliance with this Clause 6, and provided that nothing in this Clause 6 shall:

(i) require any Indemnified Person to provide the Company with a copy of any document which it, in good faith, considers to be held by it subject to a duty of confidentiality or to be privileged whether in the context of any litigation connected with the claim or otherwise; or

(iv) require an Indemnified Person to do, or refrain from doing, anything which would, or which the Company considers might, either prejudice any insurance cover to which it or any other Indemnified Person may from time to time be entitled, or from which it or any of them may benefit or which may prejudice

the reputation or standing of such Indemnified Person or of any other Indemnified Person.

(c) The Company may participate at its own expense in the defence of any such action; *provided, however, that* legal advisers to the Company shall not (except with the consent of the relevant Indemnified Person) also be legal advisers to the Indemnified Person. The Company shall not, without the prior written consent of the relevant Indemnified Person, settle or compromise or consent to the entry of any judgment with respect to any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever in respect of which indemnification could be sought under this Clause 6 (whether or not the Indemnified Person(s) are actual or potential parties thereto), unless such settlement, compromise or consent:

(i) includes an unconditional release of each Indemnified Person from all liability arising out of such litigation, investigation, proceeding or claim; and

(ii) does not include a statement as to or an admission of fault, culpability or a failure to act by or on behalf of any Indemnified Person.

7. Costs and Expenses

7.1. Transaction Expenses

With effect from the Closing Date:

(a) the Company shall be responsible for its own expenses and the fees and expenses of all third parties (including the Calculation Agent and the Stock Exchanges) appointed under or in connection with the Bonds, in connection with the preparation and execution of the Bond Documents and the issue and performance of the Bonds; and

(b) without prejudice to any costs and expenses arrangements separately agreed in the Term Sheet and subject to Clause 6 (*Indemnity*), unless otherwise agreed by the Company (in its discretion) the Bondholders shall be responsible for their own respective costs and expenses incurred by them in connection with the Bonds.

7.2. Amendment Costs

If the Company requests an amendment, waiver or consent and such requests for amendments, waivers or consents, in the reasonable opinion of each Bondholder, require legal fees to be incurred, the Company shall, within five Business Days of demand, reimburse each Bondholder for the amount of such reasonable legal costs and expenses properly incurred by it in responding to, evaluating, negotiating or complying with that request or requirement provided that such legal costs and expenses shall be agreed with the Company in advance.

7.3. Enforcement Costs

The Company shall, within three Business Days of demand, pay to each Bondholder the amount of all costs and expenses (including legal fees) properly incurred by that Bondholder in connection with the enforcement of, or the preservation of any rights under, the Bonds and this Agreement.

8. Representations of the Company

The Company makes the representations and warranties set out below in this Clause 8 to the Initial Bondholder on the date of this Agreement and to the Initial Bondholder, by reference to the facts and circumstances then subsisting, on each of the Pricing Date and the Closing Date:

(a) that:

(i) all expressions of opinion, forecasts or estimates of the Company and/or its Group contained in any such Public Statements were made in good faith on reasonable grounds after due and careful consideration;

(ii) other than in respect of the matters which are the subject of this Agreement and the Equity Raise, the Company is not aware, after due and careful consideration, of any information relating to the Company or any member of the Group which the Company or any member of the Group is required or obliged to publish or make available to the public pursuant to applicable laws (including under applicable listing requirements), whether to correct a misleading impression or otherwise to avoid behaviour which would
constitute market abuse (in contravention of Regulation 596/2014/EU as it forms part of English law by virtue of the EUWA) which has not been published;

(iii) other than in respect of the matters which are the subject of this Agreement and the Equity Raise, neither the Company nor any of its directors or officers is aware of any non-public fact or circumstance that, if made public, would be likely to have a significant effect upon the market price of the Bonds, the ADSs or the Ordinary Shares, and in respect of which the Company has delayed disclosure in compliance with applicable law; and

(iv) the Company is in compliance with the rules and regulations of each of the Stock Exchanges (including, but not limited to, continuing disclosure obligations) in all material respects;

(b) that the Company has been duly incorporated and is validly existing and registered in England and Wales as a public limited company with limited liability and is not in liquidation, receivership or bankruptcy and the Company has full power and authority to own, lease and operate its properties to the extent material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder and conduct its business and to execute and perform its obligations under the Bond Documents and the Bonds;

(c) that the issue of the Bonds, the delivery of ADSs on conversion of the Bonds (and the issue of Ordinary Shares represented thereby) or upon any ADS Settlement under the Bonds and the execution and delivery of the Bond Documents have been duly authorised by the Company and, in the case of the Bonds and ADSs (and the Ordinary Shares represented thereby), upon due execution, issue and delivery in accordance with this Agreement and the Conditions will constitute, and, in the case of the Bond Documents, upon due execution and delivery (as applicable), constitute, legal, valid and binding obligations of the Company enforceable in accordance with their respective terms, subject to the laws of bankruptcy and other laws affecting the rights of creditors generally;

(d) that:

(i) the annual audited consolidated financial statements of the Company as of and for the years ended 30 June 2021 and 2020 were prepared in accordance with IFRS accounting principles generally accepted in the United Kingdom consistently applied and that they give a true and fair view of its financial condition and its results of operations (on a consolidated basis) as at the dates indicated; and

(ii) the unaudited interim consolidated financial statements of the Company as of and for the six months ended 31 December 2021 were prepared in accordance with IFRS accounting principles generally accepted in the United Kingdom consistently applied (subject to the qualification that they are unaudited) and that they fairly present in all material respects the financial condition of the Company as at the date indicated;

(e) since 17 July 2020, the Company has timely (including following any extensions of time for filing provided by Rule 12b-25 promulgated under the Exchange Act) filed all reports, schedules, forms, proxy statements, statements and other documents required to be filed by it with the SEC pursuant to the reporting requirements of the Exchange Act (all of the foregoing filed prior to the date hereof and all exhibits and appendices included therein and financial statements, notes and schedules thereto and documents incorporated by reference therein, and including any amendments thereto, being hereinafter referred to as the "**SEC Documents**"). As of their respective dates, the SEC Documents complied in all material respects with the requirements of the Exchange Act and the rules and regulations of the SEC promulgated thereunder applicable to the SEC Documents, and none of the SEC Documents, at the time they were filed with the SEC, contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading. As of their respective dates, the financial statements of the Company included in the SEC Documents complied in all material respects with applicable accounting requirements and the published rules and regulations of the SEC with respect thereto as in effect as of the time of filing. The Company is not currently contemplating to amend or restate any of the financial statements (including, without limitation, any notes or any letter of the independent accountants of the Company with respect thereto) included in the SEC Documents (the "**Financial Statements**"), nor is the Company currently aware of facts or circumstances which would require the Company to amend or restate any of the Financial Statements, in each case, in order for any of the Financials Statements to be in compliance with IFRS and the rules and regulations of the SEC. The Company has not been informed by its independent accountants that they recommend that the Company amend or restate any of the Financial Statements or that there is any need for the Company to amend or restate any of the Financial Statements;

(f) The Company and each member of the Group maintains internal control over financial reporting (as such term is defined in Rule 13a-15(f) under the Exchange Act) that is effective to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles, including that (i) transactions are executed in accordance with management's general or specific authorisations, (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with United States generally accepted accounting principles or IFRS and to maintain asset and liability accountability, (iii) access to assets or incurrence of liabilities is permitted only in accordance with management's general or specific authorisation and (iv) the recorded accountability for assets and liabilities is compared with the existing assets and liabilities at reasonable intervals and appropriate action is taken with respect to any difference. The Company maintains disclosure controls and procedures (as such term is defined in Rule 13a-15(e) under the Exchange Act) that are effective in ensuring that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarised and reported, within the time periods specified in the rules and forms of the SEC, including, without limitation, controls and procedures designed to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is accumulated and communicated to the Company's management, including its principal executive officer or officers and its principal financial officer or officers, as appropriate, to allow timely decisions regarding required disclosure. Neither the Company nor any member of the Group has received any notice or correspondence from any accountant, governmental entity or other Person relating to any potential material weakness or significant deficiency in any part of the internal controls over financial reporting of the Company or any member of the Group that has not been fully remediated;

(g) that no event has occurred which would constitute (if the Bond Documents had been duly executed and the Bonds were issued and outstanding) an Event of Default or a Potential Event of Default (each as defined in the Conditions);

(h) that the Company and each member of the Group (i) is not in breach of the terms of, or in default under, any instrument, agreement or order to which it is a party or by which it or its property is bound and no event has occurred which with the giving of notice or lapse of time or other condition would constitute a default under any such instrument, agreement or order, except for any such breach or default which either individually or in the aggregate would not reasonably be expected to be material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder; (ii) is not engaged (whether as defendant or otherwise) in, nor has the Company knowledge of the existence of, or any threat of, any legal, arbitration, administrative, governmental or other proceedings an adverse result of which is reasonably likely to be material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder or which is reasonably likely to have or have had a Material Adverse Effect and (iii) has not taken any action nor, to the best of their knowledge or belief having made all reasonable enquiries, have any steps been taken or legal proceedings commenced for the winding up or dissolution of the Company or any member of the Group;

(i) that:

(i) the Company has 52,266,410 fully paid and issued Ordinary Shares as at the date of this Agreement;

(ii) the Company has 10,021,260 issued and outstanding ADSs as at the date of this Agreement;

(iii) the ADSs (other than any ADSs held by "affiliates" within the meaning of the Securities Act) and Ordinary Shares currently in issue are freely tradeable and admitted to trading on the relevant Stock Exchange in compliance with all applicable listing rules and the Company is in compliance with all applicable listing rules relating to the ADSs and Ordinary Shares, and it has made and will continue to make all applicable regulatory filings in respect of the listing and admission to trading of the ADSs and the Ordinary Shares with the relevant Stock Exchange;

(iv) any ADSs to be issued or delivered on conversion of the Bonds (or upon any ADS Settlement under the Bonds) shall be fungible with any and all ADSs currently in issue (other than any ADSs held by "affiliates" within the meaning of the Securities Act), such ADSs shall be issued without any restrictions on transfer imposed by the Securities Act, and the deposit of Ordinary Shares by the Company with the Depositary (as defined in the Conditions) and the issuance of ADSs of the Depositary to the Initial Bondholder in accordance with the Deposit Agreement (as defined in the Conditions) may be effected without registration of such deposit or issuance under the Securities Act and without the requirement to include restrictive legends on such ADSs;

(v) none of the ADSs and the Ordinary Shares represented by the ADSs to be issued or delivered on conversion of the Bonds (or pursuant to any share redemption option thereunder) will be issued or delivered in violation of the pre-emptive rights of any holder of ADSs or Ordinary Shares, respectively;

(vi) none of the ADSs to be issued or delivered on conversion of the Bonds (or upon any ADS Settlement under the Bonds) shall exceed the maximum amount of ADSs registered pursuant to the Company's F-6 registration statement;

(vii) the Company has available for issue and authority to allot, free from pre-emption rights, sufficient authorised but unissued ADSs and Ordinary Shares represented by the ADSs to enable the conversion rights attaching to the Bonds to be satisfied in full, and all other rights of subscription and conversion into ADSs to be satisfied in full in accordance with their terms;

(viii) the ADSs to be issued upon conversion of the Bonds (or upon any ADS Settlement under the Bonds) and the Ordinary Shares represented by such ADSs will be fully paid and will not be subject to calls for further funds and will be subject to the terms of the Deposit Agreement;

(ix) the ADSs to be issued and/or delivered upon conversion of the Bonds (or upon any ADS Settlement under the Bonds) and Ordinary Shares represented by such ADSs will rank *pari passu* with the then outstanding ADSs and Ordinary Shares, respectively, and will be free and clear of all liens, charges, pledges, encumbrances, security interests, claims and other third party rights;

(x) there are no outstanding securities convertible into or exchangeable for, or warrants, rights or options to purchase from the Company or any member of the Group, or obligations or commitments of the Company or any member of the Group to issue, sell or otherwise dispose of, the Ordinary Shares or the ADSs, other than securities issuable pursuant to the Company's equity incentive plans and employee stock purchase plan as described in the Company's Form 20-F as filed with the SEC in respect of its annual report for the financial year ended 30 June 2021;

(xi) there are no restrictions upon the voting or transfer of any of the ADSs or the Ordinary Shares whether pursuant to any law or any agreement or otherwise (other than as set forth in articles 36 and 70 of the Company's articles of association and Sections 2.8, 3.1, 3.5, 4.10 and 5.1 of the Deposit Agreement); and

(xii) subject to general provisions of law relating to the distribution of profits, there are no restrictions on the payment of dividends and other distributions declared and payable on the ADSs or the Ordinary Shares (other than as set forth in article 129 of the Company's articles of association and Sections 2.8 and 3.1 and Article 4 of the Deposit Agreement);

(j) that that Company and the members of the Group together own, possess or can acquire on reasonable terms, adequate Intellectual Property Rights necessary to conduct the business now operated by them, or presently employed by them, and have not received any notice of infringement of or conflict with asserted rights of others with respect to any Intellectual Property Rights, except where such notice of infringement or conflict, if determined adversely, would not, individually or in the aggregate, have a Material Adverse Effect;

(k) all statutory, municipal and other licences, franchises, consents, permits, approvals, orders, authorities and other concessions necessary and material for the carrying on of the businesses and operations of the Company and each member of the Group as now carried on, as previously carried on and as proposed to be carried on have been obtained (collectively, "**Licences**") and are (or were at the relevant time) valid and subsisting, except where the lack of such Licences, individually and in the aggregate, would not have a Material Adverse Effect;

(l) all conditions applicable to any such Licence have been and are complied with and no member of the Group is in breach of any such Licence, except where such breach would not, individually or in the aggregate, have a Material Adverse Effect;

(m) there are no circumstances or proceedings of which the Company is aware which indicate that:

(i) any such Licence may be; or

(ii) if determined adversely to any member of the Group, may cause any such Licence to be,

revoked, rescinded, modified, avoided or repudiated or not renewed, in whole or in part, in the ordinary course of events, except where such circumstances or proceedings would not, individually or in the aggregate, have a Material Adverse Effect;

(n) save in each case where it would not have, individually or in aggregate, a Material Adverse Effect:

(i) neither the Company nor any member of the Group is in violation of any applicable statute, law, rule, regulation, ordinance or rule of civil or common law or any judicial or administrative interpretation thereof, including any judicial or administrative order, consent, decree or judgment, relating to pollution or protection of human health, the environment (including, without limitation, ambient air, surface water, groundwater, land surface or subsurface strata) or wildlife, including, without limitation, laws and regulations relating to the release or threatened release of chemicals, pollutants, contaminants, wastes, toxic substances, hazardous substances, petroleum or petroleum products, asbestos-containing materials or mould (collectively, "**Hazardous Materials**") or to the manufacture, processing, distribution, use, treatment, storage, disposal, transport or handling of Hazardous Materials (collectively, "**Environmental Laws**");

(ii) the Company and each member of the Group has all Authorisations required under any applicable Environmental Laws and is in compliance with their requirements;

(iii) there are no pending or, to the knowledge and belief of the Company, threatened administrative, regulatory or judicial actions, suits, demands, demand letters, claims, liens, notices of non-compliance or violation, investigation or proceedings relating to any Environmental Law against it or any member of the Group; and

(iv) to the best of the Company's knowledge, there are no events or circumstances that would reasonably be expected to form the basis of an order for clean-up or remediation, or an action, suit or proceeding by any private party or governmental body or agency, against or affecting the Company or any member of the Group relating to Hazardous Materials or Environmental Laws;

(o) that (i) there are no claims by the Company or any member of the Group under any policy or instrument of insurance as to which any insurance company is denying liability or defending under a reservation of rights clause, and neither the Company nor any member of the Group has been refused any insurance coverage sought or applied for, in any such case, where the denial of liability in respect of such claim or refusal to provide insurance coverage, as the case may be, would reasonably be expected individually or in the aggregate to have a Material Adverse Effect and (ii) neither the Company nor any member of the Group has reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that would not have a Material Adverse Effect;

(p) that (i) neither the Company nor, to the best of the Company's knowledge, any other member of the Group is overdue in the filing with the appropriate taxing authorities of any tax returns, reports and other information required to be filed by it, and the Company and, to the best of the Company's knowledge, each other member of the Group has paid all taxes due thereon, except where any such failure to file such tax returns, reports and information or to pay such taxes could be reasonably expected to not have a Material Adverse Effect or where payment of such taxes is being contested in good faith, and each such tax return, report or other information was, when filed, accurate and complete in all material respects and there is no tax liability that has been asserted against the Company or any member of the Group which could be reasonably expected to have a Material Adverse Effect; (ii) neither the Company nor, to the best of the Company's knowledge, any other member of the Group has incurred any liability (or has committed any actions, or events have occurred, which would, to the best of the Company's knowledge, subject the Company or any other member of the Group to a liability) in respect of any tax which would reasonably be considered material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder, other than any such liabilities arising in the ordinary course of the business of the Company and the Group and any such liabilities which have been publicly announced prior to the date hereof; and (iii) neither the Company nor, to the best of the Company's knowledge, any member of the Group has paid nor is liable to pay nor has acted (directly or through an agent or other representative) in such manner as to incur a liability (or potential liability) to pay any interest or penalty in connection with any tax or otherwise paid any tax after its due date for payment or become liable to pay any tax, in each case, which would reasonably be expected to be material in the context of the issue of the Bonds and the purchase thereof by the Initial Bondholder;

(q) that neither the Company nor any other member of the Group nor any director, officer, agent, employee or affiliate of the Company or any other member of the Group is currently the subject or the target of any Sanctions or conducting business with any person, entity or country which is the subject or target of any Sanctions in a manner which is prohibited by such Sanctions;

(r) that neither the Company, any other member of the Group nor any director, officer, agent, employee or affiliate of the Company or any other member of the Group:

(i) has engaged in any activity or conduct which would violate any applicable anti-bribery or anti-corruption laws or regulations (including. without limitation. to the extent applicable. the U.S. Foreign Corrupt Practices Act of 1977 or the rules and regulations promulgated thereunder or under the UK Bribery Act 2010) ("**Anti-Bribery and Anti-Corruption Laws**");

(ii) has offered, promised, paid, received, requested or agreed to receive a bribe or other unlawful payment nor offered, promised or given any financial or other advantage to a public official (or to a third party at the request or acquiescence of the public official) in an attempt to influence them in their capacity as a public official to obtain or retain business, or to obtain an advantage in the conduct of business, where such offer, promise or payment is not permitted under applicable laws (a "**Prohibited Payment**");

(iii) has, to the best of the Company's knowledge, been subject to any investigation by any governmental entity, or any action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator, with regard to any actual or alleged Prohibited Payment or violation of Anti-Bribery and Anti-Corruption Laws; or

(iv) is, to the best of the Company's knowledge, subject to any investigation by any governmental entity, or any action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator with regard to any actual or alleged Prohibited Payment or violation of Anti-Bribery and Anti-Corruption Laws, and, to the best of the Company's knowledge, no such actions, suits or proceedings are threatened or contemplated;

(s) that the Company has instituted, maintains and enforces systems, controls, policies. procedures and legal processes for the purpose of preventing it and its directors and officers, employees and any other persons acting on its or their behalf from engaging in any action in breach of Anti-Bribery and Anti-Corruption Laws;

(t) that the operations of the Company and each other member of the Group are and have been conducted at all times in compliance with applicable financial record keeping and reporting requirements and money laundering statutes in the United Kingdom and of all jurisdictions in which the Company and each other member of the Group conduct business, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency and which is binding on the Company or a member of the Group (collectively, "**Money Laundering Laws**") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or any other member of the Group with respect to Money Laundering Laws is pending and, to the best of the Company's knowledge, no such actions, suits or proceedings are threatened or contemplated;

(u) that, in respect of issuing any ADSs on conversion of the Bonds (or upon any ADS Settlement under the Bonds), if any, no stamp or other duty or similar tax is assessable or payable in the United Kingdom, the United States, or other sub-division of or authority therein or thereof having power to tax, in each case in connection with the execution or delivery of the Bond Documents, the issue or delivery of the Bonds, the issuance and delivery of the ADSs (and the Ordinary Shares represented thereby) to be issued upon conversion of the Bonds or upon any ADS Settlement under the Bonds;

(v) that the Bonds will, upon issue, constitute direct, unconditional unsubordinated and (subject to Condition 2.1 (*Negative Pledge*)) unsecured obligations of the Company and will rank *pari passu* and rateably, without any preference among themselves, and at least equally with all other existing and future unsecured and unsubordinated obligations of the Company but, in the event of an insolvency of the Company, save for such obligations that may be preferred by provisions of law that are mandatory and of general application;

(w) that the Bonds have not been and will not be registered under the Securities Act and have not been registered or qualified under any state securities or "Blue Sky" laws of the states of the United States and, accordingly, the Company acknowledges that the Bonds may not be offered or sold within the United States or to or for the account or benefit of U.S. persons except in accordance with Regulation S or pursuant to another exemption from the registration requirements of the Securities Act (terms used in this paragraph have the meaning given to them by Regulation S);

(x) the Company and each member of the Group is in compliance with any and all applicable requirements of the Sarbanes-Oxley Act of 2002, as amended, and any and all applicable rules and regulations promulgated by the SEC thereunder;

(y) the Company is not, and has never been, an issuer identified in, or subject to, Rule 144(i);

(z) the Company is a "foreign issuer" and has implemented "offering restrictions" (as such terms are defined in Regulation S); and

(aa) that none of the Company nor any of its respective affiliates, nor any persons acting on any of their behalf, has engaged or will engage in any directed selling efforts (as defined in Rule 902(c) under the Securities Act) with respect to the Bonds.

9. Representations of the Initial Bondholder

The Initial Bondholder represents, warrants and confirms to the Company as follows:

(a) that it has been duly incorporated and is validly existing and registered in its jurisdiction of incorporation and is not in liquidation, receivership or bankruptcy and it has full power and authority to execute and perform its obligations under this Agreement;

(b) that the execution and delivery of this Agreement and the performance of the terms of this Agreement (i) to the best of the Initial Bondholder's knowledge, will not infringe any law, regulation, order, rule, decree or statute applicable to the Initial Bondholder or to which its property may be subject, (ii) are not contrary to the provisions of the constitutional documents of the Initial Bondholder and (iii) will not result in any breach of the terms of, or constitute a default under, any instrument, agreement or order to which the Initial Bondholder is a party or by which the Initial Bondholder or any of its property is bound;

(c) that it understands that the Bonds have not been and will not be registered under the Securities Act or with any securities regulatory authority of any state or other jurisdiction of the United States, that any offer and sale of the Bonds to it is being made in reliance on an exemption from, or is a transaction not subject to, the registration requirements of the Securities Act in a transaction not involving any public offering in the United States;

(d) that it represents and warrants that its purchase of the Bonds is lawful under the laws of the jurisdiction of its incorporation and the jurisdiction in which it operates (if different), and that such acquisition will not contravene any law, regulation or regulatory policy applicable to it;

(e) that it is a professional client as defined in point (8) of Article 2(1) of Regulation (EU) No. 600/2014 as it forms part of United Kingdom domestic law by virtue of the EUWA;

(f) that it is an investment professional within the meaning of Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005;

(g) that it is a "qualified investor" as defined under Article 2 of Regulation (EU) 2017/1129 as it forms part of United Kingdom domestic law by virtue of the EUWA;

(h) that it is acquiring the Bonds for its own account, or for one or more accounts (and as to each of which it has authority to acquire the Bonds and exercise sole investment discretion), for investment purposes, and not with a view to, or for resale in connection with, the distribution thereof, directly or indirectly, in whole or in part, in the United States in violation of the Securities Act and that neither it nor any account for which it is acting (if any) was formed for the specific purpose of acquiring the Bonds;

(i) that it, and any account it is acquiring the Bonds for, is not a "U.S. Person" and is purchasing the Bonds in an "offshore transaction" (as such terms are defined under Regulation S) and that it understands that the Bonds will be subject to a distribution compliance period under Regulation S of the Securities Act;

(j) that it understands that the Bonds may only be resold or otherwise transferred in a transaction exempt from, or not subject to, the registration requirements of the Securities Act, and in compliance with applicable state securities law, and that the Company is not required to register the Bonds under the Securities Act;

(k) that it is not a Person whose business is or includes issuing depositary receipts for chargeable securities, or a Person whose business is or includes holding chargeable securities as nominee or agent for such a first-mentioned person, respectively within the meaning of subsections 93(2) and 93(3) Finance Act 1986, or a Person whose business is or includes the provision of clearance services for the purchase and sale of chargeable securities, or a Person whose business is or includes holding chargeable securities as nominee for such a first-mentioned person, respectively within the meaning of subsections 96(1)(a) and 96(1)(b) Finance Act 1986; and

10. Undertakings by the Company

The Company undertakes with the Initial Bondholder as follows:

(a) it will forthwith notify the Initial Bondholder if at any time prior to payment of the net subscription monies for the Bonds on the Closing Date anything occurs which renders or which they are aware is likely to render untrue or incorrect in any respect any of the representations and warranties contained in Clause 8 (*Representations of the Company*);

(b) during the period commencing on the date hereof and ending 30 days after the Closing Date (both dates inclusive) the Company will not, and will procure that none of its Subsidiaries will, without the prior written consent of the Initial Bondholder (i) directly or indirectly, issue, offer, pledge, sell, contract to issue or sell, issue or sell any option or contract to purchase, purchase any option or contract to issue or sell, grant any option, right or warrant to purchase or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or Relevant Securities or any securities convertible into or exercisable or exchangeable for Ordinary Shares or Relevant Securities or (ii) enter into any swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, any of the economic consequences of ownership of Ordinary Shares or Relevant Securities, whether any such swap or transaction described in limb (i) or (ii) above is to be settled by delivery of Ordinary Shares or Relevant Securities or such other securities, in cash or otherwise. The foregoing sentence shall not apply to (a) the issue of the Bonds, (b) any ADSs (and Ordinary Shares represented thereby) issued and/or transferred pursuant to the conversion of the Bonds, (c) the issue and sale of any Equity Raise Securities pursuant to the Equity Raise, (d) the issuance, offering, exercise, allotment, purchase, appropriation or grant of Ordinary Shares or other Securities (as defined in the Conditions (including, but not limited to, rights, warrants and options)) pursuant to any employee share schemes or benefits or incentive arrangements existing at the date hereof or entered into in the ordinary course of business, (e) the filing of any registration statement on Form S-8 relating to securities granted or to be granted pursuant to any employee share schemes or benefits or incentive arrangements existing at the date hereof or entered into in the ordinary course of business, (f) the filing of any "shelf" registration statement on Form F-3, (g) entry into an at-the-market sales agreement (but not including any issuances and sales of Relevant Securities pursuant to such agreement(s)) or (h) the issuance and sale of a number of Ordinary Shares (including Ordinary Shares represented by ADSs) equal to the remaining amount of Ordinary Shares authorised for issuance under the Company's existing shareholder authority after giving effect to the Equity Raise and issuance of the Bonds. For the purposes of this paragraph "**Relevant Securities**" shall include any participation certificates and any depositary or other receipt, instrument, rights or entitlement representing Ordinary Shares;

(c) it shall make or cause to be made on its behalf an application for the ADSs and Ordinary Shares issued pursuant to the Equity Raise to be admitted to trading and listing on the relevant Stock Exchange on or by the Closing Date, if required;

(d) it shall maintain the ADSs' listing or authorisation for quotation (as the case may be) on the relevant Stock Exchange and it shall not, and will procure that other members of the Group shall not, take any action which could be reasonably expected to result in the delisting or suspension of the ADSs on the relevant Stock Exchange;

(e) it will use the proceeds from the issue of the Bonds, as well as the proceeds of the Equity Raise for the general corporate purposes of the Company; and

(f) it will not directly or indirectly use all or part of the proceeds of the Bonds or the Equity Raise, or lend, contribute or otherwise make available all or part of such proceeds to any subsidiary, joint venture partner or other Person, for the purpose of funding or financing the activities of or business with any Person, or in any country or territory, that is, or whose government is, the subject of any Sanctions at the time of such funding or financing.

11. Transfers of Rights and Obligations

11.1. Assignment

Except as set out below in Clause 11.2 (*Permitted Transfers*), no Party may assign or transfer its rights, benefits and obligations under this Agreement or any Bond (including the Conditions).

11.2. Permitted Transfers

(a) Subject to Clauses 5.4 (*Closed Periods*), 5.5 (*Regulations Concerning Transfers and Registration*) and the other provisions of this Clause 11.2, a Bondholder (being an "**Existing Holder**") may at any time transfer a Bond or Bonds to any Person (a "**New Holder**"), *provided that*:

(i) the aggregate principal amount of such Bond or Bonds transferred is in a principal amount which at the Closing Date had an initial principal amount of not less than U.S.$200,000;

(ii) the Bond or Bonds are being transferred in a transaction exempt from, or not subject to, the registration requirements of the Securities Act, and in each case in compliance with applicable state securities law; and

(iii) prior to such transfer, such New Holder executes and delivers a duly completed and executed Transfer and Accession Deed by the Existing Holder and the New Holder, to the Company at its address for notice, together with such evidence as the Company may reasonably require to prove the title of the Existing Holder and the authority of the individuals who have executed the Transfer and Accession Deed.

(b) A Bondholder may not transfer a Bond to a Person who (i) is a retail client as defined in point (6) of Article 4(1) of Regulation (EU) 1286/2014/EU as it forms part of
English law by virtue of the EUWA, as amended; (ii) is a customer within the meaning

of the FSMA and any rules or regulations made under FSMA to implement Directive (EU) 2016/97, where that customer would not qualify as a professional client as defined in point (8) of Article 2(1) of Regulation (EU) No. 600/2014 as it forms part of United Kingdom domestic law by virtue of the EUWA; or (iii) is not a qualified investor as defined in Regulation (EU) 2017/1129 of the European Parliament and of the Council as it forms part of United Kingdom domestic law by virtue of the EUWA.

(c) A Bondholder may only transfer a Bond to a Person in circumstances that does not result in the Bondholder of the Company acting in breach of section 21 of FSMA or any equivalent legislation.

(d) Every Transfer and Accession Deed in respect of the Bonds must be delivered to the Company at its address for notice (which may include electronic delivery) and must be accompanied by the surrender of the relevant Bond Certificate.

(e) Following receipt of the Transfer and Accession Deed and the surrender of the relevant Bond Certificate (if applicable) in accordance with this Clause 11.2, the Company will (subject to and in accordance with the requirements of Schedule 7 (*Regulations Concerning Transfers and Registration of the Bonds*)) promptly register the transfer in the Register and issue a copy of the updated Register to the New Holder.

(f) Such transfer of Bonds will be effected without charge, subject to the Person making such application for transfer paying or procuring the payment of any taxes, duties and other governmental charges in connection therewith.

12. Undertaking of Bondholders

12.1. Non-Trading Periods

The Company shall, not later than ten Business Days following the occurrence of the Closing Date, give notice to the Initial Bondholder (and each subsequent Bondholder within five Business Days of such Bondholder's accession to this Agreement in accordance with Clause 11 (*Transfers of Rights and Obligations*)) of a schedule detailing each of the following dates:

(a) each period of 14 calendar days prior to an Interest Payment Date and Amortisation Payment Date (each as defined in the Conditions); and

(b) except where in respect of the first Dealing Day immediately preceding the first day of such period the Volume Weighted Average Price (as defined in the Conditions) of an ADS is equal to or more than 105 per cent. of the Conversion Price (as defined in the Conditions) at such time, each period of 6 weeks prior to each Reset Date (as defined in the Conditions),

each such period, a "**Non-Trading Period**".

12.2. Agreement Not to Short Sell Ordinary Shares or ADSs in Calculation Periods

The Initial Bondholder and each subsequent Bondholder (by its accession to this Agreement by a Transfer and Accession Deed) agrees that, for so long as it is a holder of any Bonds, it shall not sell Ordinary Shares or ADSs nor engage in any short sale transactions in Ordinary Shares or ADSs nor offer to sell, pledge, enter into any option or contract to sell, or otherwise transfer or dispose of, directly or indirectly, any Ordinary Shares or ADSs or enter into any

swap or any other agreement or any transaction that transfers, in whole or in part, directly or indirectly, any of the economic consequences of ownership of Ordinary Shares or ADSs, whether any such swap or transaction is to be settled by delivery of Ordinary Shares, ADSs or such other securities, in cash or otherwise, in each case during any Non-Trading Period. Nothing in this Clause 12.2 shall restrict a Bondholder from selling or transferring any Bonds.

12.3. **Maximum Trading Volume**

The Initial Bondholder and each subsequent Bondholder (by its accession to this Agreement by a Transfer and Accession Deed) agrees that, for so long as it is a holder of any Bonds, it shall not enter into any purchase or sale agreements for ADSs, nor engage in any short sale transactions in ADSs, in each case on any Dealing Day on which such number of ADSs subject to such transactions entered into by such Bondholder account for more than: (a) 40 per cent. of the daily volume of the ADSs calculated on the basis of the average daily traded volume during the previous 20 Dealing Days, or (b) 25 per cent. of the weekly (being all Dealing Days in any Monday to Sunday period) volume of the ADSs calculated on the basis of the average weekly (being all Dealing Days in any Monday to Sunday period) volume during the last four weeks, *provided that* nothing in this Clause 12.3 shall restrict the Initial Bondholder and each subsequent Bondholder from entering into any purchase or sale agreements for ADSs, or engaging in any short sale transactions in ADSs, in relation to up to 15,000 ADSs on any Dealing Day.

12.4. **No Liability for Other Bondholders**

Following a transfer of Bonds, the relevant transferor (including the Initial Bondholder, if applicable) shall have no liability for the actions of transferees or other Bondholders, nor shall it have any obligation to enforce the terms of Clause 12.2 (*Agreement Not to Short Sell Ordinary Shares or ADSs in Calculation Periods*) and Clause 12.3 (*Maximum Trading Volume*) or any other terms of this Agreement against any other Bondholders.

12.5. **Beneficial Ownership of Ordinary Shares**

Notwithstanding any other provision of this Agreement or the Conditions, each of the Initial Bondholder and any subsequent Bondholder (by its accession to this Agreement by a Transfer and Accession Deed) shall not at any time own or acquire the beneficial ownership (as such term is defined in Rule 13d-3 under the Exchange Act) of more than [***] of the issued and outstanding Ordinary Shares (which for this purpose shall include Ordinary Shares represented by outstanding ADSs or other depositary receipts or certificates representing Ordinary Shares) in the Company.

13. Notices

13.1. **Communications in Writing**

Any communication to be made under or in connection with the Bond Documents shall be made in writing and, unless otherwise stated, may be made by email or letter.

13.2. **Addresses**

The address and email address (and the department or officer, if any, for whose attention the communication is to be made) of each Party for any communication or document to be made or delivered under or in connection with the Bond Documents and the Bonds is:

(a) in the case of the Company:

Renalytix plc
Address: Finsgate
5-7 Cranwood Street
London EC1V 9EE
United Kingdom

Email: [***]
Attention: James McCullough, Chief Executive Officer

With copies (which shall not constitute notice) to:

Cooley (UK) LLP
Address: 22 Bishopsgate
London, UK EC2N 4BQ

Email: ckeastbutler@cooley.com
Attention: Claire Keast-Butler

Cooley LLP
Address: 500 Boylston Street, 14th Floor
Boston, Massachusetts 02116-3736

Email: mrecht@cooley.com
Attention: Marc A. Recht

(b) In the case of the Initial Bondholder:

CVI Investments, Inc.
Address: c/o Heights Capital Management, Inc.
101 California Street, Suite 3250
San Francisco, CA 94111

Email: [***]
Attention: [***]

or any substitute address or email address or department or officer as the Party may notify to the other Parties by not less than five Business Days' notice. Any such notice shall take effect, in the case of a letter, at the time of delivery, or in the case of email transmission, at the time of despatch (unless a delivery failure notification is received by the sender within 12 hours of sending such communication, in which case such notice shall be deemed not to have taken effect).

If such delivery is made after 5:00 p.m. (*London time*) or on a day which is not a London business day (in respect of matters where only London business days are specified) or Business Day (in respect of all other matters), such delivery shall be deemed to have been made on the next following London business day or Business Day, as applicable.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

14. Confidential Information

14.1. Confidentiality

Each Party agrees to keep all Bond Documents and their contents (the "**Confidential Information**") strictly confidential and not to disclose it to anyone, save to the extent permitted by Clause 14.2 (*Disclosure of Confidential Information*).

14.2. Disclosure of Confidential Information

(a) Each Party may disclose Confidential Information on a confidential basis to the accountants, legal counsels and other professional advisors retained by the Company (or its advisors) and the Bondholders, respectively, or to any other agent, clearing system or other third party proposed by the Parties to be involved in the transaction contemplated hereby, or as required by applicable law, regulation, stock exchange rules, judicial or regulatory order, or any Governmental Authority (including, without limitation, the rules and regulations of the SEC), or to any tax authority in connection with the tax affairs or reporting obligations of the disclosing Party, or to the extent that one of the Parties needs to disclose the same for the exercise, protection of enforcement of its rights under this Agreement or the Bonds, and may not disclose Confidential Information to any other Person (other than, in the case of the Bondholders, any of their affiliates, agents, management entities or funds under common management or control) without the prior written consent of the other Party.

(b) Any publications and/or or filings made by or on behalf of the Company and which include a reference to the name, identity or business of the Initial Bondholder will only be disclosed by the Company with the prior written consent of the Initial Bondholder, unless required to do so by law, regulation, stock exchange rules, judicial or regulatory order, any Governmental Authority, or any tax authority in connection with the tax affairs or reporting obligations of the Company, in which case the Company shall use all reasonable endeavours to consult with the Initial Bondholders on the content of such publication or filings insofar as it relates to the Initial Bondholder prior to such disclosure.

(c) Each Bondholder may disclose Confidential Information to any Person in connection with the potential assignment or novation their rights, benefits and/or obligations under this Agreement and the Bonds (or discussions in relation thereto), or to any New Holder with whom it duly executes a Transfer and Accession Deed.

(d) On or following the date hereof, the Company may publicly disclose this Agreement and the Conditions (and/or a summary thereof) through a regulatory information service of each of the Stock Exchanges, irrespective of whether it is required to make such disclosure under applicable law.

14.3. Restricted Information

The Company shall not (without first entering into a separate confidentiality agreement with each Bondholder) provide any Bondholder with any non-public price sensitive information regarding the Bonds, the Ordinary Shares, the ADSs, the Company or its Group.

14.4. Announcements

The Company will ensure that all announcements and documents published or statements made by it or on its behalf, which refer to any Bondholder by name will only be made or

published with the prior written consent of that Bondholder and will be true and accurate and not misleading in any material respect and, where appropriate, will contain all information necessary for legal or regulatory purposes and all opinions included will be honestly held and given after due and careful consideration. Nothing in this Clause 14.4 shall restrict the Company from at any time making any disclosure or announcement which is required by any applicable law, regulation, stock exchange rule, judicial or regulatory order, any Governmental Authority, or any tax authority in connection with the Company's tax affairs and reporting obligations.

15. Payments

All payments in respect of the obligations of the Company under this Agreement shall be made free and clear of, and without withholding or deduction for or on account of, any taxes, duties, assessments or governmental charges of whatever nature imposed, levied, collected, withheld or assessed by or on behalf of any Tax Jurisdiction (as defined in the Conditions), unless such withholding or deduction is required by law. In that event, the Company shall pay such additional amounts as will result in the receipt by each Bondholder of such amounts as would have been received by it if no such withholding or deduction had been required.

16. Severability

If any provision in or obligation under this Agreement is or becomes invalid, illegal or unenforceable in any respect under the law of any jurisdiction, that will not affect or impair (i) the validity, legality or enforceability under the law of that jurisdiction of any other provision in or obligation under this Agreement, and (ii) the validity, legality or enforceability under the law of any other jurisdiction of that or any other provision in or obligation under this Agreement.

17. Remedies and Waivers

No failure or delay by either Party to exercise any right or remedy provided under this Agreement or by law shall constitute a waiver of that or any other right or remedy, nor shall it prevent or restrict the further exercise of that or any other right or remedy. No single or partial exercise of such right or remedy shall prevent or restrict the further exercise of that or any other right or remedy.

18. Amendments and Waivers

18.1. Prior to Closing

Up to the completion of Closing, the Parties may, in their absolute discretion, agree to any modification, alteration or addition to this Agreement (including the Conditions).

18.2. **From Closing**

From the completion of Closing, the provisions of this Agreement (including the Conditions) may not be modified, altered, abrogated or added to other than as provided in, and in accordance with, Condition 14 (*Amendment and Waiver*).

19. Counterparts

This Agreement may be executed in any number of counterparts, and this has the same effect as if the signatures on the counterparts were on a single copy of this Agreement.

20. Contracts (Rights of Third Parties) Act 1999

A Person who is not a Party to this Agreement has no right under the Contracts (Rights of Third Parties) Act 1999 to enforce any term of this Agreement, but this does not affect any right or remedy of a third Party which exists or is available apart from that Act.

21. Governing Law and Jurisdiction

21.1. **Governing Law**

This Agreement, and any non-contractual obligations arising out of or in connection with it, are and shall be governed by, and construed in accordance with, English law.

21.2. **Jurisdiction**

The courts of England are to have exclusive jurisdiction to settle any disputes which may arise out of or in connection with this Agreement and any non-contractual obligations arising out of or in connection with it and accordingly any legal action or proceedings arising out of or in connection with this Agreement or any such obligations may be brought in such courts. Each of the Parties irrevocably waives any objection which it might now or hereafter have to the courts of England being nominated as the forum to hear and determine any such legal action or proceedings and agrees not to claim that any such court is not a convenient or appropriate forum.

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Schedule 1

Subscription Allocation

Name of Initial Bondholder	Aggregate principal amount of Bonds
CVI Investments, Inc.	U.S.$21,200,000.

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Schedule 2

Conditions Precedent

[***]

(a)

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Schedule 3

Form of Bond Certificate

[***]

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Schedule 4

Terms and Conditions of the Bonds

The issue of the US$21,200,000 5.5 per cent. Amortizing Senior Convertible Bonds due 2027 in an aggregate principal amount as specified in the Initial Determinations Notice (the "**Bonds**", which expression shall, unless otherwise indicated, include any Further Bonds (as defined below)) was (save in respect of any Further Bonds) authorised by a resolution of the board of directors of Renalytix plc (the "**Issuer**") passed on 30 March 2022. The Bonds are convertible into ADSs representing Ordinary Shares (each as defined in these Conditions) of the Issuer.

The Bonds are constituted by an Amended and Restated Bond Agreement dated 5 April 2022 (the "**Bond Agreement**") between the Issuer and the Initial Bondholder. The statements set out in these Terms and Conditions (the "**Conditions**") are subject to the provisions of the Bond Agreement.

The existing ADSs are, and the ADSs to be issued upon conversion of the Bonds or upon exercise by the Issuer of an ADS Settlement Option (as defined below) will be, evidenced by American Depositary Receipts ("**ADRs**") issued pursuant to a deposit agreement dated 21 July 2020, as amended, supplemented, modified, restated or superseded from time to time (the "**Deposit Agreement**") among the Issuer, Citibank, N.A. as depositary (the "**Depositary**", which term shall include any successor depositary), and the holders and beneficial owners from time to time of the ADRs.

The Issuer shall also enter into a calculation agency agreement (the "**Calculation Agency Agreement**") dated on or about the date of the Bond Agreement with Conv-Ex Advisors Limited (the "**Calculation Agent**", which expression shall include any successor as calculation agent under the Calculation Agency Agreement) whereby the Calculation Agent has been appointed to make certain calculations in relation to the Bonds. The Bondholders are deemed to have notice of those provisions applicable to them which are contained in the Calculation Agency Agreement.

Capitalised terms used but not defined in these Conditions shall have the meanings attributed to them in the Bond Agreement unless the context otherwise requires or unless otherwise stated.

1. Form, Initial Denomination, Title and Status

1.1 Form and Initial Denomination

The Bonds are in registered form in initial principal amounts of $200,000 each, as may be adjusted from time to time in accordance with Condition 7.1.

1.2 Title

Title to the Bonds will pass by transfer and registration as described in Clause 5 (*Register and Title*) of the Bond Agreement and Condition 4. Each holder of Bonds will (except as otherwise required by law or as ordered by a court of competent jurisdiction) be treated as the absolute owner of such Bond for all purposes (whether or not it is overdue and regardless of any notice of ownership, trust or any interest in such Bond, any writing on the Bond Certificate relating to such Bonds (other than a duly executed transfer thereof) or any notice of any previous loss or theft of such Bond Certificate) and no person will be liable for so treating such holder.

1.3 Status

The Bonds constitute direct, unconditional, unsubordinated and (subject to Condition 2.1) unsecured obligations of the Issuer ranking *pari passu* and rateably, without any preference among themselves, and at least equally with all other existing and future unsecured and unsubordinated obligations of the Issuer but, in the event of an insolvency of the Issuer, save for such obligations that may be preferred by provisions of law that are mandatory and of general application.

2. Covenants

2.1 Negative Pledge

For so long as the principal amount outstanding under the Bonds is equal to or exceeds U.S.$3,000,000, the Issuer shall not, and will procure that none of its Subsidiaries will, create or permit to subsist any Security Interest (as defined below), other than a Permitted Security Interest, upon the whole or any part of its present or future undertaking, assets or revenues (including any uncalled capital) to secure any Financial Indebtedness or to secure any Financial Indebtedness Guarantee, without at the same time or prior thereto securing the obligations of the Issuer under the Bonds and the Bond Agreement (including these Conditions) equally and rateably therewith or providing such other security, guarantees and/or other arrangements for the benefit of Bondholders as may be approved by all of the Bondholders.

For the purposes of this Condition:

"**Finance Lease**" means any lease or hire purchase contract, a liability under which would, in accordance with IFRS, be treated as a balance sheet liability.

"**Financial Indebtedness**" means any indebtedness of any Person for or in respect of:

(a) moneys borrowed;

(b) amounts raised by acceptance under any acceptance credit facility;

(c) amounts raised pursuant to any note purchase facility or the issue of bonds, notes, debentures, loan stock or similar instruments;

(d) the amount of any liability in respect of any Finance Leases;

(e) the amount of any liability in respect of any purchase price for assets or services the payment of which is deferred primarily as a means of raising finance or financing the acquisition of the relevant asset or service;

(f) amounts raised under any other transaction (including any forward sale or purchase agreement and the sale of receivables or other assets on a "with recourse" basis) having the commercial effect of a borrowing;

(g) any derivative transaction entered into in connection with protection against or benefit from fluctuation in any rate or price (and, when calculating the value of any derivative transaction, only the mark-to-market value shall be taken into account);

(h) any counter-indemnity obligation in respect of any guarantee, indemnity, bond, standby or documentary letter of credit or any other instrument issued by a bank or financial institution; and

(i) the amount of any liability in respect of any guarantee or indemnity for any of the items referred to in paragraphs (a) to (h) above.

"**Financial Indebtedness Guarantee**" means in relation to any Financial Indebtedness of any person, any obligation of another person to pay such indebtedness including (without limitation) (i) any obligation to purchase such indebtedness, (ii) any obligation to lend money, to purchase or subscribe shares or other securities or to purchase assets or services in order to provide funds for the payment of such indebtedness, (iii) any indemnity against the consequences of a default in the payment of such indebtedness and (iv) any other agreement to be responsible for repayment of such indebtedness.

"**Permitted Security Interest**" means in relation to the Issuer and its Subsidiaries:

(a) any Security Interest securing any Financial Indebtedness or any Financial Indebtedness Guarantee of a person existing at the time that such person is merged into, or consolidated with, the Issuer or any of its Subsidiaries or becomes a member of the Group, provided that such Security Interest was not created in contemplation of, and the principal amount secured has not increased in contemplation of or since, such merger or consolidation or acquisition of such person;

(b) any Security Interest existing on any property or assets prior to the acquisition thereof by the Issuer or any Subsidiary, provided that such Security Interest was not created in contemplation of, and the amount secured has not increased in contemplation of or since, such acquisition;

(c) any renewal of or substitution for any Security Interest permitted by any of paragraphs (a) to (c) (inclusive) of this definition, provided that with respect to any such Security Interest (i) the principal amount secured has not increased and (ii) the Security Interest has not been extended to any additional assets (other than the proceeds of such assets);

(d) any Security Interest on property acquired (or deemed to be acquired) under a Finance Lease, or claims arising from the use or loss of or damage to such property, provided that any such encumbrance secures only rentals and other amounts payable under such lease;

(e) any Security Interest arising under any retention of title, hire purchase, consignment or conditional sale arrangement (including any Finance Lease) or arrangements having similar effect in respect of goods supplied to the Issuer or any of its Subsidiaries in the ordinary course of business and on the supplier's standard or usual terms and not arising as a result of any default or omission by the Issuer or any of its Subsidiaries;

(f) any Security Interest in respect of any interest rate swap, option, cap, collar or floor agreement or any foreign currency swap agreement or other similar agreement or arrangement designed to protect the Issuer or any Subsidiary against fluctuations in interest or foreign currency rates or in respect of any commodity option, swap or other similar agreement or arrangement to protect the Issuer or any Subsidiary against fluctuations in the price of such commodity or in respect of hedging any similar risk to which any member of the Group is exposed in the ordinary course of its business;

(g) (i) a right of set-off, right to combine accounts or any analogous right which any bank or other financial institution may have relating to any credit balance of the Issuer or any of its Subsidiaries, provided that (x) such deposit account is not a dedicated secured cash account and is not subject to restrictions against access by the Issuer or any of its Subsidiaries, and (y) such account is not intended to provide security to the depository institution; and (ii) any Security Interest arising in the ordinary course of cash management, cash pooling or netting or setting off arrangements or other banking transactions, including customary credit card facilities and letters of credit;

(h) any Security Interest on any assets securing Financial Indebtedness which arises pursuant to any order or attachment, distraint or similar legal process arising in connection with court proceedings so long as the execution or other enforcement thereof is effectively stayed and the claims secured thereby are being contested in good faith by appropriate proceedings;

(i) any lien granted as part of a commercial bank's general terms and conditions;

(j) any Security Interest over rental deposits arising in the ordinary course of day-to-day business in respect of any property leased or licensed by a member of the Group; and

(k) any Security Interest arising by operation of law and in the ordinary course of business.

"**Security Interest**" means a mortgage, charge, pledge, lien or other security interest securing any obligation of any person or any other agreement or arrangement having a similar effect.

2.2 Incurrence of Indebtedness

For so long as the principal amount outstanding under the Bonds is equal to or exceeds U.S.$5,000,000, the Issuer shall not, and shall procure that its Subsidiaries shall not, at any time permit to create, incur, assume or otherwise become liable in respect of any Financial Indebtedness, contingently or otherwise, other than:

(a) any existing Financial Indebtedness of the Issuer or any of its Subsidiaries incurred on the date of the Bond Agreement and any modification, extension, exchange or refinancing thereof, provided that the principal amount thereunder shall not be increased;

(b) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness represented by the Bonds;

(c) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness in exchange for, or the proceeds of which are used to renew, refund, refinance, replace, exchange, discharge, redeem or refinance in whole or in part, any Financial Indebtedness of the by the Issuer and its Subsidiaries;

(d) the incurrence by the Issuer or any of its Subsidiaries of any trade or receivables finance Financial Indebtedness in respect of receivables owing to the Issuer or any Subsidiary and payable or dischargeable in accordance with customary trade terms; provided, however, that such trade terms may include such concessionary trade terms as the Issuer or any such Subsidiary deems reasonable under the circumstances;

(e) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness under Finance Leases of vehicles, plant, equipment or computers;

(f) the incurrence by the Issuer or any of its Subsidiaries of hedging obligations not intended for speculative purposes (as determined in good faith by the Issuer);

(g) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness in respect of letters of credit, bank guarantees, bid, performance, appeal, surety and similar bonds, completion guarantees, judgment, advance payment, customs, VAT
or similar instruments issued for the account of the Issuer or any of its Subsidiaries in the ordinary course of business

(h) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness in respect of any customary cash management, cash pooling or netting or setting off arrangements, including customary credit card facilities, entered into in the ordinary course of business;

(i) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness arising from the honouring by a bank or other financial institution of a cheque, draft or similar instrument inadvertently drawn against insufficient funds, so long as such Indebtedness is covered within five New York business days; and

(j) the incurrence by the Issuer or any of its Subsidiaries of Financial Indebtedness (other than and in addition to Financial Indebtedness permitted under the foregoing paragraphs) in an aggregate principal amount at any time outstanding not exceeding U.S.$1 million.

3. Definitions

In these Conditions, unless otherwise provided:

"**5-Day ADSSO Average Market Price**" has the meaning provided in Condition 9.9.

"**10-Day ADSSO Average Market Price**" has the meaning provided in Condition 9.9.

"**30-Day Reset Average Market Price**" means, in respect of any Reset Date, the arithmetic average (rounded to the nearest integral multiple of $0.0001 (with $0.00005 being rounded upwards)) of the Volume Weighted Average Price of an ADS (translated if necessary into US Dollars at the Prevailing Rate) on each Dealing Day in the relevant Average Market Price Observation Period, provided that:

(i) if any such Dealing Day falls on or after the Applicable Adjustment Reference Date in respect of any adjustment required to be made to the Conversion Price pursuant to these Conditions (other than an adjustment pursuant to Condition 6.4 or Condition 6.5) and such adjustment is not yet in effect on such Reset Date, the Volume Weighted Average Price on such Dealing Day shall be divided by the adjustment factor (as determined pursuant to these Conditions) applied to the Conversion Price in respect of such adjustment;

(ii) if any such Dealing Day falls before the Applicable Adjustment Reference Date in respect of any adjustment required to be made to the Conversion Price pursuant to these Conditions (other than an adjustment pursuant to Condition 6.4 or Condition 6.5) and such adjustment is in effect on such Reset Date, the Volume Weighted Average Price on such Dealing Day shall be multiplied by the adjustment factor (as determined pursuant to these Conditions) applied to the Conversion Price in respect of such adjustment; and

(iii) if any doubt shall arise as to the calculation of the 30-Day Reset Average Market Price or if the 30-Day Reset Average Market Price cannot be determined as provide d above, the 30-Day Reset Average Market Price shall be equal to such price as is determined in such other manner as an Independent Adviser shall consider to be appropriate to give the intended result.

"**Accelerated Amortisation Payment Date**" has the meaning provided in Condition 7.1(c)(ii).

"**Additional ADSs**" has the meaning provided in Condition 6.3.

"**Additional Cash Alternative Amount**" has the meaning provided in Condition 6.11.

"**Adjustment Reference Date**" means, in respect of any adjustment to the Conversion Price pursuant to Condition 6.2, (a) in the case of an adjustment pursuant to Conditions 6.2(a), 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i), the relevant record date or other due date for the establishment of entitlement of the relevant event gives to such adjustment and (b) in the case of an adjustment pursuant to Conditions 6.2(f), 6.2(g) or 6.2(h), the relevant date of the first public announcement as is mentioned in Conditions 6.2(f), 6.2(g) or 6.2(h), as the case may be.

"**ADSs**" (or an "**ADS**") means American Depositary Shares evidenced by ADRs issued pursuant to the Deposit Agreement, with each such ADS representing, as at the Closing Date, two Ordinary Shares.

"**ADS Settlement**" has the meaning provided in Condition 9.9.

"**ADS Settlement Liquidity Event**" has the meaning provided in Condition 9.9.

"**ADS Settlement Option**" means, as the case may be, an Interest ADS Settlement Option or a Principal ADS Settlement Option, as further described in Condition 9.9.

"**ADS Settlement Retroactive Adjustment**" has the meaning provided in Condition 9.9.

"**AIM** " means AIM, a market operated by London Stock Exchange plc.

"**Amortisation Payment Date**" has the meaning provided in Condition 5.1(a).

"**Amortised Payment Advancement**" has the meaning provided in Condition 5.1(a)(ii).

"**Amortised Payment Amount**" has the meaning provided in Condition 5.1(a).

"**Amortised Payment Deferral**" has the meaning provided in Condition 5.1(a)(i).

"**Applicable Adjustment Reference Date**" means, in respect of any adjustment to the Conversion Price pursuant to Condition 6.2, (i) in the case of an adjustment pursuant to Conditions 6.2(a), 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i), the relevant Ex-Date of the relevant event in respect of which such adjustment is made and (ii) in the case of an adjustment pursuant to Conditions 6.2(f), 6.2(g) or 6.2(h), the relevant Adjustment Reference Date.

"**Articles of Association**" means the articles of association of the Issuer, as amended, supplemented or replaced from time to time.

"**Average Market Price Observation Period**" means:

(b) in respect of a 5-Day ADSSO Average Market Price, the period of 5 consecutive Dealing Days ending on the Dealing Day immediately preceding the relevant ADSSO Reference Date;

(c) in respect of a 10-Day ADSSO Average Market Price, the period of 10 consecutive Dealing Days ending on the Dealing Day immediately preceding the relevant ADSSO Reference Date; and

(d) in respect of a 30-Day Reset Average Market Price, the period of 30 consecutive Dealing Days ending on the Dealing Day immediately preceding the relevant Reset Date.

"**Bondholder**" and "**holder**" mean the person in whose name a Bond is registered in the Register (as defined in the Bond Agreement).

"**Bondholder Reserved Matter**" means an amendment or waiver of any term of the Bonds or the Bond Documents which has the effect of changing or which relates to:

(e) this definition of "Bondholder Reserved Matter" or the definition of "Majority Bondholders";

(f) a modification of the date of payment (including any optional redemption pursuant to these Conditions) of any principal, interest, Cash Alternative Amount or other amount payable to a Bondholder under the Bonds or the Bond Documents;

(g) a variation in the amount or calculation of any payment of principal, interest, Cash Alternative Amount or other amount (including a number of ADSs or Ordinary Shares represented by ADSs) payable or deliverable to a Bondholder under the Bonds or the Bond Documents;

(h) to modify or cancel the Conversion Rights or the rights of Bondholders to receive ADSs or Ordinary Shares represented by ADSs and/or the Cash Alternative Amount on the exercise of Conversion Rights pursuant to the Conditions, other than pursuant to or as a result of any amendments to the Bond Documents made in order to effect a Conversion Right Transfer or pursuant to a NewCo Scheme Modification and in accordance with these Conditions;

(i) to increase the Conversion Price, other than in accordance with these Conditions or pursuant to a NewCo Scheme Modification;

(j) to receive Deliverable ADSs following exercise of an ADS Settlement Option;

(k) to change the governing law of the Bonds or the Bond Documents;

(l) a change in currency of payment of any amount under the Bonds or any Bond Document;

(m) a change to the Issuer other than in accordance with Condition 15;

(n) a change to any provision which expressly requires the consent of Bondholders; or

(o) any amendment to the rights of a Bondholder to assign or transfer its rights or obligations under the Bonds and/or the Bond Documents.

"**Bondholder Taxes**" has the meaning provided in Condition 6.10.

"**business day**" means, in relation to any place, a day (other than a Saturday or Sunday) on which commercial banks and foreign exchange markets are open for business in that place.

"**Calculation Amount**" has the meaning provided in Condition 5.1.

"**Cash Alternative Amount**" means, in respect of any exercise of Conversion Rights in respect of which the Issuer shall have made a Cash Alternative Election, an amount in US Dollars calculated by the Calculation Agent (and rounded to the nearest cent, with $0.005
rounded upwards) in accordance with the following formula and which shall be payable by
the Issuer to a Bondholder in respect of the relevant Cash Settled ADSs specified in the relevant Cash Alternative Exercise Notice:

CAA=n=1N1N×S×Pn
where:

CAA = the Cash Alternative Amount;

S = the Cash Settled ADSs;

Pn = the Volume Weighted Average Price of an ADS (translated if necessary into US Dollars at the Prevailing Rate) on the nth Dealing Day of the Cash Alternative Calculation Period; and

N = 10, being the number of Dealing Days in the Cash Alternative Calculation Period,

Provided that:

(i) if any Dividend or other entitlement in respect of the Ordinary Shares is announced, (whether on or prior to or after the relevant Conversion Date) in circumstances where the record date or other due date for the establishment of entitlement in respect of such Dividend or other entitlement shall be on or after the relevant Conversion Date and if on any Dealing Day in the Cash Alternative Calculation Period the Volume Weighted Average Price is based on a price ex- such Dividend or ex- such other entitlement, then such price shall be increased by an amount equal to the Fair Market Value of any such Dividend or other entitlement per ADS as at the Ex-Date in respect of such Dividend or entitlement, determined by the Calculation Agent on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit, all as determined by the Calculation Agent, provided that where such Fair Market Value as aforesaid cannot be determined in accordance with these Conditions before the second Dealing Day before the date on which payment of the Cash Alternative Amount is to be made, the relevant Volume Weighted Average Price as aforesaid shall be adjusted in such manner as determined in good faith to be appropriate by an Independent Adviser no later than such second Dealing Day before such payment date as aforesaid;

(ii) if any doubt shall arise as to the calculation of the Cash Alternative Amount or if such amount cannot be determined as provided above, the Cash Alternative Amount shall be equal to such amount as is determined in such other manner as an Independent Adviser shall consider in good faith to be appropriate to give the intended result.

"**Cash Alternative Calculation Period**" means the period of 10 consecutive Dealing Days commencing on the third Dealing Day following the Cash Election Date.

"**Cash Alternative Election**" has the meaning provided in Condition 6.11.

"**Cash Alternative Election Notice**" has the meaning provided in Condition 6.11.

"**Cash Election Date**" has the meaning provided in Condition 6.11.

"**Cash Settled ADSs**" means, in respect of the exercise of Conversion Rights by a Bondholder, such number of ADSs (which shall be a whole number of ADSs and shall not exceed the number of Reference ADSs in respect of such exercise) as determined by the Issuer and notified to the relevant Bondholder in the relevant Cash Alternative Election Notice in accordance with Condition 6.11.

"**Cash Settlement Ratio**" means, in respect of an exercise of Conversion Rights the subject of a Cash Alternative Election, such number as is equal to (x) the Cash Settled ADSs in respect of such exercise of Conversion Rights divided by (y) the Reference ADSs in respect of such exercise of Conversion Rights.

a "**Change of Control**" shall occur if (i) any person or persons, acting in concert (as defined in the City Code on Takeovers and Mergers), acquire(s) or becomes entitled to control more than 50 per cent. of the votes that may ordinarily be cast on a poll at a general meeting of the Issuer (other than as a result of an Exempt Newco Scheme) or (ii) an offer is made to all (or as nearly as may be practicable all) Shareholders (or all (or as nearly as may be practicable all) such Shareholders other than the offeror and/or any associate (as defined in Section 988(1) of the Companies Act) of the offeror), to acquire all or a majority of the issued ordinary share capital of the Issuer or if any person proposes a Scheme of Arrangement with regard to such acquisition (other than an Exempt Newco Scheme) and (such offer or Scheme of Arrangement having become or been declared unconditional in all respects or having become effective) the right to cast more than 50 per cent. of the votes which may ordinarily be cast on a poll at a general meeting of the Issuer has or will become unconditionally vested in the offeror(s) or any such person and/or any associate (as defined in Section 988(1) of the Companies Act) of the offeror(s) or such person, as the case may be.

"**Change of Control Conversion Price**" has the meaning provided in Condition 6.2(j).

"**Change of Control Conversion Right Amendment**" has the meaning provided in Condition 11(b)(vii).

"**Closing Date**" has the meaning provided in the Bond Agreement, and shall be specified in the Initial Determinations Notice.

"**Closing Price**" means, in respect of an ADS or any other Security, Spin-Off Security, option, warrant or other right or asset, on any Dealing Day in respect thereof, the closing price on the Relevant Stock Exchange in respect thereof (where such Relevant Stock

Exchange is a Qualifying US Market, in composite transactions) on such Dealing Day of an ADS or, as the case may be, such other Security, Spin-Off Security, option, warrant or other right or asset published by or derived from Bloomberg page HP (or any successor ticker page) (setting Last Price, or any other successor setting and using values not adjusted for any event occurring after such Dealing Day; and for the avoidance of doubt, all values will be determined with all adjustment settings on the DPDF Page, or any successor or similar setting, switched off) in respect of such ADS, such other Security, Spin-Off Security, option, warrant or other right or asset and such Relevant Stock Exchange (all as determined by the Calculation Agent) (and for the avoidance of doubt such Bloomberg code for the ADS in composite transactions as at the Closing Date is "RNLX US <equity>"), if available or, in any other case, such other source (if any) as shall be determined in good faith to be appropriate by an Independent Adviser on such Dealing Day, provided that:

(p) if on any such Dealing Day (for the purpose of this definition, the "**Original Date**") such price is not available or cannot otherwise be determined as provided above, the Closing Price of an ADS, such other Security, Spin-Off Security, option, warrant, or other right or asset, as the case may be, in respect of such Dealing Day shall be the Closing Price, determined by the Calculation Agent as provided above, on the immediately preceding Dealing Day in respect thereof on which the same can be so determined, provided however that if such immediately preceding Dealing Day falls prior to the fifth day before the Original Date, the Closing Price in respect of such Dealing Day shall be considered to be not capable of being determined pursuant to this proviso (a); and

(q) if the Closing Price cannot be determined as aforesaid, the Closing Price of ADS, such other Security, Spin-Off Security, option, warrant, or other right or asset, as the case may be, shall be determined as at the Original Date by an Independent Adviser in such manner as it shall determine in good faith to be appropriate,

and the Closing Price determined as aforesaid on or as at any Dealing Day shall, if not in the Relevant Currency, be translated into the Relevant Currency at the Prevailing Rate on such Dealing Day.

"**Companies Act**" means the Companies Act 2006.

"**Conversion Date**" has the meaning provided in Condition 6.10.

"**Conversion Notice**" has the meaning provided in the Bond Agreement.

"**Conversion Period**" has the meaning provided in Condition 6.1.

"**Conversion Premium**" means 20.00 per cent.

"**Conversion Price**" has the meaning provided in Condition 6.1.

"**Conversion Right**" has the meaning provided in Condition 6.1.

"**Conversion Right Transfer**" has the meaning provided in Condition 6.16.

"**Current Market Price** " means, in respect of an Ordinary Share or an ADS at a particular date, the arithmetic average of the daily Volume Weighted Average Price of an Ordinary Share or an ADS, as applicable, on each of the five consecutive Dealing Days ending on the Dealing Day immediately preceding such date (in respect of an Ordinary Share, divided by the number

of Ordinary Shares represented by an ADS on the relevant Dealing Day), as determined by the Calculation Agent, provided that:

(r) for the purposes of determining the Current Market Price pursuant to Condition 6.2(d) or 6.2(f) in circumstances where the relevant event relates to an issue of Ordinary Shares, if at any time during the said five dealing-day period (which may be on each of such five Dealing Days) the Volume Weighted Average Price shall have been based on a price ex-Dividend (or ex- any other entitlement) and/or during some other part of that period (which may be on each of such five Dealing Days) the Volume Weighted Average Price shall have been based on a price cum-Dividend (or cum- any other entitlement), in any such case which has been declared or announced, then:

(i) if the Ordinary Shares to be so issued do not rank for the Dividend (or entitlement) in question, the Volume Weighted Average Price on the dates on which the ADSs shall have been based on a price cum-Dividend (or cum-any other entitlement) shall for the purpose of this definition be deemed to be the amount thereof reduced by an amount equal to the Fair Market Value of any such Dividend or entitlement per ADS as at the Ex-Date in respect of such Dividend or entitlement (or, where on each of the said five Dealing Days the Volume Weighted Average Price shall have been based on a price cum-Dividend (or cum-any other entitlement), as at the date of first public announcement of such Dividend or entitlement), in any such case, determined by the Calculation Agent on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit; or

(ii) if the Ordinary Shares to be so issued do rank for the Dividend or entitlement in question, the Volume Weighted Average Price on the dates on which the ADSs shall have been based on a price ex-Dividend (or ex- any other entitlement) shall for the purpose of this definition be deemed to be the amount thereof increased by an amount equal to the Fair Market Value of any such Dividend or entitlement per ADS as at the Ex-Date in respect of such Dividend or entitlement, in any such case, determined by the Calculation Agent on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit;

(s) for the purpose of determining the Current Market Price of any Ordinary Shares (including Ordinary Shares represented by ADSs) which may be comprised in a Scrip Dividend, if on any of the said five Dealing Days the Volume Weighted Average Price of an ADS shall have been based on a price cum all or part of such Scrip Dividend, the Volume Weighted Average Price of an ADS on such Dealing Day or Dealing Days shall for the purposes of this definition be deemed to be the amount thereof reduced by an amount equal to the value (as determined in accordance with paragraph (a) of the definition of "**Dividend**") of such Scrip Dividend or part thereof per ADS; and

(t) for any other purpose, if any day during the said five-dealing-day period was the Ex-Date in relation to any Dividend (or any other entitlement) the Volume Weighted Average Prices of an ADS that shall have been based on a price cum- such Dividend (or cum- such entitlement) shall for the purpose of this definition be deemed to be the amount thereof reduced by an amount equal to the Fair Market Value of any such Dividend or entitlement per ADS as at the Ex-Date in respect of such Dividend or entitlement.

"**Dealing Day**" means, in respect of the ADSs, other Securities, Spin-Off Securities options, warrants or other rights or assets, a day (other than a Saturday or a Sunday) on which the Relevant Stock Exchange in respect thereof is open for business and on which such ADSs, other Securities, Spin-Off Securities options, warrants or other rights or assets (as the case may be) may be dealt in (other than a day on which such Relevant Stock Exchange is scheduled to or does close prior to its regular weekday closing time), provided that, unless otherwise specified or the context otherwise requires, references to "Dealing Day" shall be a Dealing Day in respect of the ADSs.

"**De-Listing Event**" shall occur if, for whatever reason: (i) the ADSs at any time are not admitted to listing and trading on a Qualifying US Market, or (ii) trading of the ADSs on the Relevant Stock Exchange in respect thereof at any time is suspended (provided that trading of the ADSs shall not be considered to be suspended on any day on which a general suspension of trading on such Relevant Stock Exchange has occurred) (x) for a period of 10 or more consecutive Stock Exchange Dealing Days or (y) in circumstances where such suspension is requested by the Issuer in connection with a corporate reorganisation, for a period of 60 or more consecutive Stock Exchange Dealing Days.

"**Deliverable ADSs**" has the meaning provided in Condition 9.9.

"**Deposit Agreement**" has the meaning given to it in the introductory paragraphs of these Conditions.

"**Depositary**" has the meaning given to it in the introductory paragraphs of these Conditions.

"**Dividend**" means any dividend or distribution to Shareholders (including a Spin-Off) whether of cash, assets or other property, and however described and whether payable out of a share premium account, profits, retained earnings or any other capital or revenue reserve or account, and including a distribution or payment to Shareholders upon or in connection with a reduction of capital (and for these purposes a distribution of assets includes without limitation an issue of Ordinary Shares (including Ordinary Shares represented by ADSs) or other Securities credited as fully or partly paid up by way of capitalisation of profits or reserves), provided that:

(u) where a Scrip Dividend is announced, then the Scrip Dividend in question shall be treated as a cash Dividend of an amount equal to the sum of:

(i) in respect of the portion (if any) of the Scrip Dividend (which may be the whole of the Scrip Dividend) for which a Shareholder or Shareholders may make an election, the value of the option with the highest value, with the value of each option being equal to the value of the relevant property comprising such option as at the Scrip Dividend Valuation Date provided that, in the case of an option comprising more than one type of property, the value of such option shall be equal to the sum of the values of each individual type of property comprising such option, determined as provided below; and

(ii) in respect of the portion (if any) of the Scrip Dividend (which may be the whole of the Scrip Dividend) which is not subject to such election, the value of such portion as determined as provided below,

and where the "**value**" of any property in or comprising of a Scrip Dividend shall be determined as follows:

(x) in the case of Ordinary Shares (including Ordinary Shares represented by ADSs) comprised in such Scrip Dividend, the Current Market Price of such Ordinary Shares as at the Scrip Dividend Valuation Date;

(y) in the case of cash comprising in such Scrip Dividend, the Fair Market Value of such cash as at the Scrip Dividend Valuation Date; and

(z) in the case of any other property or assets comprised in such Scrip Dividend, the Fair Market Value of such other property or assets as at the Scrip Dividend Valuation Date;

(b) any issue of Ordinary Shares falling within Condition 6.2(a) or Condition 6.2(b) shall be disregarded;

(c) a purchase or redemption or buy back of share capital of the Issuer (including while represented by ADSs) by or on behalf of the Issuer or any of its Subsidiaries shall not constitute a Dividend unless, in the case of a purchase or redemption or buy back of Ordinary Shares or ADSs by or on behalf of the Issuer or any of its Subsidiaries, the weighted average price per Ordinary Share or ADS (before expenses) on any day (a "**Specified Share Day**") in respect of such purchases or redemptions or buy backs (translated, if not in the Relevant Currency, into the Relevant Currency at the Prevailing Rate on such day) exceeds by more than 5 per cent. the Current Market Price of an Ordinary Share or, as the case may be, ADS:

(i) on the Specified Share Day; or

(ii) where an announcement (excluding, for the avoidance of doubt for these purposes, any general authority for such purchases, redemptions or buy backs approved by a general meeting of Shareholders or any notice convening such a meeting of Shareholders) has been made of the intention to purchase, redeem or buy back Ordinary Shares and/or ADSs at some future date at a specified price or where a tender offer is made, on the date of such announcement or, as the case may be, on the date of first public announcement of such tender offer (and regardless of whether or not a price per Ordinary Share or ADS, a minimum price per Ordinary Share or ADS or a price range or a formula for the determination thereof is or is not announced at such time),

in which case such purchase, redemption or buy back shall be deemed to constitute a Dividend in the Relevant Currency in an amount equal to the amount by which the aggregate price paid (before expenses) in respect of such Ordinary Shares or ADSs purchased, redeemed or bought back by or on behalf of the Issuer or, as the case may be, any of its Subsidiaries (translated where appropriate into the Relevant Currency as provided above) exceeds the product of (i) 105 per cent. of such Current Market Price and (ii) the number of Ordinary Shares or ADSs so purchased, redeemed or bought back;

(d) if the Issuer or any of its Subsidiaries (or any person on its or their behalf) shall purchase, redeem or buy back any depositary or other receipts or certificates representing Ordinary Shares (other than ADSs), the provisions of paragraph (c) above shall be applied in respect thereof in such manner and with such modifications (if any) as shall be determined in good faith by an Independent Adviser;

(e) where a Dividend in cash is declared which provides for payment by the Issuer in the Relevant Currency (or, in the case of a Scrip Dividend, an amount in cash is or may be paid in the Relevant Currency, whether at the option of Shareholders or otherwise), it shall be treated as a Dividend in cash (or, in the case of a Scrip Dividend, an amount in cash) in such Relevant Currency, and in any other case it shall be treated as a Dividend in cash (or, in the case of a Scrip Dividend an amount in cash) in the currency in which it is payable by the Issuer; and

(f) a dividend or distribution that is a Spin-Off shall be deemed to be a Dividend paid or made by the Issuer,

and any such determination shall be made in good faith by the Calculation Agent or, where specifically provided, an Independent Adviser and, in either such case, on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit.

"**Equity Raise**" means the offering and sale by the Company pursuant to a private sale between the Company and prospective investors of certain ADSs representing newly issued Ordinary Shares at a purchase price of U.S.$7.25 per ADS and newly issued Ordinary Shares at a purchase price of U.S.$3.625 and with total gross proceeds of approximately U.S.$8.8 million as described in an announcement made by the Company on 31 March 2022.

"**equity share capital**" means (other than for the purposes of Condition 6.2(c)), in relation to any entity, its issued share capital excluding any part of that capital which, neither as respects dividends nor as respects capital, carries any right to participate beyond a specific amount in a distribution.

"**Event of Default**" has the meaning provided in Condition 10.

"**Exchange Act**" means the U.S. Securities Exchange Act of 1934, as amended.

"**Ex-Date**" means, in relation to any Dividend (including without limitation any Spin-Off), capitalisation, redesignation, reclassification, sub-division, consolidation, issue, grant, offer or other entitlement, unless otherwise defined herein, the first Dealing Day on which the ADSs are traded ex- the relevant Dividend, capitalisation, redesignation, reclassification, sub-division, consolidation, issue, grant, offer or other entitlement on the Relevant Stock Exchange (or, in the case of a Dividend which is a purchase, redemption or buy back of Ordinary Shares (or, as the case may be, any ADSs or other depositary or other receipts or certificates representing Ordinary Shares) pursuant to paragraph (c) (or, as the case may be, paragraph (d)) of the definition of "Dividend", the date on which such purchase, redemption or buy back is made), and provided that, for the avoidance of doubt, the Ex-Date in respect of a Scrip Dividend shall be deemed to be the Ex-Date in respect of the relevant Dividend or capitalisation as referred to in the definition of "Scrip Dividend".

"**Exempt Newco Scheme**" means a Newco Scheme where, immediately after completion of the relevant Scheme of Arrangement, the ordinary shares or units or equivalent of Newco
(or depositary or other receipts or certificates representing ordinary shares or units or
equivalent of Newco) are admitted to trading on a Qualifying US Market or an internationally recognised, regularly operating and regulated stock exchange in the United Kingdom, European Economic Area or the United States.

"**Fair Market Value**" means, on any date (the "**FMV Date**"):

(a) in the case of a cash Dividend, the amount of such cash Dividend (determined by reference to the per-ADS amount of such cash Dividend where available), as determined in good faith by the Calculation Agent;

(b) in the case of any other cash amount, the amount of such cash (determined by reference to the per-ADS amount of such cash Dividend where available), as determined in good faith by the Calculation Agent;

(c) in the case of Securities (including Ordinary Shares and ADSs), Spin-Off Securities, options, warrants or other rights or assets that are publicly traded on a Relevant Stock Exchange of adequate liquidity (as determined in good faith by the Calculation Agent or an Independent Adviser), the arithmetic mean of:

(i) in the case of Ordinary Shares or ADSs or (to the extent constituting equity share capital) other Securities or Spin-Off Securities, for which a daily Volume Weighted Average Price (disregarding for this purpose proviso (ii) to the definition thereof) can be determined, such daily Volume Weighted Average Price of the Ordinary Shares or ADSs or such other Securities or Spin-Off Securities; and

(ii) in any other case, the Closing Price of such Securities, Spin-Off Securities, options, warrants or other rights or assets,

in the case of both (a) and (b) during the period of five Dealing Days on the Relevant Stock Exchange for such Securities, Spin-Off Securities, options, warrants or other rights or assets commencing on such FMV Date (or, if later, the date (the "**Adjusted FMV Date**") which falls on the first such Dealing Day on which such Securities, Spin-Off Securities, options, warrants or other rights or assets are publicly traded, provided that where such Adjusted FMV Date falls after the fifth day following the FMV Date, the Fair Market Value of such Securities, Spin-Off Securities, options, warrants or other rights or assets shall instead be determined pursuant to paragraph (iv) below, and no such Adjusted FMV Date shall be deemed to apply) or such shorter period as such Securities, Spin-Off Securities, options, warrants or other rights or assets are publicly traded, all as determined in good faith by the Calculation Agent,

(d) in the case of Securities, Spin-Off Securities, options, warrants or other rights or assets that are not publicly traded on a Relevant Stock Exchange of adequate liquidity (as aforesaid) or where otherwise provided in paragraph (c) above to be determined pursuant to this paragraph (d), an amount equal to the fair market value of such Securities, Spin-Off Securities, options, warrants or other rights or assets as determined in good faith by an Independent Adviser, on the basis of a commonly accepted market valuation method and taking account of such factors as it considers appropriate, including the market price per Ordinary Share or ADS, the dividend yield of an Ordinary Share or ADS, the volatility of such market price, prevailing interest rates and the terms of such Securities, Spin-Off Securities, options, warrants or other rights or assets, and including as to the expiry date and exercise price or the like (if any) thereof.

Such amounts shall (if not expressed in the Relevant Currency on the FMV Date (or, as the case may be, the Adjusted FMV Date)) be translated into the Relevant Currency at the Prevailing Rate on the FMV Date (or, as the case may be, the Adjusted FMV Date), all as determined in good faith by the Calculation Agent.

In addition, in the case of (a) and (b) above, the Fair Market Value shall be determined on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit.

"**Final Maturity Date**" means the fifth anniversary date of the Closing Date, as specified in the Initial Determinations Notice.

"**Floor Price**" has the meaning provided in Condition 6.4.

"**Free Float**" means the aggregate number of Ordinary Shares held by each person or "group" of persons within the meaning of Section 13(d) of the Exchange Act, other than the Issuer and its Subsidiaries and any directors or officers thereof, that owns Ordinary Shares representing less than 5 per cent, of the total number of issued and outstanding Ordinary Shares, as determined by an Independent Adviser acting reasonably and in good faith, in consultation with the Issuer and where for the purposes of this definition: (a) references to "Ordinary Shares" shall include Ordinary Shares represented by outstanding ADSs or other depositary receipts or certificates representing Ordinary Shares; (b) Ordinary Shares held by or on behalf of the Depositary from time to time shall be treated as being held by the holder of the relevant ADSs representing such Ordinary Shares, and not by the Depositary; (c) regulated investment funds, collective investment schemes, social security funds or pension funds that own Ordinary Shares representing less than 10 per cent. of the total number of issued and outstanding Ordinary Shares shall be treated as constituting part of the Free Float; (d) Ordinary Shares held by or on behalf of the Issuer or any of its Subsidiaries or any director or officer thereof shall not be treated as constituting part of the Free Float; and (e) regard shall be had to underlying beneficial holdings behind bare nominees (to the extent such information is available upon reasonable investigation).

A "**Free Float Event**" shall occur if the number of Ordinary Shares comprising the Free Float on such London and New York business day (as determined by an Independent Adviser acting in good faith) is equal to or less than 20 per cent. of the aggregate number of issued and outstanding Ordinary Shares and where for the purposes of this definition: (a) references to "Ordinary Shares" shall include Ordinary Shares represented by outstanding ADSs or other depositary receipts or certificates representing Ordinary Shares; and (b) Ordinary Shares held by or on behalf of the Depositary from time to time shall be treated as being held by the holder of the relevant ADSs representing such Ordinary Shares, and not by the Depositary on such New York business day. In any such case the Free Float Event shall be deemed to have occurred on such London and New York business day.

"**Further Bonds**" means further bonds either having the same terms and conditions in all respects as the outstanding Bonds or having the same terms and conditions in all respects as the outstanding Bonds in all respects except for the first payment of interest on them and the first date on which Conversion Rights may be exercised and so that such further issue shall be consolidated and form a single series with the outstanding Bonds, and in each case which shall be issued only in accordance with Condition 17.

"**Group**" means the Issuer and its Subsidiaries taken as a whole.

"**IFRS**" means International Financial Reporting Standards.

"**Independent Adviser**" means an independent adviser with appropriate expertise, which may be the Calculation Agent appointed by the Issuer at its own expense and (other than where the initial Calculation Agent is appointed) approved in writing by the Bondholders or, if the Issuer fails to make such appointment and such failure continues for a reasonable period (as determined by the Bondholders, acting reasonably), as may be appointed by the Bondholders (at the expense of the Issuer, and without liability for so doing) following notification to the Issuer, which appointment shall be deemed to be made by the Issuer.

"**Initial Conversion Price**" has the meaning provided in Condition 6.1.

"**Initial Determinations Notice**" has the meaning provided in Condition 16.

"**Interest ADS Settlement Option**" has the meaning provided in Condition 5.1(b).

"**Interest Cash Settlement Option Notice**" has the meaning provided in Condition 5.1(b).

"**Interest Payment Date**" has the meaning provided in Condition 5.1(a).

"**Interest Period**" has the meaning provided in Condition 5.1(a).

"**Majority Bondholders**" means, at any time, holders of more than 50 per cent. of the principal amount of the Bonds outstanding.

"**Market Price**" means the Volume Weighted Average Price of an ADS on the relevant Reference Date (translated if necessary into US Dollars at the Prevailing Rate on the Reference Date), provided that if any Dividend or other entitlement in respect of the Ordinary Shares is announced, whether on or prior to or after the relevant Conversion Date, in circumstances where the record date or other due date for the establishment of entitlement of holders of ADSs in respect of such Dividend or other entitlement shall be on or after the Conversion Date and if, on the relevant Reference Date, the Volume Weighted Average Price of an ADS is based on a price ex-Dividend or ex- any other entitlement, then such Volume Weighted Average Price shall be increased by an amount equal to the Fair Market Value (translated into US Dollars at the Prevailing Rate on the Reference Date) of such Dividend or entitlement per ADS as at the date of first public announcement of such Dividend or entitlement (or if that is not a Dealing Day, the immediately preceding Dealing Day), as determined in good faith by the Calculation Agent on a gross basis and disregarding any withholding or deduction required to be made for or on account of tax, and disregarding any associated tax credit) and provided that, for the avoidance of doubt, there shall be no double-counting in respect of any Dividend or entitlement.

"**Material Subsidiary**" means at any relevant time a Subsidiary of the Issuer:

(e) whose total assets, revenues or profits before taxation (where the Subsidiary in question prepares consolidated accounts, whose total consolidated assets or gross consolidated revenues, as the case may be) attributable to the Issuer represent more than 10 per cent. of the total assets, revenues or profits before taxation of the Issuer, all as calculated by reference to the then latest audited accounts (or consolidated accounts, as the case may be) of such Subsidiary and the then latest audited consolidated accounts of the Issuer and its consolidated Subsidiaries; or

(f) to which is transferred all or substantially all of the assets and undertaking of a Subsidiary which immediately prior to such transfer is a Material Subsidiary.

"**Newco Scheme**" means a Scheme of Arrangement:

(g) which effects the interposition of a limited liability company ("**Newco**") between the Shareholders immediately prior to the Scheme of Arrangement (the "**Existing Shareholders**") and the Issuer; or

(h) pursuant to which Newco acquires all the outstanding Ordinary Shares and shares of one or more other entities in exchange for the issue of Exchange Securities to the Existing Shareholders and the issue of Exchange Securities (and, if applicable, such other consideration) to some or all of the holders of such shares ("**Existing Shares**") of such other entity or entities ("**Existing Holders**") immediately prior to the Scheme of Arrangement,

provided that:

(i) in the case of paragraphs (a) and (b) (except for a nominal holding by initial subscribers) Exchange Securities are only issued to Existing Shareholders and (in the case of paragraph (b) above) Existing Holders;

(ii) immediately after completion of the Scheme of Arrangement, Newco is (or one or more wholly-owned Subsidiaries of Newco are) the only shareholder (or shareholders) of the Issuer;

(iii) all Subsidiaries of the Issuer immediately prior to the Scheme of Arrangement (other than (A) Newco, if Newco is then a Subsidiary of the Issuer; or (B) any other Subsidiary of the Issuer or Subsidiaries of the Issuer being disposed of or demerged (or similar) in whole or in part for value on an arms' length basis in connection with the Newco Scheme) are Subsidiaries of the Issuer (or of Newco) immediately after completion of the Scheme of Arrangement and at such time the Issuer (or Newco) holds, directly or indirectly, the same percentage of the ordinary share capital and equity share capital of those Subsidiaries as was held by the Issuer immediately prior to the Scheme of Arrangement; and

(iv) no person or persons acting in concert (as defined in the City Code on Takeovers and Mergers) shall, as a result of the Newco Scheme (A) own, acquire or control (or have the right to own, acquire or control) the right to cast more than 50 per cent. of the votes which may ordinarily be cast on a poll at a general meeting of Newco; or (B) own, acquire or control (or have the right to own, acquire or control) more than 50 per cent. of the issued ordinary shares of Newco; or (C) obtain the power to appoint and/or remove all or a majority of the members of the board of directors of Newco,

and for the purposes of this definition "**Exchange Securities**" means ordinary shares, units or equivalent of Newco or depositary receipts or certificates representing ordinary shares, units of equivalent of Newco.

"**Newco Scheme Modification**" means amendments to these Conditions, the Bond Documents or the Bonds which are made pursuant to or in accordance with the provisions of Condition 6.16 in order to effect a Conversion Right Transfer or Condition 11(g) following or as part of a Newco Scheme (and subject to and in accordance with Condition 15).

"**Notice Business Day**" means a day which is a business day in each of London and New York.

"**Offer Period**" has the meaning provided in Condition 9.9(c).

"**Ordinary Shares**" means fully paid ordinary shares in the capital of the Issuer with, on the Closing Date, a nominal amount of £0.0025 each.

"**outstanding**" means, in relation to the Bonds, all Bonds issued except (a) those which have been redeemed in accordance with these Conditions, (b) those in respect of which Conversion Rights have been exercised and the Issuer's obligations to issue and/or deliver Ordinary Shares (and/or, in the case of a Cash Alternative Election, the Issuer's obligation to pay the Cash Alternative Amount (and Additional Cash Alternative Amount, if any)) have been duly performed, (c) those in respect of which the date for redemption has occurred and the redemption moneys (including all interest accrued on such Bonds to the date for such redemption and any interest payable under Condition 5 after such date) have been duly paid to the relevant Bondholder and for any obligations to issue or deliver Ordinary Shares or ADSs have been performed, and (d) those which have been purchased and cancelled as provided in Condition 7; provided that for the purposes of (1) ascertaining the right to vote on any voting matters pursuant to Condition 14, (2) the determination of how many and which Bonds are outstanding for the purposes of Conditions 10 and 14, and (3) the exercise of any discretion, power or authority which each Bondholder is required, expressly or impliedly, to exercise, those Bonds which are beneficially held by or on behalf of the Issuer or any member of the Group or any of their respective affiliates and not cancelled shall (unless no longer so held) be deemed not to remain outstanding.

"**Payment Details**" means, with respect to each Bondholder, the instructions provided by it to the Issuer for the payment to the Bondholder of US Dollar cash payments and issue or delivery to the Bondholder of ADSs (and which shall, for so long as the ADSs are held through DTS, include DTS account details), and which may be updated by a Bondholder at any time by giving notice to the Issuer.

"**Permitted Cessation of Business**" has the meaning provided in Condition 6.16.

a "**person**" includes any individual, company, corporation, firm, partnership, joint venture, trust, undertaking, association, organisation, or state or agency of a state or any political subdivisions thereof (in each case whether or not being a separate legal entity).

"**Physically Settled ADSs**" means, in respect of any exercise of Conversion Rights, (i) the Reference ADSs or (ii) where such exercise is the subject of a Cash Alternative Election, such number of ADSs (which may be equal to zero) as is equal to the Reference ADSs minus the Cash Settled ADSs.

"**Potential Event of Default**" means an event or circumstance which could, with the giving of notice, lapse of time, issue of a certificate and/or fulfilment of any other requirement provided for in Condition 10, become an Event of Default.

"**Prevailing Rate**" means, in respect of any pair of currencies on any day, the spot mid-rate of exchange between the relevant currencies prevailing as at 4.00p.m. (London time) on that date (for the purpose of this definition, the "**Original Date**") as appearing on or derived from Bloomberg page BFIX (or any successor page) in respect of such pair of currencies, or, if such a rate cannot be so determined, the rate prevailing as at 4.00p.m. (London time) on the immediately preceding day on which such rate can be so determined, provided that if such immediately preceding day falls earlier than the fifth day prior to the Original Date or if such rate cannot be so determined (all as determined in good faith by the Calculation Agent), the Prevailing Rate in respect of the Original Date shall be the rate determined in such other manner as an Independent Adviser shall consider appropriate.

"**Principal ADS Settlement Option**" has the meaning provided in Condition 7.1(b).

"**Principal Cash Settlement Option Notice**" has the meaning provided in Condition 5.1(b).

"**Qualifying US Market**" means each of the NASDAQ Capital Market, NASDAQ Global Market, NASDAQ Select Market, New York Stock Exchange or NYSE American (or any of their respective successors).

"**Record Date**" has the meaning provided in Condition 9.3.

"**Reference Date**" means, in relation to a Retroactive Adjustment or an ADS Settlement Retroactive Adjustment, the date as of which the relevant Retroactive Adjustment or, as the case may be, the relevant ADS Settlement Retroactive Adjustment takes effect or, in any such case, if that is not a Dealing Day, the next following Dealing Day.

"**Reference ADS Price** " means U.S.$7.25.

"**Reference ADSs**" means, in respect of the exercise of Conversion Rights by a Bondholder, the number of ADSs (rounded down, if necessary, to the nearest whole number) determined in good faith by the Calculation Agent by dividing the principal amount of the Bonds which are the subject of the relevant exercise of Conversion Rights by the Conversion Price in effect on the relevant Conversion Date, except that where the Conversion Date falls on or after the date an adjustment to the Conversion Price takes effect pursuant to Conditions 6.2(a), 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i) but on or prior to the record date or other due date for establishment of entitlement in respect of the relevant event giving rise to such adjustment, then the Conversion Price in respect of such exercise shall be such Conversion Price as would have been applicable to such exercise had no such adjustment been made.

"**Relevant Currency**" means, at any time, the currency in which the ADSs are quoted or dealt in at such time on the Relevant Stock Exchange in respect thereof.

"**Relevant Date**" means, in respect of any Bond, whichever is the later of:

(i) the date on which payment in respect of it first becomes due; and

(j) if any amount payable is improperly withheld or refused, the date on which payment in full of the amount outstanding is made to Bondholders.

A "**Relevant Event**" shall occur upon the occurrence of any of the following:

(k) a Change of Control; or

(l) a De-Listing Event; or

(m) a Free Float Event.

"**Relevant Event Notice**" has the meaning provided in Condition 6.9.

"**Relevant Event Period**" means the period commencing on the date on which a Relevant Event occurs and ending 60 calendar days following such date or, if later, 60 calendar days following the date on which a Relevant Event Notice is given to Bondholders as required by Condition 6.9 or, in any such case, if that is not a Notice Business Day, the next following Notice Business Day.

"**Relevant Event Put Date**" has the meaning provided in Condition 7.2.

"**Relevant Stock Exchange**" means:

(n) in respect of the ADSs, NASDAQ Global Market or, if at the relevant time the ADSs are not at that time listed and admitted to trading on NASDAQ Global Market, the principal stock exchange or securities market on which the ADSs are then listed and admitted to trading;

(o) in respect of the Ordinary Shares, AIM or, if at the relevant time the Ordinary Shares are not at that time admitted to trading on AIM, the principal stock exchange or securities market on which the Ordinary Shares are then listed, admitted to trading or quoted or dealt in, if applicable; and

(p) in respect of any Securities (other than ADSs), Spin-Off Securities, options, warrants or other rights or assets, the principal stock exchange or securities market on which such Securities, Spin-Off Securities, options, warrants or other rights or assets are then listed and admitted to trading,

where "**principal stock exchange or securities market**" shall mean the stock exchange or securities market on which such ADSs, Ordinary Shares, such other Securities, Spin-Off Securities, options, warrants or other rights or assets are listed and admitted to trading, provided that if such ADSs, Ordinary Shares, such other Securities, Spin-Off Securities, options, warrants or other rights or assets are listed and admitted to trading (as the case may be) on more than one stock exchange or securities market at the relevant time, then "**principal stock exchange or securities market**" shall mean that stock exchange or securities market on which such ADSs, Ordinary Shares, such other Securities, Spin-Off Securities, options, warrants or other rights or assets are then traded as determined by the Calculation Agent (if the Calculation Agent determines that it is able to make such determination) or (in any other case) by an Independent Adviser by reference to the stock exchange or securities market with the highest average daily trading volume in respect of such ADSs, Ordinary Shares, such other Securities, Spin-Off Securities, options, warrants or other rights or assets.

"**Reset Conversion Price**" has the meaning provided in Condition 6.4.

"**Reset Date**" has the meaning provided in Condition 6.4.

"**Reset Price Floor**" has the meaning provided in Condition 6.4.

A "**Retroactive Adjustment**" shall occur if the Conversion Date in relation to the conversion of any Bond shall be (i) after the date which is the record date in respect of any consolidation, reclassification, redesignation or sub-division as is mentioned in Condition 6.2(a), or which is the record date or other due date for the establishment of entitlement for any such issue, distribution, grant or offer (as the case may be) as is mentioned in Condition 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i), or which is the date of the first public announcement of the terms of any such issue or grant as is mentioned in Condition 6.2(f) and 6.2(g) or of the terms of any such modification as is mentioned in Condition 6.2(h); and (ii) before the relevant adjustment to the Conversion Price becomes effective under Condition 6.2.

"**Scheduled Amortisation Payment Date**" has the meaning provided in Condition 5.1(a).

"**Scheme of Arrangement**" means a scheme of arrangement, share for share exchange or analogous procedure.

"**Scrip Dividend**" means:

(q) a Dividend in cash which is to be satisfied, or a Dividend in cash which may at the election of a Shareholder or Shareholders be satisfied, in whole or in part, by the issue or delivery of Ordinary Shares (including Ordinary Shares represented by ADSs) and/or other property or assets; or

(r) an issue of Ordinary Shares (including Ordinary Shares represented by ADSs) or other property or assets by way of a capitalisation of profits or reserves (including any share premium account or capital redemption reserve, and whether described as a scrip or share dividend or distribution or otherwise) which is to be satisfied, or which may at the election of a Shareholder or Shareholders be satisfied, in whole or in part, by the payment of cash.

"**Scrip Dividend Valuation Date**" means:

(s) in respect of any portion of a Scrip Dividend for which a Shareholder or Shareholders may make an election, the later of (i) the Ex-Date in relation to the relevant dividend or capitalisation, (ii) the last day on which the relevant election can be made by such Shareholder or Shareholders, and (iii) the date on which the number of Ordinary Shares, amount of cash, or amount of other property or assets, as the case may be, which may be issued or delivered is publicly announced; or

(t) in respect of any portion of a Scrip Dividend which is not subject to such election, the later of (i) the Ex-Date in relation to the relevant dividend or capitalisation and (ii) the date on which the number of Ordinary Shares (including Ordinary Shares represented by ADSs), amount of cash or amount of such other property or assets, as the case may be, to be issued and delivered is publicly announced.

"**Securities**" means any equity securities including, without limitation, Ordinary Shares, ADSs and any other shares in the capital of the Issuer, and options, warrants or other rights to subscribe for or purchase or acquire Ordinary Shares or ADSs or any other shares in the capital of the Issuer.

"**Securities Act**" means the United States Securities Act of 1933, as amended.

"**Shareholders**" means the holders of Ordinary Shares (including Ordinary Shares represented by ADSs).

"**Specified Date**" has the meaning provided in Conditions 6.2(f), 6.2(g) and 6.2(h).

"**Specified Taxes**" has the meaning provided in Condition 6.10.

"**Spin-Off**" means:

(u) a distribution of Spin-Off Securities by the Issuer to Shareholders as a class; or

(v) any issue, transfer or delivery of any property or assets (including cash or shares or other securities of or in or issued or allotted) by any entity (other than the Issuer) to Shareholders as a class or, in the case of or in connection with a Scheme of Arrangement, Existing Shareholders as a class (but excluding the issue and allotment of ordinary shares (or depositary or other receipts or certificates representing such ordinary shares) by Newco to Existing Shareholders as a class), pursuant in each case to any arrangements with the Issuer or any of its Subsidiaries.

"**Spin-Off Securities**" means equity share capital of an entity other than the Issuer or options, warrants or other rights to subscribe for or purchase equity share capital of an entity other than the Issuer.

"**Stock Exchange Dealing Day**" means a day (other than a Saturday or a Sunday) on which the Relevant Stock Exchange in respect of the ADSs is open for business (whether or not such day is a Dealing Day) (other than a day on which such Relevant Stock Exchange is scheduled to or does close prior to its regular weekday closing time).

"**Subsidiary**" means a subsidiary undertaking within the meaning of section 1162 of the Companies Act 2006 as if the words "is a member of the undertaking and" had been deleted from subsections 1162(2)(b) and (d).

"**Successor in Business**" has the meaning provided in Condition 6.16.

"**Volume Weighted Average Price**" means, in respect of an ADS, such other Security or, as the case may be, a Spin-Off Security, on any Dealing Day in respect thereof, the volume weighted average price on such Dealing Day on the Relevant Stock Exchange (where the Relevant Stock Exchange is a Qualifying US Market, in composite transactions) on such Dealing Day of an ADS, such other Security or, as the case may be, a Spin-Off Security, as published by or derived from Bloomberg page HP (or any successor page) (setting Weighted Average Line or any other successor setting and using values not adjusted for any event occurring after such Dealing Day; and for the avoidance of doubt, all values will be determined with all adjustment settings on the DPDF Page, or any successor or similar setting, switched off) in respect of such ADS, such other Security, or, as the case may be, Spin-Off Security and such Relevant Stock Exchange (and for the avoidance of doubt such Bloomberg code for the ADSs in composite transactions as at the Closing Date is "RNLX US <equity>" and for the Ordinary Shares on their Relevant Stock Exchange as at the Closing Date is "RENX LN <equity>") if available or, in any other case, such other source (if any) as shall be determined in good faith to be appropriate by an Independent Adviser on such Dealing Day provided that:

(w) if on any such Dealing Day (for the purposes of this definition, the "**Original Date**") such price is not available or cannot otherwise be determined as provided above, the Volume Weighted Average Price of an ADS, an Ordinary Share, such other Security or Spin-Off Security, as the case may be, in respect of such Dealing Day shall be the Volume Weighted Average Price, determined as provided above, on the immediately preceding Dealing Day in respect thereof on which the same can be so determined, provided however that if such immediately preceding Dealing Day falls prior to the fifth day before the Original Date, the Volume Weighted Average Price in respect of such Dealing Day shall be considered to be not capable of being determined pursuant to this proviso (a); and

(x) if the Volume Weighted Average Price cannot be determined as aforesaid, the Volume Weighted Average Price of an ADS, an Ordinary Share, such other Security or Spin-Off Security, as the case may be, shall be determined as at the Original Date by an Independent Adviser in such manner as it shall determine in good faith to be appropriate,

and the Volume Weighted Average Price determined as aforesaid on or as at any Dealing Day shall, if not in the Relevant Currency, be translated into the Relevant Currency at the Prevailing Rate on such Dealing Day.

"**Voting Rights**" means in relation to any entity the right generally to vote at a general meeting of Shareholders of such entity (irrespective of whether or not, at the time, stock of any other

class or classes shall have, or might have, voting power by reason of the happening of any contingency) or to elect the majority of the members of the board of directors or other governing body of such entity.

"**£**" means the lawful currency for the time being of the United Kingdom.

"**$**", "**U.S.$**", "**USD**" and "**US Dollar**" means the lawful currency for the time being of the United States.

References to any act or statute or any provision of any act or statute shall be deemed also to refer to any statutory modification or re-enactment thereof or any statutory instrument, order or regulation made thereunder or under such modification or re-enactment.

References to any issue or offer or grant to Shareholders or Existing Shareholders "**as a class**" or "**by way of rights**" shall be taken to be references to an issue or offer or grant to all or substantially all Shareholders or Existing Shareholders, as the case may be, other than Shareholders or Existing Shareholders, as the case may be, to whom, by reason of the laws of any territory or requirements of any recognised regulatory body or any other stock exchange or securities market in any territory or in connection with fractional entitlements, it is determined not to make such issue or offer or grant.

In making any calculation or determination of 5-Day ADSSO Average Market Price, 10-Day ADSSO Average Market Price, 30-Day Reset Average Market Price Closing Price, Current Market Price or Volume Weighted Average Price, such adjustments (if any) shall be made in good faith and as the Calculation Agent or an Independent Adviser considers appropriate to reflect any change in the number of Ordinary Shares represented by an ADS or any consolidation or sub-division of the Ordinary Shares or any issue of Ordinary Shares by way of capitalisation of profits or reserves, or any like or similar event.

For the purposes of Conditions 6.1, 6.2, 6.3, 6.10 and 6.12 and Condition 11 only, (i) references to the "**issue**" of ADSs or Ordinary Shares or ADSs or Ordinary Shares being "**issued**" shall include the transfer and/or issue and delivery of ADSs or Ordinary Shares (including without limitation Ordinary Shares represented by ADSs), whether newly issued and allotted or previously existing or held by or on behalf of the Issuer or any of its Subsidiaries, and (ii) Ordinary Shares (including without limitation Ordinary Shares represented by ADSs) held by or on behalf of the Issuer or any of its Subsidiaries (and which, in the case of Condition 6.2(d), do not rank for the relevant right or other entitlement) shall not be considered as or treated as "**in issue**" or "**issued**", or entitled to receive the relevant Dividend, right or other entitlement.

4. Registration and Transfer of Bonds

4.1 Registration

The Issuer will keep or will cause to be kept a Register as provided in Clause 5 (*Register and Title*) of the Bond Agreement.

4.2 Transfer

Bonds may be transferred in accordance with the provisions of Clauses 5 (*Register and Title*) and 11 (*Transfer of Rights and Obligations*) of the Bond Agreement.

5. Interest

5.1 Interest Rate

(a) Interest Rate

The Bonds bear interest from (and including) the Closing Date at the rate of 5.5 per cent. per annum (the "**Rate of Interest**") payable quarterly in arrear in equal instalments of $13.75 per each $1,000 (the "**Calculation Amount**") in principal amount of the Bonds outstanding on the date falling three months after the Closing Date and on each three-month anniversary date thereof (each such date, an "**Interest Payment Date**", as specified in the Initial Determinations Notice), with the final Interest Payment Date falling on the Final Maturity Date.

The amount of interest payable per each Calculation Amount in principal amount of the Bonds outstanding in respect of any period which is shorter than an Interest Period shall be calculated by the Calculation Agent as the product (rounded to nearest integral multiple of $0.01 (with $0.005 being rounded upwards)) of: (i) the Calculation Amount; (ii) the Rate of Interest; and (iii) a fraction, the numerator of which is the number of days in the relevant period and the denominator of which is the product of (A) the number of days from (and including) the immediately preceding Interest Payment Date (or, if none, the Closing Date) to (but excluding) the next Interest Payment Date and (B) 4, being the number of Interest Periods normally ending in any year.

"**Interest Period**" means the period beginning on (and including) the Closing Date and ending on (but excluding) the first Interest Payment Date and each successive period beginning on (and including) an Interest Payment Date and ending on (but excluding) the next succeeding Interest Payment Date.

(b) Deemed Interest ADS Settlement Option Exercise

In respect of the interest payment due on each Interest Payment Date, the Issuer shall be deemed to have exercised its option (the "**Interest ADS Settlement Option**") to make payment of the relevant interest amount by the issue or transfer and delivery of Deliverable ADSs (and, if applicable, Additional Deliverable ADSs) to Bondholders with respect to all, and not some only, of the Bonds subject to and in accordance with the provisions of Condition 9.9, except if (i) the Issuer shall elect (in its sole discretion), by giving notice thereof (an "**Interest Cash Settlement Option Notice**") (which notice shall be irrevocable) to Bondholders in accordance with Condition 16 at least two Notice Business Days prior to such Interest Payment Date, to satisfy its obligation to make payment on such Interest Payment Date pursuant to this Condition 5.1 by paying in cash, or (ii) an ADS Settlement Liquidity Event is occurring or occurs prior to the issue or transfer and delivery of the relevant Deliverable ADSs (in which case, in the case of (i) or (ii) the interest payment shall be paid by the Issuer in cash).

5.2 Accrual of Interest

Each Bond will cease to bear interest (i) where the Conversion Right shall have been exercised by a Bondholder, from the Interest Payment Date immediately preceding the relevant Conversion Date or, if none, the Closing Date (subject in any such case as provided in Condition 6.13) or (ii) where such Bond is redeemed or repaid pursuant to Condition 7 or Condition 10 from the due date for redemption or repayment thereof unless payment of principal is improperly withheld or refused or, following any election by the Issuer to exercise the ADS Settlement Option, the Issuer fails duly to perform its obligations to issue and deliver the Deliverable ADSs in accordance with Condition 9.9, in which event interest will continue to accrue at the rate specified in Condition 5.1 (both before and after judgment) up to, but excluding, the Relevant Date or, as the case may be, until such issue and delivery of Deliverable ADSs is duly made in accordance with Condition 9.9.

6. Conversion of Bonds

6.1 Conversion Period and Conversion Price

Subject to the right of the Issuer to make a Cash Alternative Election and as otherwise provided in these Conditions, each Bond shall entitle the holder to convert each principal amount of such Bond which is outstanding into new and/or existing ADSs representing Ordinary Shares (or representing rights to receive Ordinary Shares, such Ordinary Shares being issued to and held by the Depositary) as determined by the Issuer, credited as fully paid (a "**Conversion Right**").

The number of ADSs to be issued and/or transferred and delivered on exercise of a Conversion Right (subject to the right of the Issuer to make a Cash Alternative Election) shall be equal to the Reference ADSs in respect of such exercise, subject to Condition 6.3.

The "**Conversion Price**" is initially U.S.$8.70 (the "**Initial Conversion Price**"). The Conversion Price is subject to adjustment in the circumstances described in Condition 6.2, Condition 6.4 and Condition 6.5.

Subject to and as provided in these Conditions, the Conversion Right in respect of a Bond may be exercised, at the option of the holder thereof, at any time subject to any applicable fiscal or other laws or regulations and as hereinafter provided from (and including) the 41 st day after the Closing Date to (and including) the date falling five London and New York business days prior to the Final Maturity Date, unless there shall be a default in making payment in respect of such Bond on any such date fixed for redemption, in which event the Conversion Right shall extend up to (and including) the date on which the full amount of such payment becomes available for payment and notice of such availability has been given to Bondholders or, if earlier, the Final Maturity Date; provided that, in each case, if such final date for the exercise of Conversion Rights is not a London and New York business day, then the period for exercise of Conversion Rights by Bondholders shall end on (and including) the immediately preceding London and New York business day.

The period during which Conversion Rights may (subject as provided below) be exercised by a Bondholder is referred to as the "**Conversion Period**".

Fractions of ADSs will not be issued or transferred and delivered on exercise of Conversion Rights or pursuant to Condition 6.3 and no cash payment or other adjustment will be made in lieu thereof. However, if the Conversion Right in respect of more than one Bond is exercised at any one time such that ADSs to be issued and/or transferred and delivered on conversion or pursuant to Condition 6.3 are to be registered in the same name, the number of such ADSs to be issued and/or transferred and delivered in respect thereof shall, in accordance with the definition of "Reference ADSs", be calculated by the Calculation Agent on the basis of the aggregate principal amount of such Bonds being so converted and rounded down to the nearest whole number of ADSs.

Conversion Rights may not be exercised (i) following the giving of notice by the holders of at least one-quarter in principal amount of the Bonds then outstanding pursuant to Condition 10; (ii) in respect of a Bond in respect of which the relevant holder has exercised its right to require the Issuer to redeem pursuant to Condition 7.2; or (iii) in the period from the Record Date immediately preceding an Interest Payment Date or Amortisation Payment Date until such Interest Payment Date or Amortisation Payment Date (both dates inclusive).

Subject to the right of the Issuer to make a Cash Alternative Election, the Issuer will procure that ADSs to be issued and/or transferred and delivered on exercise of Conversion Rights

will be issued and/or transferred and delivered to, or to the order of, the holder of the Bonds in accordance with the Payment Details in accordance with the provisions of Condition 6.10. Such ADSs will be deemed to be issued and/or transferred and delivered as of the relevant Conversion Date. Any Additional ADSs to be issued and/or transferred and delivered pursuant to Condition 6.3 will be deemed to be issued and/or transferred and delivered as of the relevant Reference Date.

Where there is any change to the number of Ordinary Shares represented by each ADS, or where following a change in the Relevant Stock Exchange for the Shares or otherwise the Ordinary Shares are no longer represented by ADSs but are instead represented by depositary or other receipts or certificates which are not ADSs, such modification shall be made to the operation of these Conditions, including without limitation, the adjustment provisions as is appropriate to give the intended result, as determined by an Independent Adviser or (if the Calculation Agent determines in its sole discretion it is capable of making such determination in its capacity as Calculation Agent) the Calculation Agent.

The Bondholder covenants that neither it nor any person acting on its behalf or pursuant to any understanding with it will deliver the ADSs received pursuant to conversion of the Bonds (including ADSs received pursuant to any ADS Settlement Option) to close out or repay the borrow associated with any Short Sale executed by it, except in compliance with applicable law. "Short Sales" include, without limitation, all "short sales" as defined in Rule 200 of Regulation SHO promulgated under the Exchange Act, and all types of direct and indirect stock pledges, forward sale contracts, options, puts, calls, short sales, swaps, derivatives and similar arrangements (including on a total return basis), and sales and other transactions through non-U.S. broker-dealers or foreign regulated brokers.

Prior to the 41st day after the Closing Date, no offer or sale of Bonds may be made, and no transfer of the Bonds will be effected, except in compliance with Rule 903 or Rule 904 of Regulation S, pursuant to registration of the Bonds under the Securities Act or pursuant to an available exemption from the registration requirements of the Securities Act.

6.2 Adjustment of Conversion Price

Subject to the provisions of this Condition 6, upon the occurrence of any of the events described below, the Conversion Price shall be adjusted by the Calculation Agent as follows:

(a) Consolidation, reclassification, redesignation or subdivision

If and whenever there shall be a consolidation, reclassification, redesignation or subdivision affecting the number of Ordinary Shares in issue, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A}{B} \times \frac{C}{D}$$

where:

A is the aggregate number of Ordinary Shares in issue immediately before such consolidation, reclassification, redesignation or subdivision, as the case may be;

B is the aggregate number of Ordinary Shares in issue immediately after, and as a result of, such consolidation, reclassification, redesignation or subdivision, as the case may be;

C is the number of Ordinary Shares represented by an ADS following or as a result or consequence of such consolidation, reclassification, redesignation or subdivision, as the case may be; and

D is the number of Ordinary Shares represented by an ADS immediately prior to such consolidation, reclassification, redesignation or subdivision, as the case may be.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (a), the date on which the consolidation, reclassification, redesignation or sub-division, as the case may be, takes effect.

(b) Capitalisation of profits or reserves

If and whenever the Issuer shall issue any Ordinary Shares credited as fully paid to Shareholders by way of capitalisation of profits or reserves, including any share premium account or capital redemption reserve (other than an issue of Ordinary Shares constituting a Scrip Dividend) the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A}{B} \times \frac{C}{D}$$

where:

A is the aggregate number of Ordinary Shares in issue immediately before such issue;

B is the aggregate number of Ordinary Shares in issue immediately after such issue;

C is the number of Ordinary Shares represented by an ADS following or as a result or consequence of such issue of Ordinary Shares; and

D is the number of Ordinary Shares represented by an ADS immediately prior to such issue of Ordinary Shares.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (b), the date of issue of such Ordinary Shares.

(c) Dividends

$$\frac{A-B}{A}$$

where:

A is the Current Market Price of one Ordinary Share on the Ex-Date in respect of such Dividend; and

B is the portion of the Fair Market Value of the aggregate Dividend attributable to one Ordinary Share, with such portion being determined by dividing the Fair Market Value of the aggregate Dividend by the number of Ordinary Shares entitled to receive the relevant Dividend (or, in the case of a purchase, redemption or buy back of Ordinary Shares, ADSs or any depositary or other receipts or certificates representing Ordinary Shares by or on behalf of the Issuer or any Subsidiary of the Issuer, by the number of Ordinary Shares in issue immediately following such purchase, redemption or buy back, and treating as not being in issue any Ordinary Shares, or any Ordinary Shares represented by ADSs or other depositary or other receipts or certificates, purchased, redeemed or bought back).

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (c)(i), the later of (A) the Ex-Date in respect of such `Dividend and (B) the first date upon which the Fair Market Value of the relevant Dividend is capable of being determined as provided herein.

(i) For the purposes of the above, Fair Market Value shall (subject as provided in the definition of "Dividend" and in the definition of "Fair Market Value") be determined as at the Ex-Date in respect of the relevant Dividend.

(d) Rights issues

If and whenever the Issuer or any Subsidiary of the Issuer or (at the direction or request or pursuant to any arrangements with the Issuer or any Subsidiary of the Issuer) any other company, person or entity shall issue any Ordinary Shares to Shareholders as a class by way of rights, or shall issue or grant to Shareholders as a class by way of rights, any options, warrants or other rights to subscribe for or purchase or otherwise acquire any Ordinary Shares, or any other Securities which by their terms of issue carry (directly or indirectly) rights of conversion into, or exchange or subscription for, or the right to otherwise acquire, any Ordinary Shares (or shall grant any such rights in respect of existing Securities so issued), in each case at a consideration receivable per Ordinary Share (based, where appropriate, on such number of Ordinary Shares as is determined pursuant to the definition of "**C**" and the proviso below) which is less than 95 per cent. of the Current Market Price per Ordinary Share on the Ex-Date in respect of the relevant issue or grant, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A+B}{A+C}$$

where:

A is the number of Ordinary Shares in issue on such Ex-Date;

B is the number of Ordinary Shares which the aggregate consideration (if any) receivable for the Ordinary Shares issued by way of rights, or for the Securities issued by way of rights and upon exercise of rights of conversion into, or exchange or subscription for, or the right to otherwise acquire, Ordinary Shares, or for the options or warrants or other rights issued by way of rights and for the total number of Ordinary Shares deliverable on the exercise thereof, would purchase at such Current Market Price per Ordinary Share on the Ex-Date; and

C is the number of Ordinary Shares to be issued or, as the case may be, the maximum number of Ordinary Shares which may be issued upon exercise of such options, warrants or rights calculated as at the date of issue of such options, warrants or rights or upon conversion or exchange or exercise of rights of subscription or purchase or other rights of acquisition in respect thereof at the initial conversion, exchange, subscription, purchase or acquisition price or rate;

provided that if on such Ex-Date such number of Ordinary Shares is to be determined by reference to the application of a formula or other variable feature or the occurrence of any event at some subsequent time, then for the purposes of this paragraph (d), "C" shall be determined by the application of such formula or variable feature or as if the relevant event occurs or had occurred as at such Ex-Date and as if such conversion, exchange, subscription, purchase or acquisition had taken place on such Ex-Date.

Such adjustment shall become effective on the Effective Date.

"**Effective Date** " means, in respect of this paragraph (d), the later of (i) the Ex-Date in respect of the relevant issue or grant and (ii) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (d).

(e) Issue of Securities to Shareholders

If and whenever the Issuer or any Subsidiary of the Issuer or (at the direction or request or pursuant to any arrangements with the Issuer or any Subsidiary of the Issuer) any other company, person or entity shall (other than in the circumstances the subject of paragraph (d) above and other than constituting a Scrip Dividend) issue any Securities to Shareholders as a class by way of rights or grant to Shareholders as a class by way of rights any options, warrants or other rights to subscribe for or purchase or otherwise acquire any Securities, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A-B}{A}$$

where:

A is the Current Market Price of one Ordinary Share on the Ex-Date in respect of the relevant issue or grant; and

B is the Fair Market Value on such Ex-Date of the portion of the rights attributable to one Ordinary Share.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (e), the later of (i) the Ex-Date in respect of the relevant issue or grant and (ii) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (e).

(f) Issue of Ordinary Shares at below Current Market Price

If and whenever the Issuer shall issue (otherwise than as mentioned in paragraph (d) above) wholly for cash or for no consideration any Ordinary Shares (other than Ordinary Shares represented by ADSs transferred or delivered on conversion of the Bonds (which term shall for this purpose include any Further Bonds) or on the exercise of any rights of conversion into, or exchange or subscription for or purchase of, or rights to otherwise acquire, Ordinary Shares and other than constituting a Scrip Dividend) or if and whenever the Issuer or any Subsidiary of the Issuer or (at the direction or request or pursuant to any arrangements with the Issuer or any Subsidiary of the Issuer) any other company, person or entity shall issue or grant (otherwise than as mentioned in paragraph (d) above) wholly for cash or for no consideration any options, warrants or other rights to subscribe for or purchase or otherwise acquire any Ordinary Shares (other than the Bonds, which term shall for this purpose include any Further Bonds), in each case at consideration receivable per Ordinary Share (based, where appropriate, on such number of Ordinary Shares as is determined pursuant to the definition of "C" and the proviso below) which is less than 95 per cent. of the Current Market Price per Ordinary Share on the date of first public announcement of the terms of such issue or grant, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A+B}{A+C}$$

where:

A is the number of Ordinary Shares in issue immediately before the date of first public announcement of the terms of such issue of Ordinary Shares or issue or grant of options, warrants or other rights as provided above;

B is the number of Ordinary Shares which the aggregate consideration (if any) receivable for the issue of such Ordinary Shares or, as the case may be, for the Ordinary Shares to be issued or otherwise made available upon the exercise of any such options, warrants or rights, would purchase at such Current Market Price per Ordinary Share on the date of first public announcement of the terms of such issue or grant; and

C is the number of Ordinary Shares to be issued pursuant to such issue of such Ordinary Shares or, as the case may be, the maximum number of Ordinary Shares which may be issued upon exercise of such options, warrants or rights calculated as at the date of issue of such options, warrants or rights;

provided that if on the date of first public announcement of the terms of such issue or grant (as used in this paragraph (f), the "**Specified Date**") such number of Ordinary Shares is to be determined by reference to the application of a formula or other variable feature or the occurrence of any event at some subsequent time, then for the purposes of this paragraph (f), "C" shall be determined by the application of such formula or variable feature or as if the relevant event occurs or had occurred as at the Specified Date and as if such conversion, exchange, subscription, purchase, acquisition had taken place on the Specified Date.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (f), the later of (i) the date of issue of such Ordinary Shares or, as the case may be, the issue or grant of such options, warrants or rights and (ii) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (f).

(g) Other issues

If and whenever the Issuer or any Subsidiary of the Issuer or (at the direction or request of or pursuant to any arrangements with the Issuer or any Subsidiary of the Issuer) any other company, person or entity shall (otherwise than as mentioned in paragraphs (d), (e) or (f) above) issue wholly for cash or for no consideration any Securities (other than the Bonds which term shall for this purpose exclude any Further Bonds and other than constituting a Scrip Dividend) which by their terms of issue carry (directly or indirectly) rights of conversion into, or exchange or subscription for, purchase of, or rights to otherwise acquire, Ordinary Shares (or shall grant any such rights in respect of existing Securities so issued) or Securities which by their terms might be reclassified or redesignated as Ordinary Shares, and the consideration per Ordinary Share (based, where appropriate, on such number of Ordinary Shares as is determined pursuant to the definition of "C" and the proviso below) receivable upon conversion, exchange, subscription, purchase, acquisition, reclassification or redesignation is less than 95 per cent. of the Current Market Price per Ordinary Share on the date of first public announcement of the terms of the issue of such Securities (or the terms of such grant), the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A+B}{A+C}$$

where:

A is the number of Ordinary Shares in issue immediately before the date of first public announcement of the terms of the issue of such Securities (or the terms of such grant);

B is the number of Ordinary Shares which the aggregate consideration (if any) receivable for the Ordinary Shares to be issued or otherwise made available

upon conversion or exchange or upon exercise of the right of subscription,

purchase or acquisition attached to such Securities or, as the case may be, for the Ordinary Shares to be issued or to arise from any such reclassification or redesignation would purchase at such Current Market Price per Ordinary Share on the date of first public announcement of the terms of the issue of such Securities (or the terms of such grant); and

C is the maximum number of Ordinary Shares to be issued or otherwise made available upon conversion or exchange of such Securities or upon the exercise of such right of subscription, purchase or acquisition attached thereto at the initial conversion, exchange, subscription, purchase or acquisition price or rate or, as the case may be, the maximum number of Ordinary Shares which may be issued or arise from any such reclassification or redesignation;

provided that if on the date of first public announcement of the terms of the issue of such Securities (or the terms of such grant) (as used in this paragraph, the "**Specified Date**") such number of Ordinary Shares is to be determined by reference to the application of a formula or other variable feature or the occurrence of any event at some subsequent time (which may be when such Securities are converted or exchanged or rights of subscription, purchase or acquisition are exercised or, as the case may be, such Securities are reclassified or redesignated or at such other time as may be provided), then for the purposes of this paragraph (g), "**C**" shall be determined by the application of such formula or variable feature or as if the relevant event occurs or had occurred as at the Specified Date and as if such conversion, exchange, subscription, purchase or acquisition, reclassification or, as the case may be, redesignation had taken place on the Specified Date.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (g), the later of (i) the date of issue of such Securities or, as the case may be, the grant of such rights and (ii) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (g).

(h) Modification of rights

If and whenever there shall be any modification of the rights of conversion, exchange, subscription, purchase or acquisition attaching to any Securities (other than the Bonds, which term shall for this purpose include any Further Bonds) which by their terms of issue carry (directly or indirectly) rights of conversion into, or exchange or subscription for, or the right to otherwise acquire, any Ordinary Shares (other than in accordance with the terms (including terms as to adjustment) applicable to such Securities upon issue) so that following such modification the consideration per Ordinary Share (based, where appropriate, on such number of Ordinary Shares as is determined pursuant to the definition of "**C**" and the proviso below) receivable upon conversion, exchange, subscription, purchase or acquisition has been reduced and is less than 95 per cent. of the Current Market Price per Ordinary Share on the date of first public announcement of the terms for such modification, the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A+B}{A+C}$$

where:

A is the number of Ordinary Shares in issue immediately before the date of first public announcement of the terms for such modification;

B is the number of Ordinary Shares which the aggregate consideration (if any) receivable for the Ordinary Shares to be issued or otherwise made available upon conversion or exchange or upon exercise of the right of subscription, purchase or acquisition attached to the Securities so modified would purchase at such Current Market Price per Ordinary Share on the date of first public announcement of the terms for such modification or, if lower, the existing conversion, exchange, subscription, purchase or acquisition price or rate of such Securities; and

C is the maximum number of Ordinary Shares which may be issued or otherwise made available upon conversion or exchange of such Securities or upon the exercise of such rights of subscription, purchase or acquisition attached thereto at the modified conversion, exchange, subscription, purchase or acquisition price or rate but giving credit in such manner as the Calculation Agent shall consider appropriate for any previous adjustment under this paragraph (h) or paragraph (g) above;

provided that if on the date of first public announcement of the terms of such modification (as used in this paragraph (h), the "**Specified Date**") such number of Ordinary Shares is to be determined by reference to the application of a formula or other variable feature or the occurrence of any event at some subsequent time (which may be when such Securities are converted or exchanged or rights of subscription, purchase or acquisition are exercised or at such other time as may be provided), then for the purposes of this paragraph (h), "C" shall be determined by the application of such formula or variable feature or as if the relevant event occurs or had occurred as at the Specified Date and as if such conversion, exchange, subscription, purchase or acquisition had taken place on the Specified Date.

Such adjustment shall become effective on the Effective Date.

"**Effective Date**" means, in respect of this paragraph (h), the later of (i) the date of modification of the rights of conversion, exchange, subscription, purchase or acquisition attaching to such Securities and (ii) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (h).

(i) Certain arrangements

If and whenever the Issuer or any Subsidiary of the Issuer or (at the direction or request of or pursuant to any arrangements with the Issuer or any Subsidiary of the Issuer) any other company, person or entity shall offer any Ordinary Shares or such other Securities in connection with which Shareholders as a class are entitled to participate in arrangements whereby such Ordinary Shares or Securities may be acquired by them (except where the Conversion Price falls to be adjusted under paragraphs (b), (c), (d), (e), (f), (g), (j), or (g) above or (j) below (or, where applicable, would fall to be so adjusted if the relevant issue or grant was at less than 95 per cent. of the Current Market Price per Ordinary Share on the relevant day), the Conversion Price shall be adjusted by multiplying the Conversion Price in force immediately prior to the Effective Date by the following fraction:

$$\frac{A-B}{A}$$

where:

A is the Current Market Price of one Ordinary Share on the Ex-Date in respect of the relevant offer; and

B is the Fair Market` Value on such Ex-Date of the portion of the relevant offer attributable to one Ordinary Share.

Such adjustment shall become effective on the Effective Date.

"**Effective Date** " means, in respect of this paragraph (i), the later of (A) the Ex-Date in respect of the relevant offer and (B) the first date upon which the adjusted Conversion Price is capable of being determined in accordance with this paragraph (i).

(j) Change of Control

If a Change of Control shall occur, then, upon any exercise of Conversion Rights where the Conversion Date falls during the Change of Control Period, the Conversion Price solely for the purpose of such exercise (the "**Change of Control Conversion Price**") shall be determined as set out below:

$$\text{COCCP} = \frac{\text{OCP}}{1 + \left(CP \times \frac{c}{t}\right)}$$

where:

COCCP = means the Change of Control Conversion Price

OCP = means the Conversion Price in effect on the relevant Conversion Date

CP = means the Conversion Premium, being 20 per cent.

c = means the number of days from and including the date the Change of Control occurs to but excluding the Final Maturity Date

t = means the number of days from and including the Closing Date to but excluding the Final Maturity Date

(k) Other adjustments

Subject to Condition 6.7, if either the Issuer (following consultation with the Calculation Agent) or the Majority Bondholders (each acting reasonably) determines that an adjustment (for the purpose of compensating for dilution) should be made to the Conversion Price (or that a determination should be made as to whether an adjustment should be made) as a result of one or more circumstances not referred to above in this Condition 6.2) (except for events specifically excluded from the operation of paragraphs (a) to (j) above), the Issuer shall, at its own expense and acting reasonably, request an Independent Adviser to determine, in consultation with the Calculation Agent, if different as soon as practicable what adjustment (if any) to the Conversion Price is fair and reasonable to take account thereof and the date on which

such adjustment (if any) should take effect and upon such determination such adjustment (if any) shall be made and shall take effect in accordance with such determination, provided that an adjustment shall only be made pursuant to this paragraph (k) if such Independent Adviser is so requested to make such a determination not more than 21 days after the date on which the relevant circumstances arises (or, if later, 21 days after the date on which the relevant circumstances are made public or otherwise are made known to the Bondholders) and if the adjustment would result in a reduction to the Conversion Price.

(l) Modifications

Notwithstanding the foregoing provisions:

(i) where the events or circumstances giving rise to any adjustment pursuant to this Condition 6.2 have already resulted or will result in an adjustment to the Conversion Price or where the events or circumstances giving rise to any adjustment arise by virtue of any other events or circumstances which have already given or will give rise to an adjustment to the Conversion Price or where more than one event which gives rise to an adjustment to the Conversion Price occurs within such a short period of time that, in the opinion of the Issuer, acting reasonably and following consultation with the Calculation Agent, a modification to the operation of the adjustment provisions is required to give the intended result, such modification shall be made to the operation of the adjustment provisions as may be determined in good faith by an Independent Adviser to be in its opinion appropriate to give the intended result;

(ii) such modification shall be made to the operation of these Conditions as may be determined in good faith by an Independent Adviser, in consultation with the Calculation Agent (if different), to be in its opinion appropriate (A) to ensure that an adjustment to the Conversion Price or the economic effect thereof shall not be taken into account more than once and (B) to ensure that the economic effect of a Dividend is not taken into account more than once; and

(iii) other than pursuant to Condition 6.2(a) or Condition 6.5 or pursuant to a NewCo Scheme Modification, no adjustment shall be made that would result in an increase to the Conversion Price.

(m) Calculation of consideration

For the purpose of any calculation of the consideration receivable or price pursuant to paragraphs (d), (f), (g) and (h) above, the following provisions shall apply:

(i) the aggregate consideration receivable or price for Ordinary Shares issued for cash shall be the amount of such cash (determined by reference to the per-ADS amount of such cash where available);

(ii) if the consideration or price determined pursuant to (i) or (ii) above (or any component thereof) shall be expressed in a currency other than the Relevant Currency (other than in circumstances where such consideration is also expressed in the Relevant Currency, in which case such consideration shall be treated as expressed in the Relevant Currency in an amount equal to the amount of such consideration when so expressed in the Relevant Currency), it shall be converted by the Calculation Agent into the Relevant Currency at the Prevailing Rate on the relevant Ex-Date (for the purposes of paragraph (d) above) or the relevant date of first public announcement (for the purposes of paragraph (f), (g) and (h) above, as the case may be);

(iii) in determining the consideration or price pursuant to the above, no deduction shall be made for any commissions or fees (howsoever described) or any expenses paid or incurred for any underwriting, placing or management of the issue of the relevant Ordinary Shares or such other Securities or options, warrants or rights, or otherwise in connection therewith;

(iv) the consideration or price shall be determined as provided above on the basis of the consideration or price received, receivable, paid or payable, regardless of whether all or part thereof is received, receivable, paid or payable by or to the Issuer or another entity;

(v) if as part of the same transaction, Ordinary Shares shall be issued or issuable for a consideration receivable in more than one or in different currencies then the consideration receivable per Ordinary Share shall be determined by dividing the aggregate consideration (determined as aforesaid and converted, if and to the extent not in the Relevant Currency, into the Relevant Currency as aforesaid) by the aggregate number of Ordinary Shares so issued; and

(vi) references in these Conditions to "cash" shall be construed as cash consideration within the meaning of Section 583(3) of the Companies Act.

6.3 Retroactive Adjustments

If a Retroactive Adjustment occurs in relation to any exercise of Conversion Rights, the Issuer shall procure that there shall be issued and/or transferred and delivered to, or to the order of, the relevant Bondholder in accordance with the Payment Details, such additional number of ADSs (if any) (the "**Additional ADSs**") as, together with the ADSs issued and/or transferred and delivered on the relevant exercise of Conversion Rights, is equal to the number of Physically Settled ADSs which would have been required to be issued and/or transferred and delivered on such exercise if the relevant adjustment to the Conversion Price had been made and become effective immediately prior to the relevant Conversion Date (such number of Physically Settled ADSs as aforesaid being for this purpose calculated as (i) where such exercise of Conversion Rights is not the subject of a Cash Alternative Election, the Reference ADSs in respect of such exercise of Conversion Rights determined for this purpose by reference to such deemed Conversion Price as aforesaid, and (ii) where such exercise of Conversion Rights is the subject of a Cash Alternative Election, the difference between (A) such number of Reference ADSs as is determined pursuant to (i) and (B) the product of (x) such number of Reference ADSs determined as aforesaid and (y) the Cash Settlement Ratio in respect of such exercise of Conversion Rights), all as determined in good faith by the Calculation Agent or an Independent Adviser, provided that if in the case of Conditions 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i) the relevant Bondholder shall be entitled to receive the relevant Ordinary Shares (including Ordinary Shares represented by ADSs), Dividends or such other Securities in respect of the Reference ADSs to be issued and/or transferred and delivered to it, then no such Retroactive Adjustment shall be made in relation to the relevant event and the relevant Bondholder shall not be entitled to receive Additional ADSs in relation thereto.

6.4 Conversion Price Reset

Subject to the following sentence, on each Reset Date, the Conversion Price will be adjusted by the Calculation Agent to be equal to the Reset Conversion Price. An adjustment to the Conversion Price pursuant to this Condition 6.4 on any Reset Date (each such adjustment, a "**Conversion Price Reset**") shall be made only if the Conversion Price so adjusted is lower than the Conversion Price that would, but for the operation of this Condition 6.4 in respect of such Reset Date, be in effect on such Reset Date.

The "**Reset Conversion Price**" means, on each Reset Date, the US Dollar price per ADS which is the greater of:

(a) the 30-Day Reset Average Market Price; and

(b) the relevant Reset Price Floor on such Reset Date,

as determined by the Calculation Agent.

The "**Reset Price Floor**" on each "**Reset Date**" (being each of the dates set out in (i), (ii) and (iii) below, as specified in the Initial Determinations Notice) means the US Dollar price per ADS calculated (and rounded to the nearest integral multiple of $0.0001 (with $0.00005 being rounded upwards)) as follows:

(i) for the date falling on the first anniversary date of the Closing Date: (RCP x 2 / 3) + (FP / 3)

(ii) for the date falling on the second anniversary date of the Closing Date: (RCP / 3) + (FP x 2 / 3)

(iii) for the date falling on the third anniversary date of the Closing Date: FP

where:

RCP = means the Reference Conversion Price on the relevant Reset Date.

FP = means the Floor Price on the relevant Reset Date.

"**Reference Conversion Price**", for the purposes of this Condition 6.4, on any date means, initially, U.S.$8.70, as shall from time to time be adjusted *pro rata* for any adjustment made to the Conversion Price (and with effect from the date on which such adjustment becomes effective) pursuant to Condition 6.2 (but, for the avoidance of doubt, not adjusted for any adjustment made to the Conversion Price pursuant to this Condition 6.4 or Condition 6.5 and ignoring for these purposes Condition 6.2(j)); and

"**Floor Price**" on any date means, initially U.S.$7.25, as shall from time to time be adjusted *pro rata* for any adjustment made to the Conversion Price (and with effect from the date on which such adjustment becomes effective) pursuant to Condition 6.2 (but, for the avoidance of doubt, not adjusted for any adjustment made to the Conversion Price pursuant to this Condition 6.4 or Condition 6.5 and ignoring for these purposes Condition 6.2(j)).

Any adjustment to the Conversion Price pursuant to this Condition 6.4 shall become effective as of the relevant Reset Date (or, if later, the first date on which such adjustment is capable of being determined in accordance with these Conditions) and notice of any such adjustment shall be given by the Issuer to Bondholders in accordance with Condition 16.

On any adjustment to the Reference Conversion Price or Floor Price, the resultant Reference Conversion Price or Floor Price, as the case may be, if not an integral multiple of $0.0001, shall be rounded down to the nearest whole multiple of $0.0001. No adjustment shall be made to the Reference Conversion Price or Floor Price where such adjustment (rounded down if applicable) would be less than one per cent. of the Reference Conversion Price or Floor Price, as the case may be, then in effect. Any adjustment not required to be made and/or any amount by which the Reference Conversion Price or Floor Price, as the case may be, has been rounded down, shall be carried forward and taken into account in any subsequent adjustment, and such subsequent adjustment shall be made on the basis that the adjustment not required to be made had been made at the relevant time and/or, as the case may be, that the relevant rounding down had not been made.

Notice of any adjustments to the Reference Conversion Price and Floor Price, as the case may be, and the resulting Reset Price Floor for each Reset Date falling on or after the date on which such adjustment becomes effective (determined, solely for the purpose of such notice, on the basis of the Reference Conversion Price and Floor Price so adjusted), shall be given by the Issuer to Bondholders in accordance with Condition 16 promptly after the determination thereof.

6.5 Conversion Price Reset Clawback at the Issuer's Option

Following the occurrence of a Conversion Price Reset (as defined in Condition 6.4) pursuant to Condition 6.4 on a Reset Date (the "**Reference Reset Date**"), if the Volume Weighted Average Price of an ADS (translated if necessary into US Dollars at the Prevailing Rate) on each of at least 20 Dealing Days in any period of 30 consecutive Dealing Days commencing

on or after such Reference Reset Date shall have exceeded 150% of the Reference
Conversion Price (as defined in Condition 6.4) on such Dealing Day (or, if such Dealing Day falls on or after the Applicable Adjustment Reference Date in respect of any adjustment required to be made to the Conversion Price pursuant to these Conditions (other than an adjustment pursuant to Condition 6.4 or Condition 6.5) and such adjustment is not yet in effect on such Dealing Day, the Volume Weighted Average Price on such Dealing Day shall be divided by the adjustment factor (as determined pursuant to these Conditions) applied to the Conversion Price in respect of such adjustment), as verified by the Calculation Agent, then the Issuer will have the right (but not the obligation) to require the Calculation Agent to adjust the Conversion Price (the "**Reset Clawback**") such that it shall be the Conversion Price which would otherwise have been in effect on the Clawback Effective Date (as defined below) had the most recent Conversion Price Reset not been made.

For the avoidance of doubt, if there shall have been Conversion Price Resets pursuant to Condition 6.4 on more than one Reset Date, the Issuer's exercise of the Reset Clawback (if the Issuer's right should arise and be exercised under this Condition 6.5) shall apply solely in relation to the most recent Conversion Price Reset and shall have no effect on any Conversion Price Reset which occurred prior to the most recent Conversion Price Reset.

Notice of any adjustment to the Conversion Price pursuant to this Condition 6.5 shall promptly be given by the Issuer to Bondholders in accordance with Condition 16, and any adjustment to the Conversion Price pursuant to this Condition 6.5 shall become effective as of the date on which such notice is given to Bondholders (any such date, a "**Clawback Effective Date**"). Any such notice shall specify the Conversion Price so adjusted.

The Issuer may only exercise its right of the Reset Clawback under this Condition 6.5 on one occasion during the term of the Bonds.

6.6 Decision and Determination of the Calculation Agent or an Independent Adviser

Adjustments to the Conversion Price shall be determined and calculated by the Calculation Agent upon request from the Issuer and/or, to the extent so specified in the Conditions and upon request from the Issuer, by an Independent Adviser.

Adjustments to the Conversion Price calculated by the Calculation Agent or, where applicable, an Independent Adviser and any other determinations made by the Calculation Agent or, where applicable, an Independent Adviser, or an opinion of an Independent Adviser, pursuant to these Conditions shall in each case be made in good faith and shall be final and binding (in the absence of manifest error) on the Issuer, the Bondholders and the Calculation Agent (in the case of a determination by an Independent Adviser).

The Calculation Agent may consult, at the expense of the Issuer, on any matter (including, but not limited to, any legal matter), any legal or other professional adviser and it shall be able to rely upon, and it shall not be liable and shall incur no liability as against the Bondholders in respect of anything done, or omitted to be done, relating to that matter in good faith in accordance with that adviser's opinion.

The Calculation Agent shall act solely upon the request from, and exclusively as agent of, the Issuer and in accordance with these Conditions. Neither the Calculation Agent (acting in such capacity) nor any Independent Adviser appointed in connection with the Bonds (acting in such capacity) will thereby assume any obligations towards or relationship of agency or trust and shall not be liable and shall incur no liability in respect of anything done, or omitted to be done in good faith, in their capacity as Calculation Agent, or as the case may be, Independent Adviser, as against the Bondholders.

If following consultation between the Issuer and the Calculation Agent any doubt shall arise as to whether an adjustment falls to be made to the Conversion Price or as to the appropriate adjustment to the Conversion Price, following consultation between the Issuer and an Independent Adviser, a written opinion of such Independent Adviser in respect thereof shall be conclusive and binding on the Issuer, the Bondholders and the Calculation Agent (if different), save in the case of manifest error.

The Issuer shall promptly notify Bondholders in accordance with Condition 16 of each determination, calculation or adjustment performed by the Calculation Agent and/or Independent Adviser pursuant to these Conditions.

6.7 Share or Option Schemes, Dividend Reinvestment Plans, Equity Raise

No adjustment will be made to the Conversion Price where ADSs, Ordinary Shares or other Securities (including, but not limited to, rights, warrants and options) are issued, offered, exercised, allotted, purchased, appropriated, modified or granted (i) to, or for the benefit of, employees or former employees (including directors holding or formerly holding executive office or non-executive office, consultants or former consultants, or the personal service company of any such person) or their spouses or relatives, in each case, of the Issuer or any of its Subsidiaries or any associated company or to a trustee or nominee to be held for the benefit of any such person, in any such case pursuant to any share or option or incentive scheme or (ii) pursuant to any dividend reinvestment plan or similar plan or scheme.

No adjustment will be made to the Conversion Price in respect of any Ordinary Shares (including without limitation Ordinary Shares represented by ADSs) or any warrants to purchase Ordinary Shares (including without limitation Ordinary Shares represented by ADSs) in each case issued pursuant to the Equity Raise.

6.8 Rounding Down and Notice of Adjustment to the Conversion Price

On any adjustment, the resultant Conversion Price, if not an integral multiple of $0.0001, shall be rounded down to the nearest whole multiple of $0.0001. No adjustment shall be made to the Conversion Price where such adjustment (rounded down if applicable) would be less than one per cent. of the Conversion Price then in effect. Any adjustment not required to be made and/or any amount by which the Conversion Price has been rounded down, shall be carried forward and taken into account in any subsequent adjustment, and such subsequent adjustment shall be made on the basis that the adjustment not required to be made had been made at the relevant time and/or, as the case may be, that the relevant rounding down had not been made.

Notice of any adjustments to the Conversion Price shall be given by the Issuer to Bondholders promptly after the determination thereof.

The Conversion Price shall not in any event be reduced so that on conversion of the Bonds, Ordinary Shares or ADSs would fall to be issued in circumstances not permitted by applicable laws or regulations. The Issuer undertakes that it shall not take any action, and shall procure that no action is taken, that would otherwise result in an adjustment to the Conversion Price to below any minimum level permitted by applicable laws or regulations or that would otherwise result in Ordinary Shares or ADSs being required to be issued or transferred and delivered in circumstances not permitted by applicable laws or regulations.

6.9 Relevant Event

Within 14 calendar days following the occurrence of a Relevant Event, the Issuer shall give notice thereof to Bondholders in accordance with Condition 16 (a "**Relevant Event Notice**").

The Relevant Event Notice shall contain a statement informing Bondholders of (i) their entitlement to exercise their Conversion Rights as provided in these Conditions and (ii) their entitlement to exercise their rights to require redemption of their Bonds pursuant to Condition 7.2.

The Relevant Event Notice shall also specify:

(a) all information material to Bondholders concerning the Relevant Event;

(b) the Conversion Price immediately prior to the occurrence of the Relevant Event and, in the case of a Change of Control, the Change of Control Conversion Price applicable pursuant to Condition 6.2(j) on the basis of the Conversion Price in effect immediately prior to the occurrence of the Change of Control;

(c) the Closing Price of an ADS as at the latest practicable date prior to the publication of the Relevant Event Notice;

(d) the Relevant Event Period; and

(e) the Relevant Event Put Date.

6.10 Procedure for exercise of Conversion Rights

Conversion Rights may be exercised by a Bondholder (provided that the relevant Conversion Date falls during the Conversion Period) by delivering the relevant Bond Certificate to the Issuer accompanied by a Conversion Notice. The conversion date in respect of a Bond (the "**Conversion Date**") shall be the business day in London and New York on the date of the delivery (or deemed delivery) of the relevant Conversion Notice and Bond Certificate as provided in this Condition 6.10 and shall be deemed to be the date on which the Conversion Right is exercised in respect of such Bond.

If such delivery is made after 5.00p.m. London time or on a day which is not a London and New York business day, such delivery shall be deemed for all purposes of these Conditions to have been made on the next following London and New York business day.

Conversion Rights may only be exercised in respect of the whole of a Bond.

A Conversion Notice, once delivered, shall be irrevocable.

The Issuer shall pay all capital, stamp, issue and registration and transfer taxes and duties assessable or payable in the United Kingdom or in the United States or in any other jurisdiction in which the Issuer may be domiciled or resident or to whose taxing jurisdiction it may be generally subject ("**Specified Taxes**"), in respect of the issue or transfer and delivery of any ADSs (including the allotment, issue and delivery of Ordinary Shares represented thereby) in respect of the exercise of such Conversion Right (including any Additional ADSs) and any ADS Settlement. If the Issuer fails to pay any Specified Taxes assessable or payable in respect of the issue or transfer and delivery of any ADSs (including the allotment, issue and delivery of Ordinary Shares represented thereby) in respect of the exercise of such Conversion Right (including any Additional ADSs) and any ADS Settlement, the relevant Bondholder shall be entitled to tender and pay the same and the Issuer, as a separate and independent stipulation, covenants to reimburse and indemnify each Bondholder in respect of any payment thereof and any interest and penalties payable and documented costs incurred in respect thereof.

A Bondholder exercising Conversion Rights must pay directly to the relevant authorities of a relevant jurisdiction any capital, stamp, issue, registration and transfer taxes and duties arising on the exercise of Conversion Rights excluding any Specified Taxes (which shall be payable by the Issuer). A Bondholder must also pay, or procure the payment of, all, if any, taxes imposed on it and arising by reference to any disposal or deemed disposal by it of a Bond or interest therein in connection with the exercise of Conversion Rights by it. Any such capital, stamp, issue, registration or transfer taxes or duties or other taxes payable by a Bondholder are referred to as "**Bondholder Taxes**". If the Bondholder fails to pay any Bondholder Taxes, the Issuer shall be entitled to tender and pay the same and the Bondholder, as a separate and independent stipulation, covenants to reimburse and indemnify the Issuer in respect of any payment thereof and any interest and penalties payable and any documented costs incurred in respect thereof.

For the avoidance of doubt, the Calculation Agent shall not be responsible for determining whether any Specified Taxes or Bondholder Taxes are payable or the amount thereof and shall not be responsible or liable for any failure by the Issuer to pay such Specified Taxes or by a Bondholder to pay such Bondholder Taxes.

ADSs to be issued or transferred and delivered on exercise of Conversion Rights (including any Additional ADSs) will be issued or delivered in uncertificated form through DTC to its direct and indirect participants to the account specified by the relevant Bondholder in the Payment Details, unless at the relevant time the ADSs (including Additional ADSs) are not a participating security in DTC, in which case the Deliverable ADSs (including Additional Deliverable ADSs) will be issued or delivered in certificated form. Where Deliverable ADSs (including Additional Deliverable ADSs) are to be issued or transferred and delivered in certificated form, a certificate in respect thereof will be dispatched by mail free of charge to the relevant Bondholder in accordance with its Payment Details or as it may otherwise direct.

Such ADSs will be issued or transferred and delivered to the relevant Bondholder no later than four London and New York business days following the relevant Conversion Date or, in the case of any Additional ADSs, not later than four London and New York business days following the relevant Reference Date.

A Bondholder exercising a Conversion Right will be required to certify that it will become the beneficial owner of any relevant ADSs received pursuant to the exercise of its Conversion Right and is not an officer, director (or person performing similar functions) or other affiliate of the Issuer or a person acting on behalf of such an affiliate. ADSs issued or transferred and delivered to Bondholders (i) pursuant to an exercise of Conversion Rights (including any Additional ADSs), and (ii) pursuant to an exercise by the Issuer of an ADS Settlement Option (including any Additional Deliverable ADSs), will be immediately freely tradeable under the Securities Act by holders who are not affiliates of the Issuer, and have not been, affiliates of the Issuer within the preceding three months.

Except as otherwise provided in these Conditions or in the Bond Agreement, the Issuer will pay all costs, fees and expenses, including, where relevant, those of the Depositary and any custodian acting on behalf of such Depositary, but excluding any Bondholder Taxes, in connection with the delivery of ADSs on each exercise of Conversion Rights and in relation to each ADS Settlement.

Notwithstanding any other provisions of these Conditions, a Bondholder exercising Conversion Rights following a Change of Control Conversion Right Amendment as described in Condition 11(b)(vii) will be deemed, for the purposes of these Conditions, to have received the ADSs to be issued or transferred and delivered arising on conversion of its Bonds in the manner provided in these Conditions, and have exchanged such ADSs for the consideration that it would have

received therefor if it had exercised its Conversion Right in respect of such Bonds at the time of the occurrence of the relevant Change of Control.

6.11 Cash Alternative Election

(a) Upon exercise of a Conversion Right, the Issuer may make an election (a "Cash Alternative Election") by giving notice (a "Cash Alternative Election Notice") to the relevant Bondholder by not later than the date (the "Cash Election Date") falling four Dealing Days after the relevant Conversion Date (with a copy to the Calculation Agent) to satisfy the exercise of the Conversion Right in respect of the relevant Bonds by (i) making payment, or procuring that payment is made, to the relevant Bondholder of the Cash Alternative Amount in respect of the Cash Settled ADSs in respect of such exercise as specified in the relevant Cash Alternative Election Notice, and (ii) where the Cash Settled ADSs are less than the Reference ADSs in respect of the relevant exercise of Conversion Rights, by issuing or transferring and delivering the Physically Settled ADSs, together in any such case with any other amount payable by the Issuer to such Bondholder pursuant to these Conditions in respect of or relating to the relevant exercise of Conversion Rights, including any interest payable pursuant to Condition 6.13.

(b) The Cash Alternative Election Notice shall be irrevocable and shall specify:

(i) the Conversion Price in effect on the relevant Conversion Date and the number of Reference ADSs in respect of such exercise of Conversion Rights;

(ii) the number of Cash Settled ADSs in respect of the relevant exercise of Conversion Rights, by reference to which the Cash Alternative Amount is to be calculated; and

(iii) if the number of Cash Settled ADSs (determined as aforesaid) is less than the number of Reference ADSs in respect of the relevant exercise of Conversion Rights, the number of Physically Settled ADSs to be transferred and delivered by the Issuer to the relevant Bondholder in respect of such exercise.

(c) The Issuer will pay the Cash Alternative Amount not later than three New York business days following the last day of the Cash Alternative Calculation Period by transfer to a US Dollar bank account in accordance with the Payment Details.

(d) If there is a Retroactive Adjustment to the Conversion Price following the exercise of Conversion Rights by a Bondholder in circumstances where (x) a Cash Alternative Election is made in respect of such exercise and (y) if any Dealing Day comprised in the Cash Alternative Calculation Period in respect of such exercise of Conversion Rights falls on or after the Applicable Adjustment Reference Date in respect of such Retroactive Adjustment, then the Issuer shall pay to the relevant Bondholder an additional amount (the "**Additional Cash Alternative Amount**") calculated in good faith by the Calculation Agent and equal to the Market Price of such number of ADSs (rounded down if necessary to the nearest whole number of ADSs) (if any) as is equal to that by which the number of Cash Settled ADSs would have been increased if the relevant adjustment to the Conversion Price had been made and become effective immediately prior to the relevant Conversion Date (such number of Cash Settled ADSs as aforesaid being for this purpose calculated as the product of (x) the Reference ADSs determined for this purpose by reference to such deemed Conversion Price as aforesaid and (y) the Cash Settlement Ratio, in the case of (x) and (y) in respect of such exercise of Conversion Rights), all as determined in good faith by the Calculation Agent.

(e) The Issuer will pay the Additional Cash Alternative Amount not later than three London and New York business days following the relevant Reference Date by transfer to a US Dollar bank account in accordance with the Payment Details.

6.12 Ranking and entitlement in respect of ADSs (and Ordinary Shares represented thereby)

ADSs (including any Additional ADSs) issued or transferred and delivered on exercise of Conversion Rights will be fully paid and will in all respects rank pari passu with the fully paid ADSs in issue on the relevant Conversion Date or, in the case of Additional ADSs, on the relevant Reference Date, and without prejudice to the provisions of the Deposit Agreement, the relevant holder shall be entitled to all rights, distribution or payments the record date or other due date for the establishment of entitlement for which falls on or after the relevant Conversion Date, or as the case may be, the relevant Reference Date, except in any such case for any right excluded by mandatory provisions of applicable law or as otherwise may be provided in these Conditions. Such ADSs or, as the case may be, Additional ADSs will not rank for (or, as the case may be, the relevant holder shall not be entitled to receive) any rights, distributions or payments the record date or other due date for the establishment of entitlement for which falls prior to the relevant Conversion Date or, as the case may be, the relevant Reference Date.

Ordinary Shares represented by ADSs issued and/or transferred and delivered to the Bondholders on exercise of Conversion Rights will be fully paid and in all respects will rank *pari passu* with all other Ordinary Shares in issue on the relevant Conversion Date (or, in the case of Ordinary Shares represented by Additional ADSs, the relevant Reference Date) (except for any right excluded by mandatory provisions of applicable law) and such Ordinary Shares will be entitled to all rights to the same extent as all other fully-paid Ordinary Shares of the Issuer.

6.13 Interest on Conversion

No payment or adjustment shall be made on exercise of Conversion Rights for any interest which otherwise would have accrued on the relevant Bonds since the last Interest Payment Date preceding the Conversion Date relating to such Bonds (or, if such Conversion Date falls before the first Interest Payment Date, since the Closing Date).

6.14 Purchase or Redemption of Ordinary Shares or ADSs

The Issuer or any Subsidiary of the Issuer may exercise such rights as they may from time to time enjoy to purchase or redeem or buy back any shares of the Issuer (including Ordinary Shares) or ADSs or any depositary or other receipts or certificates representing the same without the consent of the Bondholders provided that it is in compliance with the terms of the Deposit Agreement and the Issuer or any Subsidiary of the Issuer will obtain U.S. legal advice and take all steps necessary to ensure that the application of the proposed transaction does not violate the provisions of the Securities Act, or any other applicable laws (including, without limitation, the Investment Company Act of 1940, as amended, the Exchange Act or the securities laws of the states of the United States).

6.15 No Duty to Monitor

The Calculation Agent shall not be under any duty to monitor whether any event or circumstance has happened or exists or may happen or exist and which requires or may
require an adjustment to be made to the Conversion Price or be responsible or liable to any person for any loss arising from any failure by any of them to do so. The Calculation Agent shall also not be responsible or liable to any person (other than in the case of the Calculation

Agent, to the Issuer strictly in accordance with the relevant provisions of the Calculation Agency Agreement) for any determination as to whether or not an adjustment to the Conversion Price is required or should be made or for any determination or calculation of any such adjustment.

6.16 Consolidation, Amalgamation or Merger

Without prejudice to Condition 6.2(j), in the case of any consolidation, amalgamation or merger of the Issuer with any other corporation (other than constituting a Change of Control or a consolidation, amalgamation or merger in which the Issuer is the continuing corporation) (a "**Successor in Business**"), the Issuer will forthwith give notice thereof to Bondholders in accordance with Condition 16 of such event and will take such steps as shall be required, subject to applicable law and as provided in Condition 15 (and including the execution of a deed supplemental to or amending the Bond Agreement):

(a) to ensure that the Successor in Business is substituted in place of the Issuer as the principal debtor under the Bonds and the Bond Agreement;

(b) to ensure that each Bond then outstanding will (during the period in which Conversion Rights may be exercised) be convertible into equity share capital (or similar (including without limitation depositary or other receipts or certificates representing equity share capital)) of the Successor in Business, on such basis and with a Conversion Price (subject to adjustment as provided in these Conditions) economically equivalent to the Conversion Price existing immediately prior to the implementation of such consolidation, amalgamation or merger, as determined in good faith by an Independent Adviser (each a "**Conversion Right Transfer**"); and

(c) to ensure that the Bond Agreement (as so amended or supplemented if applicable) and the Conditions provide at least the same or equivalent powers, protections, rights and benefits to the Bondholders following the implementation of such consolidation, amalgamation or merger as they provided to the Bondholders prior to the implementation of such consolidation, amalgamation or merger, mutatis mutandis.

The satisfaction of the requirements set out above in this Condition 6.16 by the Issuer is herein referred to as a "**Permitted Cessation of Business**". Notwithstanding any other provision of these Conditions, a Permitted Cessation of Business shall not result in a breach of undertaking, constitute an Event of Default or otherwise result in any breach of any provision of these Conditions or the Bond Agreement. Following the occurrence of a Permitted Cessation of Business, references in these Conditions and the Bond Documents to the "Issuer" will be construed as references to the relevant Successor in Business (but without prejudice to the provisions of the Calculation Agency Agreement).

At the request of the Issuer, but subject to the Issuer's compliance with the provisions of this Condition 6.16, the Bondholders shall (at the expense of the Issuer, including payment by the Issuer of the reasonably incurred fees of Bondholders' legal counsel in relation to such Conversion Right Transfer) concur with the Issuer in effecting any substitution under subparagraph (a) above and Conversion Right Transfer (including, *inter alia*, the execution of a deed supplemental to or amending the Bond Agreement), provided that the Bondholders shall not be obliged so to concur if in the opinion of the Bondholders doing so would impose more onerous obligations upon any of them or expose any of them to any additional duties, responsibilities or liabilities in any way.

If, following consultation with the Calculation Agent, any doubt shall arise (or upon the request to the Issuer of the Majority Bondholders) as to how determinations, calculations or

adjustments which are specifically required to be performed by the Calculation Agent in these Conditions should be performed following any such consolidation, amalgamation or merger, a written opinion of an Independent Adviser in respect thereof shall be conclusive and binding on the Successor in Business, the Issuer, the Bondholders, the Calculation Agent and all other parties, save in the case of manifest error.

The above provisions of this Condition 6.16 will apply, mutatis mutandis, to any subsequent consolidations, amalgamation or mergers.

7. Redemption and Purchase

7.1 Mandatory Redemption by Amortisation

(a) Scheduled Amortisation Payments

Subject to Condition 7.1(c) below, on the date falling three months after the Closing Date and on each three month anniversary thereof ending on (and including) the Final Maturity Date (each such date, a "**Scheduled Amortisation Payment Date**", as specified in the Initial Determinations Notice, and each such date as may become subject to deferral or advancement as provided in Condition 7.1(c), an "**Amortisation Payment Date**"), each Bond outstanding (except for any Bond in respect of which Conversion Rights have been exercised) will be redeemed in instalments of $10,000 per Bond (each an "**Amortised Payment Amount**") together with interest accrued and unpaid to (but excluding) the relevant Amortisation Payment Date as provided in Condition 5.

(b) Deemed Principal ADS Settlement Option Exercise

In respect of the Amortisation Payment Amount due on each Amortisation Payment Date, the Issuer shall be deemed to have exercised its option (the "**Principal ADS Settlement Option**") to make payment of the relevant Amortised Payment Amount by the issue or transfer and delivery of Deliverable ADSs (and, if applicable, Additional Deliverable ADSs) to Bondholders with respect to all, and not some only, of the Bonds subject to and in accordance with the provisions of Condition 9.9, except if (i) the Issuer shall elect (in its sole discretion), by giving notice thereof (a "**Principal Cash Settlement Option Notice**") (which notice shall be irrevocable) to Bondholders in accordance with Condition 16 at least two Notice Business Days prior to such Amortisation Payment Date, to satisfy its obligation to make payment on such Amortisation Payment Date pursuant to this Condition 7.1 by paying the Amortised Payment Amount in cash, or (ii) an ADS Settlement Liquidity Event is occurring or occurs prior to the issue or transfer and delivery of the relevant Deliverable ADSs (in which case of (i) or (ii), the Amortised Payment Amount shall be paid by the Issuer in cash). Upon each redemption of an Amortised Payment Amount on an Amortisation Payment Date the principal amount of each Bond shall be reduced accordingly on such Amortisation Payment Date.

(c) Deferral and Advancement of Amortisation Payments

(i) The Majority Bondholders may, by giving notice thereof to the Issuer at least three Notice Business Days prior to a Scheduled Amortisation Payment Date, exercise the right of the Bondholders to defer the Amortised Payment Amount in respect of such Scheduled Amortisation Payment Date and each Bond outstanding at such time so that such payment shall not be payable on its

Scheduled Amortisation Payment Date and instead shall become payable on such subsequent Scheduled Amortisation Payment Date as is specified in such notice (an "**Amortised Payment Deferral**"). The Majority Bondholders may exercise their right to defer Amortised Payment Amounts under this Condition 7.1(c)(i) in respect of a maximum of two Scheduled Amortisation Payment Dates during the term of the Bonds.

(ii) Subject to paragraph (iii) below, the Majority Bondholders may, by giving not less than three Notice Business Days' notice to the Issuer, exercise their right to bring forward the payment of some or all future Amortised Payment Amounts such that the relevant Amortised Payment Amount(s) in relation to the following Scheduled Amortisation Payment Date(s) shall become payable on the date specified in such notice (an "**Accelerated Amortisation Payment Date**", which shall be not earlier than three Notice Business Days following the date of such notice) (an "**Amortised Payment Advancement**"). In relation to an Amortised Payment Advancement, except if (A) the Issuer shall elect (in its sole discretion in accordance with Condition 7.1(a)) to satisfy its obligation to make payment on such Amortisation Payment Date by paying the Amortised Payment Amount in cash (in accordance with Condition 7.1(a)) or (B) an ADS Settlement Liquidity Event is occurring or occurs prior to the issue or transfer and delivery of the relevant Deliverable ADSs (in which case, in the case of (A) or (B) the Amortised Payment Amount shall be paid by the Issuer in cash), then in respect of the Principal ADS Settlement Option the calculation of the relevant Deliverable ADSs which shall be issued or delivered to the Bondholders shall be determined as if such Accelerated Amortisation Payment Date was the immediately preceding Scheduled Amortisation Payment Date (and if there shall have occurred an event or circumstance requiring an adjustment to the Reference Conversion Price in accordance with Condition 6 after the Scheduled Amortisation Payment Date immediately preceding the relevant Accelerated Amortisation Payment Date, then such adjustment to the Relevant ADS Settlement Price as may be required shall be determined by the Calculation Agent (if the Calculation Agent determines that it is able to make such determination) or (in any other case) by an Independent Adviser in such other manner as it shall consider to be appropriate to give the intended result) and in accordance with Condition 9.9.

(iii) The Majority Bondholders' right to require Amortised Payment Advancements shall be subject to the following: (A) there shall be no Accelerated Amortisation Payment Date in the period from (and including) the Closing Date to (but excluding) the first anniversary of the Closing Date; (B) no more than two Accelerated Amortisation Payment Dates may occur in any 12-month period; and (C) no more than one Accelerated Amortisation Payment Date may occur in any 3-month period; provided that (B) and (C) shall not apply to any Amortised Payment Advancement in relation to an Amortised Payment Amount which was the subject of an Amortised Payment Deferral.

(d) No other redemption

Unless previously purchased and cancelled, redeemed or converted as herein provided, the Bonds will be redeemed at their then outstanding principal amount on the Final Maturity Date. Other than as provided in this Condition 7.1, the Bonds may only be redeemed at the option of the Issuer prior to the Final Maturity Date in accordance with Condition 7.3 and may only be redeemed by Bondholders prior to the Final Maturity Date in accordance with Condition 7.2.

7.2 Redemption at the Option of Bondholders

Following the occurrence of a Relevant Event, each Bondholder will have the right to require the Issuer to redeem all, but not some only, of its Bonds on the Relevant Event Put Date at their principal amount, together with accrued and unpaid interest up to (but excluding) the Relevant Event Put Date. To exercise such right, the holder of the relevant Bond must give notice thereof to the Issuer at any time during the Relevant Event Period.

The "**Relevant Event Put Date**" shall be the fourteenth London and New York business day after the expiry of the Relevant Event Period.

Payment in respect of any such Bond shall be made in accordance with Condition 8.

Any notice given by a Bondholder to exercise its put right pursuant to this Condition 7.2, once delivered, shall be irrevocable and the Issuer shall redeem all Bonds the subject of such notices delivered as aforesaid on the Relevant Event Put Date.

7.3 Purchase

Subject to the requirements (if any) of any stock exchange on which the Bonds may be admitted to listing and trading at the relevant time and subject to compliance with applicable laws and regulations, the Issuer or any Subsidiary of the Issuer may at any time purchase any Bonds in the open market or otherwise at any price. Bonds purchased by the Issuer or any of its Subsidiaries shall be cancelled and may not be reissued or re-sold.

7.4 Cancellation

All Bonds which are redeemed or in respect of which Conversion Rights are exercised will be cancelled and may not be reissued or resold.

8. Taxation

All payments made by or on behalf of the Issuer in respect of the Bonds will be made free and clear of and be made without deduction or withholding for or on account of any present or future taxes, duties, assessments or governmental charges of whatever nature imposed or levied by or on behalf of any jurisdiction, unless deduction or withholding of such taxes, duties, assessments or governmental charges is required to be made by law (a "**Tax Withholding**").

If any such Tax Withholding is required to be made in respect of taxation arising in the United Kingdom or any political subdivision or any authority thereof or therein having power to tax (or any other jurisdiction in which the Issuer may be domiciled or resident or to whose taxing jurisdiction it may be generally subject) ("**Tax Jurisdiction**"), the Issuer will pay such additional amounts as will result in the receipt by the Bondholders of the amounts which would

have been received by them had no such Tax Withholding been required, except that no such additional amounts shall be payable on any Bond:

(a) to a Bondholder (or to a third party on behalf of a Bondholder) which is subject to such taxes, duties, assessments or governmental charges in respect of such Bond by reason of having some connection with the Tax Jurisdiction otherwise than merely by holding the Bond or by the receipt of amounts in respect of the Bond; or

(b) where the Bondholder would have been able lawfully to avoid (but has not so avoided) such withholding or deduction by complying, or (if it is within the Bondholder's control to do so) procuring that any person who is associated or connected with the Bondholder for the purposes of any taxes, duties, assessments or governmental charges complies, with any statutory requirement or by making, or (if it is within the Bondholder's control to do so) procuring that any such person makes, a declaration of non-residence or any other claim for exemption to any tax authority.

References in these Conditions to principal and/or interest and/or any other amounts payable in respect of the Bonds shall be deemed also to refer to any additional amounts which may be payable under this Condition.

Where a Tax Withholding is imposed or levied by or on behalf of the United Kingdom or any political subdivision or any authority thereof or therein having power to tax, the exclusions in the second paragraph of this Condition 8 shall only apply if the Bonds have been (and remain) listed on any recognised stock exchange (within the meaning of Section 1005 of ITA 2007) or admitted to trading on a "multilateral trading facility" operated by a UK or EEA-regulated recognised stock exchange (within the meaning of Sections 987 and 1005 of the ITA 2007).

9. Payments

9.1 Principal

Payment of principal and interest in respect of the Bonds and delivery of any ADSs pursuant to these Conditions will be made to, or to the order of, and in accordance with the Payment Details provided by, the persons shown in the Register (as defined in the Bond Agreement) at the close of business on the Record Date.

9.2 Other amounts

Payments of all amounts other than as provided in Condition 9.1 will be made as provided in these Conditions.

9.3 Record Date

"**Record Date**" means the fifth London and New York business day before the due date for the relevant payment.

9.4 Payments

(a) Each payment in respect of Bonds pursuant to Conditions 9.1 and 9.2 will, with respect to each relevant Bondholder, be made by transfer to a US Dollar account in accordance with the relevant Payment Details.

(b) All payments in respect of the Bonds are subject in all cases to any applicable fiscal or other laws and regulations in the place of payment.

(c) The Issuer shall initiate, or shall procure the initiation of, payment instructions for value the due date, or, if the due date is not a New York business day, for value the next succeeding New York business day.

9.5 Delay in payment

Bondholders will not be entitled to any interest or other payment for any delay after the due date in receiving the cash amount due to be paid or, as the case may be, the ADSs due to be delivered:

(a) as a result of the due date not being a business day in New York or in the city in which the recipient account is based; or

(b) as a result of the relevant Bondholder failing to provide fulsome and correct Payment Details.

9.6 Calculation Agent

The Issuer reserves the right, subject to the prior approval of the Bondholders (not to be unreasonably withheld, and after being given not less than 10 Notice Business Days' notice), under the Calculation Agency Agreement at any time to vary or terminate the appointment of the Calculation Agent and appoint another Calculation Agent, provided that it will maintain a Calculation Agent which shall be a financial institution of international repute or an independent financial adviser with appropriate expertise. The Issuer shall promptly notify the Bondholders of any such proposal of a variation, termination or appointment.

9.7 No charges

Without prejudice to the provisions in the sixth paragraph of Condition 6.10 and Condition 9.9(e)(iii), neither the Issuer nor any person or agent acting on its behalf shall make or impose on a Bondholder any charge or commission in relation to any payment, transfer or conversion in respect of the Bonds including any issue or delivery of Ordinary Shares or ADSs pursuant to the exercise of any ADS Settlement Option by the Issuer.

9.8 Fractions

When making payments to Bondholders, if the relevant payment is not of an amount which is a whole multiple of the smallest unit of the relevant currency in which such payment is to be made, such payment will be rounded down to the nearest unit.

9.9 ADS Settlement Option

(a) Conditions to exercise

The Issuer may elect to satisfy its obligation to pay cash interest on the Bonds on any Interest Payment Date pursuant to Condition 5.1(a) or to redeem in cash a principal amount of the Bonds in an Amortised Payment Amount on any Amortisation

Payment Date pursuant to Condition 7.1(a) by the issue or transfer and delivery of

Deliverable ADSs (and, if applicable, Additional Deliverable ADSs) to Bondholders, by exercising its Interest ADS Settlement Option or its Principal ADS Settlement Option, as applicable, (each of the Interest ADS Settlement Option and the Principal ADS Settlement Option, an "**ADS Settlement Option**" in respect of the relevant Interest Payment Date or Amortisation Payment Date, as applicable) with respect to all, but not some only, of the Bonds on the relevant Interest Payment Date or Amortisation Payment Date, as applicable, provided that if an ADS Settlement Liquidity Event shall have occurred on any date falling in the period from (and including) the Interest Payment Date or Amortisation Payment Date (as applicable) immediately preceding the relevant ADSSO Reference Date (or, if none, from (and including) the Closing Date) to (and including) the date immediately preceding the date on which the Deliverable ADSs are issued and/or transferred and delivered to Bondholders, then any such exercise of the ADS Settlement Option shall be null and void and such interest or principal amount shall be payable in cash.

An "**ADS Settlement Liquidity Event**" shall have occurred on any date if one or more of the following conditions is met:

(i) the ADSs are not listed and admitted to trading on a Qualifying US Market as at such date, or are suspended from trading on such market (provided that trading of the ADSs shall not be considered to be suspended on any day on which a general suspension of trading on such market has occurred) on such date;

(ii) it would not be possible to issue and deliver to the Bondholders ADSs which are immediately freely tradeable under the Securities Act by holders who are not affiliates of the Issuer, and have not been affiliates of the Issuer within the preceding three months;

(iii) an Event of Default or Potential Event of Default shall have occurred and be continuing as at such date;

(iv) a Free Float Event shall have occurred and be continuing as at such date; or

(v) an Offer Period (as defined below) shall be continuing as at such date.

(b) ADS Settlement

Where the ADS Settlement Option has been exercised, the Issuer shall, in lieu of paying cash in respect of interest on the relevant Interest Payment Date or in respect of Amortised Payment Amount on the relevant Amortisation Payment Date, as applicable, effect such payment or partial redemption in respect of each Bond by issuing and/or transferring and delivering the Deliverable ADSs to the Bondholders not later than four London and New York business days following such ADSSO Reference Date, and, if applicable, issuing and/or transferring and delivering the Additional Deliverable ADSs not later than four London and New York business days following the relevant Reference Date (each, a "**ADS Settlement**").

Fractions of ADSs will not be issued or transferred or delivered pursuant to this Condition 9.9 and no cash payment will be made in lieu thereof. However, to the extent that the ADSs to be issued and/or transferred and delivered pursuant to this Condition 9.9 are to be registered in the same name, the number of ADSs to be issued and/or transferred and delivered in respect thereof shall be calculated on the basis of the

aggregate principal amount of such Bonds, as determined in good faith by the Calculation Agent.

Promptly following the determination of the Relevant ADS Settlement Price and the number of Deliverable ADSs, the Issuer shall give notice thereof to the Bondholders in accordance with Condition 16.

(c) Certain definitions

For the purposes of these Conditions:

"**Offer Period**" means (i) any period commencing on the date of first public announcement of an offer or tender (howsoever described) by any person or persons in respect of all or a majority of the issued and outstanding Ordinary Shares and ending on the date that offer or tender ceases to be open for acceptance or, if earlier, on which that offer or tender lapses or terminates or is withdrawn or (ii) any period commencing on the date of first public announcement of a Scheme of Arrangement relating to the acquisition of all or a majority of the issued and outstanding Ordinary Shares and ending on the date such Scheme of Arrangement is or becomes effective or, if earlier, the date such Scheme of Arrangement is cancelled or terminated or (iii) the period during which the Issuer is stated as being in an offer period on the Takeover Panel's Disclosure Table on the Takeover Panel's website.

"**Deliverable ADSs**" means, in respect of any Bond and any Interest Payment Date or Amortisation Payment Date, such number of ADSs (unrounded) determined in good faith by the Calculation Agent by dividing the relevant interest amount in respect of such Bond (which would otherwise be payable in cash) on such Interest Payment Date or the relevant Amortised Payment Amount in respect of such Bond (which would otherwise be payable in cash) on such Amortisation Payment Date, as applicable, by the Relevant ADS Settlement Price in respect of such Interest Payment Date or Amortisation Payment Date (as applicable).

"**Relevant ADS Settlement Price**" means, in respect of any ADSSO Reference Date, the product (rounded to the nearest whole multiple of $0.0001 (with $0.00005 being rounded upwards) of (i) 85 per cent. and (ii) the US Dollar price per ADS which is the lower of:

(i) the 5-Day ADSSO Average Market Price in respect of such ADSSO Reference Date;

(ii) the 10-Day ADSSO Average Market Price in respect of such ADSSO Reference Date;

(iii) the Volume Weighted Average Price of an ADS (translated if necessary into US Dollars at the Prevailing Rate) on such ADSSO Reference Date; and

(iv) the Conversion Price in effect on such ADSSO Reference Date, except that where such ADSSO Reference Date falls on or after the date an adjustment to the Conversion Price takes effect pursuant to Conditions 6.2(a), 6.2(b), 6.2(c), 6.2(d), 6.2(e) or 6.2(i) but on or prior to the record date or other due date for establishment of entitlement in respect of the relevant event giving rise to such adjustment, then provided the Issuer is able to confer the benefit of relevant consolidation, reclassification, redesignation or subdivision, Dividend, issue or grant (as the case may be) to the relevant Bondholder in respect of the

relevant ADSs to be issued and/or transferred and delivered to such Bondholder pursuant to this Condition 9.9, the Conversion Price for the purpose of this definition shall be such Conversion Price as would have been applicable on such ADSSO Reference Date had no such adjustment been made,

as determined by the Calculation Agent.

"**ADSSO Reference Date** " means, in respect of any ADS Settlement, the relevant Interest Payment Date or Amortisation Payment Date in respect of which the ADS Settlement Option is exercised; and in the case of ADS Settlement of any Amortisation Payment Amount which is subject to an Amortised Payment Deferral, shall be the relevant Amortisation Payment Date to which such payment has been deferred; and in the case of ADS Settlement of any Amortisation Payment Amount which is subject to an Amortised Payment Advancement (including any Amortisation Payment Amount which was previously subject to an Amortised Payment Deferral), shall be the Amortisation Payment Date immediately preceding the relevant Accelerated Amortisation Payment Date.

"**5-Day ADSSO Average Market Price**" and "**10-Day ADSSO Average Market Price**" each means, in respect of any ADSSO Reference Date, the arithmetic average of the Volume Weighted Average Price of an ADS (translated if necessary into US Dollars at the Prevailing Rate) on each Dealing Day in the Average Market Price Observation Period in respect of such 5-Day ADSSO Average Market Price or 10-Day ADSSO Average Market Price, as the case may be, provided that:

(i) if any such Dealing Day falls on or after (A) the Applicable Adjustment Reference Date in respect of any adjustment required to be made to the Conversion Price pursuant to these Conditions (other than an adjustment pursuant to Condition 6.4 or Condition 6.5) and such adjustment is an ADS Settlement Retroactive Adjustment or (B) the Ex-Date in respect of any Dividend (or other entitlement) which the ADSs to be issued and/or transferred and delivered pursuant to this Condition 9.9 are entitled to, then the Volume Weighted Average Price of an ADS on such Dealing Day shall (in the case of (A)) be divided by the adjustment factor (as determined pursuant to these Conditions) applied to the Conversion Price in respect of such adjustment or (in the case of (B)) increased by amount equal to the Fair Market Value of such Dividend (or other entitlement) as at such Ex-Date as aforesaid;

(ii) if any such Dealing Day falls before the Applicable Adjustment Reference Date in respect of any adjustment required to be made to the Conversion Price pursuant to these Conditions (other than an adjustment pursuant to Condition 6.4 or Condition 6.5) and such adjustment is in effect on such ADSSO Reference Date, then the Volume Weighted Average Price on such Dealing Day shall be multiplied by the adjustment factor (as determined pursuant to these Conditions) applied to the Conversion Price in respect of such adjustment; and

(iii) if any doubt shall arise as to the calculation of the 5-Day ADSSO Average Market Price or 10-Day ADSSO Average Market Price, as the case may be, or if the 5-Day ADSSO Average Market Price or 10-Day ADSSO Average Market Price, as the case may be, cannot be determined as provided above, the 5-Day ADSSO Average Market Price or 10-Day ADSSO Average Market Price, as the case may be, shall be equal to such price as is determined in such

other manner as an Independent Adviser shall consider to be appropriate to give the intended result.

(d) ADS Settlement Option Annulment

If either (a) the Issuer does not exercise its ADS Settlement Option (including electing to make the relevant payments in cash in accordance with Condition 5.1(b) or Condition 7.1(b)) or (b) the Issuer does exercise its ADS Settlement Option but an ADS Settlement Liquidity Event occurs thereafter but on or prior to the issue or transfer and delivery of the Deliverable ADSs (such circumstances being referred to as an "**ADS Settlement Option Annulment**"), the relevant interest amount or Amortised Payment Amount shall be paid in cash in accordance with the relevant provisions of Condition 5.1(a) or Condition 7.1(a), as applicable, and payment in respect thereof shall be made in accordance with this Condition 9.

(e) Provisions relating to the ADS Settlement Option

If the Issuer elects to exercise the ADS Settlement Option in respect of any ADSSO Reference Date, the following provisions shall apply:

(i) Ordinary Shares represented by ADSs issued and/or transferred and delivered to the Bondholders pursuant to this Condition 9.9 will be fully paid and in all respects will rank pari passu with all other Ordinary Shares in issue on the relevant ADSSO Reference Date (or, in the case of Ordinary Shares represented by Additional Deliverable ADSs, the relevant Reference Date) (except for any right excluded by mandatory provisions of applicable law) and such Ordinary Shares will be entitled to all rights to the same extent as all other fully-paid Ordinary Shares of the Issuer. ADSs (including any Additional Deliverable ADSs) issued and/or transferred and delivered pursuant to this Condition 9.9 will be fully paid and will in all respects rank *pari passu* with the other ADSs in issue on the such ADSSO Reference Date (or, in the case of Additional Deliverable ADSs, on the relevant Reference Date) (except in any such case for any right excluded by mandatory provisions of applicable law) and without prejudice to the provisions of the Deposit Agreement, the relevant Bondholder shall be treated as the holder thereof with effect from, and be entitled to all rights, distribution, payments and entitlements relating to such ADSs in respect of which the record date or other due date for the establishment of entitlement in respect of the Ordinary Shares represented by such ADSs on or after the ADSSO Reference Date, or as the case may be, the relevant Reference Date. Such Deliverable ADSs or, as the case may be, Additional Deliverable ADSs will not rank for (or, as the case may be, the relevant holder shall not be entitled to receive) any rights, distributions or payments relating to such ADSs in respect of which the record date or other due date for the establishment of entitlement in respect of the Ordinary Shares represented by the ADSs for which falls prior to such ADSSO Reference Date or, as the case may be, the relevant Reference Date.

(ii) Deliverable ADSs (including any Additional Deliverable ADSs) issued or transferred and delivered in connection with an ADS Settlement Option will be immediately freely tradeable under the Securities Act by holders who are not affiliates of the Issuer, and have not been, affiliates of the Issuer within the preceding three months.

(iii) A Bondholder must pay any capital, stamp, issue and registration and transfer taxes or duties arising on the issue or transfer and delivery of the relevant Deliverable ADSs or Additional Deliverable ADSs, excluding any Specified Taxes (which shall be payable by the Issuer). Such Bondholder must pay, or procure payment of, all, if any, taxes arising by reference to any disposal or deemed disposal of a Bond or interest therein by it in connection with the exercise of such ADS Settlement. If the Bondholder fails to pay any such taxes (other than any Specified Taxes, which shall be payable by the Issuer) referred to in the foregoing provisions of this Condition 9.9(e)(iii), the Issuer shall be entitled to tender and pay the same and the Bondholder, as a separate and independent stipulation, covenants to reimburse and indemnify the Issuer in respect of any payment thereof and any interest and penalties payable and any documented costs incurred in respect thereof.

(iv) Delivery of Deliverable ADSs (including Additional Deliverable ADSs) will be made in uncertificated form through DTC to its direct and indirect participants to the account specified by the relevant Bondholder in the Payment Details, unless at the relevant time the Deliverable ADSs (including Additional Deliverable ADSs) are not a participating security in DTC, in which case the Deliverable ADSs will be issued or delivered in certificated form.

(v) Where Deliverable ADSs are to be issued or transferred and delivered in certificated form, a certificate in respect thereof will be dispatched by mail free of charge to the relevant Bondholder in accordance with its Payment Details or as it may otherwise direct.

10. Events of Default

If any of the following events (each an "**Event of Default**") occurs and is continuing, the holders of at least one-quarter in principal amount of the Bonds then outstanding may give notice in writing to the Issuer that the Bonds are, and upon such notice the Bonds shall accordingly immediately become, without further action or formality, due and repayable at the Relevant Amount together with accrued interest (if any) to (but excluding) the date of payment:

(a) default for 14 days in the payment when due of any interest or any other amounts (other than principal or any Cash Alternative Amount) with respect to the Bonds;

(b) default for seven days in the payment when due of the principal of the Bonds or any Cash Alternative Amount (on an Amortisation Payment Date, at final maturity, upon redemption or otherwise);

(c) the Issuer fails to deliver ADSs following any exercise of Conversion Rights or ADS Settlement Option and such failure continues for seven days;

(d) the Issuer does not perform or comply with any one or more of its other obligations in the Bonds or the Bond Documents or if any event occurs or any action is taken or failed to be taken which is (or but for the provisions of any applicable law would be) a breach of any such obligation, and which default or breach is incapable of remedy or is not remedied within 30 days after notice of such default or breach shall have been received by the Issuer from any Bondholder requiring the same to be remedied and in such case such breach would reasonably likely to be materially prejudicial to the interests of the Bondholders;

(e) it becomes unlawful for the Issuer to perform or comply with any one or more of its obligations under any of the Bonds or the Bond Documents and in such case such breach would be reasonably likely to be materially prejudicial to the interests of the Bondholders;

(f) (i) any other present or future Financial Indebtedness of the Issuer or any of its Material Subsidiaries becomes due and payable prior to its stated maturity by reason of any event of default or the like (howsoever described), or

(ii) any such Financial Indebtedness is not paid when due or, as the case may be, within any originally applicable grace period, or

(iii) the Issuer or any of its Material Subsidiaries fails to pay when due any amount payable by it under any present or future Financial Indebtedness Guarantee,

provided that the aggregate amount of the relevant Financial Indebtedness and/or Financial Indebtedness Guarantee in respect of which one or more of the events mentioned above in this Condition 10(f) have occurred equals or exceeds 3 per cent. of the total gross consolidated assets of the Group (calculated by reference to the most recent audited consolidated financial statements of the Issuer);

(g) a distress, attachment, execution or other legal process is levied, enforced or sued out on or against the property, assets or revenues of the Issuer or any of its Material

Subsidiaries with a value, individually or in the aggregate, in excess of $5 million, or its equivalent and is not discharged within 30 days;

(h) any mortgage, charge, pledge, lien or other encumbrance, present or future, created or assumed by the Issuer or any of its Material Subsidiaries, over assets with a value, individually or in the aggregate, in excess of $5 million, or its equivalent, becomes enforceable and any step is taken to enforce it (including the taking of possession or the appointment of a receiver, administrative receiver, administrator, manager or other similar person) and is not discharged within 30 days;

(i) the Issuer or any of its Material Subsidiaries is (or is determined by law or a court to be) insolvent or bankrupt or unable to pay its debts, stops, suspends or threatens to stop or suspend payment of all or a material part of (or a material part of a particular type of) its debts, proposes or makes a general assignment or an arrangement or composition with or for the benefit of the relevant creditors in respect of any of such debts or a moratorium is agreed or declared or comes into effect in respect of or affecting all or any part of (or of a particular type of) the debts of the Issuer or any of its Material Subsidiaries, except for the purpose of and followed by a reconstruction, amalgamation, reorganisation, merger or consolidation (i) on terms approved by the Majority Bondholders, or (ii) in the case of a Material Subsidiary, whereby the undertaking and assets of the Material Subsidiary are transferred to or otherwise vested in the Issuer or another of its Subsidiaries; or

(j) an administrator is appointed, an order is made or an effective resolution passed for the winding-up or dissolution or administration of the Issuer or any of its Material Subsidiaries (and such order is not discharged within 30 days), or the Issuer ceases or threatens to cease to carry on all or a substantial part of its business or operations, except (i) for the purpose of and followed by a reconstruction, amalgamation, reorganisation, merger or consolidation (A) on terms approved by the Majority Bondholders, or (B) in the case of a Material Subsidiary, whereby the undertaking and assets of the Material Subsidiary are transferred to or otherwise vested in the Issuer or another of its Subsidiaries or (ii) in relation to any solvent winding-up or dissolution as part of a NewCo Scheme permitted by the Conditions (and in accordance with Condition 11(g) and Condition 15).

For the purposes of this Condition 10, "**Relevant Amount**" means, in respect of the principal amount of each Bond which is outstanding (as may be adjusted from time to time in accordance with Condition 7.1), an amount equal to such principal amount, save that if the relevant Event of Default occurs as a result of or in connection with a failure by the Issuer to comply with any of its obligations in relation to the exercise of Conversion Rights or ADS Settlement Option (except in *de minimis* respects), it means an amount in cash equal to the higher of:

(a) the Fair Market Value (determined as at the relevant Conversion Date, Interest Payment Date or Amortisation Payment Date referred to below, as applicable) of the ADSs per Bond and any other amounts which would have been payable and/or deliverable on conversion or in respect of such ADS Settlement, in respect of such Bond had the date of such declaration of the relevant Event of Default been the Conversion Date relating to such exercise of Conversion Rights or the relevant Interest Payment Date or Amortisation Payment Date in respect of which such ADS Settlement Option was exercised (as applicable); and

(b) such principal amount.

Following an Event of Default and the Bondholders having given notice to the Issuer that the Bonds are due and pay`able, references in these Conditions and the Bond Agreement to the principal amount of the Bonds shall, unless the context otherwise requires, include the Relevant Amount.

11. Undertakings

The Issuer will, save with the approval of the holders of at least 90 per cent. in principal amount of the Bonds outstanding:

(a) not issue or pay up any Securities, in either case by way of capitalisation of profits or reserves, other than:

(i) pursuant to a Scheme of Arrangement involving a reduction and cancellation of Ordinary Shares and the issue to Shareholders of an equal number of Ordinary Shares by way of capitalisation of profits or reserves; or

(ii) pursuant to or in connection with a Newco Scheme; or

(iii) by the issue of fully paid Ordinary Shares or other Securities to Shareholders and other holders of shares in the capital of the Issuer which by their terms entitle the holders thereof to receive Ordinary Shares or other Securities on a capitalisation of profits or reserves; or

(iv) by the issue of fully paid Ordinary Shares, issued wholly, ignoring fractional entitlements, in lieu of the whole or part of a Dividend in cash; or

(v) by the issue of Ordinary Shares or any equity share capital to, or for the benefit of, employees or former employees, director or executive holding or formerly holding executive office (including directors holding or formerly holding executive office or non-executive office, consultants or former consultants or the personal service company of any such person) or their spouses or relatives, in each case of the Issuer or any of its Subsidiaries or any associated company or to a trustee or nominee to be held for the benefit of any such person, in any such case pursuant to an employee, contractor, director or executive share or option or incentive scheme whether for all employees, contractors, directors or executives or any one or more of them

((i) to (v) above each being a "**Permitted Issue**"), unless, in any such case, the same constitutes a Dividend or otherwise falls to be taken into account for a determination as to whether an adjustment is to be made to the Conversion Price pursuant to
Condition 6.2, regardless of whether in fact an adjustment falls to be made in respect

of the relevant event (or would, but for the provisions of Condition 6.8 relating to roundings and minimum adjustments or the carry forward of adjustments, give rise to an adjustment to the Conversion Price);

(b) not modify the rights attaching to the Ordinary Shares with respect to voting, dividends or liquidation nor issue any other class of equity share capital carrying any rights which are more favourable than the rights attaching to the Ordinary Shares but so that nothing in this Condition 11(b) shall prevent:

(i) any consolidation, reclassification, redesignation or subdivision of the Ordinary Shares; or

(ii) any modification of such rights which is not, in the opinion of an Independent Adviser acting in good faith, materially prejudicial to the interests of the holders of the Bonds; or

(iii) any issue of equity share capital where the issue of such equity share capital results, or would, but for the provisions of Condition 6.8 relating to roundings and minimum adjustments or the carry forward of adjustments or Condition 6.2(l) or, where comprising Ordinary Shares, the fact that the consideration per Ordinary Share receivable therefor is at least 95 per cent. of the Current Market Price per Ordinary Share at the relevant time for determination thereof pursuant to the relevant provisions of Condition 6.2, otherwise result, in an adjustment to the Conversion Price; or

(iv) without prejudice to any rule of law or legislation (including regulations made under Sections 783, 784(3), 785 and 788 of the Companies Act or any other provision of that or any other legislation), the conversion of Ordinary Shares into, or the issue of any Ordinary Shares in, uncertificated form (or the conversion of Ordinary Shares in uncertificated form to certificated form) or the amendment of the Articles of Association of the Issuer to enable title to securities (including Ordinary Shares) to be evidenced and transferred without a written instrument or any other alteration to the Articles of Association of the Issuer made in connection with the matters described in this Condition 11(b) or which is supplemental or incidental to any of the foregoing (including any amendment made to enable or facilitate procedures relating to such matters and any amendment dealing with the rights and obligations of holders of Securities, including Ordinary Shares, dealt with under such procedures); or

(v) any issue of equity share capital or modification of rights attaching to the Ordinary Shares, where prior thereto the Issuer shall have instructed an Independent Adviser to determine what (if any) adjustments should be made to the Conversion Price as being fair and reasonable to take account thereof and such Independent Adviser shall have determined in good faith either that no adjustment is required or that an adjustment resulting in a decrease in the Conversion Price is required and, if so, the new Conversion Price as a result thereof and the basis upon which such adjustment is to be made and, in any such case, the date on which the adjustment shall take effect (and so that the adjustment shall be made and shall take effect accordingly); or

(vi) any amendment of the Articles of Association of the Issuer following or in connection with a Change of Control to ensure that any Bondholder exercising Conversion Rights where the Conversion Date falls on or after the occurrence of a Change of Control will receive, in whatever manner, the same consideration for the Ordinary Shares arising on such exercise as it would have received in respect of any Ordinary Shares had such Ordinary Shares been entitled to participate in the relevant Scheme of Arrangement or to have been submitted into, and accepted pursuant to, the relevant offer or tender (a "**Change of Control Conversion Right Amendment**"); or

(vii) a Permitted Issue;

(c) except as part of or in connection with or pursuant to any employee, contractor, director or executive share or option or incentive scheme (whether for all employees, contractors, directors or executives or any one or more of them), procure that no Securities which were originally issued (whether issued by the Issuer or any Subsidiary of the Issuer or procured by the Issuer or any Subsidiary of the Issuer to be issued or issued by any other person pursuant to any arrangement with the Issuer or any Subsidiary of the Issuer) without rights to convert into, or exchange or subscribe for, Ordinary Shares (or ADSs or other depositary or other receipts or certificates representing Ordinary Shares) shall subsequently be granted such rights exercisable at a consideration per Ordinary Share which is less than 95 per cent. of the Current Market Price per Ordinary Share at the relevant time for determination thereof pursuant to the relevant provisions of Condition 6.2 unless the same gives rise (or would, but for the provisions of Condition 6.8 relating to roundings and minimum adjustments or the carry forward of adjustments or Condition 6.2(l), give rise) to an adjustment to the Conversion Price and that at no time shall there be in issue Ordinary Shares of differing nominal values, save where such Ordinary Shares have the same economic rights;

(d) not make any issue, grant or distribution or take or omit to take any other action if the effect thereof would be that, on the exercise of Conversion Rights, Ordinary Shares to be issued and represented by ADSs could not, under any applicable law then in effect, be legally issued as fully paid;

(e) not reduce its issued share capital, share premium account, or any uncalled liabili ty in respect thereof, or any non-distributable reserves, except:

(i) pursuant to the terms of issue of the relevant share capital; or

(ii) by means of a purchase or redemption of share capital of the Issuer to the extent permitted by applicable law; or

(iii) where the reduction does not involve any distribution of assets to Shareholders; or

(iv) solely in relation to a change in the currency in which the nominal value of the Ordinary Shares is expressed; or

(v) to create distributable reserves; or

(vi) pursuant to a Scheme of Arrangement involving a reduction and cancellation of Ordinary Shares and the issue to Shareholders of an equal number of Ordinary Shares by way of capitalisation of profits or reserves; or

(vii) as provided in Condition 11(a)(i); or

(viii) pursuant to a Newco Scheme; or

(ix) by way of transfer to reserves as permitted under applicable law; or

(x) where the reduction is permitted by applicable law and the Bondholders are advised by an Independent Adviser, acting as an expert and in good faith, that in its opinion the interests of the Bondholders will not be materially prejudiced by such reduction; or

(xi) where the reduction is permitted by applicable law and results (or, in the case of a reduction in connection with a Change of Control, will result) in (or would, but for the provisions of Condition 6.8 relating to roundings or the carry forward of adjustments, result in) an adjustment to the Conversion Price or is (or, in the case of a reduction in connection with a Change of Control, will be) otherwise taken into account for the purposes of determining whether such an adjustment should be made; or

(xii) as permitted by Section 610 (2) and (3) of the Companies Act; or

(xiii) a reduction of its share premium account to facilitate the writing off of goodwill arising on consolidation which requires the confirmation of the High Court and which does not involve the return, either directly or indirectly, of an amount standing to the credit of the share premium account of the Issuer and in respect of which the Issuer shall have tendered to the High Court such undertaking as it may require prohibiting, so long as any of the Bonds remains outstanding, the distribution (except by way of capitalisation issue) of any reserve which may arise in the books of the Issuer as a result of such reduction;

provided that, without prejudice to the other provisions of these Conditions, the Issuer may exercise such rights as it may from time to time be entitled pursuant to applicable law to purchase, redeem or buy back its Ordinary Shares and any depositary or other receipts or certificates representing Ordinary Shares without the consent of Bondholders;

(f) in the event of a Newco Scheme, take (or shall procure that there is taken) all necessary action to ensure that (to the satisfaction of the Bondholders) immediately after completion of the Scheme of Arrangement:

(i) at the Issuer's option, either (a) Newco is substituted under the Bonds and the Bond Documents as principal obligor in place of the Issuer (with the Issuer providing a guarantee) subject to and as provided in Condition 15; or (b) Newco becomes a guarantor under the Bonds and the Bond Documents, in each case on terms satisfactory to the Bondholders;

(ii) such amendments are made to these Conditions and the Bond Documents as are necessary, in the opinion of the Bondholders, to ensure that the Bonds may be converted into or exchanged for cash and/or ordinary shares or units or the equivalent in Newco (or depositary or other receipts or certificates representing ordinary shares or units or the equivalent in Newco) *mutatis mutandis* in accordance with and subject to these Conditions with a Conversion Price (subject to adjustment as provided in these Conditions) economically equivalent to the Conversion Price immediately prior to the implementation of such amendments, as determined in good faith by an Independent Adviser;

(iii) the ordinary shares or units or equivalent of Newco (or depositary or other receipts or certificates representing ordinary shares or units or equivalents of Newco) are admitted to trading on a regulated, regularly operating, recognised stock exchange or securities market as determined by Newco; and

(iv) the Bond Documents and the Conditions provide at least the same or equivalent powers, protections, rights and benefits to the Bondholders following the implementation of such Newco Scheme as they provided to the Bondholders prior to the implementation of the Newco Scheme, *mutatis mutandis*,

and the Bondholders shall (at the expense of the Issuer, including payment by the Issuer of the reasonably incurred fees of Bondholders' legal counsel, and subject to the satisfaction of the conditions set out in (i) to (iv) above and provided that the interests of Bondholders are not materially adversely prejudiced thereby) be obliged to concur in effecting such substitution or grant of such guarantee and in either case making any such amendments, provided that the Bondholders shall not be obliged so to concur if, in the opinion of the Bondholders, doing so would impose more onerous obligations upon any of them or expose any of them to any additional duties, responsibilities or liabilities in any way.

(g) use all reasonable endeavours to ensure that the ADSs issued and/or transferred and delivered upon exercise of Conversion Rights or in relation to an ADS Settlement will, as soon as is practicable, be listed and admitted to trading on the Relevant Stock Exchange and will be listed, quoted or dealt in, as soon as is practicable, on any other stock exchange or securities market on which the ADSs may then be listed or quoted or dealt in (but so that this undertaking shall be considered as not being breached as a result of a Change of Control (whether or not recommended or approved by the board of directors of the Issuer) that causes or gives rise to, whether following the operation of any applicable compulsory acquisition provision or otherwise, (including at the request of the person or persons controlling the Issuer as a result of the Change of Control) a de-listing of the ADSs);

(h) use all reasonable endeavours to maintain the ADS facility in accordance with the Deposit Agreement such that ADSs can be delivered as and when required to satisfy Conversion Rights;

(i) use all reasonable endeavours to ensure that any limit imposed upon the ADS facility would not be exceeded, which includes increasing the number of ADSs registered, should ADSs deliverable upon conversion of all outstanding Bonds be delivered;

(j) use all reasonable endeavours to ensure that there are no restrictions on conversion of Ordinary Shares into ADSs (save as provided in the Deposit Agreement) which would preclude the new ADSs issued upon conversion of all outstanding Bonds or delivered in connection with an ADS Settlement Option from being fungible with existing ADSs, including being immediately freely tradeable under the Securities Act by holders who are not affiliates of the Issuer, and have not been, affiliates of the Issuer within the preceding three months;

(k) request its legal advisers to provide to the Depositary such legal opinions as to US law (and other laws) as required by the Depositary in connection with the issuance, transfer, conversion or cancellation of ADSs or as provided for under the terms of the Deposit Agreement;

(l) use all reasonable endeavours to procure that it shall not become domiciled or resident for relevant tax purposes in any jurisdiction other than the United Kingdom or within the United Kingdom unless:

(i) it would not thereafter be required pursuant to then current laws and regulations to make any greater withholding or deduction for or on account of any taxes, duties, assessments or governmental charges of whatever nature imposed or levied by or on behalf of such jurisdiction or any applicable sub-division thereof or therein having power to tax; and

(ii) holders of the Bonds (whether upon transfer of Bonds or otherwise) would not thereafter be required to pay any additional stamp, issue, transfer, documentary or other similar taxes and duties,

in each case in respect of any payment on or in respect of the Bonds or the Bond Documents, or the transfer of any Bonds, (as applicable) than would be the case were the Issuer to remain domiciled and resident solely within the United Kingdom;

(m) at all times keep available for issue, free from pre-emptive or other preferential rights out of its authorised but unissued capital sufficient allotment authority in respect of Ordinary Shares to enable the exercise of Conversion Rights in respect of all the

Bonds (including any Further Bonds) then outstanding and all other rights of subscription and exchange for Ordinary Shares, to be satisfied in full, provided that notwithstanding anything to the contrary herein the Issuer shall neither issue more than the number of Ordinary Shares (including Ordinary Shares represented by ADSs) permitted by the applicable Shareholders authorisation in effect from time to time, unless further Shareholders authorisation has been obtained;

(n) by not later than the first Interest Payment Date, make an application for admission to listing and trading of the Bonds on a "recognised stock exchange" (within the meaning of Section 1005 of the Income Tax Act 2007 (the "**ITA 2007**") or their admission to trading on a "multilateral trading facility" operated by a UK or EEA-regulated recognised stock exchange (within the meaning of Sections 987 and 1005 of ITA 2007) and thereafter use all reasonable endeavours to maintain such listing or admission to trading provided that if the Issuer determines in good faith that it can no longer comply with its requirements for such listing or admission to trading, having used reasonable endeavours, or if the maintenance of such listing or admission to trading is unduly onerous or if, owing to a change of law after the Closing Date, such listing or admission to trading no longer provides an exemption from the obligation to deduct or withhold United Kingdom withholding tax on interest from payments made under or in respect of the Bonds, the Issuer will no longer be required to maintain that listing or admission to trading but will immediately obtain and maintain a listing on such other "recognised stock exchange" (within the meaning of Section 1005 of ITA 2007) or an admission to trading of the Bonds on such "multilateral trading facility" operated by a UK or EEA-regulated recognised stock exchange (within the meaning of Sections 987 and 1005 of ITA 2007) as the Issuer may in good faith determine;

(o) with respect to any calculation, determination or adjustment performed by the Calculation Agent or an Independent Adviser at the instruction of the Issuer, promptly notify the Bondholders of the relevant results thereof (and, upon request from any Bondholder, shall promptly provide such Bondholder with relevant details of such calculation or determination as such Bondholder may reasonably require) and, at any time upon request from any Bondholder, confirm to the Bondholders (and with notice to the Calculation Agent) the Conversion Price and the Floor Price then in effect and details of any relevant prior calculations, determinations or adjustments as such Bondholder may reasonably require;

(p) promptly upon:

(i) the Issuer becoming aware that a Free Float Event may have occurred (or would be likely to have occurred, if an Independent Adviser had been requested to make such determination), acting reasonably, based on publicly available information (including but not limited to reports filed with the SEC pursuant to Section 13(d) of the Exchange Act) and without any requirement to make any further enquires; or

(ii) a request being made by the Majority Bondholders (acting reasonably, and such request not being made more than once in any six-month period),

the Issuer shall instruct an Independent Adviser to make a determination as to the number of Ordinary Shares comprising the Free Float;

(q) so far as permitted by applicable law and any applicable contractual obligations of confidentiality, at any time upon request from a Bondholder, as soon as practicable furnish to each Bondholder such information or materials as may be relevant to the operation of any of the provisions in the Bond Documents, including but not limited to any potential Change of Control, Free Float Event, De-Listing Event or ADS Settlement Liquidity Event, whether at any time a Subsidiary constitutes a Material Subsidiary and the relevant supporting calculations, evidence of the Issuer's due and punctual performance of its obligations under the Bonds and the Bond Documents, provided that the Issuer shall not (without first entering into a separate confidentiality agreement with the relevant Bondholders) furnish any such information to the relevant Bondholders in connection with the Bonds, the ADSs, the Ordinary Shares, the Issuer or the Group that is of a price sensitive nature or inside information.

12. Prescription

Claims against the Issuer for payment in respect of the Bonds shall be prescribed and become void unless made within 10 years (in the case of principal or any other amount (other than interest)) or five years (in the case of interest) from the appropriate Relevant Date in respect of such payment.

Claims in respect of any other obligation in respect of the Bonds, including delivery of Ordinary Shares, shall be prescribed and become void unless made within 10 years following the due date for performance of the relevant obligations.

13. Replacement of Bond Certificates

If any Bond Certificate is lost, stolen, mutilated, defaced or destroyed, it may be replaced by the Issuer subject to and in accordance with Clause 5.6 (*Replacement of Bond Certificates*) of the Bond Agreement.

14. Amendment and Waiver

14.1 Amendment

Subject to Condition 14.2 and Condition 14.4, the Bonds and the Bond Documents may be amended, or waivers or consents given in respect thereof, with the agreement of the Issuer and the Majority Bondholders and (without prejudice to the terms of the Calculation Agency Agreement) any such amendment, waiver or consent will be binding on all Bondholders and shall be notified by the Issuer to Bondholders as soon as practicable.

14.2 Reserved Matters

The Issuer shall not agree to make any amendment, and no waiver or consent shall be effective, in respect of any Bondholder Reserved Matter, without the consent of the holders of at least 90 per cent. in principal amount of the Bonds outstanding.

14.3 Voting Evidence

In relation to any consent to be provided by Bondholders in accordance with the Bonds or the relevant Bond Documents, the Issuer shall provide or procure the provision of evidence satisfactory to each Bondholder (in each case acting reasonably) that specifies:

(a) the principal amount outstanding held by Bondholders that delivered an instruction to consent, abstain or dissent to any proposal; and

(b) the principal amount outstanding of Bonds held by or on behalf of the Issuer or any member of the Group or any of their respective affiliates (as referred to in the definition of "outstanding" in Condition 3).

14.4 Exclusions

The consent of the Bondholders shall not be required in the event the Issuer effects any amendment to the Bonds or the Bond Documents pursuant to a NewCo Scheme Modification or otherwise effects a substitution in accordance with Condition 15 (so long as the interests of Bondholders are not materially adversely prejudiced thereby, and the terms and conditions set out in these Conditions are complied with), provided that the Issuer provides not less than 20 Notice Business Days' written notice of such amendments to the Bondholders.

15. Substitution

The Issuer may at any time, without the consent of the Bondholders, effect any substitution as provided in, and for the purposes of, Condition 11(g) in connection with a Newco Scheme and Condition 6.16 in connection with a Successor in Business (and any such substitute issuer being, the "**Substitute Issuer**"), provided that:

(a) the Issuer provides not less than 60 calendar days' written notice to each Bondholder of such substitution, including the proposed effective date of such substitution, the identity of the Substitute Issuer and the latest audited financial statements of the Substitute Issuer, and such other information as the Bondholders may reasonably request upon receipt of such written notice;

(b) the Bonds continue to be convertible, *mutatis mutandis* as provided in the Conditions, into ordinary shares in the capital of the Substitute Issuer with like rights, *mutatis mutandis*, to the ADSs (and the Ordinary Shares represented by the ADSs);

(c) a deed is executed by the Substitute Issuer in a form and manner satisfactory to the Bondholders (acting reasonably), agreeing to be bound by the Bonds and each of the Bond Documents as if the Substitute Issuer has been named in such Bond Documents and the Bonds as the principal debtor in place of the Issuer, and therefrom releasing the Issuer from any or all of its obligations under the Bond Documents and the Bonds;

(d) legal opinions from reputable counsel acceptable to the Bondholders are addressed and delivered to (at the expense of the Substitute Issuer) the Bondholders on the entry into the amendment deed and all other relevant documentation and performance of the Substitute Issuer's obligations under the Bonds and the enforceability thereof, in a form satisfactory to the Bondholders (acting reasonably);

(e) arrangements are made to the satisfaction of the Bondholders (acting reasonably) to have or be able to have the same or equivalent rights against the Substitute Issuer as they have against the Issuer (or any such previous substitute under this paragraph);

(f) that, from the date of the substitution:

(i) no greater withholding or deduction for or on account of any taxes, duties, assessments or governmental charges of whatever nature is imposed or levied by or on behalf of the taxing jurisdiction of the Substitute Issuer or any applicable sub-division thereof or therein having power to tax is applicable in respect of any payment on or in respect of the Bonds or the Bond Documents; and

(ii) holders of the Bonds (whether upon transfer of Bonds or otherwise) would not thereafter be required to pay any additional stamp, issue, transfer, documentary or other similar taxes and duties in the tax jurisdiction of the Substitute Issuer,

or that an indemnity in respect of any such additional amounts is provided by the Substitute Issuer to the satisfaction of the Bondholders (acting reasonably); and

(g) any two directors of the Substitute Issuer certify that it will be solvent immediately after such substitution.

Upon the satisfaction of such conditions, the Substitute Issuer will be deemed to be named in the Bond Documents (but without prejudice to the terms of the Calculation Agency Agreement) and the Bonds as the principal debtor in place of the Issuer (or of any previous substitute) and each Bond Document and the Bonds will be deemed to be modified in such manner as shall be necessary to give effect to the substitution.

With effect from (and including) the date of such substitution, all payments of principal and interest payable in respect of the Bonds by the Substitute Issuer shall be made free and clear of, and without withholding or deduction for, any taxes, duties, assessments or governmental charges (including any penalties, interest and additions to tax related thereto) of whatsoever nature imposed, levied, collected, withheld or assessed by or on behalf of its taxing jurisdiction, unless such withholding or deduction is required by law. If, following the date of the substitution of the Substitute Issuer, there is any increase from the amounts or rates initially determined in Condition 15(f)(i) in respect of such withholding or deduction for or on account of any taxes, duties, assessments or governmental charges of whatever nature payable in respect of any payment on or in respect of the Bonds or the Bond Documents, the Substitute Issuer shall pay such additional amounts as will result in the receipt by the Bondholders of such amounts as would have been received by them if such withholding or deduction had not been increased (including any deduction or withholding attributable to the additional amounts).

16. Notices

All notices required to be given to Bondholders pursuant to the Conditions will (unless otherwise provided in these Conditions) be given in accordance with, Clause 13 (*Notices*) of the Bond Agreement, or such other contact details as any Bondholder may subsequently

provide in writing to the Issuer from time to time or pursuant to a duly completed and executed Transfer and Accession Deed.

The Issuer shall send a copy of all notices given by it to Bondholders (or a Bondholder) pursuant to these Conditions promptly to the Calculation Agent.

As soon as reasonably practicable following the Closing Date, the Issuer shall by notice to the Bondholders in accordance with this Condition 16 (the "**Initial Determinations Notice**"), confirm the following details in relation to these Conditions: (a) the Reset Price Floor for each Reset Date (determined, solely for the purpose of such notice, on the basis of such initial Floor Price and Reference Conversion Price); (b) the Closing Date; (c) the Interest Payment Dates; (d) the Amortisation Payment Dates; (e) the Reset Dates; (f) the Final Maturity Date; and (g) each period of 14 calendar days prior to an Interest Payment Date and Amortisation Payment Date that constitutes a "**Non-Trading Period**" and each period of 6 weeks prior to each Reset Date that may constitute a "**Non-Trading Period**", in each case as referred to and subject as provided in Clause 12.1 of the Bond Agreement.

17. Further Issues

The Issuer may not create and issue Further Bonds except with the prior written approval of all of the Bondholders. Any Further Bonds shall be constituted by a deed supplemental to the Bond Agreement.

18. Contracts (*Rights of Third Parties*) Act 1999

No person shall have any right to enforce any term or condition of the Bonds under the Contracts (Rights of Third Parties) Act 1999.

19. Governing Law

These Conditions, the Bond Agreement, the Calculation Agency Agreement and the Bonds and any non-contractual obligations arising out of or in connection with them are governed by, and shall be construed in accordance with, English law.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Schedule 5

Form of Transfer and Accession Deed

From: [*New Holder*] (the "**New Holder**") and [*Existing Holder*] (the "**Existing Holder**")

To: Renalytix plc (the "**Issuer**")

[*Date*]

To whom it may concern,

U.S.$21,200,000 Amortising Senior Convertible Bonds due 2027 issued by the Issuer pursuant to the Bond Agreement dated 31 March 2022 (as amended or supplemented from time to time) (the "Agreement")

(A) We refer to the Agreement. This is a Transfer and Accession Deed. Terms defined in the Agreement have the same meaning herein unless given a different meaning in this Deed.

(B) The Existing Holder confirms that the principal amount outstanding of Bonds which it holds is U.S.$[●].

(C) We refer to Clause 11 (*Transfers of Rights and Obligations*) of the Agreement:

(a) the Existing Holder transfers to the New Holder the Existing Holder's rights and obligations under the Bonds and the Agreement in the amount referred to in the schedule below.

(b) the proposed transfer date is [●] 20[●] (the "**Transfer Date**").

(c) With immediate effect from the Transfer Date:

(i) the Existing Holder shall be released from all the obligations of the Existing Holder under the Bonds and the Agreement which correspond to [the principal amount of Bonds held and owned by the Existing Holder and specified in paragraph 2 above]/[U.S.$[●] in principal amount of Bonds held and owned by the Existing Holder]; and

(ii) the New Holder agrees to accede to the Agreement and agrees to be bound by, and undertakes to perform, the obligations binding a Bondholder under the Bonds and the Agreement.

(D) The administrative details for the New Holder for the purposes of the Bonds and the Agreement are as follows:

[*Insert postal address, email address and attention details for notices and account details for payments*]

(E) This Deed may be entered into in any number of counterparts and this has the same effect as if the signatures on the counterparts were on a single copy of the Deed.

(F) The provisions of Clause 8 (*Governing Law and Jurisdiction*) of the Agreement shall apply mutatis mutandis to this Deed as if set out fully herein.

In Witness Whereof this Deed has been executed as a deed and delivered on the date stated at the beginning.

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

RENALYTIX PLC

as ***Issuer*** acting by [*Name of first director*], a director in the presence of:

By:

Director

Witness's Signature ____

Name: __

Address: _

Occupation: __

[●]
as ***Existing Holder*** acting by [●]

By:

By:

[●]
as ***New Holder*** acting by [●]

By:

By:

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Schedule 6

Form of Register

[***]

CERTAIN CONFIDENTIAL INFORMATION CONTAINED IN THIS DOCUMENT, MARKED BY [***], HAS BEEN OMITTED BECAUSE IT IS BOTH (I) NOT MATERIAL AND (II) IS THE TYPE THAT THE REGISTRANT TREATS AS PRIVATE OR CONFIDENTIAL.

Schedule 7

Regulations Concerning Transfers and Registration of the Bonds

1. The Company shall maintain a Register in respect of the Bonds and enter in it:

   (a) the initial principal amount of the Bonds, all amortising payments of principal, and the remaining principal amount of the Bonds at any time;

   (b) the date of issue of the Bonds;

   (c) all subsequent transfers and changes of ownership of Bonds;

   (d) the names and contact details of the holders of the Bonds;

   (e) the Conversion Price, Reference Conversion Price and Reset Price Floor (each as defined in the Conditions) in effect at any time;

   (f) details of all conversions of Bonds; and

   (g) details of all redemptions and cancellations of Bonds or replacements of Bond Certificates (whether because of their purchase by the Company, its Subsidiaries, their affiliates or otherwise).

2. The Company shall maintain the Register and update it on a regular basis to reflect any changes to the information specified in paragraph 1 above and any changes in holdings or ownership.

3. Without prejudice to Clause 5.2 (*Title*), a Bondholder may inspect the Register from 9.00 a.m. to 5.00 p.m. on any Business Day.

4. Subject to Clause 5.4 (*Closed Periods*) and 11.2 (*Permitted Transfers*), Bonds may be transferred by execution of the relevant Transfer and Accession Deed under the hand of the transferor and the transferee or, where the transferor or transferee is a corporation, under its common seal or under the hand of two of its officers duly authorised in writing. Where and to the extent that any duty or tax is required to be paid before the effect of a transfer may lawfully be registered in the Register, the Company shall not be required to take any action in respect of such transfer (whether under this Schedule or under Clause 11.2 or otherwise) unless and until it has received evidence to its satisfaction that such tax or duty has been paid.

5. The Bond Certificate issued in respect of the Bonds to be transferred must be surrendered for registration, together with the Transfer and Accession Deed (including any certification as to compliance with any restrictions on transfer), duly completed and executed, at the registered office of the Company, and together with such evidence as the Company may reasonably require to prove the title of the transferor and the authority of the persons who have executed the Transfer and Accession Deed.

6. The executors or administrators of a deceased Bondholder of a Bond shall be the only persons recognised by the Company as having any title to such Bond.

7. Where there is more than one transferee (to hold other than as joint Bondholders), separate Transfer and Accession Deeds must be completed in respect of each new holding.

8. Joint holdings of Bonds shall not be permitted and the entries in the Register shall identify a single person as the Bondholder of each Bond.

EXHIBIT 12.1

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, James McCullough, certify that:

1. I have reviewed this annual report on Form 20-F of Renalytix plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

    c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 31, 2022

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

EXHIBIT 12.2

CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934, AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, O. James Sterling, certify that:

1. I have reviewed this annual report on Form 20-F of Renalytix plc;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the company as of, and for, the periods presented in this report;

4. The company's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the company and have:

    a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Company, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared; and

    b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles; and

    c. Evaluated the effectiveness of the Company's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

    d. Disclosed in this report any change in the Company's internal control over financial reporting that occurred during the period covered by the annual report that has materially affected, or is reasonably likely to materially affect, the Company's internal control over financial reporting; and

5. The company's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the company's auditors and the audit committee of the company's board of directors (or persons performing the equivalent functions):

    a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the company's ability to record, process, summarize and report financial information; and

    b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the company's internal control over financial reporting.

Date: October 31, 2022

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

EXHIBIT 13.1

CERTIFICATION BY THE PRINCIPAL EXECUTIVE OFFICER AND PRINCIPAL FINANCIAL OFFICER PURSUANT TO 18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

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

1. The Company's Annual Report on Form 20-F for the year ended June 30, 2022, to which this Certification is attached as Exhibit 13.1 (the "Report") fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: October 31, 2022

/s/ James McCullough
Name: James McCullough
Title: Chief Executive Officer
(Principal Executive Officer)

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

Exhibit 15.1

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in the Post-Effective Amendment No.1 to the Registration Statement on Form F-3 (No. 333-265280) and to the Registration Statement on Form S-8 (No. 333-248741) pertaining to the Share Option Plan for Employees with Non-Employee Sub-Plan and U.S. Sub-Plan, 2020 Employee Share Purchase Plan, and 2020 Equity Incentive Plan of Renalytix plc, of our report dated October 31, 2022, with respect to the consolidated financial statements of Renalytix plc included in this Annual Report (Form 20-F) for the year ended June 30, 2022.

/s/ Ernst & Young LLP
Iselin, New Jersey

October 31, 2022

Exhibit 15.2

Consent of Independent Registered Public Accounting Firm

We consent to the incorporation by reference in Registration Statement No. 333-265280 on Form F-3 and Registration Statement No. 333-248741 on Form S-8 of our report dated October 27, 2020, relating to the financial statements of Renalytix plc (formerly Renalytix AI plc) appearing in this Form 20-F for the year ended June 30, 2020.

/s/ Deloitte & Touche LLP

Morristown, New Jersey
October 31, 2022

EXHIBIT 21.1

SUBSIDIARIES OF THE REGISTRANT

Name	Jurisdiction
Renalytix AI, Inc.	United States
Renalytix AI Limited	Ireland